SOLENO THERAPEUTICS INC
Form S-1/A
August 07, 2017

As filed with the Securities and Exchange Commission on August 7, 2017
Registration No. 333-217420

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

AMENDMENT NO. 3 TO
FORM S-1
REGISTRATION STATEMENT
Under
The Securities Act of 1933

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

Delaware	3,841	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.
(f/k/a Capnia, Inc.)
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Redwood City, CA 94065
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(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

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(650) 493-9300

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, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box: x

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. o

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. o

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. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a small reporting company. See definitions of “large accelerated filer,” “accelerated filer,” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	o	Accelerated filer	o
Non-accelerated filer	o (Do not check if a smaller reporting company)	Smaller reporting company	x
		Emerging growth company	x

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. o

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	Amount of Registration Fee(3)
common stock, $0.001 par value	32,730,600	$0.610	$19,965,666	$2,314.03
Total	32,730,600	$0.610	$19,965,666	$2,314.03

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

(2) Pursuant to Rule 457(c), calculated on the basis of the average of the high and low prices per share of the registrant’s common stock on the NASDAQ Capital Market on April 17, 2017.

(3) The Registrant previously paid $2,314.03 in connection with the initial filing of this Registration Statement.

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 _____

PRELIMINARY PROSPECTUS

SOLENO THERAPEUTICS, INC.

Up to 32,730,600 Shares of common stock

This prospectus relates to the sale of up to 32,730,600 shares of our common stock by Vivo Ventures Fund V, L.P., Vivo Ventures Affiliates Fund V, L.P., Forward Ventures V, L.P., Technology Partners Fund VII, L.P., Technology Partners Affiliates VII, L.P., Palo Alto Healthcare Master Fund, L.P., Palo Alto Fund II, L.P., Genovate Biotechnology Co. Ltd., Uni Pharma Co. Ltd, Giddi Pharma Co. Ltd., Top Taiwan XI Venture Capital Co. Ltd, Top Taiwan VIII Venture Capital Co. Ltd, Mahendra Shah, Aquilo Capital, DLA Piper, Neil Cowen, Glaze Family Revocable Trust dtd 6/17/04, Richard A. Glaze, Jeffrey A. Staffa and Jo-Ann Staffa Trustees, or their successors, in trust, under the Jeffrey and Jo-Ann Staffa Living Trust, dated December 10, 2015, and any amendments thereto, Khaled Yamount, Debra Robertson, Richard Pasternak, Alain Baron, Aaron Berg, Gloria Lin and Joy Becker, collectively also referred to in this prospectus as the selling stockholders. The prices at which the selling stockholders may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive proceeds from the sale of the shares by the selling stockholders.

The selling stockholders are considered as an “underwriter” within the meaning of the Securities Act of 1933, as amended. 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 August 4, 2017, the last reported sale price per share of our common stock was $0.43 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 8 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 August 7, 2017.

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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.

Recent Developments

On July 18, 2017, we completed the sale of stock of our 100% wholly-owned subsidiary, NeoForce, Inc., or NFI, primarily related to our portfolio of neonatology resuscitation business, pursuant to a Stock Purchase Agreement, or NFI Purchase Agreement, dated as of July 18, 2017, with NeoForce Holdings, Inc., or NFI 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. We will also receive the total outstanding accounts receivable and inventory held by NFI at the date of sale, as it is collected or sold, respectively. The transactions contemplated by the NFI Purchase Agreement are a continuation of a process previously disclosed by us of evaluating strategic alternatives and focusing on our rare disease therapeutic business. The NFI Purchase Agreement includes customary terms and conditions, including an adjustment to the purchase price based on inventory and accounts receivables, and provisions that require us to indemnify NFI Holdings for certain losses that it incurs as a result of a breach by us of our representations and warranties in the NFI Purchase Agreement and certain other matters. Proceeds from the sale are payable to us as follows: (1) a $720,000 payment to us 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.

Company Overview

On March 7, 2017, we completed our merger, or the Merger, with Essentialis, Inc., a Delaware corporation, or Essentialis. After the Merger, our primary focus is transitioning to 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 metabolic 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 Tablet, or DCCR, as a treatment for Prader-Willi Syndrome, or PWS, a complex metabolic/neurobehavioral disorder.

In addition, we continue to commercialize innovative medical devices to address unmet medical needs. We have two commercial products based on our proprietary technologies, including those which utilize precision metering of gas flow. Our most recent product to launch commercially is Serenz® Nasal Relief, or Serenz. In the U.S., we have concluded that Serenz is a Class I, 510(k) exempt device. Serenz is a proprietary handheld device that delivers non-inhaled CO_2 topically to the nasal mucosa. Serenz is used only when needed, and does not need to be used on a regular basis.

We are also selling 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. When present in neonates with jaundice, excessive hemolysis is a dangerous condition which can lead to adverse neurological outcomes. CoSense is 510(k) cleared for sale in the U.S. and received CE Mark certification for sale in the E.U. In addition, through our wholly owned subsidiary NeoForce, Inc., or NFI, we also develop and globally market assets relating to innovative pulmonary resuscitation solutions for the inpatient and ambulatory neonatal markets. NFI's primary product is the NeoPip T-piece resuscitator and related consumable, which delivers consistent pre-set inspiratory pressure and positive end-expiratory pressures. Other NFI products include temperature probes, scales, surgical tables and patient surfaces.

Following the Merger, we initiated a comprehensive review of strategic alternatives for our legacy products and product candidates, including Serenz® Allergy Relief, CoSense® ETCO Monitor, and our portfolio of innovative

pulmonary resuscitation solutions for the neonatal market. We may also license elements of our Sensalyze Technology Platform to other companies that have complementary development or commercial capabilities. 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.

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 is a benzothiadiazine that acts by stimulating ion flux through ATP sensitive K^+ channels (K_{ATP}). 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 were approved, and there has been nearly 40 years of use of the orally-administered drug in the approved indications.

A pilot study was conducted between June 2014 and March 2016 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 10 and 22. The first phase of the study was open label during which subjects were initiated on a DCCR dose target and were dose escalated every 14 days at the discretion of the investigator. This open-label treatment phase was followed by randomized double-blind, placebo-controlled withdrawal phase. Changes from baseline in the aggressive, threatening, and destructive behavior subset of the 23-item PWS-associated behaviors questionnaire were evaluated. There was a statistically significant improvement in aggressive, threatening and destructive behaviors.

DCCR is being developed in the U.S. under a current Investigational New Drug, or IND. The IND was recently transferred from the Division of Metabolism and Endocrinology Products to the Division of Psychiatry Products, or DPP, at the Food and Drug Administration, or FDA. A general scientific advice meeting (Type C) has been granted by DPP to discuss a proposed New Drug Application, or NDA, enabling clinical trial design in the second quarter of 2017. This study is a six month randomized, double-blind, placebo-controlled, parallel group study in patients with genetically-confirmed PWS with hyperphagia, or an abnormally increased appetite for food, which is anticipated to be conducted at sites in the U.S. and Europe. A validated nine item questionnaire developed to evaluate changes in hyperphagia in clinical trials, will be used to assess the primary endpoint of change in hyperphagia. The study is also designed to assess the potential for DCCR treatment to reduce the severity and frequency of aggressive behaviors, to improve quality of life and to reduce cardiovascular risk. It is anticipated that the feedback obtained from this meeting will be used to finalize the protocol to enable study initiation in the second half of 2017. The six month double-blind, placebo controlled clinical study would be followed by a six month open-label trial in which all subjects who completed the first study were eligible to be enrolled.

Serenz

We believe that Serenz has an ideal profile for an as-needed therapeutic for allergic rhinitis, or AR, and may provide advantages over regularly dosed, slow to act currently marketed products.

AR, which is commonly and colloquially referred to as “allergies,” is characterized by symptoms that are often episodic and include nasal congestion, itching, sneezing and runny nose. There are approximately 123 million sufferers in the U.S., France, Germany, Italy, Spain, the U.K. and Japan, according to research firm GlobalData. Prevalence of AR is growing rapidly in the developed world. The most common AR drug therapies include antihistamines and intranasal steroids. Leukotriene inhibitors and other drugs are also currently prescribed to AR patients. Several of these drugs have generated sales in excess of $1 billion per year as branded products. However, these products have significant limitations and AR sufferers remain dissatisfied with the available treatments. Thus, there is a need for a more effective treatment with a faster onset of action and improved safety profile.

Serenz is based upon the observation that non-inhaled CO_2 delivered at a low-flow rate into the nasal cavity, alleviates the symptoms of AR. Serenz is a convenient, hand-held device that delivers low-flow CO_2 to the nasal mucosa. It contains a pressurized canister of gas, with approximately enough gas to dose as-needed for one to two weeks. The device is disposable and engineered for ease of use. Our proprietary technology ensures very precise control of aspects such as flow rate and volume, which we believe are both critical to achieve the desired clinical performance.

In our clinical trials to date, Serenz has shown a large effect size, an onset of effect within 30 minutes and has been well tolerated. We believe that these characteristics position Serenz well to be a potential first-line treatment for any AR sufferer. Serenz can be taken as a stand-alone treatment and can be used on an as-needed basis. Serenz has the the ideal characteristics of an AR therapeutic, including:

- Rapid relief
- Relief from nasal congestion, sneezing and itchy/runny nose
- Non-sedating

- Tolerant side effect profile
- Acts locally in the nasal cavity
- Non-sedating
- Non-steroidal
- No known long-lasting side effects

We have CE Mark certification for Serenz Allergy Relief.

In the U.S., we have concluded that Serenz Nasal Relief is a Class I, 510(k) exempt device. The device meets FDA regulations as a class 1 medical device (i.e., not a pharmaceutical) and is 510(k) exempt in the U.S. (Product Code, KMA; Regulation Number, 21 CFR 874.5550, Powered Nasal Irrigator). The following intended use of the Serenz Nasal Relief device is consistent with 21 CFR 874.5550 which identifies powered nasal irrigators as "…powered device intended to wash the nasal cavity…" Serenz Nasal Relief is intended to irrigate and wash the nasal cavity with a controlled flow of carbon dioxide. The wash is intended to provide rapid relief for adults experiencing nasal allergy symptoms such as stuffy, runny or itchy nose or sneezing. The device classification is based on the fact that the primary mode of action for the Serenz Nasal Relief device is a physical wash of the nasal cavity using pressurized gas, and no pharmaceutical action occurs with the usage of the Serenz Nasal Relief device as indicated. This is demonstrated by data demonstrating the 10-second application per nostril (20 seconds total) of nasal, non-inhaled CO_2 is insufficient to induce a pharmacologic effect.

In March 2017, we initiated the pilot launch of Serenz Nasal Relief in the U.S. We initially gave away 2,146 Serenz nasal relief samples to qualified leads identified by Lifescript Advantage, or LSA, a division of Lifescript, Inc., a digital healthcare media and publishing company. The purpose of this promotion was to build and raise awareness of Serenz Nasal Relief using content marketing, which a type of marketing that involves the creation and sharing of online material (such as videos, blogs, and social media posts).

CoSense

Approximately 143 million babies are born annually worldwide, with approximately 9.2 million of these born in the U.S. and E.U. It is estimated that up to 60% of term neonates and 80% of preterm neonates may have jaundice. We believe CoSense has the potential to become a part of routine pre-discharge screening, by aiding in the differential diagnosis of hemolysis in infants that present with, or are at risk of developing, jaundice. Red blood cell breakdown is a normal phenomenon, but in certain situations the breakdown is accelerated or is excessive and is referred to as hemolysis. The most common cause of hospital readmission during the neonatal phase is jaundice, and we expect that CoSense will help reduce such readmissions. Many causes of jaundice do not represent a significant health threat. However, when severe jaundice occurs in the presence of hemolysis, rapid diagnosis and treatment may be necessary for infants to avoid life-long neurological impairment or other disability. Also, unnecessary treatment increases hospital expenses, is stressful for both infant and parents and may increase morbidity. There is an unmet need, therefore, for more accurate diagnostics for hemolysis, particularly if they are non-invasive, rapid, and easy to use. CoSense detects hemolysis by measuring CO in the "end-tidal" component of the breath, and the measurement performed with CoSense is referred to as end-tidal carbon monoxide, or ETCO. The American Academy of Pediatrics, or AAP, guidelines, published in the journal Pediatrics in 2004, recommend ETCO measurement be performed to assess the presence of hemolysis in neonates requiring phototherapy, neonates unresponsive to phototherapy or readmitted for phototherapy and neonates with bilirubin levels approaching transfusion levels. Today, CoSense is the only device commercially available for accurately measuring the ETCO levels associated with the rate of hemolysis in clinical practice in neonates. As a result, we believe that CoSense is the only device on the market that enables physicians to practice in accordance with the AAP guidelines when evaluating jaundiced neonates for potential treatment of hemolysis. Physicians are free to practice in accordance with their own judgment; however, we believe that the current AAP guidelines will be a significant factor in the adoption of CoSense.

NFI Pulmonary Solutions

Approximately 10% of newborns require some assistance to begin breathing at birth and represents the number of patients that would benefit from our products. Of this 10%, approximately 1% requires extensive resuscitative measures. Although the vast majority of newborns do not require intervention to make the transition from intra uterine to extra uterine life, because of the large number of births, a sizable number will require some degree of resuscitation. A T-piece resuscitator is a two-piece manually operated resuscitation delivery device used for infants and small children (less than 10 kg) to effectively deliver inhalation breaths at preset peak inspiratory pressures, or PIP, and a small back pressure to keep the lungs from collapsing on exhalation, known as positive end expiratory pressures, or PEEP, at a preset Fi02, or percent oxygen. In general, it is a modern replacement for the traditional bag and mask which requires significant user training and experience to deliver breaths to infants with tiny and very delicate lungs.

Recent Developments

Merger with Essentialis, Inc.

On December 22, 2016, we entered into an Agreement and Plan of Merger, or the Merger Agreement, with Essentialis. Consummation of the Merger with Essentialis was subject to various closing conditions, including our consummation of a financing of at least $8 million at, or substantially contemporaneous with, the closing of the Merger and the receipt of stockholder approval of the Merger at a special meeting of our stockholders.

On March 6, 2017, we held a special stockholder meeting and received approval for the issuance of the merger shares under the Merger Agreement with Essentialis, the issuance of the shares of common stock for the $8 million of concurrent financing and the issuance of the shares of common Stock for the $2 million investment by Aspire Capital, LLC, or Aspire Capital.

On March 7, 2017, we completed the Merger with Essentialis and issued 18,916,940 shares of common stock to stockholders of Essentialis. We held back 913,379 shares of common stock as partial recourse to satisfy indemnification claims, and such shares will be issued to Essentialis stockholders on the 1 year anniversary of the closing of the Merger. We are also obligated to issue an additional 4,566,948 shares of common stock to Essentialis stockholders upon the achievement of a development milestone. Assuming that we issue all of the shares of our common stock held back and the development milestone is achieved, we would issue a total of 24,397,267 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 $30 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.

In addition, we issued 8,333,333 shares of common stock for an investment of $8 million from the completion of the concurrent financing and issued 2,083,333 shares of common stock for an investment of $2 million from Aspire Capital.

Risks Associated With Our Business

Our business is subject to numerous risks and uncertainties related to the development and commercialization of DCCR, Serenz, CoSense and our neonatology products, 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 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, which makes it difficult to evaluate our business and assess our future viability. As of December 31, 2016, we had an accumulated deficit of $98.3 million.
- We are significantly dependent upon the success of DCCR, our sole therapeutic product candidate and if we fail to obtain regulatory approval for DCCR in the U.S. and E.U., our business would be harmed. 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.

- The safety and preliminary efficacy results from the pilot study of DCCR conducted in the treatment of PWS subjects may not be indicative of the outcome of the proposed NDA-enabling clinical trial.
- The FDA may challenge our conclusion that Serenz Nasal Relief is a Class I, 510(k) exempt device.
- Serenz, CoSense and our other neonatology 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.
- The challenges involved in establishing distribution and sales operations may expose us to a higher than usual level of risk with respect to commercializing our products. We may be required to conduct additional clinical trials prior to obtaining additional approval for our products. We may not obtain such approvals for sale on a predictable timeframe, or at all.
- We have not manufactured the active drug ingredients contained in DCCR, CoSense, its associated consumables or Serenz on a large commercial scale, and there are risks associated with scaling up manufacturing. Our commercial manufacturing partners may not be successful in achieving the levels of production volume, quality, or manufacturing costs necessary to support commercial success.
- Our executive officers, directors and principal stockholders may continue to maintain the ability to control all matters submitted to stockholders for approval.
- 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 and cause dilution to our existing stockholders.
- Our business depends on our continuing to satisfy the FDA and any other applicable U.S. and international regulatory requirements with respect to medical diagnostics, devices or therapeutics, including requirements which may change or be created in the future.
- We need to obtain or maintain patents or other appropriate protection for the intellectual property utilized in our current and planned product offerings, and we must avoid infringement of third-party intellectual property.

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. On May 12, 2017, we formally changed our corporate name from "Capnia, Inc." to "Soleno Therapeutics, Inc."

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012. As such, we are eligible for exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and reduced disclosure obligations regarding executive compensation.

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of our initial public offering, or IPO, which occurred on November 18, 2014, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.0 billion, (3) the date on which we are deemed to be a large accelerated filer, which means the market value of 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.

“Soleno Therapeutics,” “CoSense,” “Serenz,” “Sensalyze,” “NeoForce,” our logo and our other trade names, trademarks and service marks appearing in this prospectus are our property. Other trade names, trademarks and service marks appearing in this prospectus are the property of their respective holders.

The Offering	
Common stock being offered by the selling stockholder	32,730,600 shares
Selling Stockholders	Vivo Ventures Fund V, L.P., Vivo Ventures Affiliates Fund V, L.P., Forward Ventures V, L.P., Technology Partners Fund VII, L.P., Technology Partners Affiliates VII, L.P., Palo Alto Healthcare Master Fund, L.P., Palo Alto Fund II, L.P., Genovate Biotechnology Co. Ltd., Uni Pharma Co. Ltd, Giddi Pharma Co. Ltd., Top Taiwan XI Venture Capital Co. Ltd, Top Taiwan VIII Venture Capital Co. Ltd, Mahendra Shah, Aquilo Capital, DLA Piper, Neil Cowen, Glaze Family Revocable Trust dtd 6/17/04, Richard A. Glaze, Jeffrey A. Staffa and Jo-Ann Staffa Trustees, or their successors, in trust, under the Jeffrey and Jo-Ann Staffa Living Trust, dated December 10, 2015, and any amendments thereto, Khaled Yamount, Debra Robertson, Richard Pasternak, Alain Baron, Aaron Berg, Gloria Lin and Joy Becker
Common stock outstanding	47,479,879 (as of March 10, 2017)
Use of proceeds	The selling stockholders will receive all of the proceeds from the sale of the shares offered for sale by it 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 2,934,856 shares of our common stock issuable upon exercise of outstanding stock options, 10,534,952 shares of our common stock available for future issuance under the stock option plans, outstanding warrants exercisable for 602,109 shares of our common stock, 12,179,000 shares of our common stock issuable upon the conversion of our outstanding Series B Convertible Stock, 2,425,605 shares of our common stock issuable upon exercise of our outstanding Series A Warrants, 590,415 shares of our common stock issuable upon exercise of our outstanding Series C Warrants, 2,930,812 shares of our common stock issuable upon exercise of our outstanding Series D Warrants, each of which securities are outstanding or available for issuance as of March 10, 2017.

Merger with Essentialis, Inc.

On March 7, 2017, we completed the Merger with Essentialis and issued 18,916,940 shares of common stock to stockholders of Essentialis. We held back 913,379 shares of common stock as partial recourse to satisfy indemnification claims, and such shares will be issued to Essentialis stockholders on the 1 year anniversary of the closing of the merger. We are also obligated to issue an additional 4,566,948 shares of common stock to Essentialis stockholders upon the achievement of a development milestone. Assuming that we issue all of the shares of our common stock held back and the development milestone is achieved, we would issue a total of 24,397,267 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 $30 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.

In addition, we issued 8,333,333 shares of our common stock for an investment of $8 million from the completion of the concurrent financing. Concurrently with entering into the Merger Agreement and stock purchase agreements entered into for the concurrent financing, we agreed to file one or more registration statements, including the registration statement of which this prospectus is a part, as permissible and necessary to register under the Securities Act of 1933, as amended, or the Securities Act, the sale of the shares of our common stock that have been issued to the selling stockholders under the Merger Agreement and stock purchase agreements.

Pursuant to the Merger Agreement and the terms of the stock purchase agreements entered into for the concurrent financing, we are registering 32,730,600 shares of our common stock under the Securities Act. 27,250,273 shares of common stock have already been issued to the selling stockholders. An additional 913,379 shares of common stock could be issued to Essentialis stockholders on the 1 year anniversary of the closing of the Merger and 4,566,948 shares of common stock could be issued to Essentialis stockholders upon the achievement of a development milestone.

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. 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 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 have generated limited commercial sales to date, 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 diagnostics 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 medical 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 March 31, 2017, we had an accumulated deficit of $101.2 million.

We expect that our future financial results will depend primarily on our success in launching, selling and supporting our products. This will require us to be successful in a range of activities, including 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 approved 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

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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, 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:

- 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;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- 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, if applicable, 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

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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 commercialization of our products, as well as the completion of the development and the potential commercialization of planned products, will require substantial funds. As of March 31, 2017, we had approximately $10.5 million in cash and cash equivalents. Our future financing requirements will depend on many factors, some of which are beyond our control, including the following:

- the cost of activities and added personnel associated with the commercialization of our products, including marketing, manufacturing, and distribution;
- the cost to manufacture our products on a larger scale;
- the degree and rate of market acceptance of our products, and the revenue that we are able to collect as a result;
- our ability to set a commercially attractive price for our products, and our customers' perception of the value relative to the prices we set;
- the timing of, and costs involved in, seeking and obtaining approvals from the FDA and other regulatory authorities for our products;
- our ability to obtain and maintain partners on attractive economic terms, or engage in commercial sales of our products on our own or through distributors, or maintain existing distributors;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights and/or the loss of those rights;
- our ability to enter into distribution, collaboration, licensing, commercialization or other arrangements and the terms and timing of such arrangements;
- the emergence of competing technologies or other adverse market developments;
- the costs of attracting, hiring and retaining qualified personnel;
- unforeseen developments during our clinical trials;
- unforeseen changes in healthcare reimbursement for any of our approved products;
- our ability to maintain commercial scale manufacturing capacity and capability with a commercially acceptable cost structure;
- unanticipated financial resources needed to respond to technological changes and increased competition;
- enactment of new legislation or administrative regulations;
- the application to our business of new regulatory interpretations;
- claims that might be brought in excess of our insurance coverage;
- the failure to comply with regulatory guidelines; and
- the uncertainty in industry demand.

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

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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.

The extent to which we utilize the 2017 Aspire Purchase Agreement (see Note 2) with Aspire Capital as a source of funding will depend on a number of factors, including the prevailing market price of our common stock, the volume of trading in our common stock and the extent to which we are able to secure funds from other sources. The number of shares that we may sell to Aspire Capital under the 2017 Aspire Purchase Agreement on any given day and during the term of the agreement is limited. Additionally, we and Aspire Capital may not effect any sales of shares of our common stock under the 2017 Aspire Purchase Agreement during the continuance of an event of default or on any trading day that the closing sale price of our common stock is less than $0.25 per share. Even if we are able to access the full $17.0 million under the 2017 Aspire Purchase Agreement, we will still need additional capital to fully implement our business, operating and development plans.

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

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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 Relating to the Company after the Merger with Essentialis

Completion of the Merger and concurrent financing transactions, which happened on March 7, 2017 (see Note 14), resulted in the issuance of a significant amount of additional our common stock, which could depress the trading price of our common stock.

The Merger and concurrent financing resulted in the issuance of a significant amount of our common stock. The common stock issued in the Merger and concurrent financing represents an increase in the outstanding our common stock as of the date of the completion of the Merger of up to approximately 172% of the common stock currently outstanding. The issuance of such a significant amount of our common stock could depress the trading price of our common stock and you may lose all or a part of your investment.

Our executive officers, directors and principal stockholders will maintain the ability to control or significantly influence all matters submitted to stockholders for approval and under certain circumstances may have control over key decision making.

Our executive officers, directors and principal stockholders own a majority of our outstanding common stock. Entities associated with Vivo Ventures, Forward Ventures, Technology Partners and our Chairman, Ernest Mario, as of March 7, 2017, own approximately 64.7% of our common stock. As a result, the forgoing 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.

Failure to retain key employees could diminish the benefits of the Merger and concurrent financing transactions.

Continued success will depend in part on the retention of key personnel at Essentialis, including senior management. There can be no assurances that we will be able to retain Essentialis's key personnel. In addition, no assurance can be given that after the transactions, that we will be able to attract or retain key management personnel and other key employees to the same extent that we or Essentialis had been previously able to attract or retain their own employees.

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

We will now be primarily a clinical-stage company, with a relatively limited operating history upon and with no approved therapeutic products or revenues from the sale of therapeutic products. Essentialis's operations prior to the Merger had been limited to organizing, staffing and financing, applying for patent rights, undertaking clinical trials of its primary product candidate, DCCR, and engaging in research and development. Prior to the Merger, Essentialis had not yet demonstrated an ability to obtain regulatory approval, manufacture commercial-scale products, or conduct the sales and marketing activities necessary for successful product commercialization. As a result, there is limited information about Essentialis for investors to use when assessing our future viability as a combined company 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 will now be significantly dependent upon the success of DCCR, our sole therapeutic product candidate.

Prior to the Merger, Essentialis had invested, and following the Merger, we expect to continue to 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 in any region to commercialize, or, if approved, obtain coverage and adequate reimbursement from third-parties, including government payors, for DCCR 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 E.U. and U.S.;
- 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 payors;
- 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.

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

We require 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, and demonstrating efficacy with statistical significance 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 manufacturing processes or facilities are insufficient to support approval. As such, we may need to conduct more clinical trials than we currently anticipate and upgrade our 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.

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 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.

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 on time 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 preclinical, toxicology, or other in vivo or in vitro 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 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 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 with new or existing laws or regulations;
- have a sufficient number of clinical trial sites to conduct the trials;
- timely manufacture sufficient quantities of product candidate for use in clinical trials; 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.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the 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 following the merger. 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. These regulations differ from country to country. To gain approval to market our product candidates, we must provide 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 DCCR receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third party payors and others in the medical community necessary for commercial success.

If DCCR receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third party payors and others in the medical community. If DCCR does not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- the prevalence and severity of any side effects;
- the ability to offer our product candidates for sale at competitive prices;
- 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 of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments; and
- sufficient third party coverage or reimbursement.

Our ability to negotiate, secure and maintain third party coverage and reimbursement may be affected by political, economic and regulatory developments in the U.S., E.U., and other jurisdictions. Governments continue to impose cost containment measures, and third party payors are increasingly challenging prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. These and other similar developments could significantly limit the degree of market acceptance of DCCR or any of our other potential product candidates that receive marketing approval.

Our patent rights may prove to be an inadequate barrier to competition following the completion of the Merger.

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 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.

Risks related to the development and commercialization of our products

Our success depends heavily on the successful commercialization of our CoSense device to aid in diagnosis of neonatal hemolysis and of our Serenz device to relieve the nasal symptoms of allergic rhinitis. If we are unable to sell sufficient numbers of our products, our revenues may be insufficient to achieve profitability.

With the exception of revenue generated from the sale of products acquired from NFI, we will derive substantially all of our revenues from sales of CoSense devices and consumables globally and our Serenz devices for the foreseeable future. If we cannot generate sufficient revenues from sales, we may be unable to finance our continuing operations.

We may not be successful in commercializing our approved products

Our efforts to launch CoSense into the neonatology marketplace and Serenz are subject to a variety of risks, any of which may prevent or limit sales of CoSense and Serenz. Furthermore, commercialization of products into the medical marketplace 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, Serenz, our neonatology, and 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, Serenz and for our neonatology products 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 payors 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 physicians decide not to order our neonatology products in significant numbers, we may be unable to generate sufficient revenue to sustain our business.

To generate demand for our neonatology and other planned products, we will need to educate physicians, neonatologists, pediatricians, and other health care professionals on the clinical utility, benefits and value of the tests we provide through

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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 CoSense 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.

In addition, although treatment guidelines recommend ETCO testing, physicians are free to practice in accordance with their own judgment, and may not adopt ETCO testing to the extent recommended by the guidelines, or at all. While the current AAP guidelines recommend ETCO measurement be performed to assess the presence of hemolysis in neonates requiring phototherapy, neonates unresponsive to phototherapy or readmitted for phototherapy, and neonates with bilirubin levels approaching exchange transfusion levels. AAP guidelines are updated approximately every ten years, and since the current guidelines were published in 2004, these guidelines may change in the near term.

If we cannot convince medical practitioners to order and pay for our current test and our planned tests, and if we cannot convince institutions to pay for our current test and our planned tests, we will likely be unable to create demand in sufficient volume for us to achieve sustained profitability.

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 diagnostic results or treatments. With respect to our neonatology and other diagnostic products, we believe that our customers are likely to be particularly sensitive to test defects and errors, and prior products made by other companies for the same diagnostic purpose have failed in the marketplace, in part as a result of poor diagnostic accuracy. As a result, the failure of our neonatology and other 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 we cannot compete successfully with other diagnostic modalities, we may be unable to increase or sustain our revenues or achieve and sustain profitability.

Our principal competition for CoSense comes from mainstream diagnostic methods, used by physicians for many years, which focus on invasive blood tests such as the Coombs test, blood counts and serum bilirubin. In addition, transcutaneous monitors of bilirubin also create a competitive threat. It may be difficult to change the methods or behavior of neonatologists and pediatricians to incorporate CoSense in their practices in conjunction with, or instead of, blood tests.

