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

FORM 10-K

(Mark One)

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

For the fiscal year ended: December 31, 2017

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

For the transition period from _____ to _____ .

Commission File No.: 001-36593

Soleno Therapeutics, Inc.

(formerly known as Capnia, Inc.)
(Exact name of Registrant as specified in its charter)

Delaware	**77-0523891**
(State or other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
1235 Radio Road, Suite 110 Redwood City, California	**94065**
(Address of Principal Executive Offices)	**(Zip Code)**

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

Securities Registered Pursuant to Section 12(b) of the Act:

Title of Each Class:	**Name of Each Exchange on which Registered:**
Common Stock, par value $0.001 per share	**The NASDAQ Capital Market**
Series A warrants to purchase Common Stock	**The NASDAQ Capital Market**

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☒
	Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of voting stock held by non-affiliates of the registrant on June 30, 2017, based on the closing price of $2.51 for shares of the registrant's common stock as reported by the NASDAQ Capital Market, was approximately $6.8 million. Shares of Common Stock beneficially held by each executive officer, director and holder of 5% or more of the outstanding Common Stock have been excluded in that such persons may be deemed affiliates.

As of March 21, 2018 there were 19,486,729 shares of the registrant's Common Stock, par value $0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement to be filed with the Commission pursuant to Regulation 14A in connection with the registrant's 2018 Annual Meeting of Stockholders, to be filed subsequent to the date hereof, are incorporated by reference into Part III of this Report. Such Definitive Proxy Statement will be filed with the Securities and Exchange Commission not later than 120 days after the conclusion of the registrant's fiscal year ended December 31, 2017. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part of this Form 10-K.

Soleno Therapeutics, Inc.
(formerly known as Capnia, Inc.)
Annual Report on Form 10-K
For the Year Ended December 31, 2017

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

PART I

ITEM 1. BUSINESS

Company Overview

On March 7, 2017, we completed our merger, or the Merger, with Essentialis, Inc., a Delaware corporation, or Essentialis in accordance with the Merger Agreement by and between Soleno Therapeutics and Essentialis dated December 22, 2016, or the Merger Agreement. After the Merger, our primary focus 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 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. DCCR has orphan designation for the treatment of PWS in the United States, or U.S., as well as in the European Union, or E.U.

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, with a secondary emphasis on our joint venture with OptAsia Healthcare Limited, a Hong Kong company limited by shares, or OAHL, for the development and commercialization of Capnia's Sensalyze technology, which includes the CoSense End-Tidal Carbon Monoxide monitor that assists in the detection of excessive hemolysis in neonates, and other related products. CoSense is 510(k) cleared for sale in the U.S. and received CE Mark certification for sale in the E.U. We continue to separately evaluate alternatives for our Serenz portfolio.

Diazoxide Choline Controlled-Release Tablets

DCCR tablets consist of the active ingredient diazoxide choline, the 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 (KATP). The KATP channel links the cellular energy status to the membrane potential. Diazoxide appears to act on signs and symptoms of PWS in a variety of ways. Agonizing the KATP channel in the hypothalamus has the potential to address hyperphagia, which is an 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 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 it suitable for once-a-day dosing. The control of release and absorption of diazoxide achieved using DCCR results in very level and consistent intraday circulating drug levels, and consistent levels of diazoxide in tissues that are the site of action

of the drug (the hypothalamus). In circulation, diazoxide is extensively protein bound. Only unbound diazoxide is active. The consistent absorption of diazoxide may also result in some level of disequilibrium in protein binding, potentiating the therapeutic response to treatment. The controlled rate of absorption, level intraday circulating drug levels and the disequilibrium in protein binding likely results in the potential for improved therapeutic response to treatment. Avoiding significant swings in circulating drug levels also has the potential to reduce adverse events which are often associated with transiently high circulating drug levels that often follow rapid absorption from immediate release product formulations.

Prader Willi Syndrome

PWS is a rare, complex neurobehavioral/metabolic disorder, which is due to the absence of normally active paternally expressed genes from the chromosome 15q11-q13 region. PWS is an imprinted condition with 70-75% of the cases due to a de novo deletion in the paternally inherited chromosome 15 11-q13 region, 20-30% from maternal uniparental disomy 15, or UPD, where the affected individual inherited 2 copies of chromosome from their mother and no copy from their father, and the remaining 2-5% from either microdeletions or epimutations of the imprinting center (i.e., imprinting defects; IDs). The committee on genetics of the American Academy of Pediatrics states PWS affects both genders equally and occurs in people from all geographic regions; its estimated incidence is 1 in 15,000 to 1 in 25,000 live births. The mortality rate among PWS patients is 3% a year across all ages and 7% in those over 30 years of age. The mean age of death reported from a 40-year mortality study in the U.S. was 29.5 ± 15 years (range: 2 months - 67 years).

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

Other complications in PWS patients include greater risk for autistic symptomatology, psychosis, sleep disorders, distress, food stealing, withdrawal, sulking, nail-biting, hoarding and overeating, and more pronounced attention-deficit hyperactivity disorder symptoms, insistence on sameness, and their association with maladaptive conduct problems. The reported rates of psychotic symptoms, between 6% and 28%, are higher than those for individuals with other intellectual disabilities. Individuals with PWS show age-related increases in internalizing problems such as anxiety, sadness and a feeling of low self-esteem. Males are at greater risk for aggressive behavior, depression and dependent personality disorder and overall severity of psychopathology than females. Cognitively, most individuals with PWS function in the mild 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, reduces hypotonia, may reduce cognitive impairment, but has no effect on hyperphagia. A global patient survey conducted by the Foundation for Prader-Willi Research (n=779), found that 96.5% of respondents rated reducing hunger and 91.2% rated improving behavior around food as very important or most important symptom to be relieved by a new treatment. Physical function and body composition symptoms for which a high percentage of respondents indicated were very important or most important included: 92.9% indicated improving metabolic health (reduces fat / increases muscle) and 81.3% indicated the related symptom of improving activity and stamina. The behavioral and cognitive symptoms rated by respondents as very or most important were: 85.2% indicated reduction of obsessive/compulsive behavior, 84.6% indicated improvements to intellect/development, and 83.2% indicated reduction of temper outburst severity and frequency. See the Foundation for Prader-Willi Research: Prader-Willi Syndrome “Patient Voices” Online Survey and Results.

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

Clinical Trial of DCCR for PWS

A Phase II clinical trial 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 11 and 21. The first phase of the study was open label during which subjects were initiated on a DCCR dose that was escalated every 14 days at the discretion of the investigator. Any subject who showed an increase in resting energy expenditure and/or a reduction in hyperphagia from baseline at certain study visits would be designated a responder, whereas all others would be designated non-responders. This 10-week open-label treatment phase was followed by randomized double-blind, placebo-controlled, withdrawal phase. Responders were randomized in a 1:1 ratio either to continue on active treatment at the dose they were treated with, or to the placebo equivalent of that dose for an additional 4 weeks. Of the 13 subjects who enrolled, 11 were designated as responders; the remaining two subjects had discontinued prematurely.

Key efficacy results included a statistically significant reduction in hyperphagia from baseline to the end of the open-label treatment phase. In addition, greater improvement in hyperphagia from baseline was observed in those subjects with moderate to severe hyperphagia who received DCCR doses of 4.2 mg/kg (the planned population and target dose for the Phase III study). There was a significant improvement in the number of subjects reporting one or more aggressive and destructive behaviors. During the open-label treatment phase, a mean decrease in body fat mass and increases in lean body mass and lean body mass / fat mass ratio were seen. These changes were associated with a statistically significant reduction in waist circumference, consistent with the loss of visceral fat. Statistically significant reductions from baseline in LDL cholesterol and non-HDL cholesterol were observed. The change in triglycerides, while marked, did not reach statistical significance.

Safety of DCCR in the Treatment of PWS

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

Regulatory Status of DCCR for the Treatment of PWS

DCCR is being developed in the U.S. under a current IND, and is designated as an Orphan Product. We announced the successful completion of a scientific advice meeting with FDA on July 5, 2017. The FDA expressed support for change in hyperphagia score (without a change in weight) compared to placebo as the primary endpoint for the study. In addition, based on the data provided in the meeting briefing information, the dosing paradigm proposed by the Company for the study was accepted. The FDA proposed, and Soleno agreed, that the duration of the randomized, double-blind, placebo-controlled study should be shorter (3-4 months) and that DCCR safety information could be obtained in a long-term, safety extension study. On September 25, 2017 we announced the receipt of advice from the Committee for Medicinal Products for Human Use (CHMP) of the EMA regarding DCCR for the treatment of PWS. The EMA indicated that a single pivotal trial would support a Marketing Authorisation Application. They also indicated their general acceptance of several key aspects of the proposed development plan, on which general agreement had been reached previously with the FDA. The EMA expressed their support for change in hyperphagia compared to placebo as the primary endpoint for the study. In addition, the dosing paradigm proposed by Soleno for the study was accepted. The EMA also commented that Soleno could treat children with hyperphagia in the study without further toxicology work. On October 12, 2017, we announced the receipt of a positive opinion from the Committee for Orphan Medicinal Products (COMP) of

the EMA recommending DCCR for designation as an orphan medicinal product for the treatment of PWS. The designation has subsequently been granted as EU/3/17/1941.

Market opportunity

An estimated 300,000 to 400,000 individuals worldwide have PWS. An overall prevalence ranging from 1:15,000 to 1:25,000 has been reported regardless of geography or ethnicity. The numbers of identified PWS patients is growing at a rate that is higher than the rate of general population because of improved rates of diagnosis. We anticipate that DCCR could be the first effective treatment for hyperphagia in PWS to reach the market both in the U.S. and Europe and would therefore be likely to be used in a large proportion of patients.

Sales and Marketing

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

Pricing

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

Competition

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

Essentialis Acquisition

On December 22, 2016, the Company entered into the Merger Agreement with Essentialis. Consummation of the merger was subject to various closing conditions, including the Company's consummation of a financing of at least $8 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, the Company held a special shareholder 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, the Company completed the merger with Essentialis and issued 3,783,388 shares of common stock to shareholders of Essentialis. The Company held back 182,676 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. The Company is also obligated to issue an additional 913,389 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 4,879,453 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.

On May 8, 2017, we received stockholder approval to amend the Amended and Restated Certificate of Incorporation of the Company, to change the name of the Company to Soleno Therapeutics, Inc.

Joint Venture for CoSense

In December 2017, we entered into a joint venture with OAHL with respect to our CoSense product by selling shares of Capnia, our previously wholly owned subsidiary, to OAHL. 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. Under the terms of the joint venture agreement, OAHL will invest up to $2.2 million in tranches to purchase shares of our Capnia subsidiary and as a result of this investment, Capnia will no longer be a wholly-owned subsidiary of us. Going forward, OAHL will be responsible for funding the operations of Capnia. In addition, OAHL has the option to buy our remaining interest in Capnia as set forth in the joint venture agreement. As of December 31, 2017, OAHL had acquired no shares of Capnia. The first target market for CoSense is for the use of ETCO measurements to aid in detection of hemolysis in neonates, a disorder in which CO and bilirubin are produced in excess as byproducts of the breakdown of red blood cells. Our entry into the joint venture is part of a comprehensive review of strategic alternatives for our legacy products and product candidates following our transition to a primarily therapeutic drug product company. As part of the joint venture, Anthony Wondka, our former Senior Vice President, Research and Development, transitioned to a full-time employee of Capnia. Going forward, OAHL will be responsible for funding the operations of Capnia.

Manufacturing

Pharmaceuticals

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

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

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

Medical Devices

We have manufactured the Serenz device in partnership with an OEM supplier based in Shenzhen, China and have the possibility of manufacturing future supply with this same OEM supplier and utilize to complete the final packaging and labeling of Serenz for future supplies.

Our joint venture with OAHL requires us to support Capnia in the manufacture of CoSense monitors at our facility in Redwood City, California. We assemble components for our joint venture from a variety of original equipment manufacturer, or OEM, sources.

Regulation of Pharmaceutical Manufacturing Processes

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

Intellectual Property

DCCR Patent Portfolio

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

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

Government Regulation - Pharmaceuticals

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

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

Nonclinical Testing

Before a drug candidate in can be tested in humans, it must be studied in laboratory experiments and in animals to generate data to support the drug candidate's potential benefits and/or safety. Additional nonclinical testing may be required during the clinical development process such as reproductive toxicology and juvenile toxicology studies. 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 I Studies. During Phase I studies, researchers test a new drug in normal volunteers who are healthy. In most cases, 20 to 80 healthy volunteers or people with the disease/condition participate in Phase 1. Phase I studies are closely monitored and gather information about how a drug interacts with the human body. Researchers adjust dosing schemes based on animal data to find out how much of a drug the body can tolerate and what its acute side effects are. As a Phase I trial continues, researchers answer research questions related to how it works in the body, the side effects associated with increased dosage, and early information about how effective it is to determine how best to administer the drug to limit risks and maximize possible benefits. This is important to the design of Phase 2 studies.

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

Phase III Studies. Researchers design Phase 3 studies to demonstrate whether or not a product offers a treatment benefit to a specific population. Sometimes known as pivotal studies, these studies generally involve a larger number of participants than do Phase II studies. Phase III studies provide most of the safety data. In Phase II studies, it is possible that less common side effects might have gone undetected. Because these studies are larger and longer in duration, the results are more likely to show long-term or rare side effects.

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

Clinical trials involve the administration of an investigational drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research

subjects provide their informed consent in writing for their participation in any clinical trial. Sponsors of clinical trials generally must register and report, at the NIH-maintained website ClinicalTrials.gov, key parameters of certain clinical trials.

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

FDA Approval Process

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

The FDA may also require Phase 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. 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. Manufacturers may not promote a drug that is still under development and has not been approved by the FDA. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses, and a company that is found to have improperly promoted off label uses may be subject to significant liability.

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

Drugs that are developed for rare diseases (i.e., in the U.S., the disease or condition has an prevalence of < 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 through a single application and review process. If this centralized approval procedure is not used, approval in one country of the European Union can be used to obtain approval in another country of the European Union under one of two simplified application processes: the mutual recognition procedure or the decentralized procedure, both of which rely on the principle of mutual recognition. After receiving regulatory approval through any of the European registration procedures, separate pricing and reimbursement approvals are also required in most countries. The European Union also has requirements for approval of manufacturing facilities for all products that are approved for sale by the European regulatory authorities.

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. The process for the regulatory approval of Serenz in the US has yet to commence

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.

Other Corporate Transactions

Sale of NFI

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

NeoForce Group, Inc.("NeoForce"). NFI markets innovative pulmonary resuscitation solutions for the inpatient and ambulatory neonatal markets. The Company sold NFI in a stock transaction that was completed on July 18, 2017, pursuant to a Stock Purchase Agreement with Neoforce Holdings, Inc. a wholly-owned subsidiary of Flexicare Medical Limited, a privately-held United Kingdom company.

Sabby 2016 Stock Purchase

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 2,756,000 shares of our common stock, based on a fixed conversion price of $5.00 per share on an as-converted basis. Under the terms of the Series B Convertible Preferred Stock, in no event shall shares of common stock be issued to Sabby upon conversion of the Series B Convertible Preferred Stock to the extent such issuance of shares of common stock would result in Sabby having ownership in excess of 4.99%. 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 841,081 shares of common stock on an as-converted basis. The sale of the Series B Convertible Preferred Stock occurred in two separate closings. 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 the repurchase of the Series A Convertible Preferred Stock and estimated transaction expenses, the Company received approximately $5.6 million of net proceeds.

Aspire Stock Purchase

On January 27, 2017, we entered into a Common Stock Purchase Agreement (the "2017 Aspire Purchase Agreement") with Aspire Capital Fund, LLC ("Aspire Capital"), which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $17.0 million in value of shares of our Common Stock over the 30-month term of the 2017 Aspire Purchase Agreement. The Company issued 1,666,666 shares of common stock for an investment of $8 million from the completion of the financing with the closing of the Essentialis acquisition and also issued 416,666 shares of common stock for an investment of $2 million from Aspire Capital. The 2017 Aspire Purchase Agreement was terminated upon the closing of the 2017 PIPE Offering.

2017 PIPE Offering

On December 11, 2017, we entered into the Unit Purchase Agreement with certain stockholders, pursuant to which we sold and issued 8,141,116 immediately separable units at a price per unit of $1.84, for aggregate gross proceeds of approximately $15,000,000. Each unit consisted of one share of our common stock and a warrant to purchase 0.74 shares of our common stock at an exercise price of $2.00 a share, for an aggregate of 8,141,116 Shares and corresponding warrants to purchase an aggregate of 6,024,425 Warrant Shares, together referred to as the Resale Shares. We also granted certain registration rights to these stockholders, pursuant to which, among other things, we prepared and filed a registration statement with the SEC to register for resale the Resale Shares. The registration statement was declared effective in February 2018.

Employees

As of December 31, 2017, we had twelve full-time employees and six full-time or part-time consultants providing services to us. None of our employees is represented by a labor union or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Corporate and Available Information

Our principal corporate offices are located at 1235 Radio Road, Suite 110, Redwood City, California 94065 and our telephone number is (650) 213-8444. We were incorporated in Delaware on August 25, 1999. Our internet address is www.soleno.life. We make available on our website, free of charge, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to those reports, as soon as reasonably practicable after we electronically file such materials with, or furnish it to, the Securities Exchange and Commission. Our Securities Exchange and Commission reports can be accessed through the Investor Relations section of our internet website. The information found on our internet website is not part of this or any other report we file with or furnish to the Securities Exchange and Commission.

ITEM 1A. RISK FACTORS

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

Risks related to our financial condition and capital requirements

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

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

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

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

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

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

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

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

We are a developer of therapeutics and medical devices with a limited commercialization history. Evaluating our performance, viability or future success will be more difficult than if we had a longer operating history or approved products for sale on the market. We continue to incur significant research and development and general and administrative expenses related to our operations. Investment in product development is highly speculative, because it entails substantial upfront capital expenditures and significant risk that any planned product will fail to demonstrate adequate accuracy or clinical utility. We have incurred significant operating losses in each year since our inception and expect that we will not be profitable for an indefinite period of time. As of December 31, 2017, we had an accumulated deficit of $114.0 million.

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

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

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

- develop a commercial organization capable of sales, marketing and distribution of any products for which we obtain marketing approval in markets where we intend to commercialize independently;
- achieve market acceptance of our current and future products, if any;
- set a commercially viable price for our current and future products, if any;
- establish and maintain supply and manufacturing relationships with reliable third parties, and ensure adequate and legally compliant manufacturing to maintain that supply;
- obtain coverage and adequate reimbursement from third-party payors, including government and private payors;
- find suitable global and U.S. distribution partners to help us market, sell and distribute our products in other markets;
- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities;
- complete development activities successfully and on a timely basis;

- establish, maintain and protect our intellectual property rights and avoid third-party patent interference or patent infringement claims; and
- attract, hire and retain qualified personnel.

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

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

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

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

- our ability to enroll patients in clinical trials and the timing of enrollment;
- the cost and risk of initiating sales and marketing activities;
- the timing and cost of, and level of investment in, research and development activities relating to our planned products, which will change from time to time;
- the cost of manufacturing our products may vary depending on FDA and other regulatory requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional planned products and technologies;
- the design, timing and outcomes of clinical studies;
- changes in the competitive landscape of our industry, including consolidation among our competitors or potential partners;
- any delays in regulatory review or approval in the U.S. or globally, of any of our planned products;
- the level of demand for our products may fluctuate significantly and be difficult to predict;

- the risk/benefit profile, cost and reimbursement policies with respect to our future products, if approved, and existing and potential future drugs that compete with our planned products;
- competition from existing and potential future offerings that compete with our products;
- our ability to commercialize our products inside and outside of the U.S., either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

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

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

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As of December 31, 2017, we have incurred significant operating losses since inception and continue to generate losses from operations and have an accumulated deficit of $114.0 million. These matters raise substantial doubt about our ability to continue as a going concern. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should we be unable to continue as a going concern.

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

At December 31, 2017, our cash balance was $17.1 million. We intend to raise additional capital, either through debt or equity financings to achieve its business plan objectives. We believe that we can be successful in obtaining additional capital; however, no assurance can be provided that we will be able to do so. There is no assurance that any funds raised will be sufficient to enable us to attain profitable operations or continue as a going concern. To the extent that we are unsuccessful, we may need to curtail or cease our operations and implement a plan to extend payables or reduce overhead until sufficient additional capital is raised to support further operations. There can be no assurance that such a plan will be successful.

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

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time we may consider strategic transactions, such as acquisitions, asset purchases and sales, and out-licensing or in-licensing of products, product candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near and long-term expenditures, could not result in perceived benefits that were contemplated upon entering into the transaction, and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations, solvency and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown and contingent liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- the timing and likelihood of payment of milestones or royalties;
- write-downs of assets or goodwill or impairment charges;
- increased operating expenditures, including additional research, development and sales and marketing expenses;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel; and
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership.

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

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

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

Risks related to the development and commercialization of our products

We may not be successful in commercializing our approved products

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

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

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

- the outcomes of clinical utility studies of such products in collaboration with key thought leaders to demonstrate our products' value in informing important medical decisions such as treatment selection;
- the success of our distribution partners;
- whether healthcare providers believe such tests provide clinical utility;
- whether the medical community accepts that such tests are sufficiently sensitive and specific to be meaningful in-patient care and treatment decisions; and
- whether hospital administrators, health insurers, government health programs and other payers will cover and pay for such tests and, if so, whether they will adequately reimburse us.

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

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

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

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

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

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

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

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

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

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

Our success depends on the market's confidence that our products can provide reliable, high-quality results or treatments. We believe that our customers are likely to be particularly sensitive to any test defects and errors in

our products, and prior products made by other companies for the same diagnostic purpose have failed in the marketplace, in part as a result of poor accuracy. As a result, the failure of our current and planned products to perform as expected would significantly impair our reputation and the clinical usefulness of such tests. Reduced sales might result, and we may also be subject to legal claims arising from any defects or errors.

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

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

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

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

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

- be delayed in obtaining marketing approval for our planned products;
- not obtain marketing approval at all;
- obtain approval for indications that are not as broad as intended;
- have the product removed from the market after obtaining marketing approval;

- be subject to additional post-marketing testing requirements; or
- be subject to restrictions on how the product is distributed or used.

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

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

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

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

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

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

- generate sufficient nonclinical, toxicology, or other in vivo or in vitro data, or clinical safety data to support the initiation or continuation of clinical trials;
- obtain regulatory approval, or feedback on trial design, to commence a trial;
- identify, recruit and train suitable clinical investigators;
- reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;

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

Patient enrollment is a significant factor in the timing of clinical trials and is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' or caregivers' perceptions as to the potential advantages of the drug candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating or any investigational new drugs or treatment under development for the indications we are investigating.

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

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

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

The research, development, testing, manufacturing, labeling, packaging, approval, promotion, advertising, storage, record keeping, marketing, distribution, post-approval monitoring and reporting, and export and import of drug products are subject to extensive regulation by the FDA, and by foreign regulatory authorities in other countries. The legislation and regulations differ from country to country. To gain approval to market our product candidates, we must provide development, manufacturing and clinical data that adequately demonstrates the safety and efficacy of the product for the intended indication. We have not yet obtained regulatory approval to

market any of our product candidates in the U.S. or any other country. Our business depends upon obtaining these regulatory approvals. The FDA can delay, limit or deny approval of our product candidates for many reasons, including:

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

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

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

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

- the prevalence and severity of any side effects;
- their effectiveness and potential advantages compared to alternative treatments;
- the price we charge for our planned products;
- the willingness of physicians to change their current treatment practices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

- the strength or effectiveness of marketing and distribution support or partners; and
- the availability of third-party coverage or reimbursement.

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.

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

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

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

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

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

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

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

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

We face significant competition in seeking appropriate strategic partners, and the negotiation process to secure favorable terms is time-consuming and complex. 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 any planned products will prove safe enough to receive regulatory approval. Undesirable side effects caused by any of our products could cause us or regulatory authorities to interrupt, delay or halt clinical trials or could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. Additionally, if any of our planned products receives additional marketing approvals, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including:

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

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

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

Alternatives exist for our products and we will likely face competition with respect to any planned products that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty

pharmaceutical companies, medical device companies, and biotechnology companies worldwide. 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 our products might otherwise be able to offer to payers. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Many of these competitors are attempting to develop therapeutics for our target indications.

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

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

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

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

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

Our ability to commercialize our products successfully also will depend in part on the extent to which reimbursement for these products and related treatments becomes available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payers, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third-party payers have attempted to control costs by limiting

coverage and the amount of reimbursement for particular medications. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with products administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any planned product that we successfully develop.

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

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

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

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

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

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

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

Our success in implementing our business strategy depends largely on the skills, experience and performance of key members of our executive management team and others in key management positions, including Dr. Anish Bhatnagar, our Chief Executive Officer, Neil M. Cowen, our Senior Vice President of Drug Development, and Kristen Yen, our Vice President of Clinical Operations. The collective efforts of each of these persons, and others working with them as a team, are critical to us as we continue to develop our technologies, tests and research and development and sales programs. As a result of the difficulty in locating qualified new management, the loss or incapacity of existing members of our executive management team could adversely affect our operations. If we were to lose one or more of these key employees, we could experience difficulties in finding qualified successors, competing effectively, developing our technologies and implementing our business strategy. Our officers all have employment agreements; however, the existence of an employment agreement does not guarantee retention of members of our executive management team and we may not be able to retain those individuals for the duration of or beyond the end of their respective terms. We have secured a $1,000,000 “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.

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

Management turnover creates uncertainties and could harm our business

We have recently experienced changes in our executive leadership. Specifically, on August 29, 2017, David O’Toole, Senior Vice President and Chief Financial Officer, notified us of his decision to resign from employment effective September 11, 2017. Mr. Jonathan Wolter, a partner at FLG Partners, LLC, was retained as our interim Chief Financial Officer; however, no permanent replacement has been appointed. In addition, as part of our joint venture with OAHL, Anthony Wondka transitioned from our Senior Vice President, Research & Development to an employee of Capnia. We also expect that we may have other officers leave as we continue to transition our primary focus to our DCCR development program, and away from our legacy businesses. Changes to strategic or operating goals, which can often times occur with the appointment of new executives, can create uncertainty, may negatively impact our ability to execute quickly and effectively, and may ultimately be unsuccessful. In addition, executive leadership transition periods are often difficult as the new executives gain detailed knowledge of our operations, and friction can result from changes in strategy and management style. Management turnover inherently causes some loss of institutional knowledge, which can negatively affect strategy and execution. Until we integrate new personnel, and unless they are able to succeed in their positions, we may be unable to successfully manage and grow our business, and our financial condition and profitability may suffer.

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

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

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

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

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

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

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

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

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

- failure to comply with the Foreign Corrupt Practices Act, including its books and records provisions and its anti-bribery provisions, by maintaining accurate information and control over sales activities and distributors' activities.

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

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

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

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

With respect to our joint venture, the accuracy of CoSense depends, in part, on the function of proprietary software run by the microprocessors embedded in the device, and despite our efforts to test the software extensively, it is potentially subject to malfunction, physical break-ins, hackers, improper employee or contractor access, computer viruses, programming errors, or similar problems. Any of these might result in confidential medical, business or other information of other persons or of ourselves being revealed to unauthorized persons.