In addition, several larger companies have extensive sales presence in the neonatology area and could potentially develop non-invasive diagnostic tests that compete with our neonatology or other planned products. These include General Electric Healthcare, Fischer & Paykel, Philips, Draeger, Covidien, Masimo, Natus Medical, and CAS Medical. Some of our present and potential competitors have widespread brand recognition and substantially greater financial and technical resources and development, production and marketing capabilities than we do. Others may develop lower-priced tests that payors and physicians could view as functionally equivalent to our current or planned tests, which could force us to lower the list price of our tests. This would impact our operating margins and our ability to achieve and maintain profitability. If we cannot compete successfully against current or future competitors, we may be unable to increase or create market acceptance and sales of our current or planned tests, which could prevent us from increasing or sustaining our revenues or achieving or sustaining profitability.

We expect to continue to incur significant expenses to develop and market additional diagnostic tests, which could make it difficult for us to achieve and sustain profitability.

In recent years, we have incurred significant costs in connection with the development of CoSense. For the three months ended March 31, 2017, our research and development expenses were $1 million. We expect our expenses to increase for the foreseeable future, as we conduct studies of CoSense and continue to develop our planned products, including tests for hydrogen nitric oxide and other analytes. We will also incur significant expenses to establish a sales and marketing infrastructure, and to drive adoption of and reimbursement for our products. As a result, we need to generate significant revenues in order to achieve sustained profitability.

Commercialization of Serenz may not be successful

In the U.S., we have concluded that Serenz Nasal Relief is a Class I, 510(k) exempt device. The device meets FDA regulations as a class 1 medical device (i.e., not a pharmaceutical) and is 510(k) exempt in the United States (Product Code,

KMA; Regulation Number, 21 CFR 874.5550, Powered Nasal Irrigator). We cannot be certain that the FDA will not challenge this position.

In March 2017, we initiated the pilot launch of Serenz Nasal Relief in the U.S. We initially gave away 2,146 Serenz Nasal Relief samples to qualified leads identified by LSA. The purpose of this promotion was to build and raise awareness of Serenz Nasal Relief using content marketing, which a type of marketing that involves the creation and sharing of online material (such as videos, blogs, and social media posts).

The commercial success of the product will depend on a number of factors, including the following:

- establishment of commercially viable pricing, and obtaining approval for adequate reimbursement from third-party and government payors;
- our ability, or that of third-party manufacturers that we may retain, to manufacture quantities of Serenz using commercially viable processes at a scale sufficient to meet anticipated demand and reduce our cost of manufacturing, and that are compliant with cGMP regulations;
- our success in educating physicians and patients about the benefits, administration and use of Serenz;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- acceptance of Serenz as safe and effective by patients, caregivers and the medical community; and
- a continued acceptable safety profile of Serenz following approval.

Many of these factors are beyond our control. If we are unable to successfully commercialize Serenz, or unable to obtain a partner to commercialize it, we may not be able to earn any revenues related to Serenz. This would result in an adverse effect on our business, financial condition, results of operations and growth prospects.

One or more countries in the E.U. may reassess the Class 2a designation and determine that Serenz be regulated in a different manner.

Serenz has CE Mark certification in the E.U. based on it being treated as a Class 2a medical device in constituent E.U. countries. One or more countries in the E.U. may reassess the Class 2a designation and determine that Serenz be regulated differently and if this occurs, controlled clinical trials and other development work may be necessary to maintain regulatory clearances in any such jurisdictions. We may be required to demonstrate with substantial evidence, gathered in preclinical and well-controlled clinical studies, that Serenz is safe and effective for use. We may not be able to conduct such a trial or may not successfully enroll or complete any such trial. Serenz may not achieve the required primary endpoint in the clinical trial. As a result, the regulatory process in any such jurisdictions may take several years to complete, and requisite clearances may never be obtained.

The mechanism of action of Serenz has not been fully determined or validated

The exact mechanism of action(s) of Serenz is unknown. Therapeutics are increasingly focused on target-driven development, and an understanding of a future product’s mechanism of action is typically believed to make development less risky. The FDA may view this as increasing the potential risks, and diminishing the potential benefits, of Serenz. In addition, potential partners may view this as a limitation of the program, and it may be more challenging for us to obtain a partnership on favorable terms as a result.

Because the results of preclinical testing and earlier clinical trials, and the results to date in various clinical trials, are not necessarily predictive of future results, Serenz may not have favorable results in later clinical trials or receive regulatory approval.

Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the effectiveness and safety of an investigational product. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier clinical trials. Despite the results to date in the various clinical studies performed with Serenz, we do not know whether the FDA will require clinical trials to demonstrate adequate effectiveness and safety to obtain new regulatory approvals to market Serenz. If these subsequent clinical trials do not produce favorable results, regulatory approval for Serenz may not be maintained.

There can be no assurance that Serenz will not exhibit new or increased safety risks in subsequent clinical trials. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many other companies that have believed their planned products performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval for the marketing of their products.

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.

The FDA or similar regulatory authorities outside the U.S. may not continue to allow us to market Serenz or may limit it with restrictions on the label, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Even after regulatory authorities have approved Serenz, the approval may include additional restrictions on the label that could make Serenz less attractive to physicians and patients compared to other products that may be approved for broader indications, which could limit potential sales of Serenz. In addition, we cannot be certain that the FDA will not challenge our position that Serenz should be regulated as a Class I, 510(k) exempt device.

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.

For example, a number of companies offer therapies for treatment of AR patients based on a daily regimen, and physicians, patients or their families may not be willing to change their current treatment practices in favor of Serenz even if it is able to offer additional efficacy or more attractive product attributes. If our products do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable on a sustained basis or at all.

We currently have limited sales and distribution personnel, and limited marketing capabilities. 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 neonatology products, Serenz, or other planned products.

We are currently building a sales and marketing infrastructure and have no experience in the sale, marketing or distribution of diagnostic or therapeutic products. To achieve commercial success for any approved product, we must either develop a sales and marketing infrastructure or outsource these functions to third parties.

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.

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. In addition, the termination of our license agreement for Serenz with our former partner, may negatively impact the perception of Serenz held by other potential partners for the program. 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 this or 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 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. There are several large pharmaceutical and biotechnology companies that currently market and sell AR therapies to our target patient group. These companies may reduce prices for their competing drugs in an effort to gain or retain market share, and

undermine the value proposition that Serenz or our neonatology

products might otherwise be able to offer to payors. 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.

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 payors, 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 payors 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., while we expect payments for CoSense to be part of a diagnosis-related group, or DRG (also known as a bundled payment), we may have to obtain reimbursement for it from payors directly. There may be significant delays in obtaining reimbursement for CoSense, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. Moreover, 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 payors 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 payors 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 payors 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 CoSense, 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, David D. O'Toole, our Senior Vice President, Chief Financial Officer, Neil Cowen, our Senior Vice President of Drug Development, Anthony Wondka, our Senior Vice President of Research and Development, Otho Boone, our Vice President and General Manager of Neonatology, and Kristen Yen, our Vice President of Clinical & Regulatory. 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 Chief Executive Officer, Chief Financial Officer, Vice President & General Manager of Neonatology, Vice President of Clinical & Regulatory, Senior Vice President of Drug Development and Senior Vice President of Research and Development 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 $1,000,000 "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. The loss of a key employee, the failure of a key employee to perform in his or her current position or our inability to attract and retain skilled employees could result in our inability to continue to grow our business or to implement our business strategy.

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.

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 and medical device businesses, we may not succeed in attracting or retaining the personnel we require to continue and grow our operations.

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We may encounter manufacturing problems or delays that could result in lost revenue. Additionally, we currently rely on third-party suppliers for critical materials needed to manufacture our Serenz devices, CoSense monitors and consumables, other neonatology products, as well as our planned products. Any problems experienced by these suppliers could result in a delay or interruption of their supply to us, and as a result, we may face delays in the commercialization of our neonatology products or the development and commercialization of planned products.

We perform final assembly of CoSense monitors and consumables at our facility in Redwood City, CA. We believe that we currently have adequate manufacturing capacity. If demand for our current products and our planned products increases significantly, we will need to either expand our manufacturing capabilities or outsource to other manufacturers. We currently have limited experience in commercial-scale manufacturing of our planned products, and we currently rely upon third-party contract manufacturing organizations to manufacture and supply components for our products. The manufacture of these products in compliance with the FDA's regulations requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of medical device products often encounter difficulties in production, including difficulties with production costs and yields, quality control, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced FDA requirements, other federal and state regulatory requirements, and foreign regulations.

We currently purchase components for our products under purchase orders and do not have long-term contracts with most of the suppliers of these materials. If suppliers were to delay or stop producing our components, or if the prices they charge us were to increase significantly, or if they elected not to sell to us, we would need to identify other suppliers. We could experience delays in manufacturing the instruments or consumables while finding another acceptable supplier, which could impact our results of operations. The changes could also result in increased costs associated with qualifying the new materials or reagents and in increased operating costs. Further, any prolonged disruption in a supplier's operations could have a significant negative impact on our ability to manufacture and deliver products in a timely manner. Some of the components used in our products are currently sole-sourced, and substitutes for these components might not be able to be obtained easily or may require substantial design or manufacturing modifications. Any significant problem experienced by one of our sole source suppliers may result in a delay or interruption in the supply of components to us because the number of third-party manufacturers with the necessary manufacturing and regulatory expertise and facilities is limited. Any delay or interruption would likely lead to a delay or interruption in our manufacturing operations. The inclusion of substitute components must meet our product specifications and could require us to qualify the new supplier with the appropriate government regulatory authorities. It could be expensive and take a significant amount of time to arrange for alternative suppliers, which could have a material adverse effect on our business. New manufacturers of any planned product would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing the product. Obtaining the necessary FDA approvals or other qualifications under applicable regulatory requirements and ensuring non-infringement of third-party intellectual property rights could result in a significant interruption of supply and could require the new manufacturer to bear significant additional costs that may be passed on to us.

We currently contract manufacture Serenz in China with a sole-source third party out-sourced manufacturing supplier. We do not have any backup manufacturing capability. If our sole-source supplier is harmed or rendered inoperable by natural or man-made disasters, including fire, earthquake, flooding and power outages, our supply of Serenz will be interrupted. Also there can be no guarantee that we can maintain a commercial relationship with this supplier on acceptable economic terms.

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, including the Merger with Essentialis pursuant to the Merger Agreement. We completed the Merger with Essentialis on March 7, 2017, and concurrently with the closing of the Merger, completed financing transaction with total aggregate proceeds of approximately $10 million from current stockholders and new investors (see Note 14 to the

Financial Statements for the year ended December 31, 2016). 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.

We have distribution partners for CoSense in China, India, Canada, Turkey, Denmark, Qatar and Saudi Arabia. Our business strategy contemplates international expansion, including partnering with medical device distributors, and introducing our neonatology 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 payor systems, multiple payor-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.

The accuracy of CoSense depends, in part, on the function of software run by the microprocessors embedded in the device. This software is proprietary to us. While we have made efforts to test the software extensively, it is potentially subject to malfunction. It may be 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.

The CoSense monitor also stores test results, a feature which assists medical professionals in interfacing the device with electronic medical records systems. There are a number of state, federal and international laws protecting the privacy and security of health information and personal data. 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 healthcare information by healthcare providers, healthcare clearinghouses, and health insurance plans, collectively referred to as covered entities. The HIPAA amendments also impose compliance obligations and corresponding penalties for non-compliance on individuals and entities that provide services to healthcare providers and other covered entities, collectively referred to as business associates. ARRA also made significant increases in the penalties

for improper use or disclosure of an individual's health information under HIPAA and

extended enforcement authority to state attorneys general. The amendments also create notification requirements for individuals whose health information has been inappropriately accessed or disclosed: notification requirements to federal regulators and in some cases, notification to local and national media. Notification is not required under HIPAA if the health information that is improperly used or disclosed is deemed secured in accordance with encryption or other standards developed by HHS. Most states have laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms to ensure ongoing protection of personal information. Activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers or to alleviate problems caused by such breaches.

Risks related to the operation of our business

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

We may enter into additional distribution or commercialization agreements with third parties with respect to our products. Our likely collaborators for any distribution, marketing, licensing or other collaboration arrangements include large and mid-size medical device and diagnostic companies, regional and national medical device and diagnostic 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 iterations 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.

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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 March 31, 2017, we had 26 employees and 3 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 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 device 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, clinical data management organizations, medical institutions and clinical investigators, 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 to comply with regulations and with standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical studies 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. 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, where our 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 the medical device and diagnostic 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 medical device and diagnostic 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 inter partes 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 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.

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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 medical devices 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 PMA or 510(k) clearance for a medical device 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.

Even if we receive regulatory 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 regulatory approval has been obtained, the approved product and its manufacturer are subject to continual review by the FDA or non-U.S. regulatory authorities. Our regulatory approval for CoSense, as well as any additional regulatory approval that we receive for any 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.

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

We intend to seek a distribution and marketing partner for our neonatology products outside the U.S. and may market planned products in international markets. We have obtained a CE Mark certification for CoSense and Serenz and it is therefore authorized for sale in the E.U.; however, in order to market our planned 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 enrollment 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. In addition, Congress has also proposed a number of legislative initiatives, including possible repeal of the PPACA. In December of 2015, Congress passed a two-year suspension of the 2.3% medical device tax. If after two years, the suspension is not extended, at this time we believe the 2.3% tax on sales of medical devices will be applicable to sales of CoSense devices and may be applicable to CoSense consumables and Serenz devices. We cannot assure you that after the two-year suspension, the reinstatement of the 2.3% medical device tax would not adversely affect our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect 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 payors 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 payors, 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 payor, including commercial insurers.

The PPACA, among other things, amends the intent requirement of the Federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

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

Risks related to ownership of our securities

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

Our stock price has been and is likely to continue to be volatile. The stock market in general, and the market for biotechnology and medical device companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. During the period from January 1, 2016 through December 31, 2016, the reported high and low prices of our common stock ranged from $0.73 to $1.85. 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; 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;

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- 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 costeffective 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 have issued 13,780 shares of Series B Convertible Preferred Stock, which are convertible into 13,780,000 shares of our common stock, based on a fixed conversion price of $1.00 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%.

In connection with the sale and issuance of Series B Convertible Preferred Stock to Sabby pursuant to the 2016 Sabby Purchase Agreement, we also amended the Series D Common Stock Purchase Warrants that were issued to Sabby under the 2015 Sabby Purchase Agreement. The per share exercise price of the common stock underlying the Series D Common Stock Purchase Warrants was reduced from $2.46 per share to $1.75 per share, which, if exercised, may result in sales of substantial amounts of the underlying common stock in the public market, or the perception that these sales may occur, and which 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.

In addition, on March 7, 2017, as contemplated by the Merger Agreement, we issued 8,333,333 shares of common stock for an investment of $8 million from the completion of the concurrent financing, which shares may, in the future, be available for resale upon the filing of a registration statement that covers such shares and which has been declared effective by the SEC, and issued 2,083,333 shares of common stock for an investment of $2 million from Aspire Capital pursuant to the 2017 Aspire

Purchase Agreement. Aspire Capital may ultimately purchase all, some or none of the $17.0 million worth of common stock, of which $2 million was sold on March 7, 2017, issuable under the 2017 Aspire Purchase Agreement, including the 708,333 commitment shares. 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 are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth 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. 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. 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, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.0 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 cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may suffer or be more volatile.

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.

Our executive officers, directors and principal stockholders may continue to maintain the ability to control or significantly influence all matters submitted to stockholders for approval and under certain circumstances Vivo Ventures, Technology Partners, Forward Ventures and its affiliates may have control over key decision making.

Our executive officers, directors and stockholders own a majority of our outstanding common stock. Entities associated with Vivo Ventures, Forward Ventures, Technology Partners and our Chairman, Ernest Mario, as of March 31, 2017, own approximately 64.7% of our common stock. As a result, the forgoing 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, beginning with our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, which was filed March 13, 2015. 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. 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”, which will limit our ability to utilize our existing 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.

Our common stock is eligible for sale and as a result, any such sales could depress the market price of our common stock.

As of March 31, 2017, we had Series A Warrants outstanding exercisable for an aggregate of 2,425,605 shares of common stock, Series C Warrants outstanding exercisable for an aggregate of 590,415 shares of common stock, Series D Warrants outstanding exercisable for an aggregate of 2,930,812 shares of common stock and other warrants exercisable for an aggregate of 571,906 shares of common stock. As of December 31, 2016, we had 12,780 shares of Series B Convertible Preferred Stock outstanding exercisable for an aggregate of 12,780,000 shares of common stock. As of December 31, 2016, 2,908,430 options to purchase shares of our common stock were issued and outstanding with a weighted average exercise price of $3.42 per share. The sale or even the possibility of sale of the shares of common stock, or the exercise of options or warrants to purchase shares of our common stock and subsequent sale thereof could substantially reduce the market price for our common stock or our ability to obtain future financing.

In connection with the sale and issuance of Series B Convertible Preferred Stock to Sabby pursuant to the 2016 Sabby Purchase Agreement, we also amended the 2,702,704 Series D Common Stock Purchase Warrants issued to Sabby under the 2015 Sabby Purchase Agreement. The per share exercise price of the common stock underlying the Series D common stock Warrants was reduced from $2.46 per share to $1.75 per share. The sale or even the possibility of sale of the common stock or the underlying shares of common stock issuable upon the conversion of the Series A

Convertible Preferred Stock or the Series B Convertible Preferred Stock, or upon exercise of the amended Series D Common Stock Purchase Warrants could substantially reduce the market price for our common stock or our ability to obtain future financing.

In addition, on March 7, 2017, as contemplated by the Merger Agreement, we issued 8,333,333 shares of common stock for an investment of $8 million from the completion of the concurrent financing, which shares may, in the future, be available for resale upon the filing of a registration statement that covers such shares and which has been declared effective by the SEC, and issued 2,083,333 shares of common stock for an investment of $2 million from Aspire Capital pursuant to the 2017 Aspire

Purchase Agreement. Aspire Capital may ultimately purchase all, some or none of the $17.0 million worth of common stock, of which $2 million was sold on March 7, 2017, issuable under the 2017 Aspire Purchase Agreement, including the 708,333 commitment shares. 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.

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 Warrants and Series C Warrants in cash.

If, at any time while the Series A Warrants and Series C Warrants are outstanding, we enter into a "Fundamental Transaction" (as defined in the Series A Warrant and Series C Warrant Agreements), 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 Series A Warrants and Series C Warrants as at any time prior to the consummation of the Fundamental Transaction, may elect and require us to purchase the Series A and Series C 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 Series A Warrants and Series C 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. On October 24, 2016, we received a letter from the Listing Qualifications Department of NASDAQ indicating that, based upon the closing bid price of our common stock for the last 30 consecutive business days, we did not meet the minimum bid price of $1.00 per share required for continued listing on NASDAQ pursuant to Nasdaq Listing Rule 5550(a)(2). The letter also indicated that we will be provided with a compliance period of 180 calendar days, or until April 24, 2017, in which to regain compliance pursuant to NASDAQ Listing Rule 5810(c)(3)(A). In addition, 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. On April 16, 2017, we formally requested that the Nasdaq Listing Qualifications Department allow an additional 180 day compliance period in order for us to cure the bid requirement deficiency by performing a reverse stock split of all of the outstanding shares of our common stock at a ratio between one-for-two (1:2) and one-for-ten (1:10), or the Reverse Split, to be determined by our Board. We informed the Nasdaq Listing Qualifications Department that our annual stockholder meeting, or

Annual Meeting, was scheduled for May 8, 2017, at which time we would seek approval from our stockholders to implement, at our Board's discretion, any time in the next 6 months, the Reverse Split. On May 8, 2017, the stockholders approved the Reverse Split.

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 $6.50 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 $6.25 per share prior to the expiration of the five-year term on March 4, 2020. Following 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 $1.75 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;
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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 acquiror from conducting a solicitation of proxies to elect the acquiror'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 of up to approximately $2.3 million for severance and other benefits and acceleration of vesting of stock options with a value of approximately $0.8 million, 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.

The sale of our common stock to Aspire Capital and Sabby may cause substantial dilution to our existing stockholders and the sale of common stock by Aspire Capital and Sabby could cause the price of our common stock to decline.

We have registered for sale 9,291,667 shares of common stock that we may sell to Aspire Capital under the 2017 Aspire Purchase Agreement plus 708,333 shares of common stock that were commitment shares that we issued to Aspire Capital. Depending upon market liquidity at the time, sales of shares of our common stock under the 2017 Aspire Purchase Agreement, which we have previously registered for resale, may cause the trading price of our common stock to decline. Aspire Capital may sell all, some or none of our shares that it holds or comes to hold under the 2017 Aspire Purchase Agreement, including the 708,333 commitment shares issued to it under the 2017 Aspire Purchase Agreement. Sales by Aspire Capital or any of the purchasers of our common stock in the concurrent financing may result in dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock by Aspire Capital, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of sales of our shares to Aspire Capital, and the 2017 Aspire Purchase Agreement may be terminated by us at any time at our discretion without any penalty or cost to us.

We have also registered for sale the shares of common stock underlying the Series B Convertible Preferred Stock sold and issued, or available for sale and issuance, to Sabby pursuant to the 2016 Sabby Purchase Agreement. Sabby may sell all, some or none of our shares that it holds under the 2016 Sabby Purchase Agreement. The issuance of of the shares of common stock underlying the Series B Convertible Preferred Stock and the amended Series D Common Stock Purchase Warrants to Sabby may cause substantial dilution to our existing stockholders, and the sale of the underlying shares of common stock by Sabby could cause the price of our common stock to decline. The sale of a substantial number of shares of our common stock by Sabby, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. The 2016 Sabby Purchase Agreement also provides Sabby a right to participate in any future sale

of our equity securities.

In addition, on March 7, 2017, as contemplated by the Merger Agreement, we issued 8,333,333 shares of common stock for an investment of $8 million from the completion of the concurrent financing, which shares are being registered in this offering.

Risks Associated with a proposed Reverse Stock Split

At the Annual Meeting held on May 8, 2017, we obtained stockholder approval for the Reverse Split, which ratio and effectiveness shall be determined at the sole discretion of our Board at any time within six months following the Annual Meeting. If the Reverse Split is effectuated, then it is possible that significant devaluation of our market capitalization and trading price of the common stock could result. Our Board expects that the Reverse Split of the outstanding common stock will increase the market price of the common stock. However, we cannot be certain whether the Reverse Split would lead to a sustained increase in the trading price or the trading market for our common stock. The history of similar stock split combinations for companies in like circumstances is varied. There is no assurance that:

- the market price per share of the common stock after the Reverse Split will rise in proportion to the reduction in the number of pre-split shares of common stock outstanding before the Reverse Split;
- the Reverse Split will result in a per share price that will attract brokers and investors, including institutional investors, who do not trade in lower priced stocks;
- the Reverse Split will result in a per share price that will increase our ability to attract and retain employees and other service providers;
- the market price per share post Revise Split will remain in excess of the $1.00 minimum closing bid price as required by the Nasdaq Marketplace Rules or that we would otherwise meet the requirements of Nasdaq for continued inclusion for trading on The Nasdaq Global Select Market or The Nasdaq Capital Market; and
- the Reverse Split will increase the trading market for our common stock, particularly if the stock price does not increase as a result of the reduction in the number of shares of common stock available in the public market.

The market price of the common stock will also be based on our performance and other factors, some of which are unrelated to the number of shares outstanding. If the Reverse Split is consummated and the trading price of our common stock declines, the percentage decline as an absolute number and as a percentage of our overall market capitalization may be greater than would occur in the absence of the Reverse Split. Furthermore, the liquidity of the common stock could be adversely affected by the reduced number of shares that would be outstanding after the Reverse Split and this could have an adverse effect on the market price of the common stock. If the market price of the common stock declines subsequent to the effectiveness of the Reverse Split, this will detrimentally impact our market capitalization and the market value of our public float. The Reverse Split may result in some stockholders owning “odd lots” that may be more difficult to sell or require greater transaction costs per share to sell. The Reverse Split may result in some stockholders owning “odd lots” of less than 100 shares of common stock on a post-split basis. These odd lots may be more difficult to sell, or require greater transaction costs per share to sell, than shares in “round lots” of even multiples of 100 shares. Depending on the Reverse Split ratio, certain stockholders may no longer have any equity interest in us. Based on the Reverse Split of all of the outstanding shares of our common stock at a ratio between one-for-two (1:2) and one-for-ten (1:10), certain stockholders might be fully cashed out in the Reverse Split and thus, after the Reverse Split takes effect, such stockholders would no longer have any equity interest in us and therefore would not participate in our future earnings or growth, if any. The Reverse Split may not help generate additional investor interest. There can be no assurance that the Reverse Split will result in a per share price that will attract institutional investors or investment funds or that such share price will satisfy the investing guidelines of institutional investors or investment funds. As a result, the trading liquidity of our common stock may not necessarily improve.

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," "int "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 shares by the selling stockholders.

PRICE RANGE OF COMMON STOCK AND DIVIDEND POLICY

Our common stock is currently listed on the NASDAQ Capital Market under the symbol “SLNO” and our Series A Warrants are quoted on the NASDAQ Capital Market under the symbol “SLNOW.” Our Series B Warrants, Series C Warrants and Series D Warrants are not and will not be traded on a national securities exchange.

The following table contains, for the periods indicated, the intraday high and low sale prices per share of our common stock.

	High	Low
2015		
First Quarter	$9.90	$1.02
Second Quarter	$8.24	$2.64
Third Quarter	$4.04	$1.07
Fourth Quarter	$2.46	$1.51
2016		
First Quarter	$1.85	$1.14
Second Quarter	$1.36	$1.09
Third Quarter	$1.18	$0.90
Fourth Quarter	$1.03	$0.73
2017		
First Quarter	$0.90	$0.64
Second Quarter	$0.74	$0.50

As of August 4, 2017, the last reported sale price of our common stock on the NASDAQ Capital Market was $0.43. As of April 12, 2017, there were approximately 67 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. We have never declared or paid, and do not anticipate declaring or paying, any cash dividends on any of our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends in the foreseeable future. Future determination as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors and will depend on then existing conditions, including our operating results, financial conditions, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

SOLENO THERAPEUTICS, INC (FORMERLY CAPNIA, INC) MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS
YEAR ENDED DECEMBER 31, 2016

The consolidated financial statements of Soleno Therapeutics, Inc. (formerly Capnia, Inc.) included in this prospectus and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2016, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, contained in Soleno Therapeutics's (formerly Capnia, Inc.) Annual Report on Form 10-K for the year ended December 31, 2016 and included elsewhere in this prospectus. In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 21E of the Exchange Act. These forward-looking statements are subject to risks and uncertainties, including those set forth in the section captioned "Risk Factors" and elsewhere in this prospectus that could cause actual results to differ materially from historical results or anticipated results.

Recent Developments

On July 18, 2017, we completed the sale of stock of our 100% wholly-owned subsidiary, NeoForce, Inc., or NFI, primarily related to our portfolio of neonatology resuscitation business, pursuant to a Stock Purchase Agreement, or NFI Purchase Agreement, dated as of July 18, 2017, with NeoForce Holdings, Inc., or NFI 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. We will also receive the total outstanding accounts receivable and inventory held by NFI at the date of sale, as it is collected or sold, respectively. The transactions contemplated by the NFI Purchase Agreement are a continuation of a process previously disclosed by us of evaluating strategic alternatives and focusing on our rare disease therapeutic business. The NFI Purchase Agreement includes customary terms and conditions, including an adjustment to the purchase price based on inventory and accounts receivables, and provisions that require us to indemnify NFI Holdings for certain losses that it incurs as a result of a breach by us of our representations and warranties in the NFI Purchase Agreement and certain other matters. Proceeds from the sale are payable to us as follows: (1) a $720,000 payment to us 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.

Business Overview

We are a diversified healthcare company that develops and commercializes innovative diagnostics, devices and therapeutics addressing unmet medical needs. We have a number of commercial products based on our proprietary technologies, including those which utilize precision metering of gas flow. Our most recent product to launch commercially utilizing our precision metering of gas flow technology is Serenz, which has a CE Mark certification for sale in the E.U. Serenz is a proprietary handheld device that delivers non-inhaled CO_2 topically to the nasal mucosa. Serenz is used only when needed, and does not need to be used on a scheduled basis. Pilot commercial sales of Serenz began in the U.K. and Ireland in the second quarter of 2016.

We are also selling CoSense, which measures ETCO and aids in the detection of excessive hemolysis, a condition in which red blood cells degrade rapidly. When present in neonates with jaundice, excessive hemolysis is a dangerous condition which can lead to adverse neurological outcomes. CoSense is 510(k) cleared for sale in the U.S., and received CE Mark certification for sale in the E.U. In addition, through our wholly owned subsidiary NFI, we also develop and globally market assets relating to innovative pulmonary resuscitation solutions for the inpatient and ambulatory neonatal markets. NFI's primary product is the NeoPip T-piece resuscitator and related consumable, which delivers consistent pre-set inspiratory pressure and positive end-expiratory pressures. Other NFI products include temperature probes, scales, surgical tables and patient surfaces.

Our therapeutic technology consists of the use of nasal, non-inhaled CO_2 for the treatment of the symptoms of AR, as well as for the treatment of pain associated with migraine, cluster headache and trigeminal neuralgia, or TN. Serenz is a treatment for symptoms related to AR, which, when triggered by seasonal allergens, is commonly known as hay

fever or seasonal allergies. We are also pursuing new initiatives for the development of our precision metering of gas flow technology for the treatment of trigeminally-mediated pain disorders such as cluster headache and TN. On December 18, 2015, the FDA granted us orphan drug designation for our nasal, non-inhaled CO_2 technology for the treatment of TN in the U.S. We filed an IND with the FDA and started enrolling TN patients in a pilot clinical trial in 2016.

We continue to focus our research and development efforts on diagnostic products based on our Sensalyze™ Technology Platform, a portfolio of patented and proprietary methods and systems, which enables CoSense to measure ETCO and that can

be applied to detect a variety of analytes in exhaled breath, as well as other products for the neonatology market. Our current development pipeline includes proposed diagnostic devices for asthma in children, assessment of blood CO_2 concentration in neonates and malabsorption. We may also license elements of our Sensalyze Technology Platform to other companies that have complementary development or commercial capabilities.