Risks related to the operation of our business

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

We may enter into additional distribution or commercialization agreements with third parties with respect to our products. Our likely collaborators for any distribution, marketing, licensing or other collaboration

arrangements include large and mid-size companies, regional and national companies, and distribution or group purchasing organizations. We will have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our products. Our ability to generate revenue from these arrangements will depend in part on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

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

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

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

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

As of December 31, 2017, we had twelve employees and six full-time or part-time consultants. Over the next several years, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, quality assurance, engineering, product development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The

physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Future growth would impose significant added responsibilities on members of management, including:

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

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

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

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

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

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

We rely on third parties, such as contract research organizations, or CROs, investigational product packaging, labeling and distribution, laboratories, medical institutions and clinical investigators and staff, to perform various functions for our clinical trials. Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. We remain responsible for ensuring that each of our clinical studies is conducted in accordance with the general investigational plan and protocols for the study. Moreover, the FDA requires us and third parties involved in the

set-up, conduct, analysis and reporting of the clinical studies to comply with regulations and with standards, commonly referred to as good clinical practices, or GCP, to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of patients in clinical studies are protected. Our clinical investigators are also required to comply with GCPs. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical studies in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our planned products and will not be able to, or may be delayed in our efforts to, successfully commercialize our planned products.

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

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

Risks related to intellectual property

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

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

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

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

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

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

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

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

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

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

Even if the patent applications we rely on issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and the patents we rely on may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our

technology and products. Given the amount of time required for the development, testing and regulatory review of new planned products, patents protecting such products might expire before or shortly after such products are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage.

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

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

Interference or derivation proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office, or USPTO, or any foreign patent authority may be necessary to determine the priority of inventions or other matters of inventorship with respect to patents and patent applications. We may become involved in proceedings, including oppositions, interferences, derivation proceedings 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 United States Patent and Trademark Office, or USPTO, and various governmental patent agencies outside of the U.S. in several stages over the lifetime of the patents or applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and this circumstance would have a material adverse effect on our business

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

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

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

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

If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than requested, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

Risks related to government regulation

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

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

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

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

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

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

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

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

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

FDA may also require Phase 4 non-registrational studies to explore scientific questions to further characterize safety and efficacy during commercial use of our drug. FDA may also require us to provide additional data or information, improve our manufacturing processes, procedures or facilities or may require extensive surveillance to monitor the safety or benefits of our product candidates if it determines that our filing does not contain adequate evidence of the safety and benefits of the drug. In addition, even if FDA approves a drug, it could limit the uses of the drug. FDA can withdraw approvals if it does not believe that we are complying with regulatory standards or if problems are uncovered or occur after approval.

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

Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems are identified after the product reaches the market. In addition, the FDA may require post-approval testing, including Phase 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.

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

Once marketing approval has been obtained, the approved product and its manufacturer are subject to continual review by the FDA or non-U.S. regulatory authorities. With respect to our joint venture, the current clearance for CoSense, as well as any additional regulatory approval that we receive for any of our other planned products may be subject to limitations on the indicated uses for which the product may be marketed. Future approvals may contain requirements for potentially costly post-marketing follow-up studies to monitor the safety and effectiveness of the approved product. In addition, we are subject to extensive and ongoing regulatory requirements by the FDA and other regulatory authorities with regard to the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for our products.

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

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

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and generally require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP or QSR and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP or QSR compliance.

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

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;

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

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

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

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

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

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

We intend to seek distribution and marketing partners for our current products outside the U.S. and may market planned products in international markets. Our joint venture has obtained a CE Mark certification for CoSense and Serenz and they are therefore authorized for sale in the E.U.; however, in order to market these products in Asia, Latin America and other foreign jurisdictions, we must obtain separate regulatory approvals.

We have had limited interactions with foreign regulatory authorities. The approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Moreover, clinical studies or manufacturing processes conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA and CE Mark certification does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect

on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and even if we file we may not receive necessary approvals to commercialize our products in any market.

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

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

- imposes a tax of 2.3% on the retail sales price of medical devices sold after December 31, 2012;
- could result in the imposition of injunctions;
- requires collection of rebates for drugs paid by Medicaid managed care organizations; and
- requires manufacturers to participate in a coverage gap discount program, under which they must agree to offer
- 50% point-of-sale discounts off negotiated prices of applicable branded drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

While the U.S. Supreme Court upheld the constitutionality of most elements of the PPACA in June 2012, other legal challenges are still pending final adjudication in several jurisdictions. 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 our medical device products, including CoSense devices and may be applicable to CoSense consumables sold under our joint venture and also 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 payers of healthcare services to contain or reduce costs of health care may adversely affect:

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

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

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

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

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

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;
- indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities like us which provide coding and billing advice to customers;

- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics and medical supplies to report to the HHS information related to physician payments and other transfers of value and physician ownership and investment interests;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers.

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

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

Risks related to ownership of our securities

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

Our stock price has been and is likely to continue to be volatile. The stock market in general, and the market for biotechnology and medical device companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. During the period from January 1, 2017, through December 31, 2017, the reported high and low prices of our common stock ranged from $4.55 to $1.32. 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;
- variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional products or planned products;

- developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- developments concerning our ability to bring our manufacturing processes to scale in a cost-effective manner;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders;
- general economic, industry and market conditions; and
- the other risks described in this "Risk Factors" section.

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

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

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

We have issued 13,780 shares of Series B Convertible Preferred Stock, of which 8,209 shares were converted into 1,641,800 shares of the Company's Common Stock in 2017. As of December 31, 2017, there are 4,571 shares of Series B Convertible Preferred Stock outstanding which are convertible into 914,200 shares of Common Stock. 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%.

On March 7, 2017, we issued 1,666,666 shares of common stock for an investment of $8 million from the completion of the concurrent financing and issued 416,666 shares of common stock for an investment of $2 million from Aspire Capital pursuant to the 2017 Aspire Purchase Agreement. All the shares issued under the 2017 Aspire Purchase Agreement are eligible for future resale under a registration statement on Form S-1 on February 1, 2017 that was declared effective by the SEC on February 15, 2017. We terminated the 2017 Aspire Purchase Agreement on December 15, 2017 in connection with the closing of the 2017 PIPE Offering.

On December 11, 2017, we entered into the Unit Purchase Agreement with certain stockholders, pursuant to which we sold and issued 8,141,116 immediately separable units at a price per unit of $1.84, for aggregate gross proceeds of approximately $15,000,000. We refer to such offering as the 2017 PIPE Offering. Each unit consisted of one share of our common stock and a warrant to purchase 0.74 shares of our common stock at an exercise price of $2.00 per share, for an aggregate of 8,141,116 Shares and corresponding warrants to purchase an aggregate of 6,024,425 Warrant Shares, together referred to as the Resale Shares. We also granted certain registration rights to these stockholders, pursuant to which, among other things, we prepared and filed a registration statement with the SEC to register for resale the Resale Shares. The registration statement was declared effective in February 2018.

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

We are an "emerging growth company," and 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 $1.07 billion, (3) the date on which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. We 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 principal stockholders own a majority of our outstanding common stock. Entities associated with Vivo Ventures, Oracle Investment Management, Birchview Fund, Jack W. Schuler, 683 Capital Partners, Forward Ventures and Technology Partners, as of December 31, 2017, beneficially own approximately 77.6% of our common stock. As a result, the foregoing group of stockholders are able to

control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders will control the election of directors and the approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

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

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

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, or Section 404, 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 years ended December 31, 2016, we experienced an "ownership change", and in the year ended December 31, 2017 our acquisition of Essentialis resulted in an ownership change, of which both changes will limit our ability to utilize our existing and acquired net operating losses and other tax attributes to offset taxable income. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other tax attributes to offset U.S. federal taxable income will be subject to limitations, which could potentially result in increased future tax liability to us.

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

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

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

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

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

If, at any time while the Series A, Series C and 2017 PIPE Warrants, or the Warrants, are outstanding, we enter into a "Fundamental Transaction" (as defined in the Series A Warrant, Series C and 2017 PIPE 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 Warrants as at any time prior to the consummation of the Fundamental Transaction, may elect and require us to purchase the Warrants held by such person immediately prior to the consummation of such Fundamental Transaction by making a cash payment in an amount equal to the Black Scholes Value of the remaining unexercised portion of such registered holder's Warrants.

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

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

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

The warrants we have issued and outstanding do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, holders of Series A Warrants may exercise their right to acquire the common stock and pay an exercise price of $32.50 per share prior to the expiration of the five-year term on November 12, 2019, after which date any unexercised Series A Warrants will expire and have no further value. Holders of Series C Warrants may exercise their right to acquire common stock and pay an exercise price of $31.25 per share prior to the expiration of the five-year term on March 4, 2020. Holders of the 2017 PIPE Warrants are entitled to purchase one share of our common stock at an exercise price equal to $2.00 per share prior to at the earlier of (i) December 15, 2020 or (ii) 30 days following positive Phase III results for DCCR tablet in Prader-Willi syndrome.

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

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline.

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

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our

stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions include the following:

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

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

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

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

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

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of

existing or any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

The sale of our common stock to investors in the 2017 PIPE Offering may cause substantial dilution to our existing stockholders and the sale of common stock by these investors could cause the price of our common stock to decline.

On December 11, 2017, we entered into the Unit Purchase Agreement with certain stockholders, pursuant to which we sold and issued in the 2017 Pipe Offering 8,141,116 immediately separable units at a price per unit of $1.84, for aggregate gross proceeds of approximately $15,000,000. Each unit consisted of one share of our common stock and a warrant to purchase 0.74 shares of our common stock at an exercise price of $2.00 per share, for an aggregate of 8,141,116 Shares and corresponding warrants to purchase an aggregate of 6,024,425 Warrant Shares, together referred to as the Resale Shares. We also granted certain registration rights to these stockholders, pursuant to which, among other things, we prepared and filed a registration statement with the SEC to register for resale the Resale Shares. The registration statement was declared effective in February 2018.

The sale of our common stock to Sabby under the 2016 Sabby Purchase Agreement may cause substantial dilution to our existing stockholders and the sale of common stock by Sabby could cause the price of our common stock to decline.

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 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

Facilities

Our principal facilities consist of office space in Redwood City, California, which also contains space for Capnia's final assembly and calibration facility for CoSense. We currently occupy approximately 13,436 square feet of office space under a non-cancelable operating lease that terminates in August 2019.

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

ITEM 3. LEGAL PROCEEDINGS

On February 16, 2017, a purported stockholder class action lawsuit captioned Garfield *v. Capnia, Inc., et al.*, Case No. C17-00284 was filed in Superior Court of the State of California, County of Contra Costa against us and certain of our officers and directors, or the Lawsuit. 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. We made 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. The stipulation of dismissal is pending with the court.

The Company also agreed to pay $175,000 for dismissal of the lawsuit. This amount was accrued as a current liability on the balance sheet as of December 31, 2016 and recorded as an expense in general and administrative expense on the statement of operations for the year ended December 31, 2016.

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

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

The following table sets forth the high and low sales prices per share of the common stock as reported on NASDAQ. Such quotations represent inter dealer prices without retail markup, markdown or commission and may not necessarily represent actual transactions.

	High	Low
2016		
First Quarter	$9.25	$5.70
Second Quarter	$6.80	$5.45
Third Quarter	$5.90	$4.50
Fourth Quarter	$5.15	$3.65
2017		
First Quarter	$4.55	$2.75
Second Quarter	$3.75	$2.35
Third Quarter	$3.75	$1.48
Fourth Quarter	$3.06	$1.32
2018		
First Quarter (through March 21, 2018)	$2.29	$1.53

As of March 21, 2018, the last reported sale price of our common stock on the NASDAQ Capital Market was $1.86.

As of March 1, 2018, there were 82 shareholders of record for our common stock. A substantially greater number of stockholders may be "street name" or beneficial holders, whose shares are held of record by banks, brokers and other financial institutions.

Dividend Policy

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

Unregistered Sales of Equity Securities and Use of Proceeds

(a) Recent Sales of Unregistered Equity Securities

During the year ended December 31, 2017, we issued the following unregistered securities:

- On December 11, 2017, we entered into the Unit Purchase Agreement with certain stockholders, pursuant to which we sold and issued 8,141,116 immediately separable units at a price per unit of $1.84, for aggregate gross proceeds of approximately $15,000,000. We refer to such offering as the

2017 PIPE Offering. Each unit consisted of one share of our common stock and a warrant to purchase 0.74 shares of our common stock at an exercise price of $2.00 per share, for an aggregate of 8,141,116 Shares and corresponding warrants to purchase an aggregate of 6,024,425 Warrant Shares, together referred to as the Resale Shares. We also granted certain registration rights to these stockholders, pursuant to which, among other things, we prepared and filed a registration statement with the SEC to register for resale the Resale Shares. The registration statement was declared effective in February 2018.

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

- For the year ended December 31, 2017, we granted to officers, directors, employees, consultants and other service providers options to purchase an aggregate of 622,755 shares of common stock under our 2014 Equity Incentive Plan.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions or any public offering. We believe that these transactions were exempt from the registration requirements of the Securities Act under Rule 701 promulgated under the Securities Act as offers and sales of securities pursuant to certain compensatory benefit plans and contracts relating to compensation in compliance with Rule 701. The recipients of securities in these transactions represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the stock certificates and instruments issued in such transactions. All recipients had adequate access, through their relationships with us, to information about us.

(b) Use of Proceeds

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

ITEM 6. SELECTED FINANCIAL INFORMATION

The following selected consolidated financial information should be read together with our consolidated financial statements and accompanying notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this Annual Report on Form 10-K. The selected consolidated financial information in this section is not intended to replace our consolidated financial statements and the accompanying notes. Our historical results are not necessarily indicative of our future results.

We derived the statements of operations data for the fiscal years ended December 31, 2017 and 2016 and the balance sheet data as of December 31, 2017 and 2016 from our audited financial statements appearing elsewhere in this filing. The data should be read in conjunction with the financial statements, related notes, and other financial information included herein.