In July 2015, we commenced enrollment in a pilot, single-center, investigator-sponsored clinical trial evaluating our proprietary nasal, non-inhaled CO_2 technology for the treatment of cluster headaches. The primary efficacy endpoint of the trial is the greatest change from pre-treatment headache pain intensity to post treatment.

On July 24, 2015, we entered into the 2015 Aspire Purchase Agreement with 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 $10.0 million in value of shares of our common stock over the 24-month term of the 2015 Aspire Purchase Agreement. Since July 24, 2015, we issued an aggregate of 506,585 shares of common stock to Aspire Capital in exchange for approximately $1.4 million.

On October 12, 2015, we entered into the 2015 Sabby Purchase Agreement with Sabby to purchase up to $10 million of Series A Convertible Preferred Stock together with related Series D Warrants to purchase shares of our common stock. The sale of the Series Convertible A Preferred Stock occurred in two separate closings. On October 15, 2015, the date of the first closing under the 2015 Sabby Purchase Agreement, we received proceeds of approximately $4.1 million, net of $0.4 million in estimated expenses. On January 8, 2016, the date of the second closing under the 2015 Sabby Purchase Agreement, we received proceeds of approximately $5 million, net of $0.5 million in estimated expenses.

On June 29, 2016, we entered into the 2016 Sabby Purchase Agreement with Sabby, pursuant to which we agreed to sell to Sabby, in a private placement, an aggregate of up to 13,780 shares of our Series B Convertible Preferred Stock at an aggregate purchase price of $13,780,000, which shares are convertible into 13,780,000 shares of our common stock, based on a fixed conversion price of $1.00 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%. In connection with the 2016 Sabby Purchase Agreement, we also repurchased an aggregate of 7,780 shares of Series A Convertible Preferred Stock held by Sabby for an aggregate amount of $7,780,000, which shares were originally purchased by Sabby under the 2015 Sabby Purchase Agreement and which shares represent 4,205,405 shares of common stock on an as-converted basis. The sale of the Series B Convertible Preferred Stock occurred in two separate closings. On July 5, 2016, the date of the first closing under the 2016 Sabby Purchase Agreement, we received proceeds of approximately $1.3 million, net of $0.1 million in estimated expenses. On September 29, 2016, the date of the second closing under the 2016 Sabby Purchase Agreement, we received proceeds of approximately $4.4 million, net of $0.3 million in estimated expenses. After repurchase of the Series A Convertible Preferred Stock and estimated transaction expenses, we received approximately $5.6 million of net proceeds.

On December 22, 2016, we entered into the Merger Agreement with Essentialis. Consummation of the Merger with Essentialis, was subject to various closing conditions, including our consummation of a financing of at least $8 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 we received on March 6, 2017 (see Note 14).

During the years ended December 31, 2015 and December 31, 2016, we received $0.3 million and $0.1 million, respectively, from the exercise of stock options.

During the year ended December 31, 2016, we implemented plans to reduce our operating expenses, 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.

As of December 31, 2016, we had an accumulated deficit of $98.3 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 revenue only from the 2013 license agreement pertaining to Serenz, $1.9 million in revenue from our neonatology products and $0.2 million in government grants. We may never be successful in commercializing our neonatology products, therapeutic products or in developing additional 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.

On May 12, 2017, we formally changed our name from "Capnia, Inc." to "Soleno Therapeutics, Inc."

Our management believes that we has sufficient capital resources to sustain operations through at least the next twelve months.

Financial overview

Summary

We have not generated net income from operations to date, and, at December 31, 2016 and December 31, 2015, we had an accumulated deficit of approximately $98.3 million and $86.2 million, respectively, primarily as a result of research and development and general and administrative expenses. We may never be successful in commercializing our neonatology products, including CoSense, therapeutic products or in developing additional 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.

Revenue recognition

We apply the provisions of Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 605, Revenue Recognition, to recognize revenue. We begin recognizing revenue when persuasive evidence of an arrangement exists, such as a contract or purchase order, delivery has occurred, no significant obligations with regard to implementation or integration exist, the fee is fixed or determinable, and collectability is reasonably assured.

Research and development expenses

Research and development costs are expensed 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.

Sales and marketing expenses

Sales and marketing expenses consist principally of personnel-related costs, professional fees for consulting expenses, 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 CoSense.

General and administrative expenses

General and administrative expenses consist principally of personnel-related costs, 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.

Other income (expense), net

Other income (expense), net is primarily comprised of changes in the fair value of the Series A, Series B and Series C 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 B Warrants

We account for the Series B Warrants issued in connection with our IPO in accordance with the guidance in Accounting Standards Codification (ASC) 815-40. The warrants have a cashless exercise provision that allows for exercise of the warrants at any time between four and fifteen months after issuance, on a cashless basis for a number of common shares that increases as the market price of our common stock decreases, and exercisable at a discount to

the price of our common stock at the time. The terms of the Series B warrants do not explicitly limit the potential number of shares, thereby the exercise of the B warrants could result in our obligation to deliver potentially unlimited number of shares upon settlement. As such, share settlement in not within our control and as provided under ASC 815-40, the warrants do not meet the criteria for equity treatment and are

recorded as a liability. Accordingly, we classified the Series B warrants as liabilities at their fair market value at the date of the IPO and will re-measure the warrants at each balance sheet date until they are exercised or they expire. Any change in the fair value is recognized as other income (expense) in our statement of operations.

The fair value of the warrant liability was determined using a Monte Carlo simulation model. This model is dependent upon several variables such as the warrant's term, exercise price, current stock price, risk-free interest rate estimated over the expected term, estimated volatility of our stock over the term of warrant and the estimated market price of our stock during the cashless exercise period. The risk-free rate is based on U.S. Treasury securities with similar maturities as the expected terms of the warrants. The volatility is estimated based on blending the volatility rates for a number of similar publicly-traded companies.

In accordance with the guidance under ASC 815-40-25, we have evaluated that we have a sufficient number of authorized and unissued shares as December 31, 2015, to settle all existing commitments.

Series A and Series C Warrants

We account for the Series A and Series C in accordance with the guidance in ASC 815 Derivatives and Hedging. The Series A and Series C 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 the sole control of Soleno Therapeutics 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 is equivalent to fair value computed using the Binomial Lattice Valuation Model.

We classified the Series A and Series C Warrants as 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 our statement of operations.

Series D Warrants

We account for the Series D 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. 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. We are required to comply with certain requirements to cause or maintain the effectiveness of a registration statement for the offer and sale of these securities. Such change in control events include tender offers or hostile takeovers, which are not within our sole control as the issuer of these warrants. However, the Series D Warrant agreement specifically provides that under no circumstances will we be required to settle any Series D Warrant exercise for cash, whether by net settlement or otherwise. Accordingly, we have classified the value of the Series D Warrants as permanent equity.

Series A and Series B Convertible Preferred Stock

We classified our Series A and Series B Convertible Stock as permanent equity on our 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, we evaluated our 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, we followed the whole instrument approach which compares an individual feature against the entire preferred stock instrument which includes that feature. Our analysis was based on a consideration of the economic characteristics and risks of each series of preferred stock. More specifically, we 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, we concluded 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.

Research and development expense

Research and development costs are expensed as incurred. Research and development expense includes payroll and personnel expenses; consulting costs; external contract research and development expenses; and allocated overhead, including rent, equipment depreciation and utilities, and relate to both company-sponsored programs as well as costs incurred pursuant to reimbursement arrangements. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed.

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing contracts and purchase orders, reviewing the terms of our intellectual property agreements, communicating with our applicable personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees to:

- contract manufacturers in connection with the production of clinical trial materials;
- contract research organizations and other service providers in connection with clinical studies;
- investigative sites in connection with clinical studies;
- vendors in connection with preclinical development activities; and
- professional service fees for consulting and related services.

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows and expense recognition. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual accordingly. Our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in our reporting changes in estimates in any particular period. To date, there have been no material differences from our estimates to the amounts actually incurred. However, due to the nature of these estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical studies or other research activity.

Stock-based compensation expense

For the years ended December 31, 2016 and December 31, 2015 stock-based compensation expense was $871,270 and $942,369, respectively. As of December 31, 2016 we had $1,553,427 of total unrecognized compensation expense, which we expect to recognize over a period of approximately 2.7 years. The intrinsic value of all outstanding stock options as of December 31, 2016 was approximately zero. We expect to continue to grant equity incentive awards in the future as we continue to expand our number of employees and seek to retain our existing employees, and to the extent that we do, our actual stock-based compensation expense recognized in future periods will likely increase.

Stock-based compensation costs related to stock options granted to employees are measured at the date of grant based on the estimated fair value of the award, net of estimated forfeitures. 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 fair value of an equity award granted to a non-employee 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. In June 2016, we granted 55,000 NSOs to sales

representatives of Bemes, Inc. Of the 55,000 options granted, 27,499 options with a fair value of $26,355 vested immediately upon grant. Accelerated vesting of the remaining options were contingent on the satisfaction of certain performance requirements, that were not met. Regardless of not achieving accelerated vesting, the remaining options have a one year cliff vesting. As a result, we recognized $13,502 in expense for the remaining options during 2016, which will vest during the first quarter of 2017. Total expense for the two groups of options reflects the fair value of our common stock on the applicable vesting commencement dates.

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 a peer index of common stock of comparable companies.
- 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.

There were 955,713 options granted in the year ended December 31, 2015. There were 1,339,259 options granted in the year ended December 31, 2016. In addition to the assumptions used in the Black-Scholes option-pricing model, we must also estimate a forfeiture rate to calculate the stock-based compensation expense for our awards. We will continue to use judgment in evaluating the expected volatility, expected terms, and forfeiture rates utilized for our stock-based compensation expense calculations on a prospective basis.

Impairment of Goodwill

Goodwill represents the excess of the purchase price of an acquired enterprise or assets over the fair value of the identifiable assets acquired and liabilities assumed. Goodwill is presumed to have an indefinite life and is not subject to amortization. We test for impairment of goodwill on an annual basis in the fourth quarter and at any other time when events occur or circumstances indicate that the carrying amount of goodwill may not be recoverable. Circumstances that could trigger an impairment test include, but are not limited to: a significant adverse change in the business climate or legal factors, an adverse action or assessment by a regulator, change in customer, target market and strategy, unanticipated competition, loss of key personnel, or the likelihood that a reporting unit or significant portion of a reporting unit will be sold or otherwise disposed.

An assessment of qualitative factors may be performed to determine whether it is necessary to perform the two-step quantitative goodwill impairment test. If the result of the qualitative assessment is that it is more likely than not (i.e. greater than 50% likelihood) that the fair value of a reporting unit, is less than its carrying amount, then the quantitative test is required. Otherwise, no further testing is required. At our testing date, we did not perform the qualitative assessment.

Under the quantitative test, if the carrying amount of a reporting unit's goodwill exceeds the implied fair value of that goodwill, an impairment loss is recorded in the Consolidated Statements of Operations as "Impairment of goodwill." Measurement of the fair value of a reporting unit is based on one or more of the following fair value measures: amounts at which the unit as a whole could be bought or sold in a current transaction between willing parties, using present value techniques of estimated future cash flows, or using valuation techniques based on multiples of earnings or revenue, or a similar performance measure.

Based on our organizational structure and our financial information during 2016 and 2015, we determined we operate in one segment and two reporting units. The only reporting unit with goodwill was the NeoForce ("NFI") unit. During the fourth quarter of 2016, we tested the NFI reporting unit's goodwill for impairment under the two-step quantitative goodwill impairment test in accordance with authoritative guidance. There were no triggering events during the interim periods of 2016.

Under the first step of the authoritative guidance for impairment testing, the fair value of the NFI reporting unit was determined based on the income approach, which estimates fair value based on the future discounted cash flows. We assumed a cash flow period of 5 years, annual revenue growth rates of 38.2% to 63.9%, a discount rate of 20.5%, and a terminal value equivalent to one times final year sales. While projected revenue growth is above average, beginning revenue is quite low and

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the acquisition of new customers, mainly hospitals and health plans, is expected to result in relatively large increments of growth. We also performed sensitivity analyses to estimate the effect of significantly lower revenue growth on estimated fair value. We believe the assumptions and rates used in the impairment test are reasonable, but they are judgmental, and variations in any of the assumptions or rates could result in a materially different calculation of impairment. The determination of estimated fair value of goodwill required the use of significant unobservable inputs which are considered Level 3 fair value measurements. Based on the first step of the authoritative guidance on impairment testing, we concluded that the fair value of the NFI reporting unit was in excess of its carrying value. The NFI reporting unit was acquired during the fourth quarter of 2015. We had no other goodwill during 2015 or 2016.

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. Valuation allowances are provided when necessary 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.

In assessing the realizability of deferred tax assets, we consider whether it is more likely than not that some portion or all of the deferred tax assets will be realized on a jurisdiction by jurisdiction basis. The ultimate realization of deferred tax assets is dependent upon the generation of taxable income in the future. We have recorded a deferred tax asset in jurisdictions where ultimate realization of deferred tax assets is more likely than not to occur.

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.

Results of Operations

Comparison of the Years Ended December 31, 2016 and 2015

	Year Ended December 31,		Increase (decrease)	
	2016	2015	Amount	Percentage
Revenue	$1,450,788	$607,472	$843,316	139 %
Cost of goods sold	1,509,306	352,683	1,156,623	328 %
Gross profit	(58,518)	254,789	(313,307)	(123)%
Operating expenses:				
Research and development	5,184,803	4,536,244	648,559	14 %
Sales and marketing	1,630,591	1,737,470	(106,879)	(6)%
General and administrative	6,736,203	6,140,821	595,382	10 %
Total	13,551,597	12,414,535	1,137,062	9 %
Income (Loss) from operations	(13,610,115)	(12,159,746)	(1,450,369)	12 %
Other income (expense), net	1,566,601	(3,748,800)	5,315,401	(142)%
Loss before provision for income taxes	(12,043,514)	(15,908,546)	3,865,032	(24)%
Provision for deferred taxes	21,700	—	21,700	— %
Net loss	$(12,065,214)	$(15,908,546)	3,843,332	(24)%

Revenue

During the year ended December 31, 2015, we recognized $220 thousand of government grant revenue from a new grant awarded during the second quarter of 2015, and $388 thousand of product revenue from sales of CoSense, Precision Sampling Sets and NFI products, of which $279,000 related to NFI products subsequent to the acquisition of NeoForce's assets in September 2015. During the year ended December 31, 2016, we recognized $1.5 million of product revenue from sales of CoSense, Precision Sampling Sets and NFI products. Revenue increased by $843 thousand primarily due to the inclusion of a full year of revenue related to NFI products.

Research and development expense

Research and development expense for the year ended December 31, 2016 increased $649 thousand as compared to the year ended December 31, 2015. The increase was primarily due to increases in compensation expense of $502 thousand, travel and entertainment of $55 thousand and $92 thousand of outside services.

Sales and marketing expense

Sales and marketing expense for the year ended December 31, 2016 decreased $107 thousand over the year ended December 31, 2015 primarily due to the decrease of direct sales personnel concurrent with signing a distributor agreement with Bemes.

General and administrative expense

General and administrative expense for the year ended December 31, 2016 increased $595 thousand as compared to the year ended December 31, 2015. The increase was primarily due to increases in legal expenses of $284 thousand, $136 thousand of compensation expense and $175 thousand for the settlement of the Lawsuit.

Other income (expense), net

Of the $3.7 million expense in 2015, $0.2 million was due to the value of the commitment shares of common stock issued to Aspire Capital, $3.1 million was due to the issuance of the Series C Warrants which were treated as an inducement and the change in the fair value of the warrants by $0.5. Other income in 2016 primarily represented the decrease in warrants by $1.7 million, offset by $0.1 million of Cease-use expense (see Note 4).

Liquidity and Capital Resources

On July 24, 2015, we entered into the 2015 Aspire Purchase Agreement with 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 $10.0 million in value of shares of our common stock over the 24-month term of the purchase agreement. During the quarter ended September 30, 2015, we issued an aggregate of 506,585 shares of common stock to Aspire Capital in exchange for approximately $1.4 million.

On October 12, 2015, we entered into the 2015 Sabby Purchase Agreement with Sabby to purchase up to $10 million of Series A Convertible Preferred Stock together with related Series D Warrants to purchase shares of our common stock. The sale of the Series A Convertible Preferred Stock took place in two separate closings. On October 15, 2015, the date of the first closing, we received proceeds of approximately $4.1 million, net of $0.4 million in estimated expenses. On January 8, 2016, the date of the second closing, we received proceeds of approximately $5 million, net of $0.5 million in estimated expenses.

On June 29, 2016, we entered into the 2016 Sabby Purchase Agreement with Sabby, pursuant to which we agreed to sell to Sabby, in a private placement, an aggregate of up to 13,780 shares of our Series B Convertible Preferred Stock at an aggregate purchase price of $13,780,000, which shares are convertible into 13,780,000 shares of our common stock, based on a fixed conversion price of $1.00 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%. In connection with the 2016 Sabby Purchase Agreement, we also repurchased an aggregate of 7,780 shares of Series A Convertible Preferred Stock held by Sabby for an aggregate amount of $7,780,000, which shares were originally purchased by Sabby under the 2015 Sabby Purchase Agreement and which shares represent 4,205,405 shares of common stock on an as-converted basis. The sale of the Series B Convertible Preferred Stock occurred in two separate closings. On July 5, 2016, the date of the first closing under the 2016 Sabby Purchase Agreement, we received proceeds of approximately $1.3 million, net of $0.1 million in estimated expenses. On September 29, 2016, the date of the second closing under the 2016 Sabby Purchase Agreement, we received proceeds of approximately $4.4 million, net of $0.3 million in estimated expenses. After repurchase of the Series A Convertible Preferred Stock and estimated transaction expenses, we received approximately $5.6 million of net proceeds.

On December 22, 2016, we entered into the Merger Agreement with Essentialis. Consummation of the Merger was subject to various closing conditions, including our consummation of a financing of at least $8 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 we held on March 6, 2017 where we received stockholder approval (see Note 14).

On January 27, 2017, we entered into the 2017 Aspire Purchase Agreement with 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. Further, on the date of the closing of the financing, as defined in the Merger Agreement, we sold to Aspire Capital, and Aspire Capital purchased from us, an aggregate of $2.0 million of our common stock. On March 7, 2017, we received the $2.0 million from Aspire Capital (see Note 14).

During the year ended December 31, 2016, we implemented plans to reduce our expenses, including reducing its workforce, eliminating outside consultants, reducing legal fees and implementing a plan to allow Board members to receive common stock, in lieu of cash payments.

At December 31, 2016, we had cash and cash equivalents of $2.7 million, of which $2.3 million is invested in a money market fund at an AAA-rated financial institution.

We believe that, based on our current level of operations, our existing cash resources, including the $10 million in financing that we received on March 7, 2017 (see Note 14), will provide adequate funds for ongoing operations, planned capital expenditures and working capital requirements for at least the next 12 months.

We expect to incur substantial expenditures in the foreseeable future for the development and potential commercialization of Serenz and CoSense products, as well as clinical trials for our therapeutic products. We may continue to require additional financing to develop our future products and fund operations for the foreseeable future. We will continue to seek funds through equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. We anticipate that we may need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the rate of progress in the commercialization of our products and the generation of revenue from product sales;
- the degree and rate of market acceptance of any products launched by us or future partners;

- the cost of commercializing our products, including the costs of sales, marketing, and distribution;
- the costs of developing our anticipated internal sales and marketing capabilities;
- the cost of preparing to manufacture our products on a larger scale;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- our ability to enter into additional collaboration, licensing, commercialization or other arrangements and the terms and timing of such arrangements;
- the emergence of competing technologies or other adverse market developments; and,
- the cost of clinical trials for Cluster Headache, TN and Serenz.

If we are unable to raise additional funds when needed, our ability to complete planned clinical trials and attain commercial success with CoSense, or our other potential products, may be impaired. We may also be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to others technologies or future products or programs that we would prefer to develop and commercialize ourselves.

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,	
	2016	2015
Cash Flows from Continuing Operations:		
Net cash used in operating activities	$(13,497,980)	$(10,299,330)
Net cash used in investing activities	(38,680)	(1,320,777)
Net cash provided by financing activities	10,768,133	9,157,920
Net decrease in cash and cash equivalents	$(2,768,527)	$(2,462,187)

Cash used in operating activities

During the year ended December 31, 2016, net cash used in operating activities was $13.5 million, which was primarily due to the net loss of $12.1 million, as well as adjustments for non-cash items including the $1.7 million change in fair value of warrants and decreases in accounts payable and accrued liabilities of $0.6 million and inventory of $0.1 million, offset by stock-based compensation of $0.8 million.

During the year ended December 31, 2015, net cash used in operating activities was $10.2 million, which was primarily due to the net loss of $15.9 million, offset by $0.5 million change in fair value of warrants, Series C Warrants inducement charge of $3.0 million, $0.9 million of stock based compensation expense, and increases in accounts payable and accrued liabilities of $1.5 million.

Cash used in investing activities

Cash used in investing activities in the year ended December 31, 2016 consisted of investment in equipment

During the year ended December 31, 2015, we used $1.0 million to acquire NeoForce. Cash used in other investing activities in the year ended December 31, 2015 consisted primarily of investment in equipment, change in restricted cash and payment to acquire patents.

Cash provided by financing activities

During the year ended December 31, 2016, cash provided by financing activities was $10.8 million, consisting primarily of $5.1 million, net of costs, and $13.5 million, net of costs, in proceeds from issuance of Series A and Series B Convertible Preferred stock, respectively, offset by $7.8 million used to repurchase the outstanding Series A Convertible Preferred stock. $0.1 million was received from the exercise of common stock options.

During the year ended December 31, 2015 cash provided by financing activities was $9.2 million, consisting primarily of $4.2 million in proceeds from issuance of Series A Convertible Preferred stock, $3.9 million form the issuance of common

stock as a result of the exercise of Series A Warrants and Series B Warrants, issuance of common stock to Aspire Capital for $1.4 million and the $0.3 million received from the exercise of common stock options, offset by payment of IPO costs and Series B transaction costs of $0.6 million and the repayment of the outstanding balance on our line of credit of $0.1 million.

As of December 31, 2016, we had cash and cash equivalents of approximately $2.7 million. We believe that our cash resources, including the $10 million of financing that we received on March 7, 2017 (see Note 14) are sufficient to meet our cash needs for at least the next 12 months.

Contractual obligations and commitments

As of December 31, 2016, we had net lease obligations totaling $1,714,788, 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 July of 2019. We had previously signed a sublease for our prior operating facilities at 3 Twin Dolphins Drive in Redwood City, with an expiration date of June 2018.

The following table summarizes our contractual obligations as of December 31, 2016.

	Payments due by period				
	Less than 1 year	1 to 3 years	4 to 5 years	After 5 years	Total
Lease obligations	$750,118	$964,670	$ —	$ —	$1,714,788
Total	$750,118	$964,670	$ —	$ —	$1,714,788

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.

On February 28, 2017, we settled the Lawsuit (see Note 14) by agreeing to provide supplemental disclosures and pay $175,000 in attorney's fees. This amount was recorded as a current liability on the balance sheet as of December 31, 2016 and recognized as general and administrative expense in the statement of operations for the year ended December 31, 2016. The stipulation of dismissal was approved by the court on April 14, 2017, and we expect to pay the $175,000 in attorney's fees within 30 days from the date of the order.

Off-Balance Sheet Arrangements

As of December 31, 2016, 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 for a detailed discussion).

SOLENO THERAPEUTICS, INC (FORMERLY CAPNIA, INC) MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS
QUARTER ENDED MARCH 31, 2017

The interim consolidated financial statements included in this prospectus and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2016, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, contained in the Company's Form 10-K for the year ended December 31, 2016 and included elsewhere in this prospectus. In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements are subject to risks and uncertainties, including those set forth in the section captioned "Risk Factors" and elsewhere in this prospectus that could cause actual results to differ materially from historical results or anticipated results.

Recent Developments

On July 18, 2017, we completed the sale of stock of our 100% wholly-owned subsidiary, NeoForce, Inc., or NFI, primarily related to our portfolio of neonatology resuscitation business, pursuant to a Stock Purchase Agreement, or NFI Purchase Agreement, dated as of July 18, 2017, with NeoForce Holdings, Inc., or NFI 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. We will also receive the total outstanding accounts receivable and inventory held by NFI at the date of sale, as it is collected or sold, respectively. The transactions contemplated by the NFI Purchase Agreement are a continuation of a process previously disclosed by us of evaluating strategic alternatives and focusing on our rare disease therapeutic business. The NFI Purchase Agreement includes customary terms and conditions, including an adjustment to the purchase price based on inventory and accounts receivables, and provisions that require us to indemnify NFI Holdings for certain losses that it incurs as a result of a breach by us of our representations and warranties in the NFI Purchase Agreement and certain other matters. Proceeds from the sale are payable to us as follows: (1) a $720,000 payment to us 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.

Overview

On March 7, 2017, we completed our merger, or the Merger, with Essentialis, Inc., a Delaware corporation, or Essentialis. After the Merger with Essentialis, our primary focus is on 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 metabolic diseases where there is increased mortality and risk of cardiovascular and endocrine complications. Essentialis has been developing Diazoxide Choline Controlled Release, or DCCR, tablets as a treatment for Prader Willi Syndrome, or PWS, a complex metabolic/neurobehavioral disorder.

We continue to commercialize innovative medical devices to address unmet medical needs, although they are no longer our primary focus and will likely be monetized in the future. We have two commercial products based on our proprietary technologies. Our most recent product to launch commercially is Serenz, a proprietary handheld device that gently cleanses nasal mucosa. A similar product, Serenz Allergy Relief, has CE Mark certification in the European Eunion, or E.U. In the United States, or U.S., we have concluded that Serenz is a Class I, 510(k) exempt device. Serenz is used only when needed, and does not need to be used on a regular basis. We also sell CoSense, which measures end-tidal carbon monoxide, or ETCO, and aids in the detection of excessive hemolysis, a condition in which red blood cells degrade rapidly. When present in neonates with jaundice, excessive hemolysis is a dangerous condition which can lead to adverse neurological outcomes. CoSense is 510(k) cleared for sale in the U.S. and received CE Mark certification for sale in the E.U.

We also market innovative pulmonary resuscitation solutions for the inpatient and ambulatory neonatal markets through our subsidiary, NeoForce, Inc., or NFI. NFI's primary product is the NeoPip™ T-piece resuscitator and related consumable, which delivers consistent pre-set inspiratory pressure and positive end-expiratory pressures. Other

products include temperature probes, scales, surgical tables and patient surfaces.

Following our Merger with Essentialis, we initiated a comprehensive review of strategic alternatives for our legacy products and product candidates, including Serenz Nasal Relief, Serenz Allergy Relief, CoSense ETCO Monitor, and our portfolio of innovative pulmonary resuscitation solutions for the neonatal market.

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.

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 abnormally increased appetite for food. 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 in 1976 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 CHI, and in adults with insulinoma, which is a tumor of the pancreas that produces excessive amounts of insulin. Insulinoma patients tend to be older, with 50% of them over 70 years old. The average duration of use of Proglycem in CHI and insulinoma patients is 5 years and 7 years, respectively.

DCCR tablets were formulated with the goals of improving the safety and bioavailability of orally-administered diazoxide and reducing the frequency of daily dosing required by current diazoxide formulations. Diazoxide choline is formulated into a controlled-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.

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, 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, which is an abnormally increased appetite for food, 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. Other complications in PWS patients include greater risk for autistic symptomatology, psychosis, sleep disorders, skin-picking, distress, mood lability, 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 mental retardation range with a mean IQ in the 60s to low 70s. The combination of food-related preoccupations and numerous maladaptive behaviors makes it difficult for individuals with PWS to perform to their IQ potential.

On December 22, 2016, we entered into an Agreement and Plan of Merger, or the Merger Agreement, with Essentialis.

On March 6, 2017, we held a special stockholder meeting and received approval for the issuance of the merger shares under the Merger Agreement with Essentialis, the issuance of the shares of common stock for the $8 million of

concurrent financing and the issuance of the shares of Common Stock for the $2 million investment by Aspire Capital, LLC, or Aspire Capital.

On March 7, 2017, we completed the Merger with Essentialis and issued 18,916,940 shares of Common Stock to stockholders of Essentialis. We held back 913,379 shares of Common Stock as partial recourse to satisfy indemnification claims, and such shares will be issued to Essentialis stockholders on the 1 year anniversary of the closing of the Merger. We are

also obligated to issue an additional 4,566,948 shares of common stock to Essentialis stockholders upon the achievement of a development milestone. Assuming that we issue all of the shares of our Common Stock held back and the development milestone is achieved, we would issue a total of 24,397,267 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 $30 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.

In addition, we issued 8,333,333 shares of CommonStock for an investment of $8 million from the completion of the concurrent financing and issued 2,083,333 shares of Common Stock for an investment of $2 million from Aspire Capital.

During the year ended December 31, 2016 and the three months ended March 31, 2017, we received $0.1 million and zero, respectively, from the exercise of stock options.

As of March 31, 2017, we had an accumulated deficit of $101.2 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 revenue only from the 2013 license agreement pertaining to Serenz, $2.2 million in revenue from our neonatology products and $0.2 million in government grants. We may never be successful in commercializing our neonatology products, therapeutic products or in developing additional 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.

Management believes that we have sufficient capital resources to sustain operations through at least the next twelve months.

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 unaudited condensed consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these consolidated 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 of the accompanying unaudited condensed consolidated financial statements.