	Years Ended December 31,	
	2017	2016
Statement of Operations Data:		
Operating expenses		
Research and development	$ 3,068,742	$ 2,247,141
Sales and marketing	25,731	—
General and administrative	6,584,650	6,076,976
Change in fair value of contingent consideration	2,492,192	—
Total Operating expenses	12,171,315	8,324,117
Operating loss	(12,171,315)	(8,324,117)
Total interest and other income (expense), net	(1,553,002)	1,586,497
Loss from continuing operations, net of income tax benefit	(13,724,317)	(6,737,620)
Provision for income tax benefit	1,650,467	—
Loss from continuing operations, net of provision for income tax benefit	(12,073,850)	(6,737,620)
Loss from discontinued operations, net of tax effect	(3,593,575)	(5,327,594)
Net loss	(15,667,425)	(12,065,214)
Loss on extinguishment of convertible preferred stock	—	3,651,172
Net loss applicable to common stockholders	$ (15,667,425)	$ (15,716,386)
Weighted average common shares outstanding		
Basic and diluted	8,977,795	3,101,496
Net loss per common share from continuing operations, basic and diluted	$ (1.35)	$ (3.35)
Net loss per common share from discontinued operations, basic and diluted	(0.40)	(1.72)
Net loss per common share, basic and diluted	$ (1.75)	$ (5.07)

	December 31	
	2017	2016
Balance Sheet Data		
Cash and cash equivalents	$ 17,099,507	$ 2,725,996
Working capital	$ 16,261,038	$ 2,093,916
Total assets	$ 39,021,665	$ 5,564,852
Total stockholders' equity	$ 26,534,908	$ 3,435,197

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

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

Business Overview

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. On May 8, 2017, the Company received stockholder approval to amend the Amended and Restate Certificate of Incorporation of the Company to change the name of the Company to Soleno Therapeutics, Inc. The Company was initially established as a diversified healthcare company that developed and commercialized innovative diagnostics, devices and therapeutics addressing unmet medical needs, which consisted of: precision metering of gas flow technology marketed as Serenz® Allergy Relief, or Serenz; CoSense® End-Tidal Carbon Monoxide (ETCO) Monitor, or CoSense, which measures ETCO and aids in the detection of excessive hemolysis, a condition in which red blood cells degrade rapidly and which can lead to adverse neurological outcomes; and, products that included temperature probes, scales, surgical tables, and patient surfaces.

The Company's wholly-owned subsidiary NeoForce, Inc. ("NFI") also marketed innovative pulmonary resuscitation solutions for the inpatient and ambulatory neonatal markets.

On December 22, 2016, we entered into the Merger Agreement with Essentialis, Inc. Essentialis's efforts prior to the merger were focused primarily on developing and testing product candidates that target the ATP-sensitive potassium channel, a metabolically regulated membrane protein whose modulation has the potential to impact a wide range of rare metabolic, cardiovascular, and CNS diseases. Essentialis has tested Diazoxide Choline Controlled Release Tablet, or DCCR, as a treatment for Prader-Willi Syndrome, or PWS, a complex metabolic/neurobehavioral disorder. DCCR has orphan designation for the treatment of PWS in the U.S. as well as in the E.U. Consummation of the merger was subject to various closing conditions, including our consummation of a financing of at least $8 million at, or substantially contemporaneous with, the closing of the merger, which occurred on March 7, 2017 and the receipt of stockholder approval of the merger at a special meeting of our stockholders, which was held on March 6, 2017. See the section titled "Business—Essentialis Acquisition" for more information.

The Company subsequently explored opportunities to divest, sell or otherwise dispose of the CoSense, NFI and Serenz businesses. Accordingly, and pursuant to ASC 205-20-45-10, the assets and liabilities related to the discontinued operations of CoSense, NFI and Serenz are presented separately in the Balance Sheet as held for sale items, and the related operations reported herein for the CoSense, NFI and Serenz businesses are reported as discontinued operations in the Statement of Operations.

The Company determined to divest, sell or otherwise dispose of the CoSense, NFI and Serenz businesses in order to focus on the development and commercialization of novel therapeutics for the treatment of rare diseases. 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.

The Company sold NFI in a stock transaction that was completed on July 18, 2017, pursuant to a Stock Purchase Agreement with Neoforce Holdings, Inc. a wholly-owned subsidiary of Flexicare Medical Limited, a privately-held United Kingdom company, for $720,000 and adjustments for inventory and the current cash balances held at NFI (see Note 8).

On December 4, 2017, we, and our wholly-owned subsidiary, Capnia, Inc., a Delaware corporation, or Capnia, entered into a joint venture with OAHL with the purpose of developing and commercializing CoSense. See the section titled “Business—Joint Venture for CoSense” for more information.

We continue to separately evaluate alternatives for our Serenz portfolio.

No stock options were exercised during 2017 and during the year ended December 31, 2016, we received $70,000 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.

On October 6, 2017, the Company effected a one-for-five (1:5) reverse stock split of its then outstanding common stock and, accordingly, all common share and per share data are retrospectively restated to give effect of the split for all periods presented herein.

As of December 31, 2017, we had an accumulated deficit of $114.0 million, primarily as a result of research and development and general and administrative expenses. While we may in the future generate revenue from a variety of sources, potentially including sales of our neonatology products, therapeutic products, other diagnostic products, license fees, milestone payments, and research and development payments in connection with potential future strategic partnerships, we have, to date, generated revenue only from the 2013 license agreement pertaining to Serenz, $2.6 million in revenue from our neonatology products and $0.2 million in government grants; these activities are reported as discontinued operations in the accompanying consolidated financial statements of the Company. We may never be successful in commercializing our novel therapeutic and in divesting, selling or otherwise disposing of our existing neonatology products or related therapeutic products. Accordingly, we expect to incur significant losses from operations for the foreseeable future, and there can be no assurance that we will ever generate significant revenue or profits.

Financings

Sabby 2016 Stock Purchase

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 2,756,000 shares of our Common Stock, based on a fixed conversion price of $5.00 per share on an as-converted basis. Under the terms of the Series B Convertible Preferred Stock, in no event shall shares of Common stock be issued to Sabby upon conversion of the Series B Convertible Preferred Stock to the extent such issuance of shares of Common Stock would result in Sabby having ownership in excess of 4.99%. 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 841,081 shares of Common Stock on an as-converted basis. The sale of the Series B Convertible Preferred Stock occurred in two separate closings. 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 the repurchase of the Series A Convertible Preferred Stock and estimated transaction expenses, the Company received approximately $5.6 million of net proceeds.

Aspire Stock Purchase

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

2017 PIPE Offering

On December 11, 2017, the Company entered into the Unit Purchase Agreement with purchasers of the Company's securities pursuant to which the Company sold and issued 8,141,116 immediately separable units at a price per unit of $1.84 for aggregate gross proceeds of approximately $15,000,000. Each unit consisted of one share of the Company's common stock and a warrant to purchase 0.74 of a share of the Company's common stock at an exercise price of $2.00 per share, for an aggregate of 8,141,116 shares of common stock, and corresponding warrants, or the 2017 PIPE Warrants, to purchase 6,024,425 shares of common stock. Soleno refers to the Shares and the Warrant Shares collectively as the Resale Shares. The Company also granted certain registration rights to the selling stockholders pursuant to the Unit Purchase Agreement pursuant to which, among other things, the Company prepared and filed a registration statement with the SEC to register for resale the Resale Shares. The registration statement was declared effective in February 2018.

Recent Developments

In January 2018, a fund managed by Sabby converted an aggregate of 1,000 shares of their Series B Convertible Stock into 200,000 shares of Common Stock.

On February 2, 2018, the Company issued 47,766 shares of Common Stock to members of its Board of Directors as compensation for Board of Directors fees earned during the quarter ended December 31, 2017.

Financial overview

Summary

We have not generated net income from operations to date, and, at December 31, 2017 and December 31, 2016, we had an accumulated deficit of approximately $114.0 million and $98.3 million, respectively, primarily as a result of research and development and general and administrative expenses. We may never be successful in commercializing our novel therapeutics products for the treatment of rare diseases. Accordingly, we expect to incur significant losses from operations for the foreseeable future, and there can be no assurance that we will ever generate significant revenue or profits.

Revenue recognition

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. To date, the Company has earned no revenue from the commercial development and sale of novel therapeutic products and the revenue resulting from commercialization and sale of the CoSense, Neo Force, Inc. and Serenz products is reported in discontinued operations.

Research and development expenses

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

The Company recorded the value of contingent future consideration to be paid for the acquisition of Essentialis as a liability in March 2017 at the date of the acquisition, and the change in fair value of such consideration is recorded in Research and Development expenses for the year ended December 31, 2017.

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. The Company has to date incurred no sales and marketing expenses related to the sale and commercialization of novel therapeutic products, and the sales and marketing expenses related to the CoSense, Neo Force, Inc. and Serenz products is reported in discontinued operations.

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. General and administrative expenses incurred in operating all components of the Company's business are classified as continuing operations and are not allocated to specific research and development or sales and marketing activities that have been discontinued. General and administrative expense, such as rent, which are incurred specifically to directly support research and development and sales and marketing activities for the CoSense, Neo Force, Inc. and Serenz products is reported in discontinued operations.

Other income (expense), net

Other income (expense), net is primarily comprised of changes in the fair value of the Series A, Series C and 2017 PIPE common stock warrant liabilities.

Critical Accounting Policies and Significant Judgments and Estimates

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

Series A, Series C and the 2017 PIPE Warrants

We account for the Series A, Series C and 2017 PIPE warrants, collectively referred to as the Warrants, in accordance with the guidance in ASC 815 *Derivatives and Hedging*. The Warrants contain standard anti-dilution provisions for stock dividends, stock splits, subdivisions, combinations and similar types of recapitalization events. The Warrants also contain a fundamental transactions provision that permits their settlement in cash at fair value at the option of the holder upon the occurrence of a change in control. Such change in control events include tender offers or hostile takeovers, which are not within 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 Valuation Model.

We classified the 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 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 Series D Warrants contain standard anti-dilution provisions for stock dividends, stock splits, subdivisions, combinations and similar types of recapitalization events. They also contain a cashless exercise feature that provides for their net share settlement at the option of the holder in the event that there is no effective registration statement covering the continuous offer and sale of the Series D 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 Preferred 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 expenses, and external contract research and development expenses. 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, 2017 and December 31, 2016 stock-based compensation expense was $1,000,251 and $871,270, respectively of which, stock compensation expense of approximately $120,220 and

$132,000 was classified in discontinued operations, in 2017 and 2016, respectively. As of December 31, 2017, we had $1.2 million of total unrecognized compensation expense, which we expect to recognize over a period of approximately 2.6 years. The intrinsic value of all outstanding stock options as of December 31, 2017, 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 and directors 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 11,000 NSOs to sales representatives of Bemes, Inc. Of the 11,000 options granted, 5,499 options with a fair value of $26,355 vested immediately upon grant. Accelerated vesting of the remaining options was contingent on the satisfaction of certain performance requirements, which 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 vested 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 622,755 options granted in the year ended December 31, 2017, and there were 267,851 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.

Business combinations

Business combinations are recorded in accordance with ASC 805 and with recent guidance established by ASU 2017-01 issued by the Financial Accounting Standards Board, or FASB, in January 2017. Business

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

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

Contingent consideration

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

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

Impairment of Goodwill

Goodwill represents the excess of the purchase price of an acquired enterprise or assets over the fairvalue 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 2017 and 2016, we determined we operate in one segment and two reporting units. The only reporting unit with goodwill was the NeoForce ("NFI") unit which is reported in discontinued operations in 2017 and 2016, and in assets and liabilities held for sale at December 31, 2016.

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 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 2017 or 2016. Goodwill is classified with long-term assets held for sale in the Balance Sheet.

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. For more information, see the section titled "Risk Factors—Our ability to use our net operating loss carry forwards and certain other tax attributes will be limited."

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

Results of Continuing Operations

Comparison of the Years Ended December 31, 2017 and 2016 from continuing operations

	Year Ended December 31,		Increase (decrease)	
	2017	2016	Amount	Percentage
	(in thousands)			
Operating expenses:				
Research and development	$ 3,069	$ 2,247	$ 822	37%
Sales and marketing	26	—	26	—
General and administrative	6,584	6,077	507	8%
Change in fair value of contingent consideration	2,492	—	2,492	—
Total	12,171	8,324	3,847	46%
Loss from operations	(12,171)	(8,324)	(3,847)	46%
Change in fair value of warrants, income (expense)	(967)	1,667	(2,634)	158%
Cease-use income (expense)	4	(94)	98	104%
Other income (expense)	(590)	13	(603)	4,638%
Interest and other income (expense), net	(1,553)	1,586	(3,139)	198%
Loss from continuing operations before provision for tax benefit	(13,724)	(6,738)	(6,986)	104%
Provision for tax benefit	1,650	—	1,650	—
Loss from continuing operations	(12,074)	(6,738)	(5,336)	79%
Loss from discontinued operations:				
Operating	(3,407)	(5,327)	1,920	36%
Loss on sale of assets, net of tax effect	(186)	—	(186)	—
Total	(3,593)	(5,327)	1,734	33%
Net loss	$(15,667)	$(12,065)	$(3,602)	30%

Revenue

The company has not commenced commercialization of DCCR, its current sole novel therapeutic product, and accordingly, through December 31, 2017, has generated no revenue in continuing operations.

Research and development expense

Research and development expense of $3,069,000 for the year ended December 31, 2017 increased by $822,000 over 2016 resulting primarily from efforts directed toward development of DCCR which the Company acquired with the Essentialis acquisition during 2017.

Research and development expense devoted to continuing operations in the year ended December 31, 2016, consists of approximately $950,000 of salaries and related benefit expenses for employees not directly committed to the discontinued research and development efforts, which are classified as discontinued operations, together with indirect expenses of rent, facilities, and consultants that indirectly support the Company's general research and development efforts.

Sales and marketing expense

Sales and marketing expense of $26,000 for the year ended December 31, 2017 consisted of expense incurred to revise the Company's web-site. The company has not commenced commercialization of DCCR, its current sole novel therapeutic product, and accordingly, through December 31, 2017, has incurred no sales and marketing activities in continuing operations.

General and administrative expense

General and administrative expense of $6,584,000 for the year ended December 31, 2017 increased $507,000 over that of 2016 resulting primarily from amortizing $1.6 million of the patent intangible recorded in the Essentialis acquisition, which was partially offset by a reduction in expenditures of $1.1 million for professional fees directed to corporate and intellectual property activities.

General and administrative expense for the year ended December 31, 2016, increased $86,000 compared to 2015, due primarily to increases in legal and facilities related expenses of $283,000 and $71,000, respectively, which were partially offset by a reduction in consulting related services and salaries of $240,000 and $45,000, respectively.

Change in fair value of contingent consideration

The Company is obligated to make cash payments of up to a maximum of $30 million to Essentialis stockholders upon the achievement of certain future commercial milestones associated with the sale of Essentialis' product in accordance with the terms of the Essentialis merger agreement. The fair value of the liability for the contingent consideration payable by the Company achieving the commercial sales milestones of $100 million and $200 million was initially established as approximately $2,590,000 at the time of the merger and approximately $5,082,000 at December 31, 2017, based on the Company's assessment that it could reach the commercial sales milestones of in 2023 and 2025, respectively.

Other income (expense), net

Net other expense of $1.5 million in the year ended December 31, 2017, decreased by $3.1 million from net other income of $1.6 million in 2016 primarily due to the expense resulting from the increase in the value of the liability for Series A and 2017 PIPE Warrants and to the approximated $600,000 value of the commitment shares issued to Aspire Capital. Other income in the year ended December 31, 2016 is comprised primarily of the decrease in the value of the liability for warrants by $1.7 million, which was partially offset by $100,000 of cease-use expense.

Results of Discontinued Operations

Discontinued operations consist of the Company's activities previously dedicated to the development and commercialization of innovative diagnostics, devices and therapeutics addressing unmet medical needs, which

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

	Year Ended December 31,		Increase (decrease)	
	2017	2016	Amount	Percentage
Revenue	$ 735,212	$ 1,450,788	$ (715,576)	49%
Cost of goods sold	820,098	1,509,306	(689,208)	46%
Gross profit	(84,886)	(58,518)	(26,368)	45%
Operating expenses:				
Research and development	2,426,829	2,937,662	(510,833)	17%
Sales and marketing	218,706	1,630,591	(1,411,885)	87%
General and administrative	669,175	659,227	9,948	2%
Total operating expenses	3,314,710	5,227,480	(1,912,770)	37%
Income (Loss) from operations	(3,399,596)	(5,285,998)	(1,886,402)	36%
Other income (expense), net	(8,000)	(19,896)	(11,896)	60%
Loss from discontinued operations:				
Operating loss	(3,407,596)	(5,305,894)	(1,898,298)	36%
Loss on sale of assets, net of taxes	(185,979)	—	(185,979)	—
Loss from discontinued operations	(3,593,575)	—		—
Provision for deferred taxes	—	21,700	(21,700)	—
Loss from discontinued operations, net of tax effect	$(3,593,575)	$(5,327,594)	$(1,734,019)	33%

Revenue

During the year ended December 31, 2017, product revenues of $735,000 declined by $716,000 from 2016 due primarily to the sale of NeoForce in July 2017 after which no revenues were earned or reported. 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 $843,000 during 2016 compared to the prior year primarily due to the inclusion of a full year of revenue related to NFI products.

Research and development expense

Research and development expense of $2.4 million for the year ended December 31, 2017 declined by $511,000 from 2016 due primarily to the sale of NeoForce in July 2017, after which no further research and development was directed to or recorded for that operation and for a curtailment of spending for the Serenz product as the Company considered it a discontinued operation after the acquisition of Essentialis. Research and development expense for the year ended December 31, 2016 decreased by $1.6 million compared to the prior year, which was primarily due a redirection of research and development toward the continuing operations for the development and commercialization of novel therapeutics for the treatment of rare diseases.

Sales and marketing expense

Sales and marketing expense of $219,000 for the year ended December 31, 2017, which decreased by $1,412,000 compared to the prior year, consisted primarily of expenses incurred in the United Kingdom with efforts associated with the Company's sales effort for its discontinued Serenz products primarily due to the cessation of sales of Serenz in the United Kingdom and to the reduction of sales of all medical device products in the United States. Sales and marketing expense for the year ended December 31, 2016 decreased $107,000 over the prior year, due to the decrease of direct sales personnel concurrent with signing a distributor agreement with Bemes.

General and administrative expense

General and administrative expense of $669,000 for the year ended December 31, 2017 was materially consistent with that of 2016. General and administrative expense for the year ended December 31, 2016, increased $509,000 compared to the prior year, due primarily to increases in salaries together with related benefits and legal expenses of approximately $359,000 and $177,000 respectively.

Other income (expense), net

Net other expense for the year ended December 31, 2017 was materially consistent with that of 2016. Other expense of approximately $20,000 in the year ended December 31, 2016, reflects the change in the fair value of the contingent royalty related to assets acquired in the purchase of NFI.

Liquidity and Capital Resources

On December 22, 2016, we entered into the Merger Agreement with Essentialis, Inc. 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, at which we received stockholder approval.

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 for serving on the Board and certain related committees.

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 purchase agreement. Further, on the date of the closing of the financing, as defined in the Merger Agreement, the Company sold to Aspire Capital, and Aspire Capital shall purchase from the Company an aggregate of $2.0 million of the Company's common stock. The Company issued Aspire Capital 141,666 shares of Common Stock as commitment shares under the 2017 Aspire Purchase Agreement. On March 7, 2017, we received the $2.0 million from Aspire Capital. The 2017 Aspire Purchase Agreement was terminated upon the closing of the 2017 PIPE Offering.

On December 11, 2017, the Company entered into a Securities Purchase Agreement, or the Unit Purchase Agreement, with purchasers of the Company's securities pursuant to which the Company sold and issued 8,141,116 immediately separable units at a price per unit of $1.84 for aggregate gross proceeds of approximately $15,000,000 Each unit consisted of one share of the Company's common stock and a warrant to purchase 0.74 of a share of the Company's common stock at an exercise price of $2.00 per share, for an aggregate of 8,141,116 shares of common stock, and corresponding warrants, or the 2017 PIPE Warrants, to purchase 6,024,425 shares of common stock. Soleno refers to the Shares and the Warrant Shares collectively as the Resale Shares. The Company also granted

certain registration rights to the selling stockholders pursuant to the Unit Purchase Agreement pursuant to which, among other things, the Company prepared and filed a registration statement with the SEC to register for resale the Resale Shares. The registration statement was declared effective in February 2018.

In December 2017, the Company entered into a joint venture with OAHL with respect to its CoSense product by agreeing to sell shares of Capnia, its wholly-owned subsidiary, to OAHL. CoSense was Soleno's first Sensalyze Technology Platform product to receive 510(k) clearances from the FDA and CE Mark certification. CoSense measures CO, which can be elevated due to endogenous causes such as excessive breakdown of red blood cells, or hemolysis, or exogenous causes such as CO poisoning and smoke inhalation. The first target market for CoSense is for the use of ETCO measurements to aid in detection of hemolysis in neonates, a disorder in which CO and bilirubin are produced in excess as byproducts of the breakdown of red blood cells. The Company's entry into the joint venture results from a comprehensive review of strategic alternatives for its legacy products and product candidates following its transition to a primarily therapeutic drug product company. Going forward, OAHL will be responsible for funding a portion of the Capnia operations. As of December 31, 2017, OAHL had acquired no shares of Capnia.

At December 31, 2017, we had cash and cash equivalents of $17.1 million, of which $16.8 million was invested in a money market fund at an AAA-rated financial institution.

We expect to incur substantial expenditures in the foreseeable future for the clinical trial, development and potential commercialization of the DCCR product. 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 DCCR.

Management believes that the Company does not have sufficient capital resources to sustain operations through at least the next twelve months from the date of this filing. Additionally, in view of the Company's expectation to incur significant losses for the foreseeable future it will be required to raise additional capital resources in order to fund its operations, although the availability of, and the Company's access to such resources is not assured. If we are unable to raise additional funds when needed, our ability to complete planned clinical trials and attain commercial success with DCCR, or our other potential novel therapeutic 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.

Accordingly, management believes that there is substantial doubt regarding the Company's ability to continue operating as a going concern within one year from the date of filing these financial statements.

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,	
	2017	2016
Cash Flows		
Net cash used in continuing operating activities	$ (6,918,768)	$ (7,260,708)
Net cash used in discontinued operating activities	(3,031,190)	(6,237,272)
Net cash used in operating activities	(9,949,958)	(13,497,980)
Net cash used in continuing investing activities	(561,998)	(14,795)
Net cash provided by (used in) discontinued investing activities	940,780	(23,885)
Net cash used in investing activities	378,782	(38,680)
Net cash provided by continuing by continuing financing activities	23,944,687	10,768,133
Net cash provided by financing activities	23,944,687	10,768,133
Net increase in cash and cash equivalents from continuing operations	16,584,141	3,492,630
Net decrease in cash and cash equivalents from discontinued operations	(2,210,630)	(6,261,157)
Net increase (decrease) in cash and cash equivalents	$14,373,511	$ (2,768,527)

Cash used in continuing operating activities

During the year ended December 31, 2017, the Company used net cash of $6.9 million for continuing operating activities, resulting primarily from the loss from continuing operations of $12.1 million, which was adjusted for the non-cash items consisting primarily of $1.6 million of non-cash expense for depreciation and amortization, $2.5 million of on non-cash expense for the change in the fair value of contingent consideration for the acquisition of Essentialis, $0.9 million for the non-cash expense associated with stock-based compensation, and $1.0 million for the non-cash expense resulting from the change in fair value of the liability for warrants, all of which were partially offset by the non-cash provision for income tax benefit in the amount of $1.6 million.

During the year ended December 31, 2016, net cash used in continuing operating activities was $7.3 million, resulting primarily from the net loss from continuing operations of $6.8 million, adjusted for non-cash items consisting primarily of the $1.7 million non-cash income from the change in fair value of warrants and the use of cash for increases in prepaid expenses and other long-term assets and the decrease in accounts payable, which were offset by the $739,000 of non-cash stock-based compensation expense a $534,000 increase in accrued compensation and other liabilities.

Cash used in continuing investing activities

In the year ended December 31, 2017, the Company used $573,000 of cash primarily for the payment of costs associated with the acquisition of Essentialis.

In the year ended December 31, 2016, cash was used for the purchases of equipment for continuing investment activities.

Cash provided by continuing financing activities

During the year ended December 31, 2017, the Company obtained net cash of $23.9 million resulting from the proceeds of $10.0 million issuance of common stock immediately upon closing the acquisition of Essentialis together with the $15.0 million of proceeds from the issuance of common stock and warrants on common stock resulting from the 2017 PIPE Offering, all of which proceeds were partially offset by $1.1 million of costs paid for the raising and issuance of the related securities offerings.

During the year ended December 31, 2016, cash provided by financing activities was $10.8 million, consisting primarily of $5.1 million, net of related issuance costs, and $13.5 million, net of related issuance costs, in proceeds from the issuance of Series A and Series B Convertible Preferred stock, respectively, and the $70,000 proceeds from the sale of common stock for exercised stock options, all of which were partially offset partially by $7.8 million used to repurchase the outstanding Series A Convertible Preferred stock.

Cash used in discontinued operating activities

During the year ended December 31, 2017, the Company used net cash of $3.0 million for discontinued operating activities, resulting primarily from the loss from discontinued operations of $3.6 million, adjusted for the non-cash expenses associated with stock compensation and goodwill amortization.

During the year ended December 31, 2016, the Company used $6.2 million net cash in discontinued operating activities, resulting primarily from the net loss of $5.3 million from discontinued operations adjusted for the additional cash use of reducing accrued compensation and other current liabilities in the amount of $998,000, which was partially offset by $132,000 of non-cash stock-based compensation expense.

Cash used in discontinued investing activities

In the year ended December 31, 2017, the Company obtained approximately $941,000 from investing activities for discontinued operations resulting primarily from the sale of NFI operations in July 2017 that provided cash proceeds of $720,000 and from cash received from our joint-venture partner to reimburse operating expenses.

In the year ended December 31, 2016, cash was used for the purchases of equipment for discontinued investment activities.

Discontinued financing activities

The Company had no financing activities related to discontinued operations in 2017 nor in 2016.

Contractual Obligations and Commitments

As of December 31, 2017, we had lease obligations totaling $1.0 million, consisting of operating leases for our operating facilities in Redwood City, California. We signed a lease for our current operating facilities at 1235 Radio Road in Redwood City in July 2015, which expires in August of 2019. We had previously signed a sublease for our prior operating facilities at 3 Twin Dolphin Drive in Redwood City, with an expiration date of June 2018.

The following table summarizes our contractual obligations as of December 31, 2017.

	Payments due by period				
	Less than 1 year	1 to 3 years	4 to 5 years	After 5 years	Total
Lease obligations	$629,923	$334,747	—	—	$964,670
Total	$629,923	$334,747	—	—	$964,670

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 7) by agreeing to pay $175,000 for dismissal of the Lawsuit. 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 is pending with the court.

Off-Balance Sheet Arrangements

As of December 31, 2017, we had no off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K as promulgated by the SEC.

Accounting Guidance Update

Recently Issued Accounting Guidance

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Sensitivity

We had unrestricted cash and cash equivalents totaling $17.1 million at December 31, 2017. This balance was invested primarily in money market funds and are held for working capital purposes. We do not enter into investments for trading or speculative purposes. We believe we do not have material exposure to changes in fair value as a result of changes in interest rates. Declines in interest rates, however, will reduce future investment income.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Soleno Therapeutics, Inc.