Results of Operations

Comparison of the three months ended March 31, 2017 and 2016

	Three Months Ended March 31,		Increase (decrease)	
	2017	2016	Amount	Percentage
	(in thousands)			
Product revenue	265	447	(182)	(41)%
Cost of goods sold	209	461	(252)	(55)%
Gross profit (loss)	56	(14)	70	500 %
Operating expenses:				
Research and development	994	1,772	(778)	(44)%
Sales and marketing	114	538	(424)	(79)%
General and administrative	1,158	1,939	(781)	(40)%
Total	2,266	4,249	(1,983)	(47)%
Loss from operations	(2,210)	(4,263)	2,053	(48)%
Interest Income	1	—		
Change in fair value of warrants	(69)	1,170	(1,239)	(106)%
Cease-use expense	(7)	(94)	87	(93)%
Other income (expense)	(602)	(2)	(600)	
Interest and other income (expense), net	(677)	1,074	(1,752)	(163)%
Net loss	(2,887)	(3,189)	302	(9)%

Revenue

Total revenue in the three months ended March 31, 2017 decreased 41% as compared to the three months ended March 31, 2016. During the three months ended March 31, 2017, we recognized $45 thousand of product revenue from sales of CoSense and Precision Sampling Sets, $217 thousand from NFI products and $3 thousand from the sale of Serenz. In the three months ended March 31, 2016, we recognized $125 thousand of product revenue from sales of CoSense and Precision Sampling Sets and $322 thousand from NFI products. The decrease in product revenue for NFI products was primarily due to two large orders that were expected in the first quarter of 2017, that were deferred until the second and third quarter of 2017.

Research and development expense

Research and development expense in the three months ended March 31, 2017 decreased $778 thousand as compared to the three months ended March 31, 2016. The decrease was primarily due to reduction in headcount.

Sales and marketing expense

Sales and marketing expense in the three months ended March 31, 2017 decreased $424 thousand over the three months ended March 31, 2016 primarily due to reduction in headcount.

General and administrative expense

General and administrative expense in the three months ended March 31, 2017 decreased $781 thousand as compared to the three months ended March 31, 2016. The decrease was primarily due to a decrease in legal fees and decreased headcount.

Interest and other income (expense), net

Interest and other income (expense), net in the three months ended March 31, 2017 decreased $1.8 million as compared to the three months ended March 31, 2016. The change in the fair value of the warrants decreased from an other expense of $1.2 million in the three months ended March 31, 2016 to $0.1 million in other income in the three

months ended March 31, 2016. Other income (expense) increased $0.6 million primarily due to the value of commitment shares issued to Aspire Capital in 2017 (see Note 6).

Liquidity and Capital Resources

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

	Three Months Ended March 31,	
	2017	2016
	(in thousands)	
Cash Flows from Continuing Operations:		
Net cash used in operating activities	(2,183)	$(3,984)
Net cash used in investing activities	(4,000)	(19)
Net cash provided by financing activities	10,000	5,000
Net increase in cash and cash equivalents	$7,813	$997

Cash used in operating activities

During the three months ended March 31, 2017, net cash used in operating activities was $2.2 million, which was primarily due to the use of funds for operations, and adjustments for non-cash items including the $0.1 million change in fair value of warrants and $0.2 million of stock based compensation expense, an increases in accounts payable of $0.2 million and inventory of $0.2 million.

During the three months ended March 31, 2016, net cash used in operating activities was $4.0 million, which was primarily due to the use of funds operations, including costs incurred to launch Serenz in the E.U., as well as adjustments for
non-cash items including the $1.2 million change in fair value of warrants and $0.1 million of stock based compensation
expense, offset by increases in accounts payable and accrued liabilities of $0.4 million and an increase in inventory of $0.1
million.

Cash used in investing activities

During the three months ended March 31, 2017, we used $4 thousand in investing activities. Cash used in investing activities in the three months ended March 31, 2017 consisted primarily of investment in equipment.

During the three months ended March 31, 2016, we used $19 thousand. Cash used in investing activities in the three months ended March 31, 2016 consisted primarily of investment in equipment.

Cash provided by financing activities

During the three months ended March 31, 2017 cash provided by financing activities was $10.0 million as a result of the completion of the concurrent financing associated with the Essentialis merger.

During the three months ended March 31, 2016 cash provided by financing activities was $5.0 million as a result of the
second close under the Sabby Purchase Agreement.

On March 7, 2017, the Company completed the merger with Essentialis. Concurrently, the Company issued 8,333,333 shares of common stock for an investment of $8 million from the completion of the concurrent financing and issued 2,083,333 shares of common stock for an investment of $2 million from Aspire Capital.

As of March 31, 2017, we had cash and cash equivalents of approximately $10.5 million.

We believe that the we have sufficient capital resources, after considering the $10 million of financing that we received on March 7, 2017, to sustain operations through at least the next twelve months from the date of this filing.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

BUSINESS

Recent Developments

On July 18, 2017, we completed the sale of stock of our 100% wholly-owned subsidiary, NeoForce, Inc., or NFI, primarily related to our portfolio of neonatology resuscitation business, pursuant to a Stock Purchase Agreement, or NFI Purchase Agreement, dated as of July 18, 2017, with NeoForce Holdings, Inc., or NFI 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. We will also receive the total outstanding accounts receivable and inventory held by NFI at the date of sale, as it is collected or sold, respectively. The transactions contemplated by the NFI Purchase Agreement are a continuation of a process previously disclosed by us of evaluating strategic alternatives and focusing on our rare disease therapeutic business. The NFI Purchase Agreement includes customary terms and conditions, including an adjustment to the purchase price based on inventory and accounts receivables, and provisions that require us to indemnify NFI Holdings for certain losses that it incurs as a result of a breach by us of our representations and warranties in the NFI Purchase Agreement and certain other matters. Proceeds from the sale are payable to us as follows: (1) a $720,000 payment to us 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.

Company Overview

On March 7, 2017, we completed the Merger with Essentialis. After the Merger with Essentialis, our primary focus is on 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 metabolic diseases where there is increased mortality and risk of cardiovascular and endocrine complications. Essentialis has been developing DCCR as a treatment for Prader Willi Syndrome, or PWS, a complex metabolic/neurobehavioral disorder.

We continue to commercialize innovative medical devices to address unmet medical needs, although they are not our primary focus anymore and will likely be monetized in the future. We have two commercial products based on our proprietary technologies. Our most recent product to launch commercially is Serenz, a proprietary handheld device that gently cleanses nasal mucosa. A similar product, Serenz Allergy Relief, has a CE Mark in the E.U. and in the U.S., we have concluded that it is a Class I, 510(k) exempt device. Serenz is used only when needed, and does not need to be used on a regular basis. We are also selling CoSense, which measures ETCO and aids in the detection of excessive hemolysis, a condition in which red blood cells degrade rapidly. When present in neonates with jaundice, excessive hemolysis is a dangerous condition which can lead to adverse neurological outcomes. CoSense is 510(k) cleared for sale in the U.S. and received CE Mark certification for sale in the E.U.

We also market innovative pulmonary resuscitation solutions for the inpatient and ambulatory neonatal markets through our subsidiary, NFI. NFI's primary product is the NeoPip™ T-piece resuscitator and related consumable, which delivers consistent pre-set inspiratory pressure and positive end-expiratory pressures. Other products include temperature probes, scales, surgical tables and patient surfaces.

Following the Merger with Essentialis, we initiated a comprehensive review of strategic alternatives for our legacy products and product candidates, including Serenz Nasal Relief, Serenz Allergy Relief, CoSense ETCO Monitor, and our portfolio of innovative pulmonary resuscitation solutions for the neonatal market.

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.

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 abnormally increased appetite for food. 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 in 1976 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 a controlled-release tablet that lowers peak plasma concentration compared to diazoxide oral suspension and slows release of diazoxide from DCCR, making them suitable for once-a-day dosing.

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, 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.

Other complications in PWS patients include greater risk for autistic symptomatology, psychosis, sleep disorders, skin-picking, distress, mood lability, 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 mental retardation range with a mean IQ in the 60s to low 70s. The combination of food-related preoccupations and numerous maladaptive behaviors makes 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 only addresses the short stature and limits the accumulation of visceral fat, and may reduce hypotonia, 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% of respondents indicated improving metabolic health (reduces fat / increases muscle) and 81.3% of respondents indicated the related symptom of improves 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 of respondents indicated improvements to intellect/development, and 83.2% of respondents indicated reduction of temper outburst severity and frequency. See the Foundation for Prader-Willi Research. Prader-Willi Syndrome “Patient Voices” Online Survey and Results. 1-80. 2014

Therefore, there is a clear unmet need in the treatment for 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 need.

Clinical Trial of DCCR for PWS

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A pilot study has been conducted to evaluate the safety and preliminary efficacy if 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 10 and 22. The first phase of the study was open label during which subjects were initiated on a DCCR dose target that 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 predetermined intervals would be designated a responder, whereas all others would be designated non-responders. This 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 on the same predetermined day, or to the placebo equivalent of that dose for an additional period of time. Of the 13 subjects who enrolled, 11 were designated as responders; the remaining two subjects had discontinued prematurely. After 10 weeks of open-label treatment, there was a 32% reduction in hyperphagia, as assessed by a modified multi-item questionnaire. The improvement in hyperphagia in those who were randomized to DCCR in the double-blind phase persisted through more than 3 months of treatment. Statistically significant reductions from in total cholesterol, LDL cholesterol, and non-HDL cholesterol were observed. The change in triglycerides, while marked, did not reach statistical significance. There was a statistically significant improvement in aggressive, threatening and destructive behaviors.

In addition to the therapeutic effects on hyperphagia, aggressive behaviors and cardiovascular risk, treatment of PWS patients with DCCR resulted in a range of metabolic responses. These included highly significant reductions in body fat, increases in lean body mass, and in the lean body mass/fat mass ratio. Treated subjects showed statistically significant reductions in waist circumference, suggestive of a loss of visceral fat. PWS subjects treated with DCCR for 6 months, on average, lost 7.3% of body mass, with a parallel loss of body fat.

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 included upper respiratory tract infections; hyperglycemia/glucose intolerance; bruises, scrapes and scratches; headache; hypersomnia; constipation or a worsening of constipation; ear infection; peripheral edema; and worsening of peripheral edema.

Regulatory Status of DCCR for the Treatment of PWS

DCCR is being developed in the U.S. under a current IND. A general scientific advice meeting is planned for the second quarter of 2017. Scientific advice from the European Medicines Agency, or EMA, is planned for later this year. Orphan drug designation for DCCR for the treatment of PWS was granted on May 14, 2014, and an orphan drug designation application to the EMA is anticipated to be submitted in 2017.

The criteria for qualification for orphan drug designation by EMA differs slightly from that in the U.S.:

- it must be intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating;
- the prevalence of the condition in the E.U. must not be more than 5 in 10,000 or it must be unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development; and
- no satisfactory method of diagnosis, prevention or treatment of the condition concerned can be authorized, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

Market opportunity

There are today about 7,500 identified patients with PWS in the U.S. 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. It is estimated that that there may be as many as 11,000 identified patients in Europe and about 2,000 in Japan. 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 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

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target the handful 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.

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 product for PWS is Genotropin® (somatropin) and is approved only for growth failure due to PWS. There are no approved products to address the hyperphagia and behaviors associated with PWS, or for any other abnormalities associated with the disease. Several products are under development for the treatment of PWS, including for hyperphagia, and are summarized below:

Product / Company	Status	Target (symptom or physiologic target)
Peripheral Endocannabinoid (CB1R blocker)	Nonclinical	Decrease activity of endocannabinoid system to decrease appetite
Setmelanotide (RM-493) / Rhythym Pharmaceuticals	Phase 2 Completed Q4 2016, results not yet reported	Bypasses proposed POMC neuron defect
AZP-531 / Alizé Pharma	Phase 2 Completed in XX	Unacylated ghrelin to decrease the hunger-inducing effects of acylated ghrelin
Tesomet / Saniona	Phase 2a Initiated	Combination of tesofensine and metoprolol to induce weight loss
Cannabidoil (CBD) oral solution / Insys Therapeutics	Phase 2 Planned	Suppresses appetite & reduce anxiety
Oxytocin / Investigator-sponsored	Phase 1 and 2 Ongoing	Binds to oxytocin receptors, regulates trust, emotions, with minor effect on appetite
Carbetocin (Intranasal), FE992097 / Levo Therapeutics	Phase 2 Completed; Phase 3 Pending	Binds to oxytocin receptors, regulates trust, emotions, with minor effect on appetite

Serenz Nasal Relief

AR, which is commonly and colloquially referred to as “allergies,” is characterized by symptoms that are often episodic and include nasal congestion, itching, sneezing and runny nose. It is one of the most common ailments in the western world and is growing rapidly, making AR one of the largest potential pharmaceutical markets. There are approximately 50 million sufferers in the U.S. and 48 million in France, Germany, Italy, Spain and the United Kingdom, and an additional 36 million in Japan, according to research firm GlobalData. Prevalence of AR is growing rapidly in the developed world. The most common AR drug therapies include antihistamines and intranasal steroids. Leukotriene inhibitors and other drugs are also currently prescribed to AR patients. Several of these drugs have generated sales in excess of $1 billion per year as branded products. However, these products have significant limitations and AR sufferers remain dissatisfied with the available treatments. Thus, there is a need for a more effective treatment with a faster onset of action and improved safety profile.

Serenz is based upon the observation that non-inhaled CO_2 delivered at a low-flow rate to rinse the nasal cavity, alleviates the symptoms of AR by cleansing the nasal mucosa. Serenz is a convenient, hand-held device that contains a pressurized canister of gas, with approximately enough gas to dose as-needed for one to two weeks. The device is disposable and engineered for ease of use. Our proprietary technology ensures precise control of aspects such as flow rate, which we believe is critical to achieve the desired clinical performance.In our clinical trials to date, Serenz has shown a statistically significant effect within 30 minutes and is well-tolerated. We believe that Serenz to be a potential first-line product for any AR sufferer. Contrary to dosing with commonly used medications such as antihistamines and nasal steroids, which must be dosed on a regular basis regardless of the presence of symptoms, Serenz is used on an as-needed basis and only when symptoms are present. Other nasal rinses may be used on an as-needed basis. However, other available powered nasal irrigators require an external power source and a place for the nasal rinse solution to drain. Therefore they may not be ideal for use in a location other than at home or in a restroom.

Based on clinical trials to date, we believe Serenz exhibits the ideal characteristics of an AR product, including:

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- Rapid relief
- Relief from all nasal congestion, sneezing and itchy/runny nose
- Non-sedating
- Tolerant side effect profile
- Acts locally in the nasal cavity
- Non-steroidal
- No known long-lasting side effects
- Usable on an as-needed basis
- Compact, handheld design

Clinical Trials of Serenz in Allergic Rhinitis

We have conducted six randomized, controlled clinical trials involving 975 patients, testing the safety and effectiveness of nasal CO_2 in relieving the symptoms of AR. Four of these clinical trials were in patients with seasonal AR, or SAR, and two of these clinical trials was in patients with perennial AR, or PAR. In addition, GlaxoSmithKline conducted a trial in 147 patients to assess the consumer appeal of Serenz for patients with nasal congestion. The trials using the as-needed approach showed statistically significant and clinically meaningful effects in both SAR and PAR. The effect is seen on each of the individual nasal and non-nasal symptoms, with as little as a 10 second per nostril application of Serenz. Given the rapid onset and generally mild side effect profile, we believe Serenz is ideally suited for marketing to patients for use on an as-needed basis.

The As-Needed Only Use Paradigm

As-needed use of Serenz is supported by the following studies:

- SAR-2005-This was the first randomized, placebo-controlled trial in subjects with SAR. Symptomatic subjects used a single application of active (nasal CO_2) or placebo 60 sec/nostril one time. Symptoms were measured just before and at several time points after the treatment. Statistically significant improvements in symptoms were noted as early as 10 minutes.
- C211 (PAR)-This was a randomized, placebo-controlled trial in subjects with PAR. Symptomatic subjects used a single application of active or placebo. Subjects were assigned to one of six arms: CO_2 at 5 mL/sec for 10 sec/nostril, CO_2 at 10 mL/sec for 10 sec/nostril, CO_2 at 5 mL/sec for 30 sec/nostril, CO_2 at 10 mL/sec for 30 sec/nostril, placebo for 10 sec/nostril, and placebo for 30 sec/nostril in a 2:2:2:2:1:1 ratio. Symptoms were measured just before and at several time points after use. Statistically significant improvements in symptoms were noted at 30 minutes in the CO_2 at 10 mL/sec for 10 sec/nostril group. There was sustained (4-6 hours) relief of symptoms in this arm.
- C216 (SAR)-This was the first multi-application, randomized, placebo-controlled trial in which the nasal CO_2 device was used as needed in subjects with SAR. Subjects applied active or placebo 10 sec/nostril only as needed up to six times a day for 14 days. Symptoms were measured just before and at 30 minutes after each use during the 14-day study period. Statistically significant improvements ($p<0.0001$) in symptoms were noted at 30 minutes after each use during the 14-day treatment period. These results show that the nasal CO_2 device is effective for the as needed use of SAR symptoms. The effect is rapid and the effect size is large.

Scheduled Dosing Studies with Serenz

Other studies conducted for AR have evaluated the more traditional paradigm of scheduled dosing. Effectiveness measurements in these studies, based on a Guidance Document published by the FDA, are recorded in the morning and evening, regardless of the time of the treatment or pre-treatment symptoms. These measurements therefore reflect the overall symptomatic relief during the day as opposed to measuring the true effect of a treatment. Measurement of post-treatment scores in this scheduled dosing paradigm show the efficacy to be predictably lacking since pre-treatment scores are low (subjects treat when they are scheduled to, regardless of whether they need to based on presence or absence symptoms).

Safety of Serenz

There were no application-related or device-related serious adverse events in any of the clinical trials conducted. Adverse events were generally mild and application-related, and resolved immediately upon cessation of application. The most common adverse events were transient nasal sensation and tearing of the eyes, or lacrimation, that lasted for the duration of the application only.

The nasal sensation commonly encountered during these clinical trials was described by patients differently, and ranges from tingling to burning to pain. We also observed that these sensations were generally not severe enough for patients to discontinue use of nasal CO_2, and for more than 1,000 patients treated in all of the AR clinical trials, only six patients discontinued use of nasal CO_2 due to an adverse event. We believe that these clinical trials provide evidence that gentle cleansing of the nasal mucosa with Serenz is safe, acts locally and provides rapid relief of allergy symptoms.

Serenz Regulatory Status

We have CE Mark certification for Serenz Allergy Relief.

In the U.S., we have concluded that Serenz Nasal Relief is a Class I, 510(k) exempt device. The device meets U.S. FDA regulations as a class 1 medical device (i.e., not a pharmaceutical) and is 510(k) exempt in the United States (Product Code, KMA; Regulation Number, 21 CFR 874.5550, Powered Nasal Irrigator). The following intended use of the Serenz Nasal Relief device is consistent with 21 CFR 874.5550 which identifies powered nasal irrigators as "…powered device intended to wash the nasal cavity…"

Serenz Nasal Relief is intended to irrigate and wash the nasal cavity with a controlled flow of carbon dioxide. The wash is intended to provide rapid relief for adults experiencing nasal allergy symptoms such as stuffy, runny or itchy nose or sneezing.

Sales and Marketing

In March 2017, we initiated the pilot launch of Serenz Nasal Relief in the U.S.

As part of this pilot launch, a product-specific website, www.serenz.com, was developed to provide information about Serenz Nasal Relief. This website also contains an eCommerce platform for consumer purchases of Serenz Nasal Relief. For the pilot launch, Serenz Nasal Relief can only be purchased online at www.serenz.com. We anticipate that online sales will commence in April 2017.

Using the knowledge that we acquire during the spring 2017 pilot launch, such as understanding the cost and timing of customer acquisition, lead conversion rates, customer retention and repurchase patterns, as well as the role and effectiveness of social media, we will plan the next steps for commercializing Serenz Nasal Relief in the fall of 2017 allergy season.

Pricing

Roughly 50 million people in the U.S. suffer from nasal allergies. Americans spend as much as $4.5 billion annually on medications and doctor visits to treat their allergies, about half of which is spent on medications. Seventy percent of AR sufferers (roughly 35 million) treat their symptoms with prescription or OTC products. There has been an increasing shift since 2014 in the transfer of prescription AR products to OTC status, which has driven patients to pharmacies to self-medicate rather than to physician offices.

Recent prescription-to-OTC switches for AR include budesonide (Rhinocort) in 2015, fluticasone propionate (Flonase) in 2014, and triamcinolone acetonide (Nasacort) in 2014. A month's supply will cost from $15 to $25 depending on brand and distributor/ pharmacy.

One Serenz device contains enough gas for approximately 20 washes, which we believe will last on average of one to two weeks, depending on frequency of use. Our current pricing is $29.50, which is priced it at a premium compared to existing products for AR due to the benefits we believe the product provides to patients over such products.

Competition

All OTC products are competition for Serenz Nasal Relief such as Rhinocort, Flonase, Nasacort, nasal washes such as Sinus Rinse, SinuPulse Elite and Nasaline.

CoSense

CoSense was our first Sensalyze Technology Platform product to receive 510(k) clearance 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. Our first target market 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.

Hemolysis and Bilirubin

We estimate that approximately one third of the 9.2 million newborns in the U.S. and E.U. each year are at risk for hemolysis under current practice, representing approximately 3.1 million newborns. When treatment is required, it is usually via phototherapy, which typically involves isolating the baby in a chamber that directs blue-wavelength light to the baby's skin. The light penetrates the skin and breaks down bilirubin via a photochemical reaction over a period of several hours. When treatment is performed in a timely fashion, adverse outcomes can be avoided. Some neonates with jaundice, however, will develop adverse neurodevelopmental outcomes related to hyperbilirubinemia if not properly treated.

According to the Agency for Healthcare Research and Quality, part of the U.S. Department of Health and Human Services, neonatal jaundice is the single largest cause for hospital readmission of neonates in the U.S. This results in inefficient care and can also be highly stressful and disruptive for the parents and neonate.

Exposure to excess bilirubin in the central nervous system as a result of hyperbilirubinemia is toxic and may cause long-term developmental disabilities. These abnormalities may be subtle, and include hearing problems and low IQ. Subtle forms of disability are known as Bilirubin-Induced Neurological Dysfunction, or BIND. More severe bilirubin-induced disabilities, including respiratory failure and resulting death, can be referred to as Acute Bilirubin Encephalopathy, or ABE. Bilirubin toxicity can ultimately result in a chronic, severe, and disabling condition called kernicterus. Kernicterus is a cerebral palsy-like condition in which the patient lacks muscle tone and motor control, cannot operate self-sufficiently, and typically requires long-term care. The National Quality Forum has in the past described kernicterus as a "never event," one which physicians should ensure never occurs in their practice.

Limitations of Current Diagnostic Methods

It has been reported in peer-reviewed publications that the presence of hemolysis in a neonate with jaundice is a predictor of adverse neurodevelopmental outcomes. If neonates with high rates of hemolysis could be identified before they are discharged from the hospital, treatment could begin earlier, exposure to excessive bilirubin would be minimized and readmissions for jaundice would be reduced. Prior to the introduction of CoSense accurate tools for diagnosing hemolysis in neonates were not available in the market. Tests that are commonly performed to assess hemolysis such as serial hematocrit levels, reticulocyte counts, Coombs test and peripheral smear, are all invasive blood tests, involving painful heel sticks to draw the blood and are less useful in neonates due to physiologic changes resulting from childbirth.

CoSense: FDA 510(k) Clearance and CE Mark Certification

CoSense, our first Sensalyze Technology Platform product to receive 510(k) clearance from the FDA and CE Mark certification, is a monitor of ETCO. CO is a direct byproduct of hemolysis, and based on extensive published data such as that from Stanford University, the rate of bilirubin production can be measured by analyzing the concentration of CO in a neonate's exhaled breath.

CoSense is a point-of-care device that consists of a light-weight, portable monitoring device and a single-use nasal cannula, which we refer to as our Precision Sampling Set, or PSS. The PSS is placed just inside the nostril of the patient and is connected to the device. The CoSense device is turned on and acquires the breath signal while the patient breathes. Appropriate sample acquisition takes an average of 30 seconds. The PSS can then be removed from the patient and the device takes another four minutes to report the test result.

The AAP recommends the use of ETCO monitoring for the detection of hemolysis. We believe ETCO monitoring will enable more rapid and appropriate treatment decisions and reduce overall costs of patient care. However, there is currently no device on the market other than CoSense that effectively measures ETCO in neonates.

Clinical Trials

Seven investigator-sponsored clinical trials have been performed to validate the ability of CoSense to detect the presence of hemolysis. Four of these were performed in neonates. One was performed in neonates and children up to 17 years old. Two were performed in children with sickle cell anemia, or SCA, a disease which results in chronic hemolysis.

In a pilot clinical trial at Stanford University, a bench to bedside evaluation of CoSense was undertaken to identify hemolysis in neonates, and to correlate ETCO levels with bilirubin production as defined by levels of carboxyhemoglobin, or COHb, in the blood. A strong linear correlation between COHb and ETCO was seen (r= 0.93), confirming that ETCO values with CoSense accurately measure bilirubin production and therefore hemolysis. The results were published in an article titled, “Evaluation of a new end-tidal carbon monoxide monitor from the bench to the bedside,” in Acta Paediatrica 2015.

The ability of CoSense to identify hemolysis in neonates with significant hyperbilirubinemia was evaluated at The Children’s Hospital of Zhejiang University School of Medicine in Hangzhou, China. The data from the study showed that ETCO measurement with CoSense can provide the physician with similar information to that currently provided by invasive blood tests regarding the patient’s hemolytic status, but with a simple, non-invasive breath test.

In a clinical trial at Children’s Hospital & Research Center in Oakland, California, ETCO concentration was measured in children with SCA, who are known to have chronic hemolysis, using CoSense. The data from this trial showed that CoSense may be useful to monitor the rate of hemolysis in children with SCA. This results from this study were published in an article titled, “Point-of-care end-tidal carbon monoxide reflects severity of hemolysis in sickle cell anemia,” in Pediatric Blood & Cancer 2015.

Recently, another clinical trial was conducted at Children’s Hospital & Research Center in Oakland, California and UCSF Benioff Children’s Hospital, in SCD subjects ages 2 to18 years old and age-matched controls to validate the accuracy of a CoSense device that had an extended temperature operating range and to determine if the modified device could differentiate between children with sickle cell disease and healthy controls. This study showed that the modified CoSense device provided a reliable detection of hemolysis in the sickle cell subjects.

A study of 20 neonates and children with known hemolytic disorders, such as hereditary spherocytosis or pyruvate kinase deficiency, and 20 age-matched controls was conducted to compare ETCO measurements at Intermountain Healthcare Institutions in Utah. This study shows that CoSense can detect the differences in the rate of hemolysis between neonates and children who have known hemolytic anemia and healthy age-matched neonates and children.

In a separate study at Intermountain Healthcare Institutions, ETCO was measured in 30 healthy, term (at least 37 weeks GA) newborns within the first hours after birth and again just before discharge from to home to quantify the rate of hemolysis . This study provides further evidence that low-grade hemolysis occurs normally in the first days after birth.

The results of these two studies were published in an article titled, “End-tidal carbon monoxide as an indicator of hemolytic rate,” in Blood Cells, Molecules and Diseases 2015.

In another study conducted at Intermountain Healthcare Institutions, ETCO was measured in 100 neonates. This study showed that it is feasible to use CoSense to measure ETCO and, when an elevated ETCO is found during birth hospitalization, parents were likely to comply with advice to have the TB level rechecked within 24 hours of discharge. The results of this study were published in an article titled, “Measuring End-Tidal Carbon Monoxide of Jaundiced Neonates in the Birth Hospital to Identify Those with Hemolysis,” in Neonatalogy 2016.

A multi-center investigator-sponsored trial to define the normative data (mean, median, range and interquartile ranges) for all term and late-preterm newborns for CoSense has been completed recently. This confirmed that pre-discharge measurements of TB together with ETCO can be used as an index of increased bilirubin rates due to hemolysis.

Market Opportunity

Independent market research that we conducted has identified a large market opportunity for the CoSense device in the well-baby nursery, as well as, labor and delivery units in term neonates (more than than 37 weeks), as well as in the neonatal intensive care unit, or NICU, in preterm births (less than 34 weeks) and late preterm births (between 34 and 37 weeks).

Sales and Marketing

Key elements of our sales and marketing strategy include:

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- Focus efforts on growing the volume of tests performed and associated consumables used. We plan to focus specifically on sales to the neonatal intensive care unit, or NICU, well-baby nursery, and labor/delivery units within each hospital.
- Establish and engage a network of distributors in the E.U., as well as elsewhere in the world. We may establish continuing operations at a location in the E.U. to ensure close coordination and effective execution of the CoSense sales and marketing plan in the E.U.
- Price the CoSense device at a level that allows hospitals to purchase it without protracted review via a "capital purchase committee" or analogous body.
- Price the PSS consumable sampling sets at a price that is competitive with the current costs of performing the Coombs Test and other associated invasive assays. We believe that this cost offset, complemented by potential improvements in discharge planning and clinical outcomes, will provide hospital decision-makers with a compelling economic case for adoption of CoSense.
- Build awareness of the AAP treatment guidelines, and of the benefits of CoSense, via medical education efforts to key clinical audiences, including neonatologists, pediatricians, obstetricians, and pediatric nurses.
- Collaborate with key specialty societies, including the AAP, Pediatric Academic Societies, American Academy of Family Physicians, or AAFP, and patient advocacy groups
- Support clinical trials and publications that expand the base of evidence supporting broad adoption of CoSense.

In the rest of the world, we expect to partner with distributors in each country or region, with oversight and marketing assistance from our own personnel.

Pricing and Reimbursement

We expect to continue to sell the CoSense device at a price below the typical capital expenditure approval threshold levels of most hospitals and other medical institutions in the U.S. In the U.S., since the use of CoSense is almost entirely in the inpatient setting around the time of discharge of a newborn, reimbursement may be in the form of a DRG. Frequently referred to as a bundled payment, the DRG is a specific flat-fee payment amount for all services performed by a medical institution pursuant to a single diagnosis.

Competition for CoSense

Currently CoSense is the only device commercially available with the sensitivity and accuracy necessary to measure ETCO levels that are meaningful for detecting the rate of hemolysis in neonates, and we do not know of any such device that is under development by any party.

Our Sensalyze Technology Platform

A variety of medical diagnostic testing is routinely performed via measurement of gas concentrations, either from blood samples, exhaled breath or transcutaneously. Examples include arterial blood gas measurements, capnometry and pulse oximetry, respectively. Devices used for detecting the presence of various analytes in exhaled breath typically rely on the patient performing a specified breath maneuver such as breath holding and forced expiration. The use of these devices is limited to those who can perform such maneuvers, such as adults and older children.