(formerly known as Capnia, Inc.)

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of
Soleno Therapeutics, Inc. (formerly known as Capnia, Inc.)

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Soleno Therapeutics, Inc. (formerly known as Capnia, Inc.) (the "Company") as of December 31, 2017 and 2016, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2017, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

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

Basis for Opinion

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

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

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

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2014.

San Francisco, CA
April 2, 2018

Soleno Therapeutics, Inc.
(formerly known as Capnia, Inc.)
Consolidated Balance Sheets

	December 31, 2017	December 31, 2016
Assets		
Current assets		
Cash and cash equivalents	$ 17,099,507	$ 2,725,996
Restricted cash	35,000	35,000
Prepaid expenses and other current assets	342,927	246,570
Current assets held for sale	516,373	793,728
Total current assets	17,993,807	3,801,294
Long-term assets		
Property and equipment, net	22,885	42,021
Other assets	125,530	125,530
Intangible assets, net	20,413,056	—
Long-term assets held for sale	466,387	1,596,007
Total assets	$ 39,021,665	$ 5,564,852
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 633,104	$ 410,512
Accrued compensation and other current liabilities	973,054	1,050,466
Current liabilities held for sale	126,611	246,400
Total current liabilities	1,732,769	1,707,378
Long-term liabilities		
Series A warrant liability	351,713	194,048
Series C warrant liability	5,880	85,490
2017 PIPE Warrant liability	5,076,000	—
Contingent liability for Essentialis purchase price	5,081,840	—
Other liabilities	13,163	61,739
Long-term liabilities held for sale	225,392	81,000
Total liabilities	12,486,757	2,129,655
Commitments and contingencies (Note 7)		
Stockholders' equity		
Preferred Stock, $.001 par value, 10,000,000 shares authorized:		
Series B convertible preferred stock, 13,780 shares designated at December 31, 2017, and December 31, 2016; 4,571 and 12,780 shares issued and outstanding at December 31, 2017, and at December 31, 2016, respectively. Liquidation value of zero.	5	13
Common stock, $0.001 par value, 100,000,000 shares authorized, 19,238,972 and 3,357,387 shares issued and outstanding at December 31, 2017, and December 31, 2016, respectively.	19,239	3,357
Additional paid-in-capital	140,494,976	101,743,714
Accumulated deficit	(113,979,312)	(98,311,887)
Total stockholders' equity	26,534,908	3,435,197
Total liabilities and stockholders' equity	$ 39,021,665	$ 5,564,852

See accompanying notes to consolidated financial statements

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

	For the Years Ended December 31,	
	2017	2016
Operating Expenses		
Research and development	$ 3,068,742	$ 2,247,141
Sales and marketing	25,731	—
General and administrative	6,584,650	6,076,976
Change in fair value of contingent consideration	2,492,192	—
Total operating expenses	12,171,315	8,324,117
Operating loss	(12,171,315)	(8,324,117)
Interest and other income (expense)		
Cease-use income (expense)	4,167	(93,749)
Change in fair value of warrants liabilities	(967,055)	1,667,117
Other income (expense)	(590,114)	13,129
Total other income (expense)	(1,553,002)	1,586,497
Loss from continuing operations before provision for income tax benefit	(13,724,317)	(6,737,620)
Provision for income tax benefit from continuing operations	1,650,467	—
Loss from continuing operations	(12,073,850)	(6,737,620)
Loss from discontinued operations:		
Operating loss	(3,407,596)	(5,327,594)
Loss on sale of assets, net of tax effect	(185,979)	—
Loss from discontinued operations	(3,593,575)	(5,327,594)
Net loss	(15,667,425)	(12,065,214)
Loss on extinguishment of convertible preferred stock	—	3,651,172
Net loss applicable to common stockholders	(15,667,425)	$(15,716,386)
Loss per common share from continuing operations, basic and diluted	$ (1.35)	$ (3.35)
Loss per common share from discontinued operations, basic and diluted	(0.40)	(1.72)
Net loss per common share, basic and diluted	$ (1.75)	$ (5.07)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	8,977,795	3,101,496

See accompanying notes to consolidated financial statements.

Soleno Therapeutics, Inc.
(formerly known as Capnia, Inc.)
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount			
Balances at January 1, 2016	4,555	$ 5	—	$ —	2,803,580	$ 2,804	$ 89,467,681	$ (86,246,673)	$ 3,223,816
Stock-based compensation							871,270		871,270
Issuance of Series A Convertible	5,445	5					5,444,995		5,445,000
Less transaction costs							(374,661)		(374,661)
Issuance of common stock for Series B warrant cashless exercises					97,040	97	593,487		593,584
Issuance of common stock through conversion of Series A preferred	(2,220)	(2)			240,000	240	(238)		—
Issuance of common stock for stock option exercises					11,683	12	70,091		70,103
Issuance of Series B Convertible Preferred			13,780	14			13,779,986		13,780,000
Less transaction costs							(353,105)		(353,105)
Redemption of Series A Convertible Preferred	(7,780)	(8)					(7,779,992)		(7,780,000)
Issuance of common stock through conversion of Series B preferred			(1,000)	(1)	200,000	200	(199)		—
Issuance of common stock to board members in lieu of cash payments for quarterly board fees					5,084	5	24,400		24,405
Net Loss								(12,065,214)	(12,065,214)
Balances at December 31, 2016	—	—	12,780	13	3,357,387	3,357	101,743,714	(98,311,887)	3,435,197
Stock-based compensation							1,000,251		1,000,251
Issuance of common stock on conversion of Series B Convertible Preferred shares			(8,209)	(8)	1,641,800	1,642	(1,634)		—
Issuance of common stock to board members in lieu of cash payments for quarterly board fees					90,306	90	277,695		277,786
Issuance of common stock to acquire Essentialis					3,783,388	3,783	17,242,712		17,246,495
Sale of shares under the 2017 Aspire Purchase Agreement					2,083,333	2,083	9,997,917		10,000,000
Issuance of shares to Aspire Capital in lieu of commitment fees					141,666	142	601,941		602,083
Rounding adjustment resulting from 1 for 5 reverse split					(24)	—	—		—
Sale of shares to investors in the 2017 PIPE, net of costs of $1,172,485					8,141,116	8,141	13,819,380		13,827,521
Fair value at transaction date of warrants to purchase common stock under the 2017 PIPE							(4,187,000)		(4,187,000)
Net Loss								(15,667,425)	(15,667,425)
Balances at December 31, 2017	—	$ —	4,571	$ 5	19,238,972	$19,239	$140,494,976	$(113,979,312)	$ 26,534,908

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,	
	2017	**2016**
Cash flows from operating activities:		
Net loss	$(15,667,425)	$(12,065,214)
Loss from discontinued operations	(3,593,575)	(5,327,594)
Loss from continuing operations	(12,073,850)	(6,737,620)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,611,271	18,670
Stock-based compensation expense	880,031	739,232
Income tax benefit	(1,651,267)	—
Board fees paid with common stock	277,786	24,404
Change in fair value of stock warrants	967,055	(1,667,117)
Change in fair value of contingent consideration	2,492,192	—
Loss on disposition of equipment	—	768
Inducement charge for Series C warrants		—
Noncash expense of issuing shares to Aspire Capital	602,083	—
Change in operating assets and liabilities:		
Prepaid expenses and other assets	(96,356)	(87,552)
Other long-term assets	—	(49,190)
Accounts payable	190,630	(76,828)
Accrued compensation and other current liabilities	(78,303)	534,486
Other long-term liabilities	(40,040)	40,039
Net cash used in continuing operating activities	(6,918,768)	(7,260,708)
Net cash used in discontinued operations	(3,031,190)	(6,237,272)
Net cash used in operating activities	(9,949,958)	(13,497,980)
Cash flows from investing activities:		
Costs of Essentialis acquisition	(572,592)	—
Security deposit on sublease	13,163	—
Purchase of property and equipment	(2,569)	(14,795)
Net cash used in continuing investing activities	(561,998)	(14,795)
Net cash provided by (used in) discontinued investing activities	940,780	(23,885)
Net cash provided by (used in) investing activities	378,782	(38,680)
Cash flows from financing activities:		
Proceeds from issuance of common stock	10,000,000	—
Proceeds from sale of common stock and common stock warrants	15,008,158	—
Cash paid for the cost issuance of common stock and common stock warrants	(1,063,471)	—
Proceeds from exercise of common stock options	—	70,102
Net proceeds from issuance of Series A Convertible Preferred	—	5,070,339
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)
Net cash provided by continuing financing activities	23,944,687	10,768,133
Net cash provided by discontinued financing activities	—	—
Net cash provided by financing activities	23,944,687	10,768,133
Net increase in cash and cash equivalents from continuing operations	16,584,141	3,492,630
Net decrease in cash and cash equivalents from discontinued operations	(2,210,630)	(6,261,157)
Net increase (decrease) in cash and equivalents	14,373,511	(2,768,527)
Cash and cash equivalents, beginning of period	2,725,996	5,494,523
Cash and cash equivalents, end of period	$ 17,099,507	$ 2,725,996
Supplemental disclosure of cash flow information		
Cash paid for income taxes	$ 800	$ —
Supplemental disclosures of noncash investing and financing information		
Issuance of common stock for Essentialis acquisition	$ 17,246,495	$ —
Warrants issued in connection with sale of common stock	$ 4,187,000	$ —
Contingent cash consideration of Essentialis acquisition	$ 2,589,648	$ —
Costs of issuing common stock and common stock warrants recorded in accounts payable	$ 117,164	$ —
Conversion of Series A preferred to common stock	$ —	$ 1,200,000
Conversion of Series B preferred to common stock	$ —	$ 1,000,000
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 cashless exercise	$ —	$ 593,584

See accompanying notes to consolidated financial statements.

Soleno Therapeutics, Inc.
(formerly known as Capnia, Inc.)
December 31, 2017

Notes to Consolidated Financial Statements

Note 1. Description of Business

Soleno Therapeutics, Inc. (formerly known as Capnia, Inc.) (the "Company" or "Soleno") was incorporated in the State of Delaware on August 25, 1999, and is located in Redwood City, California. The Company initially developed and commercialized neonatology devices and diagnostics. Additionally, the Company also had a therapeutics platform based on its proprietary technology for precision metering of gas flow. Upon the acquisition of Essentialis Inc., or "Essentialis" in 2017, the Company initiated actions to divest, sell or dispose its device and diagnostics business activities and focus its research and development efforts on advancing the lead drug candidate acquired with Essentialis.

On September 2, 2015, the Company established NeoForce, Inc. ("NFI"), a wholly owned subsidiary incorporated in the State of Delaware, and 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 marketed through NFI.

On April 27, 2015, the Company established Soleno Therapeutics UK Ltd. (formerly Capnia 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.

On March 7, 2017, Soleno completed its merger, or the Merger, with Essentialis, Inc., a Delaware corporation, or Essentialis in accordance with the Merger Agreement by and between Soleno Therapeutics and Essentialis dated December 22, 2016, or the Merger Agreement. After the Merger, the Company's primary focus 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 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. DCCR has orphan designation for the treatment of PWS in the United States, or U.S., as well as in the European Union, or E.U.

Subsequent to the merger with Essentialis, the Company explored opportunities to divest, sell or dispose of the NeoForce, CoSense, and Serenz businesses. The Company's current research and development efforts are primarily focused on advancing its lead candidate, DCCR tablets for the treatment of PWS into late-stage clinical development, with a secondary emphasis on its joint venture with OAHL for the CoSense technology. CoSense is 510(k) cleared for sale in the U.S. and received CE Mark certification for sale in the E.U. The Company continues to separately evaluate alternatives for its Serenz portfolio. The operations directly related to the NeoForce, CoSense, and Serenz business are reported herein as discontinued operations and the related assets are reported as assets held for sale in accordance with ASC 205-20-45-10.

On May 8, 2017, Soleno received stockholder approval to amend the Amended and Restate Certificate of Incorporation of the Company, to change the name of the Company to Soleno Therapeutics, Inc.

The Company completed the sale of stock of its 100% wholly-owned subsidiary, NeoForce, Inc. on July 18, 2017, pursuant to a Stock Purchase Agreement, or NFI Purchase Agreement, 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.

On October 6, 2017, the Company effected a one-for-five (1:5) reverse stock split of its then outstanding Common Stock and, accordingly, all common share and per share data are retrospectively restated to give effect of the split for all periods presented herein.

On December 4, 2017, Soleno, and its wholly-owned subsidiary, Capnia, Inc., a Delaware corporation, or Capnia, entered into a joint venture with OptAsia Healthcare Limited, a Hong Kong company limited by shares, or OAHL, with the purpose of developing and commercializing medical monitors, including the CoSense® End-Tidal Carbon Monoxide (ETCO) Monitor, or CoSense, that measure end-tidal carbon monoxide in breath to assist in the detection of excessive hemolysis in neonates, a condition in which red blood cells degrade rapidly and which can lead to adverse neurological outcomes.

Note 2. Going Concern and Management's Plans

The Company had a net loss of $15.7 million for the year ended December 31, 2017 and has an accumulated deficit of approximately $114.0 million at December 31, 2017 from having incurred losses since its inception. The Company has approximately $16.3 million of working capital at December 31, 2017 and used approximately $10.0 million of cash in its operating activities during the year ended December 31, 2017. The Company has financed its operations principally through issuances of equity securities.

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 the Company's Series B Convertible Preferred Stock at an aggregate purchase price of $13,780,000, which shares are convertible into 2,756,000 shares of trhe Company's Common Stock, based on a fixed conversion price of $5.00 per share on an as-converted basis. Under the terms of the Series B Convertible Preferred Stock, in no event shall shares of Common stock be issued to Sabby upon conversion of the Series B Convertible Preferred Stock to the extent such issuance of shares of Common Stock would result in Sabby having ownership in excess of 4.99%.

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 841,081 shares of Common Stock on an as-converted basis. The sale of the Series B Convertible Preferred Stock occurred in two separate closings. 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 10).

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 the Company's 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 stockholders, which the Company received on March 6, 2017 (see Note 10).

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.

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

On December 11, 2017, the Company entered into the Unit Purchase Agreement with certain stockholders, pursuant to which the Company sold and issued 8,141,116 immediately separable units at a price per unit of $1.84, for aggregate gross proceeds of approximately $15,000,000. Each unit consisted of one share of the Company's common stock and a warrant to purchase 0.74 shares of the Company's common stock at an exercise price of $2.00 a share, for an aggregate of 8,141,116 Shares and corresponding warrants to purchase an aggregate of 6,024,425 Warrant Shares, together referred to as the Resale Shares. The Company also granted certain registration rights to these stockholders, pursuant to which, among other things, the Company prepared and filed a registration statement with the SEC to register for resale the Resale Shares. The registration statement was declared effective in February 2018.

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

The Company expects to continue incurring losses for the foreseeable future and may be required to raise additional capital to complete its clinical trials, pursue product development initiatives and penetrate markets for the sale of its products. Management believes that the Company will continue to have access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations or other means, but the Company's access to such capital resources is uncertain and is not assured. If the Company is unable to secure additional capital, it may be required to curtail its clinical trials and development of new products and take additional measures to reduce 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. These matters raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should we be unable to continue as a going concern.

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

Note 3. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("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 the valuation of contingent liabilities for the purchase price of assets obtained through acquisition.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents at two U.S. 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, 2017 and 2016. The Company expects the maintenance of balances in excess of insurable limits will continue.

Segments

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

Cash and Cash Equivalents

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

Accounts Receivable

Accounts receivable as of December 31, 2017 and 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.

Accounts receivable are classified as Assets Held for Sale (See Note 8).

Prepaid Expenses and Other Current Assets

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

Inventory

Inventory consists of raw materials to be used in the assembly of the Company's products, work-in-progress and finished goods. As of December 31, 2017, the Company's inventory consists of approximately $213,000 of raw materials, $30,000 of work-in-progress, and $177,000 of finished goods. As of December 31, 2016, the Company's inventory includes approximately $382,000 of raw material, $101,000 of work-in-process and $177,000 of finished goods. Inventory is stated at the lower of cost or net realizable value under the first-in, first-out (FIFO) method.

Inventory is classified as Assets Held for Sale (See Note 8).

Patent

On May 11, 2010, we entered into an Asset Purchase Agreement with BioMedical Drug Development, Inc., or BDDI, pursuant to which BDDI agreed to sell certain technology to us and BDDI received and was entitled to receive, among other consideration, certain royalty payments related to the technology. In June 2015, the Company and BDDI amended the BDDI Asset Purchase Agreement, pursuant to which the Company committed to pay aggregate cash payments of $450,000 and issued 8,000 shares of Common Stock to an affiliate of BDDI. Under the original Asset Purchase Agreement dated June 11, 2010, the Company purchased a patent for Breath End Tidal Gas Monitor. The patent was issued on June 19, 2003 and expires on August 1, 2027. The Company 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.

The BDDI patent is reported as an Intangible Asset and classified as Assets Held for Sale. (See Note 8.)

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

Business Combinations

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

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

Property and Equipment, Net

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

Certain property and equipment are classified as Assets Held for Sale. (See Note 8.)

Long-Lived Assets

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

Intangible Assets

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

Intangible Assets in the amount of $447,000 consisting of the patent acquired in the BDDI acquisition are classified as Assets Held for Sale. (See Note 8.)

Intangible assets consist of the following at December 31, 2017.

	Amount	Accumulated Amortization	Net Amount	Useful Lives (years)
Patents and merger costs	$22,002,623	$(1,589,567)	$20,413,056	11
Total	$22,002,623	$(1,589,567)	$20,413,056	

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

Year ending December 31	Patents and trademarks
2018	$ 1,944,101
2019	1,944,101
2020	1,944,101
2021	1,944,101
2022	1,944,101
2023 and thereafter	10,692,553
Total	$ 20,413,056

Amortization expense for the years ended December 31, 2017 and 2016, was $1,661,734 and $99,343, respectively, of which amortization expense of $72,167 and $99,343 is reported in discontinued operations for the year ended December 31, 2017 and 2016, 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.

Goodwill is classified as Assets Held for Sale. (See Note 8.)

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.

Revenues are reported as Discontinued Operations. (See Note 8.)

Research and Development

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

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

Certain Research and Development expenses are reported as Discontinued Operations. (See Note 8.)

Change in fair value of contingent consideration

The Company recorded the value of contingent future consideration to be paid for the acquisition of Essentialis as a liability in March 2017 at the date of the acquisition. The increase in value of the liability for the contingent consideration of December 31, 2017, is recorded as operating expense in the consolidated statement of operations.

Income Taxes

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

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

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

Convertible Preferred Stock and other Hybrid Instruments

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

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

Common Stock Purchase Warrants and Other Derivative Financial Instruments

The Company classifies Common Stock purchase warrants and other free standing derivative financial instruments as equity if the contracts (i) require physical settlement or net-share settlement or (ii) give the Company a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share

settlement). The Company classifies any contracts that (i) require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside the control of the Company), (ii) give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement), or (iii) contain reset provisions as either an asset or a liability. The Company assesses classification of its freestanding derivatives at each reporting date to determine whether a change in classification between equity and liabilities is required. The Company determined that certain freestanding derivatives, which principally consist of Series A, Series C and the 2017 PIPE 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 Standards

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 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 control 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. Since the Company is an emerging growth company and elected to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act, this ASU 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 consolidated financial statements in future

reporting periods. The Company is also in the process of evaluating the new standard against its existing revenue recognition accounting policies to determine the effect the guidance will have on its consolidated financial statements and what changes to systems and controls may be warranted.

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 adoption of this ASU has no material impact on the Company's financial position and results of operations.

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. Early application of the amendments in ASU 2017 -01 are allowed for transactions for which the acquisition date is before the effective date of the amendments, but only when the transactions have not been reported in the financial statements that have been issued. The Company early adopted ASU 2017 -01 for the acquisition of Essentialis, Inc. (see Note 9).

In May 2017, the FASB issued ASU 2017-09: Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting which clarifies which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The standard is effective beginning after December 15, 2017; early adoption is permitted. The Company is currently evaluating the effect that ASU 2017-09 will have on the Company's consolidated financial position and results of operations.

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

On December 22, 2017, the SEC staff also issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the 2017 Tax Act. Specifically, SAB 118 provides a measurement period for companies to evaluate the impacts of the 2017 Tax Act on their financial statements. This measurement period begins in the reporting period that includes the enactment date and ends when an entity has obtained, prepared,

and analyzed the information that was needed in order to complete the accounting requirements, and cannot exceed one year. The re-measurement of U.S. deferred tax assets and liabilities were approximately $10.6 million with corresponding offset to valuation allowance. The Company estimated a loss for all its foreign entities including FIN 48 liabilities and therefore did not record for any transition tax pursuant to IRC Section 965.

In February 2018, the FASB issued ASU amends ASC 220, *Income Statement—Reporting Comprehensive Income*, to allow a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Jobs Act." In addition, under the ASU, an entity will be required to provide certain disclosures regarding stranded tax effects. The standard is effective beginning after December 15, 2018 and early adoption is permitted. The Company is currently evaluating the effect that ASU 2017-09 will have on the Company's consolidated financial position and results of operations.

Note 4. Fair Value of Financial Instruments

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

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

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

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

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

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

	Fair Value Measurements at December 31, 2017			
	Total	Level 1	Level 2	Level 3
Assets				
Money market fund	$ 16,790,456	$ 16,790,456		
Liabilities				
Series A warrant liability	$ 351,713	$ 351,713	—	—
Series C warrant liability	5,880	—	—	$ 5,880
2017 PIPE warrant liability	5,076,000	—	—	5,076,000
Essentialis purchase price contingent liability	5,081,840	—	—	5,081,840
Total common stock warrant and contingent consideration liability	$ 10,515,433	$ 351,713	—	$ 10,163,720

	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

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

On January 13, 2016, the Company entered into an agreement to sublease the Company's excess space located in Redwood City. By the end of February, the Company 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 the Company's 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 C Warrant		2017 PIPE Warrants		Purchase Price Contingent Liability
	Number of Warrants	Liability	Number of Warrants	Liability	Number of Warrants	Liability	
Balance at January 1, 2017	485,121	$194,048	118,083	$ 85,490	—	—	
Change in value of Series A Warrants	—	157,665	—	—	—	—	
Change in value of Series C Warrants	—	—	—	(79,610)	—	—	
Issuance in 2017 PIPE Warrants					6,024,425	$4,187,000	
Change in value of 2017 PIPE Warrants	—	—	—	—	—	889,000	
Issuance of contingent liability on March 7, 2017							$ 2,589,648
Change in value of contingent liability							2,492,192
Balance at December 31, 2017	485,121	$351,713	118,083	$ 5,880	6,024,425	$5,076,000	$ 5,081,840

Note 5. Property and Equipment, Net

Property and equipment consisted of the following.

	December 31, 2017	December 31, 2016
Computer hardware	$ 60,610	$ 56,527
Furniture and fixtures	23,074	23,074
Leasehold improvements	12,848	12,849
	96,532	92,450
Less accumulated depreciation and amortization	(73,647)	(50,429)
Total	$ 22,885	$ 42,021

Depreciation expense was $43,716 and $33,328 for the fiscal years ended December 31, 2017 and December 31, 2016, respectively.

Depreciation expense of $22,012 and $13,628 was classified in discontinued operations for the years ended December 31, 2017, and 2016, respectively.

Note 6. Warrant Liabilities

Warrants terms

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

The Company's Warrants contain standard anti-dilution provisions for stock dividends, stock splits, subdivisions, combinations and similar types of recapitalization events. The Series A and Series C Warrants 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 Series A Warrants and shares underlying the Series A Warrants, or the shares underlying the Series C Warrants, respectively. 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 the shares underlying the Warrants and for the offer and sale of the Series C Warrants. The Series A and Series C Warrants 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 proceeds related to the warrant financings to the registration payment arrangement. The Warrants also contain a fundamental transactions provision that permits their settlement in cash at fair value at the option of the holder upon the occurrence of a change in control. Such change in control events include tender offers or hostile takeovers, which are not within the sole control of the Company as the issuer of these warrants. Accordingly, the Warrants are considered to have a cash settlement feature that precludes their classification as equity instruments. Settlement at fair value upon the occurrence of a fundamental transaction would be computed using the Black Scholes Option Pricing Model, which 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*. 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.

Series A Warrants

The Company has issued 489,921 Series A Warrants to purchase shares of its Common Stock at an exercise price of $32.50 per share in connection with the unit offering offered in the Company's initial public offering ("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 4,800 Series A Warrants have been exercised. As of December 31, 2017, the fair value of the 485,121 outstanding Series A Warrants was approximately $352,000, and the increase of $158,000 in fair value during the year ended December 31, 2017 was recorded as other expense in the statement of operations.

Series C Warrants

On March 5, 2015, the Company entered into separate agreements with certain Series B Warrant holders, who agreed to exercise their Series B Warrants to purchase an aggregate of 117,902 shares of the Company's Common Stock at an exercise price of $32.50 per share, resulting in the de-recognition of $6.7 million of the previously issued Series B Warrant liability and gross proceeds to the Company of approximately $3.8 million based on the exercise price of the Series B Warrants. In connection with this exercise of the Series B Warrants,

the Company issued to each investor who exercised Series B Warrants, new Series C Warrants for the number of shares of the Company's Common Stock underlying the Series B Warrants that were exercised. Each Series C Warrant is exercisable at $31.25 per share and will expire on March 5, 2020.

In April 2015, the Company issued a tender offer to the remaining holders of Series B Warrants to induce the holders to cash exercise the outstanding Series B Warrants in exchange for new Series C Warrants with an exercise price of $31.25 per share that expire on March 5, 2020. The tender offer was extended to Series B Warrant holders under a registration statement filed with the SEC on Form S-4, which was declared effective on June 25, 2015 and expired on July 24, 2015. During July 2015, certain Series B Warrant holder(s) tendered their Series B Warrants under the tender offer, which resulted in the issuance of 181 shares of the Company's Common Stock, the issuance of 181 Series C Warrants and proceeds to the Company of $5,882.

The Series C Warrants are exercisable into 118,083 shares of the Company's Common Stock. As of December 31, 2017, the fair value of the Series C Warrants was determined to be $5,880. The decline in the fair value of the liability for the Series C Warrants of $79,610 in the year ended December 31, 2016 was recorded as other income in the consolidated statement of operations.

The Company has calculated the fair value of the Series C Warrants using a Black-Scholes pricing model, which is equivalent to the fair value computed using the Binomial Lattice Option Model. The Black-Scholes pricing model requires the input of highly subjective assumptions including the expected stock price volatility. The Company used the following inputs.

	December 31, 2017	December 31, 2016
Volatility	90%	90%
Expected Term (years)	2.17	3.17
Expected dividend yield	— %	— %
Risk-free rate	1.57%	1.51%

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

The 2017 PIPE Warrants were issued on December 15, 2017 in to the 2017 PIPE Offering, pursuant to a Warrant Agreement with each of the investors in the 2017 PIPE Offering, and entitle the holder to purchase one share of the Company's common stock at an exercise price equal to $2.00 per share, subject to adjustment as discussed below, at any time commencing upon issuance of the 2017 PIPE Warrants and terminating at the earlier of December 15, 2020 or 30 days following positive Phase III results for Diazoxide Choline Controlled-Release (DCCR) tablet in Prader-Willi syndrome (PWS).