The limitations of existing breath-based technologies are particularly problematic in neonates. Neonates typically have very rapid and irregular breathing patterns. They also inhale and exhale relatively small volumes, which limits the accuracy of devices that require the larger-volume sample sizes exhaled by older patients. In addition, they are not able to perform specified breath maneuvers. Our Sensalyze Technology Platform allows the measurement of analytes in all patients, from neonates to adults, regardless of their ability to actively perform a breath maneuver.

Our Sensalyze Technology Platform combines hardware, sensors, and software to provide the following novel capabilities:

- Identification of full breaths that follow a normal pattern, also known as "physiologically representative" breaths. Our platform can identify these breaths even if the patient is breathing very rapidly, a capability that is particularly relevant in infants.

- Capture of individual exhaled breaths, and segmentation of the breath into different components such as “end-tidal”, “upper airway”, and “lower airway”. This may allow the localization of the source of a given analyte to a specific anatomic area.
- Ability to move a specific micro-liter component of breath to a sensor module. When combined, these capabilities provide a novel patent protected platform for non-invasive detection of various analytes.

NeoForce Pulmonary Solutions

Approximately 10% of newborns require some assistance to begin breathing at birth and represents the number of patients that would benefit from our products. Of this 10%, approximately 1% requires extensive resuscitative measures. Although the vast majority of newly born infants do not require intervention to make the transition from intrauterine to extra uterine life, because of the large number of births, a sizable number will require some degree of resuscitation.

Respiratory Adaptation

In utero, most of the blood flow is shunted away from the lungs and directed to the placenta where fetoplacental gas exchange occurs. After birth, the airways and the alveoli must be cleared of fetal lung fluid so that the lungs can operate as a functional respiratory unit providing adequate gas exchange. Pulmonary blood flow must increase, and spontaneous respirations must be established.

NeoForce T-Piece Resuscitation Platform

A T-piece resuscitator is a manually operated resuscitation delivery device used for infants and small children (less than 10 kg) to effectively deliver inhalation breaths at preset peak inspiratory pressures, or PIP, and a small back pressure to keep the lungs from collapsing on exhalation, known as positive end expiratory pressures, or PEEP, at a preset Fi02, or percent oxygen. There are two components to T-piece Resuscitation, the “Box or T-piece Resuscitator” and a single patient use circuit. The circuit connects to the box on one end and the patient on the other through a mask. The box controls the PIP, and the circuit controls the PEEP through an adjustable valve. In general, it is a modern replacement for the traditional bag and mask which requires significant user training and experience to deliver breaths to infants with tiny and very delicate lungs and may result in injury due to inappropriately high pressure and/or larger volumes.

Resuscitation and the First Breaths of Life

Neonatal resuscitation skills are essential for all health care providers who are involved in the delivery of newborns. The transition from fetus to newborn requires intervention by a skilled individual or team in approximately 10% of all deliveries. In the U.S., 81% of all babies are born in nonteaching level I or II hospitals. In these hospitals, the volume of delivery service may not provide sufficient economic justification for the continuous in-hospital presence of specialists with high-risk delivery room experience, as recommended by the AAP Neonatal Resuscitation Guidelines, or NRP, and the American College of Obstetricians and Gynecologists, or ACOG. Perinatal asphyxia and extreme prematurity are the 2 complications of pregnancy that most frequently necessitate complex resuscitation by skilled personnel. However, only 60% of asphyxiated newborns can be predicted ante partum. The remaining newborns are not identified until the time of birth. Additionally, approximately 80% of low-birth-weight infants (infants less than 2kg) require resuscitation and cardio pumonary stabilization at post delivery.

Nearly one half of newborn deaths (many of which involve extremely premature infants) occur during the first 24 hours after birth. Many of these early deaths also have a component of asphyxia or respiratory depression as an etiology. For the surviving infants, effective management of asphyxia in the first few minutes of life can influence long-term outcome.

Even though prenatal care can identify many potential fetal difficulties ante partum, allowing maternal transfer to a referral center for care, many women who experience preterm labor are not identified prospectively and therefore are not appropriately transferred to a tertiary perinatal center. Consequently, many deliveries of extremely premature infants occur in smaller hospitals.

For these reasons, all personnel involved in delivery room care of the newborn should be trained adequately in all aspects of neonatal resuscitation. Additionally, equipment that is appropriately sized to resuscitate infants of all gestational ages should be available in all delivering institutions, even if the institution does not care for preterm or intensive care infants.

Market Opportunity

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The United Nations estimates the annual number of births worldwide to be approximately 143 million. Of these births, the number requiring assisted ventilation is approximately 10% of all births which represents the theoretical maximum addressable market potential. The addressable market is however much lower since a large number of infants are born in regions that do not have access to advanced resuscitation facilities, people or equipment. In general the market can be segmented along the economic development status of the country region where the infant is born and our current solutions are aligned to more developed regions such as the U.S., E.U., and portions of the Middle East.

In the U.S. and E.U., there are approximately 8.1 million term births and 1.1 million preterm and late preterm births each year. Approximately 10% of term births, or approximately 800,000 babies, and 80% of preterm and late preterm babies, or approximately 88,000 babies, will need assisted ventilation during the birthing process or later in the NICU as a supplement to long term ventilation management.

In the U.S., approximately the majority of all birthing hospitals have or use some form of T-piece resuscitation and are potential consumers of our T-piece solutions which include a delivery device (NeoPiP T-piece Resuscitator) or our universal T-piece single patient use circuit (NeoPiP Circuit).

Sales and Marketing

We intend to leverage the existing channels that we have in place to sell the newly acquired products from NeoForce. NFI has a well-established and efficient telemarketing presence that will supplement and extend our current distribution channel. In the U.S., we will continue to sell via a direct sales force, with potential augmentation of our reach via distributors. In the E.U., we expect to partner with distributors in each country, with oversight and marketing assistance from our personnel in the U.S.

Our U.S. direct sales efforts will continue to focus on large hospital systems with high volumes of births as the call points and decision makers for both NFI and CoSense customers are nearly identical. NFI has an installed base of over 300 customers and the existing relationships are anticipated to have a positive impact on creating interest in CoSense. The majority of NFI revenues will continue to be sales of our consumable T-piece circuits.

Key elements of our sales and marketing strategy include:

- Focus efforts on growing the volume of consumables used as our universal circuit will work with all installed base devices of NFI and its competitors.
- Establish and engage a network of distributors in the E.U. and other international markets as conditions warrant.

We will continue to evaluate expansion opportunities and pursue those where the potential to accelerate our business is deemed sufficient for the investment we put at risk.

Pricing and Reimbursement

NFI sells its products into a relatively mature market with established pricing and acquisition methods in place where the hospital focuses on price, clinical utility and improved safety as measures to “switch”. The decision to buy, therefore, will continue to be driven at the departmental level controlled by the nursing management team overseeing the newborn areas of the institution, in conjunction with respiratory therapy.

NFI is under contract with MedAssets, a GPO that represents approximately 35% of all hospitals in the U.S. and sets fixed pricing as a function of volume. We will continue to utilize this contract to help expand sales of our neonatology products and will assess other GPO organizations as conditions warrant.

There are no reimbursement issues for the NFI line of products as the devices and consumables for resuscitation are considered mission critical and covered under the hospitals operating budget at the department level.

Competition for NeoForce Resuscitation Solutions

T-piece resuscitation has been around since the early 1900’s but only became mainstream in the past 30 years, mostly due to the efforts of Fisher and Paykel and their NeoPuff ® line of resuscitation devices. Their efforts in conjunction with the widespread integration of T-piece devices built into the radiant warmers used in the delivery room has created a substantial installed base of units that can use our consumable circuit.

Companies that currently produce a T-piece solution include: GE Health Care, Fisher and Paykel, Drager Medical, Mercury Medical and CareFusion. Many of our competitors are part of large companies where T-piece is treated as an accessory or an extension of a larger portfolio of unrelated adult and pediatric solutions. Our focus on this market combined with our small size allows us to be nimble and responsive to changing market dynamics.

Manufacturing

Pharmaceuticals

Our manufacturing strategy is to contract with third parties to manufacture the majority of our active pharmaceutical ingredients (API) and solid oral dose products for DCCR (drug product). We will contract with third parties to manufacture our clinical and commercial API and drug product supplies.

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.

We believe the formulation and processes used to manufacture our products is proprietary and we have agreements with three third-party manufacturers that are intended to restrict these manufacturers from using or revealing this proprietary information.

Medical Devices

We have manufactured the Serenz device in partnership with an OEM supplier based in Shenzhen, China and intend to manufacture future supply with this same OEM supplier. We currently complete final packaging and labeling of Serenz Nasal Relief at our facility in Redwood City, California. Our manufacturing facility is registered with the FDA and certified to the ISO 13485 standard, the internationally harmonized regulatory requirement for quality management systems of medical device companies. We may utilize our current OEM supplier to complete the final packaging and labeling of Serenz for future supplies.

We currently manufacture CoSense monitors at our facility in Redwood City, California. We assemble components from a variety of original equipment manufacturer, or OEM, sources. We may, depending on sales volume and ongoing requirements in specific sales geographies, outsource manufacturing of components, or finished goods, to various OEMs in the future.

NFI has its operations in Ivyland, Pennsylvania and is FDA registered and ISO 13485 certified. NFI assembles and tests the NeoPip resuscitators at its facility in Ivyland. The NeoPiP circuit is manufactured in Taiwan at an FDA registered ISO 13485 facility, with inventory stocked at NFI for distribution.

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 are in effect in other countries.

Intellectual Property

DCCR Patent Portfolio

Our patent portfolio surrounding DCCR consists of three 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, and 9,381,202) expire in 2026 to 2028, while the allowed patent would expire in 2034. 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
- Pharmaceutical formulations of diazoxide
- Methods to treat various diseases including a number of aspects of PWS and other rare diseases with diazoxide
- Methods to treat various rare diseases including PWS with KATP channel agonists

Our Sensalyze Technology Platform Patent Portfolio

Our patent portfolio surrounding our Sensalyze Technology Platform, including CoSense, consists of two issued U.S. patents, and nine pending U.S. and corresponding Patent Cooperation Treaty, or PCT, patent applications. It is our intent to pursue the issuance of these P.C.T. applications, and future cases, in other major commercial geographies over time. Our issued U.S. patents (no.'s 8,021,308 and 9,095,276) expire in 2027 and 2026. The pending patent applications, if issued, would likely expire on dates ranging from 2023 through 2034.

The issued patents and pending patent applications include:

- use of Sensalyze Technology in various medical applications to test and screen for a variety of medical conditions;
- breath selection, algorithmically and physically, to tailor the analysis to the underlying medical condition;
- detection and storage of discrete portions of a breath;
- diversion and isolation of gases to enable measurement within a breath pattern;
- specific compositions of valving and pumps to route airflow in a tightly controlled manner;
- microfluidic collection methods for increasing the precision of measurement of small volumes of gas; and
- various methods for arrangement and specification of components to enhance precision and compensate for factors that cause inaccurate measurements.

Serenz Patent Portfolio

Successful application of therapeutic gases to the nasal mucosa is generally dependent on specific dosing, concentration, and rate of gas outflow. The CO_2 gas used in the Serenz product is packaged in small sealed cylinders with relatively high internal pressure; regulating the flow of gas from this high pressure cylinder to the relatively low flow rates required for Serenz presents significant technical challenges. Our Serenz patent portfolio addresses these challenges.

Our Serenz patent portfolio consists of 37 issued patents (12 in the U.S. and 25 outside the U.S.) and 29 pending patent applications (four in the U.S. and 25 outside the U.S.). The expiration dates for the issued patents and pending applications vary, with the latest being in 2033. Our issued patents and pending patent applications include claims directed to:

- gas dispensing devices, including various nosepiece configurations, and features for providing consistent doses of gas;
- methods for delivering therapeutic gases to patients;
- the treatment of various medical conditions via delivery of therapeutic gases to the nasal cavity; and
- combined delivery of gases with other therapeutic agents.

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 and 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 structures.

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. Carcinogencity studies in 2 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 1. 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 2. 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 1 clinical trials to fail in the more rigorous Phase 2 clinical trials.

Phase 3. If a drug candidate appears to be effective and safe in Phase 2 clinical trials, Phase 3 clinical trials are commenced to confirm those results. Phase 3 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 2 clinical trials to fail in the more rigorous and extensive Phase 3 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 an NDA 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 a recommendation to the FDA that is not binding but is 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 candidate in the United States to be marketed 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 4 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. All of 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 4 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.

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 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 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 incidence of < 200,000 persons; in the EU, 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 EU, 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 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 (which includes most major countries in Europe). 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.

Government Regulation Medical Devices

In the U.S., any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes is regulated by the FDA as medical devices under the Federal Food, Drug, and Cosmetic Act, or FFDCA. We received initial FDA 510(k) clearance for CoSense in the fourth quarter of 2012 for the monitoring of CO from endogenous and exogenous sources in exhaled breath, particularly in smoking cessation programs for the screening of CO poisoning and smoke inhalation. In the first quarter of 2014, CoSense received 510(k) clearance for the monitoring of CO from endogenous sources, including hemolysis, and exogenous sources, including CO poisoning and smoke inhalation, in exhaled breath. Serenz has not yet commenced any process for regulatory approval in the U.S. We also plan to seek FDA clearance or approval for other diagnostic products currently under development.

There are two regulatory pathways to receive authorization to market diagnostics: a 510(k) premarket notification and a premarket approval application, or PMA. The FDA makes a risk-based determination as to the pathway for which a particular diagnostic is eligible. CoSense was cleared via the 501(k) premarket notification pathway as a Class II medical device.

The information that must be submitted to the FDA in order to obtain clearance or approval to market a new medical device varies depending on how the medical device is classified by the FDA. Medical devices are classified into one of three classes on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices are subject to general controls, including labeling, registration and listing and adherence to FDA's quality system regulation, which are device-specific good manufacturing practices. Class II devices are subject to general controls and special controls, including performance standards and postmarket surveillance. Class III devices are subject to most of these requirements, as well as to premarket approval. Most Class I devices are exempt from premarket submissions to the FDA; most Class II devices require the submission of a 510(k) premarket notification to the FDA; and Class III devices require submission of a PMA. Most diagnostic kits are regulated as Class I or II devices and are either exempt from premarket notification or require a 510(k) submission.

510(k) premarket notification. A 510(k) notification requires the sponsor to demonstrate that a medical device is substantially equivalent to another marketed device, termed a "predicate device," that is legally marketed in the U.S. and for which a PMA was not required. A device is substantially equivalent to a predicate device if it has the same intended use and technological characteristics as the predicate; or has the same intended use but different technological characteristics, where the information submitted to the FDA does not raise new questions of safety and effectiveness and demonstrates that the device is at least as safe and effective as the legally marketed device. Under current FDA policy, if a predicate device does not exist, the FDA may make a risk-based determination based on the complexity and clinical utility of the device that the device is eligible for de novo 510(k) review instead of a requiring a PMA. The de novo 510(k) review process is similar to clearance of the 510(k) premarket notification, despite the lack of a suitable predicate device.

The FDA's performance goal review time for a 510(k) notification is 90 days from the date of receipt, however, in practice, the review often takes longer. In addition, the FDA may require information regarding clinical data in order to make a decision regarding the claims of substantial equivalence. Clinical studies of diagnostic products are typically designed with the primary objective of obtaining analytical or clinical performance data. If the FDA believes that the device is not substantially equivalent to a predicate device, it will issue a "Not Substantially Equivalent" letter and designate the device as a Class III device, which will require the submission and approval of a PMA before the new device may be marketed. Under certain circumstances, the sponsor may petition the FDA to make a risk-based determination of the new device and reclassify the new device as a Class I or Class II device. Any modifications made to a device, its labeling or its intended use after clearance may require a new 510(k) notification to be submitted and cleared by FDA. Some modifications may only require documentation to be kept by the manufacturer, but the manufacturer's determination of the absence of need for a new 510(k) notification remains subject to subsequent FDA disagreement.

The FDA has undertaken a systematic review of the 510(k) clearance process that includes both internal and independent recommendations for reform of the 510(k) system. The internal review, issued in August 2010, included a recommendation for development of a guidance document defining a subset of moderate risk (Class II) devices to include implantable, life-supporting or life-sustaining devices, called Class IIb, for which additional clinical or manufacturing data typically would be necessary to support a substantial equivalence determination. In the event that such new Class IIb sub-classification is adopted, we believe that most of the tests that we may pursue would be classified as Class IIa devices having the same requirements of the current Class II designation. In July 2011, the Institute of Medicine, or IOM, issued its independent recommendations for 510(k) reform. As the FDA receives public comment on the IOM recommendations and reconciles its plan of action to respond to both the internal and IOM recommendations, the availability of the 510(k) pathway for our diagnostic tests, and the timing and data burden required to obtain 510(k) clearance, could be adversely impacted. We cannot predict the impact of the 510(k) reform efforts on the development and clearance of our future diagnostic tests.

De Novo 510(k). If a previously unclassified new medical device does not qualify for the 510(k) pre-market notification process because there is no predicate device to which it is substantially equivalent, and if the device may be adequately regulated through general controls or special controls, the device may be eligible for de novo classification through what is called the de novo review process. In order to use the de novo review process, a company must receive a letter from the FDA stating that, because the device has been found not substantially equivalent to a legally marketed Class I or II medical device or to a Class III device marketed prior to May 28, 1976

for which the FDA has not required the submission of a PMA application, it has been placed into Class III. After receiving this letter, we, within 30 days, must submit to the FDA a request for a risk based down classification of the device from Class III to Class I or II based on the device's moderate or low risk profile which meets the definition of a Class I or Class II medical device. The FDA then has 60 days in which to decide whether to down classify the device. If the FDA agrees that a lower classification is warranted, it will issue a new regulation describing the device type and, for a Class II device, publish a Special Controls guidance document. The Special Controls guidance document specifies the scope of the device type and the recommendations for submission of subsequent devices for the same intended

use. If a product is classified as Class II through the de novo review process, then that device may serve as a predicate device for subsequent 510(k) pre-market notifications.

Premarket approval. The PMA process is more complex, costly and time consuming than the 510(k) process. A PMA must be supported by more detailed and comprehensive scientific evidence, including clinical data, to demonstrate the safety and effectiveness of the medical device for its intended purpose. If the device is determined to present a "significant risk," the sponsor may not begin a clinical trial until it submits an investigational device exemption, or IDE, to the FDA and obtains approval from the FDA to begin the trial.

After the PMA is submitted, the FDA has 45 days to make a threshold determination that the PMA is sufficiently complete to permit a substantive review. If the PMA is complete, the FDA will file the PMA. The FDA is subject to a performance goal review time for a PMA of 180 days from the date of filing, although in practice this review time is longer. Questions from the FDA, requests for additional data and referrals to advisory committees may delay the process considerably. Indeed, the total process may take several years and there is no guarantee that the PMA will ever be approved. Even if approved, the FDA may limit the indications for which the device may be marketed. The FDA may also request additional clinical data as a condition of approval or after the PMA is approved. Any changes to the medical device may require a supplemental PMA to be submitted and approved.

Regulation of Combination Products. In the U.S., the FDA may determine that Serenz should be regulated as a pharmaceutical product if they determine that Serenz is achieving its therapeutic effect through chemical action within or on the body of man or other animals and is dependent upon being metabolized for the achievement of its primary intended purposes. The regulation of combination products determined to have this mode of action is as a pharmaceutical product, not a medical device.

Continuing FDA Regulation

Devices. Under the medical device regulations, the FDA regulates quality control and manufacturing procedures by requiring us to demonstrate and maintain compliance with the quality system regulation, which sets forth the FDA's current good manufacturing practices requirements for medical devices. The FDA monitors compliance with the quality system regulation and current good manufacturing practices requirements by conducting periodic inspections of manufacturing facilities. We could be subject to unannounced inspections by the FDA. Violations of applicable regulations noted by the FDA during inspections of our manufacturing facilities, or the manufacturing facilities of these third parties, could adversely affect the continued marketing of our tests.

The FDA also enforces post-marketing controls that include the requirement to submit medical device reports to the agency when a manufacturer becomes aware of information suggesting that any of its marketed products may have caused or contributed to a death, serious injury or serious illness or any of its products has malfunctioned and that a recurrence of a malfunction would likely cause or contribute to a death or serious injury or illness. The FDA relies on medical device reports to identify product problems and utilizes these reports to determine, among other things, whether it should exercise its enforcement powers. The FDA may also require postmarket surveillance studies for specified devices.

FDA regulations also govern, among other things, the preclinical and clinical testing, manufacture, distribution, labeling and promotion of medical devices. In addition to compliance with good manufacturing practices and medical device reporting requirements, we will be required to comply with the FDCA's general controls, including establishment registration, device listing and labeling requirements. If we fail to comply with any requirements under the FDCA, we could be subject to, among other things, fines, injunctions, civil penalties, recalls or product corrections, total or partial suspension of production, denial of premarket notification clearance or approval of products, rescission or withdrawal of clearances and approvals, and criminal prosecution. We cannot assure you that any final FDA policy, once issued, or future laws and regulations concerning the manufacture or marketing of medical devices will not increase the cost and time to market of new or existing tests. Furthermore, any current or future federal and state regulations also will apply to future tests developed by us.

If our promotional activities fail to comply with these FDA regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to issue warning letters or untitled letters, suspend or withdraw a product from the market, require a recall or institute fines or civil fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution.

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International marketing of medical devices is subject to foreign government regulations, which vary substantially from country to country. The European Commission is the legislative body responsible for directives with which manufacturers selling medical products in the E.U. and the European Economic Area, or EEA, must comply. The E.U. includes most of the major countries in Europe, while other countries, such as Switzerland, are part of the EEA and have voluntarily adopted laws and regulations that mirror those of the E.U. with respect to medical devices. The E.U. has adopted directives that address regulation of the design, manufacture, labeling, clinical studies and post-market vigilance for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be marketed throughout the E.U. and EEA.

Outside of the E.U., regulatory pathways for the marketing of medical devices vary greatly from country to country. In many countries, local regulatory agencies conduct an independent review of medical devices prior to granting marketing approval. For example, in China, approval by the SFDA must be obtained prior to marketing an medical device. In Japan, approval by the MHLW following review by the Pharmaceuticals and Medical Devices Agency, or the PMDA, is required prior to marketing an medical device. The process in such countries may be lengthy and require the expenditure of significant resources, including the conduct of clinical trials. In other countries, the regulatory pathway may be shorter or less costly. The timeline for the introduction of new medical devices is heavily impacted by these various regulations on a country-by-country basis, which may become more lengthy and costly over time.

Additional Government Regulations

Advertising

Advertising of our commercial products are subject to regulation by the Federal Trade Commission, or FTC, under the FTC Act. The FTC Act prohibits unfair or deceptive acts or practices in or affecting commerce. Violations of the FTC Act, such as failure to have substantiation for product claims, would subject us to a variety of enforcement actions, including compulsory process, cease and desist orders and injunctions, which can require, among other things, limits on advertising, corrective advertising, consumer redress and restitution, as well as substantial fines or other penalties. Any enforcement actions by the FTC could have a material adverse effect our business.

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 of false claims or false information to government programs;
- deceptive or fraudulent conduct;
- excessive or unnecessary services or services at excessive prices; 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 $5,500 to $11,000 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. 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 $5,500 to $11,000 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 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, or CMS, beginning in 2014. 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.

Recent Developments

Merger with Essentialis, Inc.

On December 22, 2016, we entered into the Merger Agreement with Essentialis. Consummation of the Merger was subject to various closing conditions, including our consummation of a financing of at least $8 million at, or substantially contemporaneous with, the closing of the Merger and the receipt of stockholder approval of the Merger at a special meeting of stockholders.

On March 6, 2017, we held a special stockholder meeting and received approval for issuance of the Merger shares under the Merger Agreement with Essentialis, issuance of the shares of common stock for the $8 million of concurrent financing and issuance of the shares of common stock for the $2 million investment by Aspire Capital.

On March 7, 2017, we completed the Merger with Essentialis and issued 18,916,940 shares of common stock to stockholders of Essentialis. We held back 913,379 shares of common stock as partial recourse to satisfy indemnification claims, and such shares will be issued to Essentialis stockholders on the 1 year anniversary of the closing of the merger. We are also obligated to issue an additional 4,566,948 shares of common stock to Essentialis stockholders upon the achievement of a development milestone. Assuming that we issues all of the shares of our common stock held back and the development milestone is achieved, we would issue a total of 24,397,267 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 $30 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.

In addition, we issued 8,333,333 shares of common stock for an investment of $8 million from the completion of the concurrent financing and issued 2,083,333 shares of common stock for an investment of $2 million from Aspire Capital.

Employees

As of March 31, 2017, we had 26 full-time employees and 3 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.

Name Change

On May 12, 2017, we formally changed our name from "Capnia, Inc." to "Soleno Therapeutics, Inc."

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. On May 12, 2017, we formally changed our name from "Capnia, Inc." to "Soleno Therapeutics, Inc." 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.

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DESCRIPTION OF PROPERTIES

Our principal facilities consist of office space in Redwood City, California, which also contains our final assembly and calibration facility for CoSense. We currently occupy approximately 13,436 square feet of office space under a non-cancelable operating lease that terminates in August 2019. NFI operates in a facility in Ivyland, Pennsylvania occupying approximately 2,880 square feet of space under a month to month lease.

LEGAL PROCEEDINGS

On February 16, 2017, a purported stockholder class action lawsuit captioned Garfield v. Capnia, Inc., et al., Case No. C17-00284, or the Lawsuit, was filed in Superior Court of the State of California, County of Contra Costa against us and certain of our officers and directors. The Lawsuit alleged, generally, that our directors breached their fiduciary duties to our stockholders by seeking to sell control of the company through an allegedly defective process, and on unfair terms. The Lawsuit also alleged that defendants failed to disclose all material facts concerning the merger with Essentialis to stockholders. The Lawsuit sought, among other things, equitable relief that would have enjoined the consummation of the merger, compensatory and/or rescissory damages, and attorneys' fees and costs.

On February 28, 2017, we settled the Lawsuit by making certain supplemental disclosures in a Current Report on Form 8-K filed with the SEC on February 28, 2017 in connection with the plaintiff's agreement to voluntarily dismiss plaintiff's claims in the Lawsuit. We also agreed to pay $175,000 in attorney's fees. This amount was accrued as a current liability on the balance sheet as of December 31, 2016 and recorded as a general and administrative expense on the statement of operations for the year ended December 31, 2016. The stipulation of dismissal was approved by the court on April 14, 2017.

From time to time, we may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. However, litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. We are currently not aware of any such legal proceedings or claims that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or operating results.

MANAGEMENT

Directors and Executive Officers

The following table sets forth information regarding our executive officers and directors as of March 31, 2017:

Name	Age	Position
Executive Officers:		
Anish Bhatnagar, M.D.	47	President, Chief Executive Officer and Director
David D. O'Toole	58	Senior Vice President, Chief Financial Officer
Anthony Wondka	55	Senior Vice President of Research and Development
Non-Employee Directors:		
Ernest Mario, Ph.D.	78	Chairman
Edgar G. Engleman, M.D.	71	Director
Steinar J. Engelsen, M.D., M.Sc.(1)(2)(3)	66	Director
William G. Harris (1)(2)	58	Director
Stephen Kirnon, Ed.D.(1)(2)(3)	54	Director
Rajen Dalal (2)	63	Director
Mahendra Shah	71	Director
Stuart Collinson	57	Director
Jim Glasheen	49	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.

David D. O'Toole. Mr. O'Toole was appointed as our Chief Financial Officer in July 2014. He has more than 30 years of experience in the accounting and finance sectors, and for the past 14 years has focused on the medical device, tools, and diagnostics industry. From September 2012 to June 2014 Mr. O'Toole was Senior Vice President and Chief Financial Officer at Codexis, Inc., a public company focused on developing biocatalysts. From May 2010 to August 2012 Mr. O'Toole was Vice President and Chief Financial Officer at Response Genetics, Inc., and served from May 2008 to August 2010 as Executive Vice President and Chief Financial Officer of Abraxis Bioscience, Inc. From 1992 to 2008, Mr. O'Toole worked at Deloitte & Touche LLP, where he served for 12 of those years as a partner. He worked at Arthur Anderson & Co., from 1984 to 1992, as an international tax manager. Mr. O'Toole received his Bachelor of Science, Accounting from the University of Arizona and is a certified public accountant.

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

Anthony Wondka. Mr. Wondka was appointed as our Vice President of Research and Development in June 2013. Prior to that, he was a consultant for us since May 2011. He has held management and executive positions in the medical device industry for over 20 years, in large and small companies. From April 2006 to March 2011, Mr. Wondka served as VP of R&D and then VP of Technology and Clinical Affairs for Breathe Technologies, where he invented and co-invented ventilation products that address large unmet needs in chronic obstructive pulmonary disease, or COPD, and obstructive sleep apnea. From July 1997 to April 2006, Mr. Wondka was Director of R&D and VP of Manufacturing at Pulmonx, where he co-invented and led the early development of the Chartis diagnostic system and procedure that is used to guide endobronchial lung volume reduction for the treatment of COPD, and is currently being sold in the E.U. Prior to Pulmonx, Mr. Wondka worked at Pfizer subsidiary Shiley (acquired by Covidien) and Bear Medical (acquired by Carefusion), where he held lead roles in engineering and quality assurance, supporting commercialization activities for market leading ear, nose and throat, or ENT, and respiratory products. He holds over 40 issued or pending patents and has a B.S. in Bioengineering from University of California San Diego.

We believe Mr. Wondka is able to make valuable contributions as an executive officer of our company as a result of his 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., Chimerix, Inc., Kindred Biosciences Inc., Tonix Pharmaceuticals Holding Corp. and XenoPort Inc. Dr. Mario is active in numerous educational and healthcare organizations. He is Chairman of the American Foundation for Pharmaceutical Education, a Director of the Gladstone Foundation, and past Chairman of the Duke University Health System. 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.

Edgar G. Engleman, M.D. Dr. Engleman has been a member of our board of directors since June 2001. He is a founding member of Vivo Ventures, LLC (formerly BioAsia Investments) and since 1990 has served as Professor of Pathology and Medicine at Stanford University School of Medicine, where he oversees the Stanford Blood Center as well as his own immunology research group. An editor of numerous scientific journals and the inventor of multiple patented technologies, Dr. Engleman has authored more than 250 publications in medical and scientific journals and has trained more than 200 graduate students and postdoctoral fellows. Dr. Engleman has co-founded a number of biopharmaceutical companies including Cetus Immune Corporation (acquired by Chiron Corporation), Genelabs Technologies, Inc., (acquired by GlaxoSmithKline plc), National Medical Audit, and Dendreon Corporation. He is the lead inventor of the technology underlying Provenge, Dendreon's cancer vaccine, which was approved in 2010 to treat asymptomatic or minimally symptomatic metastatic hormone-refractory prostate cancer. Dr. Engleman currently serves on the boards of several private biotechnology companies, including Gryphon Therapeutics, Inc., Naryx Pharma, Inc., Eiger BioPharma, Inc., Nuveta, Inc. and Semnur Pharmaceuticals, Inc. He received his M.D. from

Columbia University School of Medicine and his B.A. from Harvard University.
We believe Dr. Engleman is able to make valuable contributions to our board of directors due to his extensive knowledge of the healthcare industry, his medical expertise, his service on other company boards of directors, and his understanding of our company.

Steinar J. Engelsen, M.D., M.Sc., CEFA. Dr. Engelsen has been a member of our board of directors since April 2004. Since November 1996, Dr. Engelsen has been a partner of Teknoinvest AS, a venture capital firm based in Norway. From June 1989 until October 1996, Dr. Engelsen held various management positions within Hafslund Nycomed AS, a pharmaceutical company based in Europe, and affiliated companies. He was responsible for therapeutic research and development, most recently serving as Senior Vice President, Research and Development of Nycomed Pharma AS from January 1994 until October 1996. He currently serves on the board of directors of Insmed, Inc. In addition, from January to November 2000, Dr. Engelsen was acting Chief Executive Officer of Centaur Pharmaceuticals, Inc., a biopharmaceutical company. Dr. Engelsen also served as Chairman of the board of directors of Centaur. Dr. Engelsen received his M.Sc. in Nuclear Chemistry and his M.D. from the University of Oslo, and is a Certified European Financial Analyst from The Norwegian School of Economics.

We believe Dr. Engelsen is able to make valuable contributions to our board of directors due to his extensive healthcare management experience, his financial and business leadership and expertise resulting from serving as a director or executive officer of multiple companies, and his understanding of our company.

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.

Stephen Kirnon, Ed.D. Dr. Kirnon has been a member of our board of directors since July 2002. He has over 20 years of operational experience in biomedical organizations. Since January 2009, he has served as the Co-founder and CEO of PharmaPlan LLC. From January 2012 until July 2013 he served as Vice President, Co-Lead Life Science Practice at Witt/Kieffer, Ford, Hadelman, Lloyd Corp. Prior to that, Dr. Kirnon was the President and Chief Executive Officer of Pepgen Corporation, a biopharmaceutical company based in Alameda, California, specializing in autoimmune diseases. He was formerly the President and CEO of Target Protein Technologies, Inc., a pharmaceutical company based in San Diego and specializing in the development of pharmaceutical compounds targeted to specific tissues and organs of the human body. Prior to TPT, he was the President and COO and a member of the Board of Yamanouchi Pharma Technologies, Inc., which is responsible for developing and commercializing Yamanouchi's proprietary drug delivery technologies as well as the U.S. development and manufacture of Yamanouchi's pharmaceuticals. Previously, Dr. Kirnon was the President of the Drug Delivery Division of Cygnus, Inc., successfully leading that Division into profitability and subsequently through sale of its business. Dr. Kirnon has also held various business development, sales, and marketing positions at Cygnus, Biogenex Laboratories, Inc., and GlaxoSmithKline plc. Dr. Kirnon received his doctorate in organization change and transformational leadership from as well as his M.B.A. from Pepperdine University, where he is an Adjunct Professor. He received a B.A. degree in Biochemistry from Harvard University. He is also a trustee of the New England College of Optometry.

We believe Dr. Kirnon is able to make valuable contributions to our board of directors due to his extensive operational experience in the biomedical and pharmaceutical industries, and his knowledge of our company.

Rajen Dalal. Mr. Dalal joined our board of directors in April 2016. Since 2011, Mr. Dalal has served as the CEO of ReLIA Diagnostic Systems, Inc., a point-of-care diagnostics company selling blood tests used in emergency medicine. Mr. Dalal also served on ReLIA's board from 2006 to 2015. Since 2011, Mr. Dalal has been a managing director of Synergenics LLC, a management company that operates a consortium of commonly-owned but independent biotech companies. Mr. Dalal also served from 2008 to 2010 on the board of Singapore based A-Bio Pharma and Dx Assays, from 2006 to 2008 as CEO and director of Aviir, a medical device company which commercialized multi-protein biomarker test for detecting risk of acute myocardial infarction, from 2003 to 2008 on the board of directors for

Vermillion, a public ovarian cancer diagnostics company, from 2002 to 2005 as CEO and a director of Guava Technologies, which commercialized a low cost bench top flow cytometer for HIV/AIDS testing, and from 2000 to 2002 on the HHS Committee for Blood Safety and Availability. Mr. Dalal was previously with Chiron as President of its Blood Testing division as well as its Vice President, Corporate Development. Prior to working in biotech, Mr. Dalal was at McKinsey & Co in New York and Cleveland. He is a graduate of the University of Chicago, Massachusetts Instituite of Technology and St. Xavier's College, Bombay with degrees in business, biochemical engineering and chemistry, respectively.

We believe Mr. Dalal is able to make a valuable contribution to our board of directors due to his extensive operational experience and board oversight in a diverse range of healthcare companies.

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 a Board member of Tioga Pharmaceuticals from 2005 and Arcturus Therapeutics from 2014. He was a Board member for 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.
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.
James Glasheen, Ph.D. Dr. Glasheen has been a member of our Board of Directors since March 2017. Since 2002, Dr. Glasheen has served as a general partner with Technology Partners, a venture capital firm that focuses on clean tech and life science companies. Prior to his work at Technology Partners, he served as Managing Director of CIT Venture Capital. From 1996 to 2000, he was a leader within McKinsey & Company's Pharmaceutical and Medical Products Practice. Dr. Glasheen also serves as an advisor to the National Science Foundation's (NSF) SBIR program in Washington D.C. Dr. Glasheen currently serves as a member of the board of directors of several privately-held biotechnology, consumer medical and medical device companies. Dr. Glasheen holds a B.S. from Duke University and an M.A. and Ph.D. from Harvard University.
We believe Dr. Glasheen is able to make valuable contributions to our Board of DDirectors due to his experience facilitating the growth of venture-backed companies, his experiences with McKinsey & Company and his consumer medical company expertise.
Board Composition
Our business and affairs are managed under the direction of our board of directors, which currently consists of ten members. The members of our board of directors were elected in compliance with the provisions of our amended and restated certificate of incorporation and a voting agreement among certain of our stockholders, as amended. The voting agreement terminated upon the closing of our IPO, and 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:

- The Class I directors are Drs. Engleman and Shah and Mr. Dalal, and their terms will expire at our annual meeting of stockholders to be held later in 2018;

- The Class II directors are Drs. Kirnon, Glasheen and Engelsen, and their terms will expire at our annual meeting of stockholders to be held in 2019; and
- The Class III 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 2017.

We expect that additional directorships resulting from an increase in the number of directors will be distributed among the three classes 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, subject to certain phase-ins.

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 Messrs. Dalal and Harris, and Drs. Engelsen, Kirnon, Glasheen 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.

In determining the independence of Drs. Glasheen and Collinson, our board of directors considered Drs. Glasheen's and Collinson's service as directors of Essentialis, Inc. prior to the effective date of the Merger with Essentialis. Our board of directors further considered Drs. Glasheen's and Collinson's relationships with Technology Partners and Forward Ventures, respectively, each of which were stockholders of Essentialis prior to the Merger and now own more than 10% of our common stock as more fully described below in the following sections: "Certain Relationships and Related Party Transactions" and "Security Ownership Of Certain Beneficial Owners And Management.

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.

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Audit committee

Our audit committee consists of Steinar J. Engelsen, William G. Harris, and Stephen Kirnon, 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 Dr. Engelsen and Mr. Harris are audit committee financial experts, 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 Steinar J. Engelsen, William G. Harris, Stephen Kirnon and James Glasheen, 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. Engelsen.

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 Steinar J. Engelsen, Stephen Kirnon, Rajen Dalal 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. Kirnon.

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.

The following table sets forth information regarding compensation earned by our non-employee directors during the fiscal year ended December 31, 2016.

Name	Cash Compensation	Option Awards(1)	Other Compensation	Total
Edgar G. Engleman(2)	$35,000	$18,610	—	$53,610
Ernie Mario(3)	$60,000	$18,610	—	$78,610
Steinar J. Engelsen(4)	$56,000	$18,610	—	$74,610
Stephen Kirnon(5)	$54,500	$18,610	—	$73,110
William James Alexander(6)	$8,750	—	—	$8,750
William G. Harris(7)	$55,000	$18,610	—	$73,610
Rajen Dalal(8)	$28,875	$32,865	—	$61,740

(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 6 and Note 9 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) Dr. Engelman joined our Board in June 2001. During 2016, Dr. Engelman was granted one option to purchase 27,083 shares outstanding. This option vests 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 meeting of stockholders, subject to continued service through each such date.

(3) Dr. Mario joined our Board in August 2007. During 2016, Dr. Mario was granted one option to purchase 27,083 shares outstanding. This option vests 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 meeting of stockholders, subject to continued service through each such date.

(4) Dr. Engelsen joined our Board in April 2004. During 2016, Dr. Engelsen was granted one option to purchase 27,083 shares outstanding. This option vests 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 meeting of stockholders, subject to continued service through each such date.

(5) Dr. Kirnon joined our Board in July 2002. During 2016, Dr. Kirnon was granted one option to purchase 27,083 shares outstanding. This option vests 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 meeting of stockholders, subject to continued service through each such date.

(6) Dr. Alexander joined our Board in June 2008 and resigned from our Board on March 28, 2016.

(7) Mr. Harris joined our Board in June 2014. During 2016, Mr. Harris was granted one option to purchase 27,083 shares outstanding. This option vests 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 meeting of stockholders, subject to continued service through each such date.

(8) Mr. Dalal joined our Board in April 2016. During 2016, Mr. Dalal was granted two options to purchase an aggregate of 47,083 shares of our common stock outstanding, comprised of an option to purchase 27,083 shares, which vests 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 meeting of stockholders, and an option to purchase 20,000 shares, which vests as to 1/48th of the shares each month, in each case subject to continued service through each such date in June 2001.

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, 2016 are:

- Anish Bhatnagar, M.D., our Chief Executive Officer, President and Chief Operating Officer;
- David D. O'Toole, our Senior Vice President, Chief Financial Officer; and
- Anthony Wondka, our Senior Vice President, Research & Development.

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

2016 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, 2016, and December 31, 2015.

Summary Compensation Table

Name and Position	Year Ended December 31,	Salary	Bonus	Stock Awards	Option Awards(1)	Non-equity Incentive Plan Compensation	Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Anish Bhatnagar Chief Executive Officer, President and Chief Operating Officer	2016	$460,000	—	—	$499,243	—	—	—	$959,243
	2015	$435,156	$185,000	—	$570,100	—	—	—	$1,190,25
David D. O'Toole Senior Vice President, Chief Financial Officer	2016	$300,000	—	—	$125,133	—	—	—	$425,133
	2015	$265,000	$47,950	—	$108,732	—	—	—	$421,682
Anthony Wondka Senior Vice President, Research & Development	2016	$266,500	—	—	$73,346	—	—	—	$339,846
	2015	$262,375	$45,500	—	$111,476	—	—	—	$419,351

(1) The amounts in this column reflect the aggregate grant date fair value of each option award granted during the fiscal years ended December 31, 2016 and 2015, 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, 2015 and December 31, 2016.

Employment offer letters and Employment Agreements

We have entered into employment agreements with our named executive officers. The employment agreements provide 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, our named executive officers were each also required to execute our standard proprietary information and inventions agreement. 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 employment agreements, which were filed as exhibits to the Current Report on Form 8-K that was filed with the SEC on May 20, 2015.

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.

Agreement with David D. O’Toole

We entered into an employment agreement with Mr. O’Toole, dated May 15, 2015, pursuant to which Mr. O’Toole serves as our Senior Vice President, Chief Financial Officer. The agreement provides for “at-will” employment and sets forth certain agreed upon terms and conditions of employment. Mr. O’Toole’s current annual base salary is $300,000.

Agreement with Anthony Wondka

We entered into an employment agreement with Mr. Wondka, dated May 15, 2015, pursuant to which Mr. Wondka serves as our Senior Vice President, Research and Development. The agreement provides for "at-will" employment and sets forth certain agreed upon terms and conditions of employment. Mr. Wondka's current annual base salary is $266,500.

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 y.ear following such termination without Cause or resignation for Good Reason to exercise any then vested options.

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

- if Mr. O'Toole's termination or resignation occurs prior to three (3) months before a Change in Control (as defined in Mr. O'Toole's employment agreement) of the Company: (i) continuing payments of severance pay at a rate equal to Mr. O'Toole's base salary rate for six (6) months from the date of such termination without Cause or resignation for Good Reason; and (ii) if Mr. O'Toole elects continuation coverage pursuant to COBRA, then the Company will reimburse Mr. O'Toole on the last day of each month for a period ending six (6) months after Mr. O'Toole's termination

date for the COBRA premiums paid during such period for such coverage (at the coverage levels in effect immediately prior to Mr. O'Toole's termination); and

If Mr. O'Toole's 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 Mr. O'Toole's base salary rate for twelve (12) months from the date of such termination without Cause or resignation for Good Reason; (ii) if Mr. O'Toole elects continuation coverage pursuant to COBRA, then the Company will reimburse Mr. O'Toole on the last day of each month for a period ending twelve (12) months after Mr. O'Toole's termination date for the COBRA premiums paid during such period for such coverage (at the coverage levels in effect immediately prior to Mr. O'Toole's termination); (iii) a payment equal to one hundred percent (100%) the annual target bonus opportunity for the year in which Mr. O'Toole is terminated without Cause or resigns for Good Reason; and (iv) one hundred

percent (100%) of any unvested equity awards held by Mr. O'Toole as of the date of such termination without Cause or resignation for Good Reason shall immediately vest and become fully exercisable.

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

If Mr. Wondka's termination or resignation occurs prior to three (3) months before a Change in Control (as defined in Mr. Wondka's employment agreement) of the Company: (i) continuing payments of severance pay at a rate equal to Mr. Wondka's base salary rate for six (6) months from the date of such termination without Cause or resignation for Good Reason; and (ii) if Mr. Wondka elects continuation coverage pursuant to COBRA, then the Company will reimburse Mr. Wondka on the last day of each month for a period ending six (6) months after Mr. Wondka's termination date for the COBRA premiums paid during such period for such coverage (at the coverage levels in effect immediately prior to Mr. Wondka's termination); and

If Mr. Wondka's 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 Mr. Wondka's base salary rate for twelve (12) months from the date of such termination without Cause or resignation for Good Reason; (ii) if Mr. Wondka elects continuation coverage pursuant to COBRA, then the Company will reimburse Mr. Wondka on the last day of each month for a period ending twelve (12) months after Mr. Wondka's termination date for the COBRA premiums paid during such period for such coverage (at the coverage levels in effect immediately prior to Mr. Wondka's termination); (iii) a payment equal to one hundred percent (100%) the annual target bonus opportunity for the year in which Mr. Wondka is terminated without Cause or resigns for Good Reason; and (iv) one hundred percent (100%) of any unvested equity awards held by Mr. Wondka 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, 2016

The following table provides information regarding outstanding equity awards held by our named executive officers as of December 31, 2016.

		Number of Securities Underlying Unexercised Options		Option Exercise	Option Expiration
Name	Grant Date	Exercisable	Unexercisable	Price	Date
Anish Bhatnagar					
	3/14/2007	4,166 (1)	—	$10.56	3/14/2017
	9/25/2007	1,041 (1)	—	$10.56	9/25/2017
	6/27/2008	11,666 (1)	—	$3.48	9/25/2018
	10/15/2008	8,333 (1)	—	$3.48	10/15/2018
	11/12/2014	327,169 (2)	103,081	$7.14	11/12/2024
	1/11/2015	159,103 (2)	56,022	$1.80	1/11/2025
	5/15/2015	104,688 (2)	45,313	$4.66	5/15/2025
	1/10/2016	68,750 (3)	231,250	$1.61	1/10/2026
	6/8/2016	169,411 (2)	131,764	$1.20	6/8/2026
David O'Toole					
	11/12/2014	83,135 (4)	46,636	$7.14	11/12/2024
	1/11/2015	19,770 (4)	12,673	$1.80	1/11/2025
	5/15/2015	11,875 (3)	18,125	$4.66	5/15/2025
	1/10/2016	13,750 (3)	46,250	$1.61	1/10/2026
	6/8/2016	31,226 (4)	59,614	$1.20	6/8/2026
Anthony Wondka					
	6/3/2013	10,461 (5)	455	$1.20	6/3/2023
	11/12/2014	30,335 (4)	30,608	$7.14	11/12/2024
	1/11/2015	7,061 (4)	9,676	$1.80	1/11/2025
	5/15/2015	5,396 (3)	31,604	$4.66	5/15/2025
	1/10/2016	11,662 (3)	28,338	$1.61	1/10/2026
	6/8/2016	11,715 (4)	35,148	$1.20	6/8/2026

(1) The options listed are fully vested or are subject to an early exercise right and may be exercised in full prior to vesting of the shares underlying such options. Vesting of all options is subject to continued service on each vesting date.

(2) The shares subject to the stock option vest over a four-year period as follows: 50% of the shares underlying the options vest immediately on the vesting commencement date, and thereafter 1/48th of the 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 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 four-year period as follows: 25% of the shares underlying the option vest on the one-year anniversary of the vesting commencement date, and thereafter 1/36th of the shares vest each month, 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.

Authorized Shares. A total of 2,908,430 shares of our common stock have been reserved for issuance pursuant to the 2014 Plan, of which awards to purchase 958,856 shares of common stock were outstanding as of December 31, 2016. In addition, the shares reserved for issuance under our 2014 Plan also include: (a) those shares reserved but unissued under our 2010 Plan (as defined below); and (b) shares returned to our 1999 Plan and 2010 Plan as the result of expiration or termination of options (provided that the maximum number of shares that may be added to the 2014 Plan pursuant to (a) and (b) is 240,906 shares). The number of shares available for issuance under the 2014 Plan also includes an annual increase on the first day of each year beginning in 2015, equal to the least of:

- 1,118,714 shares;
- 4.0% of the outstanding shares of common stock as of the last day of our immediately preceding year; or
- such other amount as our board of directors may determine.

Our compensation committee administers our 2014 Plan. In the case of options intended to qualify as "performance-based compensation" within the meaning of Section 162(m) of the Code, the committee will consist of two or more "outside directors" within the meaning of Section 162(m) of the Code.

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.

Authorized Shares. A total of 280,018 shares of our common stock are reserved for sale under the ESPP as of December 31, 2016. In addition, our 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 our board of directors authorizes commencement, equal to the least of:

- 1.0% of the outstanding shares of our common stock on the first day of such year;
- 279,680 shares; or
- such amount as determined by our board of directors.

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.

Authorized shares. Prior to the expiration of the 1999 Plan, the maximum number of shares of our common stock reserved for issuance under our 1999 Plan was 154,154 shares. As of December 31, 2015, options to purchase 154,154 shares of our common stock remained outstanding under the 1999 Plan.

Shares issued under our 1999 Plan included any authorized but unissued or reacquired shares of our common stock.

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

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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.

Authorized shares. Prior to the termination of the 2010 Plan, the maximum number of shares of our common stock reserved for issuance under our 2010 Plan is 210,314 shares. As of December 31, 2015, options to purchase 82,433 shares of our common stock remain outstanding.

Shares issued under our 2010 Plan include any authorized but unissued or reacquired shares of our common stock.

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.

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 pending 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 8,333,333 shares of common stock, par value $0.001 per share, at a purchase price of $0.96 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.

On March 7, 2017, we completed the Merger pursuant to the Merger Agreement . 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 18,916,952 shares of our common stock. We held back an 913,392 shares of common stock as partial recourse to satisfy indemnification claims made by us under the Merger Agreement, and such shares of common stock will be issued to Essentialis stockholders on the one year anniversary of the closing (subject to the limitations set forth in the Merger Agreement). We are also obligated to issue an additional 4,566,961 shares of our common stock to Essentialis stockholders upon the achievement of a development milestone associated with Essentialis' product. Assuming that we issue all of the shares of common stock held back by us and the development milestone is achieved, we would issue a total of 24,397,306 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. Engleman, Shah, Glasheen 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 1,410,461 shares of common stock in the Concurrent Financing (approximately 16.9% of the shares of common stock issued in the Concurrent Financing) and received 5,827,818 shares (approximately 30.81% of the shares of common stock issued to Essentialis stockholders in the Merger). Additionally, Dr. Shah received a portion of the Merger consideration as a participant in Essentialis' management carve-out plan.
- Entities affiliated with Technology Partners, which is affiliated with Dr. Glasheen purchased 1,332,898 shares of common stock in the Concurrent Financing (approximately 16.0 % of the shares of common stock issued in the Concurrent Financing) and received 5,717,793 shares (approximately 30.23% of the shares of common stock issued to Essentialis stockholders in the Merger).
- Entities affiliated with Forward Ventures, which is affiliated with Dr. Collinson purchased 1,423,306 shares of common stock in the Concurrent Financing (approximately 17.08 % of the shares of common stock issued in the Financing) and received 5,828,422 shares (approximately 30.81% of the shares of common stock issued to Essentialis stockholders in the Merger).

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, INC. (FORMERLY KNOWN AS CAPNIA, INC.)

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of April 12, 2017, 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, Inc. 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 47,479,879 shares of our common stock outstanding as of March 10, 2017, as reported on our Annual Report on Form 10-K for the annual period ended December 31, 2016, filed with the SEC on March 15, 2017.

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

Name of Beneficial Owner	Shares Beneficially Owned Number of Shares	%
5% Stockholders		
Entities Associated with Vivo Ventures Fund V, L.P. (1)	17,272,657	34.39%
Forward Ventures V, L.P. (2)	8,610,835	17.59%
Entities Associated with Technology Partners (3)	8,383,652	17.14%
Aspire Capital (4)	2,791,666	5.87 %
Named Executive Officers and Directors:		
Ernest Mario (5)	2,165,751	4.52 %
Anish Bhatnagar (6)	1,025,811	2.11 %
Anthony Wondka (7)	125,788	*
Edgar G. Engleman (1) (8)	17,315,739	34.45%
Steinar J. Engelsen (9)	160,693	*
Stephen Kirnon (10)	57,875	*
William G. Harris (11)	75,758	*
David D. O'Toole (12)	239,980	*
Rajen Dalal (13)	23,598	*
Mahendra Shah (14)	121,201	*
Stuart Collinson (2) (15)	8,614,630	17.60%
James Glasheen (3) (16)	8,387,480	17.14%
All current directors and executive officers as a group (13 Persons) (17)	38,314,304	70.01%

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

(1)Represents shares of common stock outstanding or issuable within 60 days of April 12, 2017, consisting of: (a) 16,674,428 shares of common stock held by Vivo Ventures Fund, V, L.P., consisting of (W) 14,076,263 shares of outstanding Common Stock, of which 7,154,140 shares of Common Stock are being registered as part of this offering, (X) zero shares of common stock subject to outstanding options that are vested and exercisable within sixty days of April 12, 2017, (Y) 1,255,019 shares of common stock issuable upon the exercise of warrants (assuming an exercise date of April 12, 2017), and (Z) 1,343,146 shares of Common Stock are potentially issuable upon the achievement of certain milestones within sixty days of April 12, 2017 and are being registered as part of this offering; (b) 195,918 shares of common stock held by Vivo Ventures V Affiliates Fund, LP., consisting of (W) 165,373 shares of outstanding Common Stock, of which 84,140 shares of Common Stock are being registered as part of this offering, (X) zero shares of common stock subject to outstanding options that are vested and exercisable within sixty days of April 12, 2017, (Y) 14,726 shares of common stock issuable upon the exercise of warrants (assuming an exercise date of April 12, 2017), and (Z) 15,819 shares of Common Stockare potentially issuable upon the achievement of certain milestones within sixty days of April 12, 2017 and are being registered as part of this offering; (c) 231,273 shares of common stock held by BDF IV Annex Fund, L.P., consisting of (W) 227,068 shares of outstanding common stock, (X) zero shares of common stock subject to outstanding options that are vested and exercisable within sixty days of April 12, 2017, and (Y) 4,205 shares of common stock issuable upon the exercise of warrants (assuming an exercise date of April 12, 2017); (d) 167,945 shares of common stock held by Biotechnology Development Fund IV, L.P., consisting of (W) 166,943 shares of outstanding common stock, (X) zero shares of common stock subject to outstanding options that are vested and exercisable within sixty days of April 12, 2017, and (Y) 1,002 shares of common stock issuable upon the exercise of warrants (assuming an exercise date of April 12, 2017); and (e) 3,093 shares of common stock held by Biotechnology Development Fund IV Affiliates, L.P., consisting of (W) 3,076 shares of outstanding common stock, (X) zero shares of common stock subject to outstanding options that are vested and exercisable within sixty days of April 12, 2017, and (Y) 17 shares of common stock issuable upon the exercise of warrants (assuming an exercise date of April 12, 2017). Vivo Ventures V 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 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.

(2) Represents an aggregate of 8,610,835 shares of Common Stock, consisting of (i) 7,251,728 shares of outstanding Common Stock, and (ii) 1,359,107 shares of Common Stock that are potentially issuable within 60 days of April 12, 2017 upon the achievement of certain milestones. 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.

(3) Represents an aggregate of 8,383,652 shares of Common Stock, consisting of (i) 7,050,691 shares of outstanding Common Stock, and (ii) 1,332,961 shares of Common Stock that are potentially issuable within 60 days of April 12, 2017 upon the achievement of certain milestones. James Glasheen is one of the managing members of Technology Partners and Technology Affiliates and has shared voting power over the shares of common stock beneficially owned by Technology Partners and Technology Affiliates.

(4) Represents shares of common stock outstanding, issuable within 60 days of April 12, 2017, upon the exercise of options or warrants: 2,791,666 shares of common stock held by Aspire Capital LLC consisting of (W) 2,791,666 shares of outstanding common stock, and (Y) no shares of common stock subject to outstanding options that are vested and exercisable within 60 days of April 12, 2017.

(5) Represents shares of common stock outstanding or issuable within 60 days of April 12, 2017, upon the exercise of options or warrants: 2,165,751 shares of common stock held by Dr. Mario, consisting of (W) 1,819,739 shares of outstanding common stock, (X) 77,134 shares of common stock subject to outstanding options that are vested and exercisable within sixty days of April 12, 2017, (Y) 268,878 shares of common stock issuable upon the exercise of warrants (assuming an exercise date of April 12, 2017).

(6) Represents shares of common stock outstanding or issuable within 60 days of April 12, 2017, upon the exercise options or warrants: 1,025,811 shares of common stock held by Dr. Bhatnagar, consisting of (W) 83,419 shares of outstanding common stock, (X) 942,392 shares of common stock subject to outstanding options that are vested and exercisable within sixty days of April 12, 2017.

(7) Represents shares of common stock outstanding or issuable within 60 days of April 12, 2017, upon the exercise of options or warrants: 125,788 shares of common stock held by Mr. Wondka, all of which are shares of common stock subject to outstanding options that are vested and exercisable within sixty days of April 12, 2017.

(8) Represents shares of common stock outstanding or issuable within 60 days of April 12, 2017: an aggregate of 17,315,739 shares of common stock held by Dr. Engleman, consisting of (Y) the shares held by the Vivo V Funds, the BDF IV Funds and BDF II as set forth above in footnote 1, and (Z) 43,082 shares of common stock subject to outstanding options that are vested and exercisable within sixty days of April 12, 2017.

(9) Represents shares of common stock outstanding or issuable within 60 days of April 12, 2017, upon the exercise of option or warrants: 160,693 shares of common stock held by Dr. Engelsen, consisting of (W) 118,738 shares of outstanding common stock, (X) 40,583 shares of common stock subject to outstanding options that are vested and exercisable within sixty days of April 12, 2017, and (Y) 1,372 shares of common stock issuable upon the exercise of warrants (assuming an exercise date of April 12, 2017).

(10) Represents shares of common stock outstanding or issuable within 60 days of April 12, 2017, upon the exercise of options or warrants: 57,875 shares of common stock held by Dr. Kirnon, consisting of (W) 14,793 shares of outstanding common stock, and (X) 43,082 shares of common stock subject to outstanding options that are vested and exercisable within sixty days of April 12, 2017.

(11) Represents shares of common stock outstanding or issuable within 60 days of April 12, 2017, upon the exercise of options or warrants: 75,758 shares of common stock held by Mr. Harris, consisting of (W) 35,175 shares of outstanding common stock and (X) 40,583 shares of common stock subject to outstanding options that are vested and exercisable within sixty days of April 12, 2017.

(12) Represents shares of common stock outstanding or issuable within 60 days of April 12, 2017, upon the exercise of options or warrants: 239,980 shares of common stock held by Mr. O'Toole, consisting of (W)

45,250 shares of outstanding common stock and (X) 194,730 shares of common stock subject to outstanding options that are vested and exercisable within sixty days of April 12, 2017.

(13) Represents shares of common stock outstanding or issuable within 60 days of April 12, 2017, upon the exercise of options or warrants: 23,598 shares of common stock held by Mr. Dalal, consisting of (W) 17,765 shares of outstanding common stock and (X) 5,833 shares of common stock subject to outstanding options that are vested and exercisable within sixty days of April 12, 2017. Rajen Dalal joined our Board on April 15, 2016 and received his initial Board option grant on this date.

(14) Represents shares of common stock outstanding or issuable within 60 days of April 12, 2017, upon the exercise of option or warrants: 121,201 shares of common stock held by Dr. Shah, consisting of (W) 97,117 shares outstanding of common stock, (Y) 1,250 shares of common stock subject to outstanding options that are vested and exercisable within sixty days of April 12, 2017, and (Z) and (iii) 1,358,965 shares of Common Stock that are potentially issuable upon the achievement of certain milestones within sixty days of April 12, 2017.

(15) Represents shares of common stock outstanding or issuable within 60 days of April 12, 2017, upon the exercise of option or warrants: 8,614,630 shares of common stock held by Dr. Collinson, consisting of (W) 2,545 shares outstanding of common stock, (Y) the shares held by Forward Ventures V, LP as set forth above in footnote 3, and (Z) 1,250 shares of common stock subject to outstanding options that are vested and exercisable within sixty days of April 12, 2017. Dr. Collinson joined our Board on March 7, 2017 and received his initial Board option grant on this date.

(16) Represents shares of common stock outstanding or issuable within 60 days of April 12, 2017, upon the exercise of option or warrants: 8,387,480 shares of common stock held by Dr. Glasheen, consisting of (W) 2,578 shares outstanding of common stock, (Y) the shares held by Technology Partners as set forth above in footnote 2, and (Z) 1,250 shares of common stock subject to outstanding options that are vested and exercisable within sixty days of April 12, 2017. Dr. Glasheen joined our Board on March 7, 2017 and received his initial Board option grant on this date.

(17) In total, 7,136,043 of these shares are attributable to options and warrants currently exercisable or potentially issuable upon the achievement of milestones within 60 days of April 12, 2017.

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 10, 2017, as reported on our Annual Report on Form 10-K for the annual period ended December 31, 2016, filed with the SEC on March 15, 2017. we had 12,179 outstanding shares of Series B Convertible Preferred Stock, convertible into 12,179,000 shares of our common stock, and 47,479,879 outstanding shares of our common stock. As of March 10, 2017 we also had outstanding 2,908,430 options to acquire shares of our common stock, having a weighted-average exercise price of $3.42 per share. As of March 10,, 2017, we had outstanding 6,029,331 warrants to purchase common stock and 519,609 warrants to purchase common stock issued prior to our IPO.

Common stock

There were 47,479,879 shares of common stock issued and outstanding as of March 10, 2017, as reported on our Annual Report on Form 10-K for the annual period ended December 31, 2016, filed with the SEC on March 15, 2017. 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 $6.50 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.

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

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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 $6.25 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 $2.46 per share to $1.75 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 $1.75 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.

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.

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 1,779 shares of Series A Convertible Preferred Stock, representing approximately 961,622 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 plan to redeem the remaining 6,001 shares of Series A Convertible Preferred Stock held by Sabby, representing approximately 3,243,783 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.

Other Outstanding Options and Warrants

As of September 30, 2016, we had outstanding options to purchase 2,938,161 shares of our common stock and additional outstanding warrants to purchase an aggregate of 571,906 shares of our common stock.

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.

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.

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 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. This registration statement on Form S-1 is part of the subject matter of this prospectus.

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, and the Placement Agent 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, and Placement Agent 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

The consolidated financial statements of Soleno Therapeutics, Inc. (formerly known as Capnia, Inc.) as of December 31, 2015 and 2016, and for the years then ended, included in this Prospectus have been so included in reliance on the report of Marcum LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

The financial statements of Essentialis, Inc. as of December 31, 2015 and 2016, and for the years then ended, included in this Prospectus have been so included in reliance on the report of PKF, LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

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

The common stock offered by this prospectus is being offered by Vivo Ventures Fund V, L.P., Vivo Ventures Affiliates Fund V, L.P., Forward Ventures V, L.P., Technology Partners Fund VII, L.P., Technology Partners Affiliates VII, L.P., Palo Alto Healthcare Master Fund, L.P., Palo Alto Fund II, L.P., Genovate Biotechnology Co. Ltd., Uni Pharma Co. Ltd, Giddi Pharma Co. Ltd., Top Taiwan XI Venture Capital Co. Ltd, Top Taiwan VIII Venture Capital Co. Ltd, Mahendra Shah, Aquilo Capital, DLA Piper, Neil Cowen, Glaze Family Revocable Trust dtd 6/17/04, Richard A. Glaze, Jeffrey A. Staffa and Jo-Ann Staffa Trustees, or their successors, in trust, under the Jeffrey and Jo-Ann Staffa Living Trust, dated December 10, 2015, and any amendments thereto, Khaled Yamount, Debra Robertson, Richard Pasternak, Alain Baron, Aaron Berg, Gloria Lin and Joy Becker, selling stockholders. The common stock may be sold or distributed from time to time by the selling stockholders directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of the common stock offered by this prospectus may be effected in one or more of the following methods:

- ordinary brokers' transactions;
- transactions involving cross or block trades;
- through brokers, dealers, or underwriters who may act solely as agents;
- "at the market" into an existing market for the common stock;
- in other ways not involving market makers or established business markets, including direct sales to purchasers or sales effected through agents;
- in privately negotiated transactions; or
- any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the registration or qualification requirement is available and complied with.

The selling stockholders may also sell shares of common stock under Rule 144 promulgated under the Securities Act, if available, rather than under this prospectus. In addition, the selling stockholder may transfer the shares of common stock by other means not described in this prospectus. Brokers, dealers, underwriters, or agents participating in the distribution of the shares as agents may receive compensation in the form of commissions, discounts, or concessions from the selling stockholder and/or purchasers of the common stock for whom the broker-dealers may act as agent. The selling stockholders are considered "underwriters" within the meaning of the Securities Act.

Neither we nor the selling stockholders can presently estimate the amount of compensation that any agent will receive. We know of no existing arrangements between the selling stockholders, any other stockholder, broker, dealer, underwriter, or agent relating to the sale or distribution of the shares offered by this prospectus. At the time a particular offer of shares is made, a prospectus supplement, if required, will be distributed that will set forth the names of any agents, underwriters, or dealers and any compensation from the selling stockholder, and any other required information.

We will pay all of the expenses incident to the registration, offering, and sale of the shares to the public other than commissions or discounts of underwriters, broker-dealers, or agents. We have agreed to indemnify the selling stockholders and certain other persons against certain liabilities in connection with the offering of shares of common stock offered hereby, including liabilities arising under the Securities Act or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities. The selling stockholders have agreed to indemnify us against liabilities under the Securities Act that may arise from certain written information furnished to us the selling stockholders specifically for use in this prospectus or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is therefore, unenforceable.

We have advised the selling stockholders that while it is engaged in a distribution of the shares included in this prospectus it is required to comply with Regulation M promulgated under the Securities Exchange Act of 1934, as amended. With certain exceptions, Regulation M precludes the selling stockholder, any affiliated purchasers, and any broker-dealer or other person

who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the shares offered hereby this prospectus.

We may suspend the sale of shares by the selling stockholders pursuant to this prospectus for certain periods of time for certain reasons, including if the prospectus is required to be supplemented or amended to include additional material information.

This offering will terminate on the date that all shares offered by this prospectus have been sold by the selling stockholders.

SELLING STOCKHOLDERS

The selling stockholders may from time to time offer and sell any or all of the shares of our common stock set forth below pursuant to this prospectus. When we refer to the “selling stockholders” in this prospectus, we mean the entities listed in the table below, and its respective pledgees, donees, permitted transferees, assignees, successors and others who later come to hold any of the selling stockholder’s interests in shares of our common stock other than through a public sale.

The following table sets forth, as of the date of this prospectus, the name of the selling stockholders for whom we are registering shares for sale to the public, the number of shares of common stock beneficially owned by the selling stockholders prior to this offering, the total number of shares of common stock that the selling stockholders may offer pursuant to this prospectus and the number of shares of common stock that the selling stockholders will beneficially own after this offering. Except as noted below, the selling stockholders do not have, or within the past three years has not had, any material relationship with us or any of our predecessors or affiliates and the selling stockholders are not or were not affiliated with registered broker-dealers.

Based on the information provided to us by the selling stockholders, assuming that the selling stockholders sells all of the shares of our common stock beneficially owned by it that have been registered by us and does not acquire any additional shares during the offering, the selling stockholder will not own any shares other than those appearing in the column entitled “Beneficial Ownership After This Offering.” 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.

			Following the Offering (1)	
	Shares of Common Stock Beneficially Owned Prior to this Offering (2)	Shares of Common Stock Being Offered (1)	Shares of Common Stock Beneficially Owned After this Offering (3)	Beneficial Ownership Percent (4)
Funds affiliated with Vivo Ventures (5) (6)	17,272,657	8,869,037	8,675,412	40.14%
Forward Ventures V, L.P. (7)	8,610,835	8,882,656	-	*
Funds affiliated with Technology Partners (8)	8,383,652	8,650,244	-	*
Palo Alto Healthcare Master Fund, L.P. (9)	261,941	271,955	-	*
Palo Alto Fund II, L.P. (10)	261,941	271,955	-	*
Genovate Biotechnology Co. Ltd. (11)	1,041,667	1,041,667	-	*
Uni Pharma Co. Ltd. (12)	1,041,667	1,041,667	-	*
Giddi Pharma Co. Ltd. (13)	1,041,667	1,041,667	-	*
Top Taiwan XI Venture Capital Co. Ltd. (14)	520,833	520,833	-	*
Top Taiwan VIII Venture Capital Co. Ltd. (15)	520,833	520,833	-	*
Mahendra Shah (16)	121,201	121,984	3,783	*
Aquilo Capital (17)	91,339	109,606	-	*
DLA Piper (18)	78,100	81,085	-	*
Neil M. Cowen (19)	730,502	767,892	-	*
Glaze Family Revocable Trust dtd 6/17/04 (20)	118,131	122,647	-	*
Richard A. Glaze (21)	1,984	2,059	-	*
Jeffrey A. Staffa and Jo-Ann Staffa Trustees, or their successors, in trust, under the Jeffrey and Jo-Ann Staffa Living Trust, dated December 10, 2015, and any amendments thereto (22)	10,274	10,666	-	*
Khaled Yamout (23)	68,573	71,194	-	*
Debra L. Robertson (24)	4,505	4,677	-	*
Richard Pasternak (25)	139,949	145,376	-	*
Alain Baron (26)	131,838	136,955	-	*
Aaron Berg (27)	35,183	36,528	-	*
Gloria Lin (28)	6,749	7,007	-	*
Joy Becker (29)	395	410	-	*

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

(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. An aggregate of 32,730,600 shares are being registered in this offering, consisting of (i) 27,250,273 shares that are issued and outstanding, (ii) 4,566,948 shares of Common Stock that are potentially issuable upon the achievement of certain milestones within sixty days of April 12, 2017, and (iii) 913,379 shares of Common Stock that are designated holdback shares that are not potentially issuable within sixty days of April 12, 2017.

(2) Includes an aggregate of 5,843,167 shares of Common Stock issuable within sixty days of April 12, 2017, consisting of (i) 1,276,219 shares of Common Stock that are potentially issuable upon the exercise of outstanding warrants and the vested portion of outstanding options within sixty days of April 12, 2017 and (ii) 4,566,948 shares of Common Stock that are potentially issuable upon the achievement of certain milestones within sixty days of April 12, 2017 and which are being registered as part of this offering. The shares excludes 913,379 shares of Common Stock that are designated holdback shares and are being registered as a part of this offering, but are not potentially issuable within sixty days of April 12, 2017.

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(3) Includes 1,276,219 shares of Common Stock that are potentially issuable upon the exercise of outstanding warrants and the vested portion of outstanding options within sixty days of April 12, 2017.

(4) Calculated based on 20,337,374 shares outstanding following the offering, based on (i) 47,587,647 shares of common stock outstanding on April 12, 2017, less (ii) 27,250,273 shares that are issued and outstanding and being offered by the Selling Stockholders as part of this offering.

(5) Represents shares of common stock outstanding or issuable within 60 days of April 12, 2017, consisting of: (a) 16,674,428 shares of common stock held by Vivo Ventures Fund, V, L.P., consisting of (W) 14,076,263 shares of outstanding Common Stock, of which 7,154,140 shares of Common Stock are being registered as part of this offering, (X) zero shares of common stock subject to outstanding options that are vested and exercisable within sixty days of April 12, 2017, (Y) 1,255,019 shares of common stock issuable upon the exercise of warrants (assuming an exercise date of April 12, 2017), and (Z) 1,343,146 shares of Common Stock are potentially issuable upon the achievement of certain milestones within sixty days of April 12, 2017 and are being registered as part of this offering; (b) 195,918 shares of common stock held by Vivo Ventures V Affiliates Fund, LP., consisting of (W) 165,373 shares of outstanding Common Stock, of which 84,140 shares of Common Stock are being registered as part of this offering, (X) zero shares of common stock subject to outstanding options that are vested and exercisable within sixty days of April 12, 2017, (Y) 14,726 shares of common stock issuable upon the exercise of warrants (assuming an exercise date of April 12, 2017), and (Z) 15,819 shares of Common Stockare potentially issuable upon the achievement of certain milestones within sixty days of April 12, 2017 and are being registered as part of this offering; (c) 231,273 shares of common stock held by BDF IV Annex Fund, L.P., consisting of (W) 227,068 shares of outstanding common stock, (X) zero shares of common stock subject to outstanding options that are vested and exercisable within sixty days of April 12, 2017, and (Y) 4,205 shares of common stock issuable upon the exercise of warrants (assuming an exercise date of April 12, 2017); (d) 167,945 shares of common stock held by Biotechnology Development Fund IV, L.P., consisting of (W) 166,943 shares of outstanding common stock, (X) zero shares of common stock subject to outstanding options that are vested and exercisable within sixty days of April 12, 2017, and (Y) 1,002 shares of common stock issuable upon the exercise of warrants (assuming an exercise date of April 12, 2017); and (e) 3,093 shares of common stock held by Biotechnology Development Fund IV Affiliates, L.P., consisting of (W) 3,076 shares of outstanding common stock, (X) zero shares of common stock subject to outstanding options that are vested and exercisable within sixty days of April 12, 2017, and (Y) 17 shares of common stock issuable upon the exercise of warrants (assuming an exercise date of April 12, 2017). Vivo Ventures V 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 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.

(6) The shares being offered by funds affiliated with Vivo Ventures in this offering represents an aggregate of 8,869,037 shares of Common Stock, consisting of (i) 7,238,280 shares of outstanding Common Stock, (ii) 271,792 shares of Common Stock that are potentially issuable upon the release date of the holdback shares, and (iii) 1,358,965 shares of Common Stock that are potentially issuable upon the achievement of certain milestones.

(7) The shares being offered by Forward Ventures V, L.P. in this offering represents an aggregate of 8,882,656 shares of Common Stock, consisting of (i) 7,251,728 shares of outstanding Common Stock, (ii) 271,821 shares of Common Stock that are potentially issuable upon the release date of the holdback shares, and (iii) 1,359,107 shares of Common Stock that are potentially issuable within 60 days of April 12, 2017 upon the achievement of certain

milestones

(8) The shares being offered by funds affiliated with Technology Partners in this offering represents an aggregate of 8,650,244 shares of Common Stock, consisting of (i) 7,050,691 shares of outstanding Common Stock, (ii) 266,592 shares of Common Stock that are potentially issuable upon the release date of the holdback shares, and (iii) 1,332,961 shares of Common Stock that are potentially issuable within 60 days of April 12, 2017 upon the achievement of certain milestones.

(9) The shares being offered by Palo Alto Healthcare Master Fund, L.P. in this offering represents an aggregate of 271,955 shares of Common Stock, consisting of (i) 211,869 shares of outstanding Common Stock, (ii) 10,014 shares of Common Stock that are potentially issuable upon the release date of the holdback shares, and (iii) 50,072 shares of

Common Stock that are potentially issuable within 60 days of April 12, 2017 upon the achievement of certain milestones.

(10) The shares being offered by Palo Alto Fund II, L.P. in this offering represents an aggregate of 271,955 shares of Common Stock, consisting of (i) 211,869 shares of outstanding Common Stock, (ii) 10,014 shares of Common Stock that are potentially issuable upon the release date of the holdback shares, and (iii) 50,072 shares of Common Stock that are potentially issuable within 60 days of April 12, 2017 upon the achievement of certain milestones.

(11) The shares being offered by Genovate Biotechnology Co. Ltd. in this offering represents an aggregate of 1,041,667 shares of Common Stock, all of which are issued and outstanding.

(12) The shares being offered by Uni Pharma Co. Ltd. in this offering represents an aggregate of 1,041,667 shares of Common Stock, all of which are issued and outstanding.

(13) The shares being offered by Giddi Pharma Co. Ltd. in this offering represents an aggregate of 1,041,667 shares of Common Stock, all of which are issued and outstanding.

(14) The shares being offered by Top Taiwan XI Venture Capital Co. Ltd. in this offering represents an aggregate of 520,833 shares of Common Stock, all of which are issued and outstanding.

(15) The shares being offered by Top Taiwan VIII Venture Capital Co. Ltd. in this offering represents an aggregate of 520,833 shares of Common Stock, all of which are issued and outstanding.

(16) The shares being offered by Mahendra Shah in this offering represents an aggregate of 121,984 shares of Common Stock, consisting of (i) 94,584 shares of outstanding Common Stock, (ii) 4,566 shares of Common Stock that are potentially issuable upon the release date of the holdback shares, and (iii) 22,834 shares of Common Stock that are potentially issuable within 60 days of April 12, 2017 upon the achievement of certain milestones. In addition to the shares being offered, Dr. Shah also beneficially holds 3,783 shares of Common Stock, of which (i) 2,533 shares are issued and outstanding, and (ii) 1,250 shares are issuable upon the exercise of vested options.

(17) The shares being offered by Aquilo Capital in this offering represents an aggregate of 109,606 shares of Common Stock, consisting of (i) 0 shares of outstanding Common Stock, (ii) 18,267 shares of Common Stock that are potentially issuable upon the release date of the holdback shares, and (iii) 91,339 shares of Common Stock that are potentially issuable within 60 days of April 12, 2017 upon the achievement of certain milestones.

(18) The shares being offered by DLA Piper in this offering represents an aggregate of 81,085 shares of Common Stock, consisting of (i) 63,171 shares of outstanding Common Stock, (ii) 2,985 shares of Common Stock that are potentially issuable upon the release date of the holdback shares, and (iii) 14,929 shares of Common Stock that are potentially issuable within 60 days of April 12, 2017 upon the achievement of certain milestones.

(19) The shares being offered by Neil M. Cowen in this offering represents an aggregate of 767,892 shares of Common Stock, consisting of (i) 543,548 shares of outstanding Common Stock, (ii) 37,390 shares of Common Stock that are potentially issuable upon the release date of the holdback shares, and (iii) 186,954 shares of Common Stock that are potentially issuable within 60 days of April 12, 2017 upon the achievement of certain milestones.

(20) The shares being offered by Glaze Family Revocable Trust dtd 6/17/04 in this offering represents an aggregate of 122,647 shares of Common Stock, consisting of (i) 95,549 shares of outstanding Common Stock, (ii) 4,516 shares of Common Stock that are potentially issuable upon the release date of the holdback shares, and (iii) 22,582 shares of Common Stock that are potentially issuable within 60 days of April 12, 2017 upon the achievement of certain milestones.

(21) The shares being offered by Richard A. Glaze in this offering represents an aggregate of 2,059 shares of Common Stock, consisting of (i) 1,605 shares of outstanding Common Stock, (ii) 75 shares of Common Stock that are potentially issuable upon the release date of the holdback shares, and (iii) 379 shares of Common Stock that are potentially issuable within 60 days of April 12, 2017 upon the achievement of certain milestones.

(22) The shares being offered by Jeffrey A. Staffa and Jo-Ann Staffa Trustees, or their successors, in trust, under the Jeffrey and Jo-Ann Staffa Living Trust, dated December 10, 2015, and any amendments thereto in this offering represents an aggregate of 10,666 shares of Common Stock, consisting of (i) 8,310 shares of outstanding

Common Stock, (ii) 392 shares of Common Stock that are potentially issuable upon the release date of the holdback shares, and (iii) 1,964 shares of Common Stock that are potentially issuable within 60 days of April 12, 2017 upon the achievement of certain milestones.

(23) The shares being offered by Khaled Yamout in this offering represents an aggregate of 71,194 shares of Common Stock, consisting of (i) 55,465 shares of outstanding Common Stock, (ii) 2,621 shares of Common Stock that are

potentially issuable upon the release date of the holdback shares, and (iii) 13,108 shares of Common Stock that are potentially issuable within 60 days of April 12, 2017 upon the achievement of certain milestones.

(24) The shares being offered by Debra L. Robertson in this offering represents an aggregate of 4,677 shares of Common Stock, consisting of (i) 3,644 shares of outstanding Common Stock, (ii) 172 shares of Common Stock that are potentially issuable upon the release date of the holdback shares, and (iii) 861 shares of Common Stock that are potentially issuable within 60 days of April 12, 2017 upon the achievement of certain milestones.

(25) The shares being offered by Richard Pasternak in this offering represents an aggregate of 145,376 shares of Common Stock, consisting of (i) 112,808 shares of outstanding Common Stock, (ii) 5,427 shares of Common Stock that are potentially issuable upon the release date of the holdback shares, and (iii) 27,141 shares of Common Stock that are potentially issuable within 60 days of April 12, 2017 upon the achievement of certain milestones.

(26) The shares being offered by Alain Baron in this offering represents an aggregate of 136,955 shares of Common Stock, consisting of (i) 106,248 shares of outstanding Common Stock, (ii) 5,117 shares of Common Stock that are potentially issuable upon the release date of the holdback shares, and (iii) 25,590 shares of Common Stock that are potentially issuable within 60 days of April 12, 2017 upon the achievement of certain milestones.

(27) The shares being offered by Aaron Berg in this offering represents an aggregate of 36,528 shares of Common Stock, consisting of (i) 28,458 shares of outstanding Common Stock, (ii) 1,345 shares of Common Stock that are potentially issuable upon the release date of the holdback shares, and (iii) 6,725 shares of Common Stock that are potentially issuable within 60 days of April 12, 2017 upon the achievement of certain milestones.

(28) The shares being offered by Aaron Berg in this offering represents an aggregate of 36,528 shares of Common Stock, consisting of (i) 28,458 shares of outstanding Common Stock, (ii) 1,345 shares of Common Stock that are potentially issuable upon the release date of the holdback shares, and (iii) 6,725 shares of Common Stock that are potentially issuable within 60 days of April 12, 2017 upon the achievement of certain milestones.

(29) The shares being offered by Joy Becker in this offering represents an aggregate of 410 shares of Common Stock, consisting of (i) 320 shares of outstanding Common Stock, (ii) 15 shares of Common Stock that are potentially issuable upon the release date of the holdback shares, and (iii) 75 shares of Common Stock that are potentially issuable within 60 days of April 12, 2017 upon the achievement of certain milestones.

INDEX TO SOLENO THERAPEUTICS (FORMRLY KNOWN AS CAPNIA, INC) CONSOLIDATED FINANCIAL STATEMENTS

SOLENO THERAPEUTICS, INC. (FORMERLY KNOWN AS CAPNIA, INC) AS OF DECMEBER 31, 2016

SOLENO THERAPEUTICS, INC. (FORMERLY KNOWN AS CAPNIA, INC) AS OF MARCH 31, 2017

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ESSENTIALIS, INC.

INDEX TO PROFORMA FINANCIAL STATEMENTS

SOLENO THERAPEUTICS, INC AND ESSENTIALIS PROFORMA

INDEX TO PROFORMA FINANCIAL STATEMENTS

SOLENO THERAPEUTICS, INC AND NEOFORCE, INC PROFORMA

Report of Independent Registered Public Accounting Firm
To the Audit Committee of the
Board of Directors and Shareholders
of Soleno Therapeutics, Inc. (formerly known as Capnia, Inc.)

We have audited the accompanying consolidated balance sheets of Soleno Therapeutics, Inc. (formerly known as Capnia, Inc.) (the "Company") as of December 31, 2016 and 2015, and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Soleno Therapeutics, Inc., as of December 31, 2016 and 2015, and the consolidated results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ Marcum LLP
Marcum LLP
New York, NY
March 15, 2017

Financial Statements for the Year Ended December 31, 2016
Soleno Therapeutics, Inc.
(formerly known as Capnia, Inc.)
Consolidated Balance Sheets

	December 31, 2016	December 31, 2015
Assets		
Current assets		
Cash and cash equivalents	$2,725,996	$5,494,523
Accounts receivable	133,337	156,127
Restricted Cash	35,000	35,000
Inventory	660,391	551,008
Prepaid expenses and other current assets	246,570	167,642
Total current assets	3,801,294	6,404,300
Long-term assets		
Property and equipment, net	102,560	85,745
Goodwill	718,003	718,003
Other intangible assets, net	817,465	916,807
Other assets	125,530	76,340
Total assets	$5,564,852	$8,201,195
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$537,891	$695,056
Accrued compensation and other current liabilities	1,169,487	1,632,679
Series B warrant liability	—	865,000
Total current liabilities	1,707,378	3,192,735
Long-term liabilities		
Series A warrant liability	194,048	1,212,803
Series C warrant liability	85,490	462,437
Other liabilities	142,739	109,404
Total liabilities	2,129,655	4,977,379
Commitments and contingencies (Note 7)		
Stockholders' equity		
Preferred Stock, $.001 par value, 10,000,000 shares authorized:		
Series A convertible preferred stock, 10,000 shares designated; zero and 4,555 issued and outstanding at December 31, 2016 and December 31, 2015, respectively. Liquidation value of zero.	—	5
Series B convertible preferred stock, 13,780 and zero shares designated at December 31, 2016 and December 31, 2015, respectively; 12,780 and zero shares issued and outstanding at December 31, 2016 and at December 31, 2015, respectively. Liquidation value of zero.	13	—
Common stock, $0.001 par value, 100,000,000 shares authorized, 16,786,952 and 14,017,909 shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively.	16,786	14,018
Additional paid-in-capital	101,730,285	89,456,466
Accumulated deficit	(98,311,887)	(86,246,673)
Total stockholders' equity	3,435,197	3,223,816
Total liabilities and stockholders' equity	$5,564,852	$8,201,195

See accompanying notes to consolidated financial statements

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Soleno Therapeutics, Inc.
(formerly known as Capnia, Inc.)
Consolidated Statements of Operations

	For the Years Ended December 31,	
	2016	2015
Product revenue	$1,450,788	$387,555
Government grant revenue	—	$219,917
Total revenue	1,450,788	607,472
Cost of goods sold	1,509,306	352,683
Gross profit	(58,518)	254,789
Expenses		
Research and development	5,184,803	4,536,244
Sales and marketing	1,630,591	1,737,470
General and administrative	6,736,203	6,140,821
Total expenses	13,551,597	12,414,535
Operating loss	(13,610,115)	(12,159,746)
Interest and other income (expense)		
Other expense	(6,767)	(183,565)
Cease-use expense	(93,749)	—
Change in fair value of warrants liabilities	1,667,117	(515,860)
Inducement charge for Series C warrants	—	(3,049,375)
Total other income (expense)	1,566,601	(3,748,800)
Loss before provision for income tax	(12,043,514)	(15,908,546)
Provision for deferred taxes	21,700	—
Net loss	(12,065,214)	(15,908,546)
Loss on extinguishment of convertible preferred stock	3,651,172	—
Net loss applicable to common stockholders	$(15,716,386)	$(15,908,546)
Basic and diluted net loss per share applicable to common stockholders	$(1.01)	$(1.69)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	15,507,484	9,425,880

See accompanying notes to consolidated financial statements.

SOLENO THERAPEUTICS, INC. (formerly known as Capnia, Inc)
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' (DEFICIT) EQUITY

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount	Shares	Amount			
Balances at January 1, 2015	—	—	—	—	6,769,106	$6,769	$59,141,405	$(70,338,127)	$(11,189,953)
Stock based compensation							942,369		942,369
Issuance of common stock for stock option exercises					83,848	84	293,489		293,573
Issuance of common stock for Series A warrant exercises					24,000	24	155,976		156,000
Issuance of common stock for Series B warrant exercises (net of transaction costs of $306,116)					619,512	619	3,720,094		3,720,713
Issuance of common stock for Series B warrant cashless exercises					5,879,560	5,880	416,660		422,540
Issuance of common stock for 2010/2012 warrant cashless exercises					13,407	13	(13)		—
Contribution of Series B warrants							3,332		3,332
Derecognition of Series A warrant liability upon exercise							42,000		42,000
Derecognition of Series B warrant liability upon exercise							18,853,215		18,853,215
Issuance of shares in conjunction with					50,000	50	112,350		112,400

BDDI asset purchase									
Issuance of shares to Aspire Capital					71,891	72	183,250		183,322
Sales of shares through Aspire ATM vehicle					506,585	507	1,433,687		1,434,194
Issuance of Series A Convertible Preferred shares(net of transaction costs of $396,343)	4,555	5					4,158,652		4,158,657
Net loss								(15,908,546)	(15,908,546)
Balances at December 31, 2015	4,555	5	—	—	14,017,909	14,018	89,456,466	(86,246,673)	3,223,816
Stock based compensation							871,270		871,270
Issuance of common stock for stock option exercises					58,419	58	70,044		70,102
Issuance of common stock for Series B warrant cashless exercises					485,202	485	593,099		593,584
Issuance of common stock on conversion of Series A Convertible Preferred shares	(2,220)	(2)			1,200,000	1,200	(1,198)		—
Issuance of Series A Convertible Preferred shares(net of transaction costs of $374,661)	5,445	5					5,070,334		5,070,339
Repurchase of Series A Convertible Preferred shares	(7,780)	(8)					(7,779,992)		(7,780,000)
Issuance of Series B Convertible Preferred			13,780	14			13,426,881		13,426,895

shares(net of transaction costs of $353,105)									
Issuance of common stock on conversion of Series B Convertible Preferred shares			(1,000)	(1)	1,000,000	1,000	(999)		—
Issuance of common stock to board members in lieu of cash payments for quarterly board fees					25,422	25	24,380		24,405
Net loss								(12,065,214)	(12,065,214)
Balances at December 31, 2016	—	—	12,780	$ 13	16,786,952	$16,786	101,730,285	$(98,311,887)	$3,435,197

See accompanying notes to consolidated financial statements

Soleno Therapeutics, Inc.
(formerly known as Capnia, Inc.)
Consolidated Statements of Cash Flows

	For the Years Ended December 31,	
	2016	2015
Cash flows from operating activities:		
Net loss	$(12,065,214)	$(15,908,546)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	131,640	108,228
Stock-based compensation expense	871,270	942,369
Board fees paid with common stock	24,404	—
Provision for deferred taxes	21,700	—
Change in fair value of stock warrants	(1,667,117)	515,860
Loss on disposition of equipment	768	—
Inducement charge for Series C warrants	—	3,049,375
Noncash expense of issuing shares to Aspire Capital	—	183,322
Change in operating assets and liabilities:		
Accounts receivable	22,790	(156,127)
Inventory	(109,383)	(441,672)
Prepaid expenses and other assets	(78,928)	84,630
Other long-term assets	(49,190)	(76,340)
Accounts payable	(149,163)	211,945
Accrued compensation and other current liabilities	(463,192)	1,187,626
Other long-term liabilities	11,635	—
Net cash used in operating activities	(13,497,980)	(10,299,330)
Cash flows from investing activities:		
Acquisition of Neoforce assets	—	(1,000,000)
Acquisition of BDDI asset (patent)	—	(250,000)
Increase in restricted cash	—	(15,000)
Purchase of property and equipment	(38,680)	(55,777)
Net cash used in investing activities	(38,680)	(1,320,777)
Cash flows from financing activities:		
Proceeds from exercise of common stock options	70,102	293,573
Proceeds from exercise of Series A warrants	—	156,000
Proceeds from exercise of Series B warrants	—	3,720,713
Proceeds from issuance of common stock to Aspire Capital	—	1,434,194
Net proceeds from issuance of Series A Convertible Preferred	5,070,339	4,230,150
Net proceeds from issuance of Series B Convertible Preferred	13,479,185	—
Redemption of Series A Convertible Preferred stock in conjunction with issuance of Series B Convertible Preferred stock	(7,780,000)	—
Series A Convertible Preferred transaction costs paid	(71,493)	—
Repayment of credit line	—	(101,529)
Initial Public Offering costs paid	—	(575,181)
Net cash provided by financing activities	10,768,133	9,157,920
Net decrease in cash and cash equivalents	(2,768,527)	(2,462,187)
Cash and cash equivalents, beginning of period	5,494,523	7,956,710
Cash and cash equivalents, end of period	$2,725,996	$5,494,523
Supplemental disclosures of noncash investing and financing information		

Conversion of Series A preferred to common stock	$1,200,000	$—
Conversion of Series B preferred to common stock	$1,000,000	$—
Series A preferred convertible stock transaction costs included in Accounts Payable	$—	$71,493
Series B preferred convertible stock transaction costs included in Accounts Payable	$52,290	$—
Fixed asset purchases included in Accounts Payable	$11,200	$—
De-recognition of Series B warrant liability through cash exercise	$—	$6,747,765
De-recognition of Series B warrant liability through cashless exercise	$593,584	$12,527,991
De-recognition of Series A warrant liability through cash exercise	$—	$42,000
BDDI patent purchase consideration included in accrued liabilities	$—	$200,000
Shares issued as consideration for BDDI patent purchase	$—	$112,400
Cashless exercise of 2010 and 2012 warrants	$—	$13
Contribution of Series B warrants	$—	$3,332

See accompanying notes to consolidated financial statements.

Soleno Therapeutics, Inc.
(formerly known as Capnia, Inc.)
December 31, 2016
Notes to Consolidated Financial Statements

Note 1. Description of Business

Soleno Therapeutics, Inc. (formerly known as Capnia, Inc.) (the “Company”) was incorporated in the State of Delaware on August 25, 1999, and is located in Redwood City, California. The Company develops and commercializes neonatology devices and diagnostics. The Company also has a therapeutics platform based on its proprietary technology for precision metering of gas flow.

On September 2, 2015, the Company established NeoForce, Inc. ("NFI"), a wholly owned subsidiary incorporated in the State of Delaware. On September 8, 2015, NFI, acquired substantially all of the assets of an unrelated privately held company NeoForce Group, Inc. ("NeoForce") in exchange for an upfront cash payment of $1.0 million and royalties on future sales. NeoForce develops innovative pulmonary resuscitation solutions for the inpatient and ambulatory neonatal markets that the Company is now marketing through NFI.

On April 27, 2015, the Company established Capnia, Inc. UK Limited, a wholly owned foreign subsidiary in the United Kingdom. The functional currency of the U.K. subsidiary is the British pound. There have been no significant activities for this entity to date.

The Company's most recent product to launch commercially utilizing precision metering of gas flow technology is Serenz® Allergy Relief, or Serenz, which has a CE Mark certification for sale in the European Union ("E.U.") Serenz is a proprietary handheld device that delivers non-inhaled CO2 topically to the nasal mucosa. Serenz is used only when needed, and does not need to be used on a scheduled basis. Pilot commercial sales of Serenz began in the U.K. and Ireland in the second quarter of 2016.

The Company also sells CoSense®, which aids in diagnosis of excessive hemolysis, a condition in which red blood cells degrade rapidly. When present in neonates with jaundice, hemolysis is a dangerous condition which can lead to adverse neurological outcomes. CoSense has 510(k) clearance for sale in the U.S. with a specific Indication for Use related to hemolysis issued, and has received CE Mark certification for sale in the E.U. CoSense is commercially available in the U.S. In addition, the Company is applying its research and development efforts to additional diagnostic products based on its Sensalyze Technology Platform, a portfolio of proprietary methods and devices which enables CoSense and can be applied to detect a variety of analytes in exhaled breath and other products for the neonatology market.

Note 2. Liquidity, Financial Condition and Management’s Plans

The Company had a net loss of $12.1 million for the year ended December 31, 2016 and has an accumulated deficit of approximately $98.3 million at December 31, 2016 from having incurred losses since its inception. The Company has approximately $2.1 million of working capital at December 31, 2016 and used approximately $13.5 million of cash in its operating activities during the year ended December 31, 2016. The Company has financed its operations principally through issuances of equity securities.

On July 24, 2015, the Company entered into the 2015 Aspire Purchase Agreement with 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 $10.0 million in value of shares of the Company’s common stock over the 24-month term of the Aspire Purchase Agreement. During the quarter ended September 30, 2015, the Company issued an aggregate of 506,585 shares of common stock to Aspire Capital in exchange for approximately $1.4 million.

On October 12, 2015, the Company entered into a 2015 Purchase Agreement with Sabby to purchase up to $10 million worth of Series A Convertible Preferred Stock (the “Preferred Stock”). The sale of the Preferred Stock took place in two separate closings. On October 15, 2015, the date of the first closing, the Company received proceeds of approximately $4.1 million, net of $0.4 million in estimated expenses. Upon the second closing, which closed on January 8, 2016, the Company received proceeds of approximately $5.0 million, net of $0.5 million in estimated expenses.

On June 29, 2016, the Company entered into the 2016 Sabby Purchase Agreement with Sabby, pursuant to which the Company agreed to sell to Sabby, in a private placement, an aggregate of up to 13,780 shares of our Series B

Convertible Preferred Stock at an aggregate purchase price of $13,780,000, which shares are convertible into 13,780,000 shares of our common stock, based on a fixed conversion price of $1.00 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%. In connection with the 2016 Sabby Purchase Agreement, the Company also repurchased an aggregate of 7,780 shares of Series A Convertible Preferred Stock held by Sabby for an aggregate amount of $7,780,000, which shares were originally purchased by Sabby under the 2015 Sabby Purchase Agreement and which shares represent 4,205,405 shares of common stock on an as-converted basis. The sale of the Series B Convertible Preferred Stock occurred in two separate closings. On July 5, 2016, the date of the first closing under the 2016 Sabby Purchase Agreement, the Company received proceeds of approximately $1.3 million, net of $0.1 million in estimated expenses. On September 29, 2016, the date of the second closing under the 2016 Sabby Purchase Agreement, the Company received proceeds of approximately $4.4 million, net of $0.3 million in estimated expenses. After repurchase of the Series A Convertible Preferred Stock and estimated transaction expenses, the Company received approximately $5.6 million of net proceeds (see Note 8).

On December 22, 2016, the Company entered into the Merger Agreement and Plan with Essentialis. Consummation of the merger was subject to various closing conditions, including our consummation of a financing of at least $8 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 the Company received on March 6, 2017 (see Note 14).

On January 27, 2017, the Company entered into the 2017 Aspire Purchase Agreement with 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 purchase agreement. Further, on the date of the closing of the financing, as defined in the Merger Agreement, the Company shall sell to Aspire Capital, and Aspire Capital shall purchase from the Company an aggregate of $2.0 million of the Company’s common stock (see Note 14).

During the year ended December 31, 2016, the Company implemented plans to reduce its expenses, including reducing its 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 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's commercial products, including CoSense, the other neonatology products and Serenz, and the distribution strategies implemented will begin to generate meaningful revenue and corresponding cash. In addition, the Company has been successful over the last 12 months in raising additional capital including the completed closings pursuant to the 2015 Sabby Purchase Agreement, the 2016 Sabby Purchase Agreement on June 29, 2016 and the financing completed as part of the merger with Essentialis. 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. 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 costs 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.

Management believes that the Company has sufficient capital resources, after considering the $10 million of financing that the Company received on March 7, 2017 (see Note 14) to sustain operations through at least the next twelve months from the date of this filing.

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 (“GAAP”) and the applicable rules and regulations of the Securities and Exchange Commission (“SEC”).

Principles of Consolidation

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

consolidation.

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 allowances for accounts receivable and inventory.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents at two commercial banks that management believes are of high credit quality. Cash and cash equivalents deposited with these commercial banks exceeded the Federal Deposit Insurance Corporation insurable limit at December 31, 2016 and December 31, 2015. The Company expects this to 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 is security of the Company credit card.

Accounts Receivable

Accounts receivable as of December 31, 2016 consist of balances due from customers in the normal course of business. The Company did not record an allowance for doubtful accounts as this balance was deemed fully collectible.

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 as of December 31, 2016 consisted of raw materials to be used in the assembly of our products. As of December 31, 2016, the Company's inventory includes approximately $382 thousand of raw material, $101 thousand of work-in-process and $177 thousand of finished goods. Inventory is stated at the lower of cost or market under the first-in, first-out (FIFO) method.

Patent

On June 30, 2015, the Company entered into an amendment of the BDDI Asset Purchase Agreement, under which the Company committed to pay aggregate cash payments of $450,000 and issued 40,000 shares of common stock to an affiliate of BDDI. With respect to the aggregate cash payments of $450,000, the Company paid an affiliate of BDDI an initial sum of $150,000 on July 1, 2015, and is obligated to pay $100,000 on each of the six, twelve and eighteen-month anniversaries of the signing of the amended agreement. The Company made the final installment of $100,000 on December 22, 2016. 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 has capitalized the fair value of the patent purchased as an intangible asset on its consolidated balance sheet, and is amortizing the fair value over the remaining useful life of the patent.

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.

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 of the assets and fair value.

Intangible Assets

Intangible assets with finite lives are amortized on a straight-line basis over their estimated useful lives, which range in term from 5 to 12 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 consist of the following at December 31, 2016:

	Amount	Accumulated Amortization	Net Amount	Useful Lives (years)
Patents and trademarks	$697,890	$ (105,524)	$592,366	5-12
Customer contracts	259,730	(34,631)	225,099	10
Total	$957,620	$ (140,155)	$817,465	

Future amortization expense for intangible assets over their remaining useful lives is as follows:

Year ending December 31:	Patents and trademarks	Customer contracts	Total Amortization
2017	$ 73,370	$25,973	$ 99,343
2018	73,370	25,973	99,343
2019	73,370	25,973	99,343
2020	64,310	25,973	90,283
2021	46,192	25,973	72,165
2022 and thereafter	261,754	95,234	356,988
Total	$ 592,366	$225,099	$ 817,465

Amortization expense for the years ended December 31, 2016 and December 31, 2105 was $99,343 and 40,813, respectively.

Goodwill

The Company tests its goodwill for impairment annually, or whenever events or changes in circumstances indicate an impairment may have occurred, by comparing its reporting unit's carrying value to its implied fair value. Impairment may result from, among other things, deterioration in the performance of the acquired business, adverse market conditions, adverse changes in applicable laws or regulations and a variety of other circumstances. If the Company determines that an impairment has occurred, it is required to record a write-down of the carrying value and charge the impairment as an operating expense in the period the determination is made. In evaluating the recoverability of the carrying value of goodwill the Company must make assumptions regarding estimated future cash flows and other factors to determine the fair value of the acquired assets. Changes in strategy or market conditions could significantly impact those judgments in the future and require an adjustment to the recorded balances. The Company did not perform the qualitative assessment, but made its determination using the quantitative approach for goodwill impairment. Using the quantitative approach, the Company determined that there was no impairment of goodwill for the year ended December 31, 2016.

Revenue Recognition

The Company began recognizing sales of CoSense during the year ended December 31, 2015. In addition, the Company began recognizing sales of NFI pulmonary resuscitation products after the acquisition of Neoforce's assets in September 2015.

The Company recognizes revenue when all of the following criteria are met:

- persuasive evidence of an arrangement exists;
- the sales price is fixed or determinable;
- collection of the relevant receivable is probable at the time of sale; and
- delivery has occurred or services have been rendered.

For a majority of sales, where the Company delivers its product to hospitals or medical facilities, the Company recognizes revenue upon delivery, which represents satisfaction of the required revenue recognition criteria. The Company does not offer rights of return or price protection and it has no post-delivery obligations. The Company offers a limited one-year warranty to most customers. Estimated warranty obligations are recorded at the time of sale and to date, warranty costs have been insignificant.

The Company also recognized revenue related to a government grant awarded during the year ended December 31, 2015. There were no government grants awarded during the year ended December 31, 2016. Government grants provide funds for certain types of expenditures in connection with research and development activities over a contractually defined period. Revenue related to government grants is recognized in the period during which the related costs are incurred and the related services are rendered, provided that the applicable performance obligations under the government grants have been met. Funds received under government grants are recorded as revenue if the Company is deemed to be the principal participant in the contract arrangements because the activities under the contracts are part of the Company's development programs. If the Company is not the principal participant, the funds from government grants are recorded as a reduction to research and development expense. Funds received from government grants are not refundable and are recognized when the related qualified research and development expenses are incurred and when there is reasonable assurance that the funds will be received.

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.

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.

Convertible Preferred Stock and other Hybrid Instruments

The Company's convertible preferred stock was classified as permanent equity on its 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 assets and liabilities is required. The Company determined that certain freestanding derivatives, which principally consist of Series A, Series B, and Series C warrants to purchase common stock, 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

For stock options granted to employees, the Company recognizes compensation expense for all stock-based awards based on the estimated fair value on the date of grant. The value of the portion of the award that is ultimately expected to vest is recognized as expense ratably over the requisite service period. The fair value of stock options is determined using the Black-Scholes option pricing model. The determination of fair value for stock-based awards on the date of grant using an option pricing model requires management to make certain assumptions regarding a number of complex and subjective variables.

Stock-based compensation expense related to stock options granted to non-employees is recognized based on the fair value of the stock options, determined using the Black-Scholes option pricing model, as they are earned. The awards generally vest over the time period the Company expects to receive services from the non-employee.

Recent Accounting Pronouncements

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. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial position or results of operations upon adoption.

In January 2017, the Financial Accounting Standard Board (the "FASB") issued Accounting Standards Update (ASU) 2017-04: "Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment " ("ASU 2017-04"), which removes Step 2 from the goodwill impairment test. It is effective for annual and interim periods beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment test performed with a measurement date after January 1, 2017. The Company expects that this new guidance will have an impact on its financial positions or results of operations, but the impact will not be material.

In January 2017, the FASB issued ASU 2017-01 "Business Combinations (Topic 805): Clarifying the Definition of a Business", which clarifies the definition of a business to assist entities with evaluating whether transactions should be accounted for as acquisitions or disposals of assets or businesses. The standard introduces a screen for determining when assets acquired are not a business and clarifies that a business must include, at a minimum, an input and a substantive process that contribute to an output to be considered a business. This standard is effective for fiscal years beginning after December 15, 2017, including interim periods within that reporting period. The Company does not expect this new guidance to have a material impact on its financial position, results of operations or financial statement disclosures.

In November 2016, the FASB issued ASU 2016-18, "Statement of Cash Flows (Topic 230): Restricted Cash" "(ASU 2016-18"). The update is effective for fiscal years beginning after December 15, 2017, including interim reporting periods within those fiscal years. Early adoption is permitted. The purpose of Update No. 2016-18 is to clarify guidance and presentation related to restricted cash in the statement of cash flows. The amendment requires beginning-of-period and end-of-period total amounts shown on the statement of cash flows to include cash and cash equivalents as well as restricted cash and restricted cash equivalents. The Company is in the process of determining the effect that the adoption will have on its financial position, results of operations or financial statement disclosures.
In October 2016, the FASB issued updated guidance related to the recognition of income tax consequences of an intra-entity transfer of an asset other than inventory. This guidance will be effective for the first quarter of tax year 2018; however, early adoption is permitted. The Company is evaluating the impact that this guidance will have its consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, "Statement of Cash Flows (Topic 230)" ("ASU 2016-15"), which seeks to reduce the existing diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. For public entities, Update 2016-15 becomes effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, with early adoption permitted. The Company is currently evaluating the provisions of Update 2016-15 and assessing the impact, if any, it may have on its financial position, results of operations, cash flows or financial statement disclosures.

In March 2016, the FASB issued ASU 2016-09, "Compensation - Stock Compensation (Topic 718)" ("ASU 2016-09"), which seeks to simplify accounting for share-based payment transactions including income tax consequences, classification of awards as either equity or liabilities, and the classification on the statement of cash flows. For public entities, Update 2016-09 becomes effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, with early adoption permitted. Early adoption is permitted. The Company has not yet determined the effect that ASU 2016-09 will have on its financial position, results of operations or financial statement disclosures.
In March 2016, the FASB issued guidance that involves several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. This guidance will be effective for the first quarter of tax year 2017; however, early adoption is permitted. The Company is evaluating the impact that this guidance will have on its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases. The new standard provides guidance intended to improve financial reporting about leasing transaction. The ASU affects all companies that lease assets such as real estate, airplanes and manufacturing equipment. The ASU will require companies that lease assets to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. The new standard will take effect for fiscal years, and interim periods with those fiscal years, beginning after December 15, 2018. Early adoption is permitted. We have not determined the potential effects of this ASU on our consolidated financial statements.

In January 2016, the FASB issued ASU 2016-01, "Recognition and Measurement of Financial Assets and Liabilities"(“ASU 2016-01”). ASU 2016-01 requires equity investments (excluding equity method investments and investments that are consolidated) to be measured at fair value with changes in fair value recognized in net income. Equity investments that do not have a readily determinable fair value may be measured at cost, adjusted for impairment and observable price changes. The ASU also simplifies the impairment assessment of equity investments, eliminates the disclosure of the

assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at cost on the balance sheet and requires the exit price to be used when measuring fair value of financial instruments for disclosure purposes. Under ASU 2016-01, changes in fair value (resulting from instrument-specific credit risk) will be presented separately in other comprehensive income for liabilities measured using the fair value option and financial assets and liabilities will be presented separately by measurement category and type either on the balance sheet or in the financial statement disclosures. ASU 2016-01 is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company has not yet determined the effect that ASU 2016-01 will have on its financial position, results of operations, or financial statement disclosures.

In August 2014, the FASB issued ASU 2014-15, "Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern." The amendments is this ASU are intended to provide guidance on the responsibility of reporting entity management. Specifically, this ASU provides guidance to management related to evaluating whether there is substantial doubt about the reporting entity's ability to continue as a going concern and about related financial statement note disclosures. Although the presumption that a reporting entity will continue to operate as a going concern is fundamental to the preparation of financial statements, prior to the issuance of this ASU, there was no guidance in U.S. generally accepted accounting principles (U.S. GAAP) related to the concept. Due to the lack of guidance in U.S. GAAP, practitioners and their clients often faced challenges in determining whether, when, and how a reporting entity should disclose the relevant information in its financial statements. As a result, the FASB issued this guidance to require management evaluation and potential financial statement disclosures. This ASU will be effective for financial statements with periods ending after December 15, 2016. The Company adopted the ASU during the year and performed going concern evaluations for its 2016 calendar year-end financial statements.

In May 2014, the FASB issued ASU 2014-09, "Revenue from Contracts with Customers (Topic 606)" ("ASU 2014-09"). ASU 2014-09 supersedes the revenue recognition requirements in ASC Topic 605, "Revenue Recognition" and some cost guidance included in ASC Subtopic 605-35, "Revenue Recognition - Construction-Type and Production-Type Contracts." The core principle of ASU 2014-09 is that revenue is recognized when the transfer of goods or services to customers occurs in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. ASU 2014-09 requires the disclosure of sufficient information to enable readers of the Company's financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. ASU 2014-09 also requires disclosure of information regarding significant judgments and changes in judgments, and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 provides two methods of retrospective application. The first method would require the Company to apply ASU 2014-09 to each prior reporting period presented. The second method would require the Company to retrospectively apply ASU 2014-09 with the cumulative effect recognized at the date of initial application. ASU 2014-09 will be effective for the Company beginning in fiscal 2019 as a result of ASU 2015-14, "Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date," which was issued by the FASB in August 2015 and extended the original effective date by one year. The Company is currently evaluating the impact of adopting the available methodologies of ASU 2014-09 and 2015-14 upon its financial statements in future reporting periods. The Company has not yet selected a transition method. The Company is in the process of evaluating the new standard against its existing accounting policies, including the timing of revenue recognition, and its contracts with customers to determine the effect the guidance will have on its financial statements and what changes to systems and controls may be warranted.

There have been four new ASUs issued amending certain aspects of ASU 2014-09, ASU 2016-08, "Principal versus Agent Considerations (Reporting Revenue Gross Versus Net)," was issued in March, 2016 to clarify certain aspects of the principal versus agent guidance in ASU 2014-09. In addition, ASU 2016-10, "Identifying Performance Obligations and Licensing," issued in April 2016, amends other sections of ASU 2014-09 including clarifying guidance related to identifying performance obligations and licensing implementation. ASU 2016-12, "Revenue from Contracts with

Customers - Narrow Scope Improvements and Practical Expedients" provides amendments and practical expedients to the guidance in ASU 2014-09 in the areas of assessing collectability, presentation of sales taxes received from customers, noncash consideration, contract modification and clarification of using the full retrospective approach to adopt ASU 2014-09. Finally, ASU 2016-20, “Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers,” was issued in December 2016, and provides elections regarding the disclosures required for remaining performance obligations in certain cases and also makes other technical corrections and improvements to the standard. With its evaluation of the impact of ASU 2014-09, the Company will also consider the impact on its financial statements related to the updated guidance provided by these four new ASUs.

The Company has considered all other recently issued accounting pronouncements and does not believe the adoption of such pronouncements will have a material impact on its financial statements.

Note 4. Fair Value of Financial Instruments

The carrying value of the Company's cash and cash equivalents, restricted cash, accounts receivable, accounts payable and accrued liabilities, 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, 2016			
	Total	Level 1	Level 2	Level 3
Assets				
Money market fund	$2,563,247	$2,563,247	—	—
Liabilities				
Series A warrant liability	194,048	194,048	—	—
Series C warrant liability	85,490	—	—	85,490
Total common stock warrant liability	$279,538	$194,048	—	$85,490

	Fair Value Measurements at December 31, 2015			
	Total	Level 1	Level 2	Level 3
Assets				
Money market fund	$3,803,929	$3,803,929	—	—
Liabilities				
Series A warrant liability	1,212,803	1,212,803	—	—
Series B warrant liability	865,000	—	—	865,000
Series C warrant liability	462,437	—	—	462,437
Total common stock warrant liability	$2,540,240	$1,212,803	—	$1,327,437

The Series A Warrant is a registered security that trades on the open market. 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 measurements of the Series B and Series C Warrants are based on significant inputs that are unobservable and thus represent Level 3 measurements. The Company's estimated fair value of the Series B Warrant liability is calculated using a Monte Carlo simulation. Key assumptions include the volatility of the Company's stock, the expected warrant term, expected dividend yield and risk-free interest rates. (see Note 6) 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. (see Note 6) The Level 3 estimates are based, in part, on subjective assumptions.

The agreement to pay the annual royalty in the NeoForce acquisition resulted in the recognition of a contingent consideration, which was recognized on the acquisition date. Subsequent changes to estimates of the amount of contingent consideration to be paid will be recognized as charges or credits in the statement of operations. The fair value of the contingent consideration is based on preliminary cash flow projections, growth in expected product sales and other assumptions. Based on the assumptions, the fair value of the royalty obligation was determined to be $153 thousand at the date of acquisition and $136 thousand as of December 31, 2016. The fair value of the royalty obligation was determined by applying the income approach, using several significant unobservable inputs for projected cash flows and a discount rate of 20% commensurate with the Company's cost of capital and expectation of the revenue growth for products at their life cycle stage. These inputs are considered Level 3 inputs under the fair value measurements and disclosure guidance.

On January 13, 2016 we entered into an agreement to sublease our excess space located in Redwood City. By the end of February we removed all equipment, furniture and fixtures being stored in this excess space and ceased use of this space. The fair value of the cease-use liability was calculated using the remaining lease payments, offset by future sub-lease payments, offset by deferred rent amortization, and discounted to present value using our current cost of capital of 20%. These inputs are considered Level 3 inputs under the fair value measurements and disclosure guidance.

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 financial instruments, which are treated as liabilities, as follows:

	Series A Warrant		Series B Warrant		Series C Warrant	
	Number of Warrants	Liability	Number of Warrants	Liability	Number of Warrants	Liability
Balance at December 31, 2015	2,425,605	$1,212,803	116,580	$865,000	590,415	$462,437
Change in value of Series A Warrants	—	(1,018,755)	—	—	—	—
De-recognition of Series B Warrant liability upon cashless exercise of warrants (485,202 shares issued)	—	—	(102,300)	(593,584)	—	—
De-recognition of Series B Warrant liability upon expiration	—	—	(14,280)	—	—	—
Change in value of Series B Warrants	—	—	—	(271,416)	—	—
Change in value of Series C Warrants	—	—	—	—	—	(376,947)
Balance at December 31, 2016	2,425,605	$194,048	—	$—	590,415	$85,490

Note 5. Property and Equipment, Net

Property and equipment consisted of the following:

	December 31, 2016	December 31, 2015
Furniture and fixtures	$182,257	$236,366
Computer hardware	66,810	52,112
Leasehold improvements	12,849	9,117
	261,916	297,595
Less accumulated depreciation and amortization	(159,356)	(211,850)
Total	$102,560	$85,745

Depreciation expense was $32,298 and $67,415 for the fiscal years ended December 31, 2016 and December 31, 2015, respectively.

Note 6. Warrant Liabilities

Warrants terms

The Company has issued Series A Warrants, Series B Warrants and Series C Warrants (the “Warrants”).

The Company’s Series A, Series B and Series C 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 requirement to cause or maintain the effectiveness of a registration statement for the offer and sale of these securities. The Warrant contracts further provide for the payment of liquidated damages at an amount per month equal to 1% of the aggregate 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 IPO or Private Transaction proceeds 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 is equivalent to fair value computed using the Binomial Lattice Option Model.

Accounting Treatment

The Company accounts for the Warrants in accordance with the guidance in ASC 815 Derivatives and Hedging. 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 statement of operations. The Series B Warrant liability was classified as a current liability in the year ended December 31, 2015, as the Warrants were set to expire on February 12, 2016.

Under ASC 815-40-35, the Company adopted a sequencing policy that reclassifies contracts, with the exception of stock options, from equity to assets or liabilities for those with the latest inception date first. Future issuance of securities will be evaluated as to reclassification as a liability under our sequencing policy of latest inception date first until either all of the Series B Warrants are settled or expire. The Series B Warrants expired on February 12, 2016.

Series A Warrants

The Company has issued 2,449,605 Series A Warrants to purchase shares of its common stock at an exercise price of $6.50 per share in connection with the unit offering offered in the Company's initial public offering ("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 these the Series A Warrants.

Since their issuance, a total of 24,000 Series A Warrants have been exercised. As of December 31, 2016, the fair value of the 2,425,605 outstanding Series A Warrants was approximately $194 thousand, and the decrease of $1 million in fair value during the year ended December 31, 2016 was recorded as other income in the statement of operations.

Series B Warrants

The Company issued 2,449,605 Series B Warrants to purchase shares of its common stock at an exercise price of $6.50 per share in connection with the IPO.

Between January 1, 2016 and the expiration date of the Series B Warrants of February 12, 2016, certain holders of Series B warrants cashless exercised a total of 102,300 Series B Warrants resulting in the issuance of 485,202 shares of common stock and the derecognition of approximately $593 thousand in Series B Warrant liability. The remaining Series B Warrant liability was reduced to zero upon expiration resulting in the recording of $272 thousand in other income in the statement of operations. The remaining Series B Warrants expired unexercised on February 12, 2016. As of February 12, 2016 and December 31, 2015 the Company used a Monte Carlo simulation to calculate the fair value of its Series B Warrant liability. This model is dependent upon several variables such as the warrant's term, exercise price, current stock price, risk-free interest rate estimated over the contractual term, estimated volatility of our stock over the term of the warrant and the estimated market price of our stock during the cashless exercise period. The risk-free rate is based on U.S. Treasury securities with similar maturities as the expected terms of the warrants. The volatility is estimated based on blending the volatility rates for a number of similar publicly-traded companies. The Company used the following inputs:

	February 12, 2016	December 31, 2015
Volatility	90 %	90 %
Expected Term (years)	0.00	0.12