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

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

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

	December 31, 2017	December 15, 2017 (date of issue)
Volatility	67%	67%
Expected Term (years)	0.8 years	0.8 years
Expected dividend yield	— %	— %
Risk-free rate	1.76%	1.71%

The 2017 PIPE Warrants were issued on December 15, 2017 with an estimated fair value of $4,187,000. At December 31, 2017, the fair value of the 2017 PIPE Warrants was estimated at $5,076,000 and the cost of $889,000 associated with the increase in the fair value of the warrants was recorded as expense in other expense in the statement of operations.

Note 7. Commitments and Contingencies

(i)Facility Leases

On July 1, 2015 the Company executed a new four-year non-cancelable operating lease agreement for 8,171 square feet of office space for its headquarters facility. The lease agreement provides for monthly lease payments of $23,300 beginning in September of 2015, with increases in the following three years. An additional 5,265 square feet of office space became part of the new lease agreement on March 1, 2016.

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

Minimum rental commitments under all noncancelable leases with an initial term in excess of one year as of December 31, 2017 were as follows.

Year ending December 31	Operating Leases
2018	$629,923
2019	334,747
Total	$964,670

The table above does not consider the impact of lease payments the Company will receive under the sublease executed in January 2016.

Rent expense was $514,000 and $595,000 during the years ended December 31, 2017 and 2016, respectively.

(ii) Shareholder lawsuit

On February 16, 2017, the Lawsuit captioned *Garfield v. Capnia, Inc., et al.*, Case No. C17-00284 was filed in Superior Court of the State of California, County of Contra Costa against the Company and certain of its officers and directors. The Lawsuit alleged, generally, that the Company's directors breached their fiduciary duties to the Company's 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 proposed merger with Essentialis to stockholders. The Lawsuit sought, among other things,

equitable relief that would have enjoined the consummation of the proposed merger, compensatory and/or rescissory damages, and attorneys' fees and costs. The Company made certain supplemental disclosures in a Current Report on Form 8-K filed with the SEC on February 28, 2017 in connection with plaintiff's agreement to voluntarily dismiss plaintiff's claims in the Lawsuit.

On February 28, 2017, the Company agreed to make additional supplemental disclosures and pay $175,000 for dismissal of the lawsuit. This amount was accrued as a current liability on the balance sheet as of December 31, 2016 and recorded as an expense in general and administrative expense on the statement of operations for the year ended December 31, 2016.

Contingencies

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

8. Discontinued Operations and Assets Held for Sale

(i) Assets held for sale and discontinued operations

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

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

The components of the Balance Sheet accounts presented as assets and liabilities held for sale follow.

	December 31,	
	2017	2016
Current assets		
Accounts receivable	$ 50,193	$ 133,337
Inventory	420,312	660,391
Prepaid expenses and other current assets	45,868	—
Current assets held for sale	516,373	793,728
Long-term assets		
Property & equipment, net	19,867	60,539
Goodwill	—	718,003
Other intangible assets	446,521	817,465
Long-term assets held for sale	466,388	1,596,007
Current liabilities		
Accounts payable	50,860	123,379
Accrued compensation and other current liabilities	75,751	119,021
Total current liabilities for sale	126,611	246,400
Long-term liabilities		
Other long-term liabilities	225,392	81,000
Long-term liabilities held for sale	$ 225,392	$ 81,000

The components of the Statement of Operations presented as Discontinued Operations follow.

	Year Ended December 31,	
	2017	2016
Product revenue	$ 735,212	$1,450,788
Total revenue	735,212	1,450,788
Cost of product revenue	820,098	1,509,306
Gross profit loss	(84,886)	(58,518)
Expenses		

	Year Ended December 31,	
	2017	2016
Research and development	2,426,829	2,937,662
Sales and marketing	218,706	1,630,591
General and administrative	669,175	659,227
Total expenses	3,314,710	5,227,480
Operating loss	(3,399,596)	(5,285,998)
Other income (expense)	(8,000)	(19,896)
Loss on sale of assets	(185,979)	—
Net loss from discontinued operations, net of tax effect of $21,700 in 2016	$(3,593,575)	$(5,327,594)

Stock-based compensation expense of approximately $120,000 and $132,000 was classified in discontinued operations for the years ended December 31, 2017, and 2016, respectively.

(ii) NFI Sale

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

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

(iii) CoSense Joint Venture Agreement

In December 2017, the Company entered into a joint venture with OAHL with respect to its CoSense product by agreeing to sell shares of Capnia, its wholly-owned subsidiary, to OAHL. CoSense was Soleno's first Sensalyze Technology Platform product to receive 510(k) clearances from the FDA and CE Mark certification. CoSense measures CO, which can be elevated due to endogenous causes such as excessive breakdown of red blood cells, or hemolysis, or exogenous causes such as CO poisoning and smoke inhalation. The first target market for CoSense is for the use of ETCO measurements to aid in detection of hemolysis in neonates, a disorder in which CO and bilirubin are produced in excess as byproducts of the breakdown of red blood cells. The Company's entry into the joint venture results from a comprehensive review of strategic alternatives for its legacy products and product candidates following its transition to a primarily therapeutic drug product company. The terms of the Joint Venture Agreement provide that OAHL will invest up to a total of $2.2 million of Capnia's common shares on an incremental quarterly basis commencing in December 2017. Going forward, OAHL will be responsible for funding a portion of the Capnia operations. As of December 31, 2017, OAHL had acquired no shares of Capnia. The Company will report for its ownership position in Capnia pursuant to ASC 810.

Note 9. Acquisition of Essentialis Inc.

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

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

In consideration, the Company issued 3,783,388 shares of common stock to stockholders of Essentialis on March 7, 2017. The Company held back 182,675 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. The Company is in-process of distributing the shares for the 1-year anniversary at the time of filing this report. The Company is also obligated to issue an additional 913,389 shares of common stock to Essentialis stockholders upon the achievement of a development milestone. Additionally, upon the achievement of certain commercial milestones associated with the sale of Essentialis' product in accordance with the terms of the Merger Agreement, the Company is obligated to make cash earnout payments of up to a maximum of $30 million to Essentialis stockholders.

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

The agreement to pay cash upon the achievement of the commercial milestones result in the recognition of a contingent consideration. The fair value of the contingent cash consideration is based on the Company's analysis of the likelihood of the drug indication moving from phase II through approval in the Federal Drug Administration approval process and then reaching the cumulative revenue milestones. In determining the likelihood of this occurring, the analysis relied on 2016 research published by BIO, Biomedtraker, & Amplion titles "Clinical Development Success Rates 2006-2015." Based on management's assessment, a 56% probability of achieving each milestone was determined to be reasonable. Additionally, the Company anticipates that it could reach the commercial milestones of $100 million and $200 million in applicable revenue in 2023 and 2025, respectively.

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

Management engaged independent professional assistance and advice in order to assess the fair value of the contingent stock and cash consideration as of March 7 and December 31, 2017. During the process of determining the fair value of the contingent consideration at December 31, 2017, the Company became aware that certain of the subjective assumptions made at the time of the initial valuation should be modified based upon management's increased understanding of the commercial capabilities of the DCCR drug of which it became aware subsequent to the acquisition. Accordingly, the Company determined that it was appropriate to adjust the provisional valuation amounts recorded for the contingent stock and cash consideration made at the inception in March 2017. As a result, the value of the contingent cash consideration to be paid upon completing successive sales milestones increased and the value of the contingent stock consideration payable upon timing milestones was reduced; the resulting combined change to the total contingent consideration was not material. The initial valuation of the contingent consideration determined the fair value of the contingent stock consideration to be $4,220,000 and the fair value of the contingent cash consideration to be $1,090,000, for the combined value of $5,310,000 for the total of the stock and cash contingent consideration. The revision of the initial valuation of

the contingent consideration, made within the measurement period, determined the fair value of the contingent stock consideration to be $2,680,000 and the fair value of the contingent cash consideration to be $2,590,000, for the combined value of $5,270,000 for the total of the contingent stock and cash consideration.

Also subsequent to March 7, 2017 and prior to reporting the balance sheet and results of operations as of December 31, 2017, and for the year then ended, the Company completed its assessment of the tax effect on the net assets acquired by obtaining the independent study and report regarding the change in control in the previously outstanding stock of Essentialis. As a result of completing the study, the Company determined that, pursuant to Section 382 of the Internal Revenue Code, the utilization of Essentialis's federal and state operating loss carryforwards were limited, which required the Company to record a net deferred tax liability in the amount of $1,651,000. As a consequence of recording the net deferred tax liability, the Company's valuation allowance was reduced by $1,651,000, which resulted in the provision for income tax benefit and an increase in the value of the intangible asset acquired.

Accordingly, the initial purchase cost of the asset acquired was adjusted as of March 2017 and to reflect the change in the fair value of the contingent stock and cash consideration and for the effect of the Section 382 limitation, and the net increase in amortization of the related intangible asset was recorded in the fourth quarter of 2017.

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

The aggregate purchase price consideration was as follows.

Fair value of stock consideration	$ 17,246,495
Fair value of contingent consideration	2,589,648
Total purchase price consideration	$ 19,836,143

The fair value of the asset acquired is as follows.

Patents	$ 19,836,143
Net Assets Acquired	$ 19,836,143

As an asset acquisition, the Company also capitalized approximately $573,000 of total costs incurred to complete the acquisition consisting of legal fees of $469,000, printing fees of $75,000 and accounting and other fees of $29,000. Additionally, the Company recorded as part of the purchase price consideration the value equivalent to the deferred tax liability that resulted from acquiring the assets in the amount of approximately $1,651,000. The total intangible asset of $22.0 million was recorded on the balance sheet and is being amortized ratably over the life of the patents through June 30, 2028.

The acquisition of Essentialis assets was completed in March 2017 and the purchase price was established at the date of closing based upon consideration paid at closing and an estimate of the future contingent consideration to be paid. Subsequent to the acquisition date and prior to reporting the balance sheet and results of operations as of December 31, 2017, and for the year then ended, the Company completed and finalized its assessments of the fair value of consideration paid and of the tax effect on the net assets acquired resulting from the change in control in the previously outstanding stock of Essentialis. As a result of completing the study of the fair value of the consideration paid, the Company revised the initial estimate of the fair value paid at closing and of the future contingent consideration to be paid; accordingly, the initial purchase cost of the asset acquired was adjusted as of March 2017 and the change in amortization of the related intangible asset was recorded in the

fourth quarter of 2017. As a result of completing the study of the tax effect, the Company determined that, pursuant to Section 382 of the Internal Revenue Code, the utilization of Essentialis's operating loss carryforwards were limited, which required the Company to record a tax liability in the amount of $1.6 million, deferred to future periods, for the assets acquired for which the cost was recorded as an element of the of assets required. Accordingly, the initial purchase cost of the asset acquired was adjusted as of March 2017 and the increase in amortization of the related intangible asset was recorded in the fourth quarter of 2017.

The fair value of the liability for the contingent consideration payable by the Company achieving the commercial sales milestones of $100 million and $200 million was initially established as approximately $2,590,000 at the time of the merger and approximately $5,082,000 at December 31, 2017, based on the Company's assessment that it could reach the commercial sales milestones of in 2023 and 2025, respectively.

Note 10. Stockholders' Equity

Convertible Preferred Stock

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

The Company issued a total of 10,000 Series A Convertible Preferred Stock under the 2015 Sabby Purchase Agreement, with a par value of $0.001 and a stated value of $1,000 per share. The Series A Convertible Preferred Stock did not have an expiration date and were not redeemable at the option of the holders. During the three months ended March 31, 2016 and June 30, 2016 the holders of the Series A Convertible Preferred Stock converted 1,665 and 555, respectively, shares of Series A Convertible Preferred Stock resulting in the issuance of 180,000 and 60,000 shares of Common Stock, respectively. Under the 2016 Sabby Purchase Agreement, the remaining 7,780 shares of Series A Convertible Preferred Stock were repurchased.

In June 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, a total of 13,780 Series B Convertible Preferred Stock, with a par value of $0.001 and a stated value of $1,000 per share. 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 July 2016, the Company issued 13,780 Series B Convertible Preferred Stock shares to Sabby, and during the years ended December 31, 2017 and 2016, the holders of the Series B Convertible Preferred Stock converted 8,209 and 1,000 shares, respectively, of the Series B Convertible Preferred Stock resulting in the issuance of 1,641,800 and 200,000, respectively, shares of Common Stock. Under the terms of the Series B Convertible Preferred Stock, in no event shall shares of Common stock be issued to Sabby upon conversion of the Series B Convertible Preferred Stock to the extent such issuance of shares of Common Stock would result in Sabby having ownership in excess of 4.99%. The Series B Convertible Preferred Stock do not have an expiration date and are not redeemable at the option of the holders. In connection with each close of the Series B Convertible Preferred Stock, the Company was obligated to repurchase the remaining outstanding Series A Convertible Preferred Stock at the original issuance price. In addition, the exercise price of the existing Series D Warrants originally issued in conjunction with the 2015 Sabby Purchase Agreement was reduced from $12.30 to $8.75 per share on the effective date of the 2016 Sabby Purchase Agreement.

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 841,081 shares of Common Stock on an as-converted basis. The sale of the Series B Convertible Preferred Stock occurred in two separate closings. 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.

The Company has recognized the repurchase of the Series A Convertible Preferred Stock as an extinguishment of the Series A Convertible Preferred Stock. The Company compared the fair value of the Series B Convertible Preferred Stock immediately after the two close dates under the 2016 Sabby Purchase Agreement to the carrying value of the Series A Convertible Preferred Stock immediately prior to the two close dates under the 2016 Sabby Purchase Agreement. The Company recorded the excess of the aggregate fair value of the Series B Convertible Preferred Stock, $3.4 million, as a loss on extinguishment. In addition, the Company estimated the effect of modifying the exercise price on the existing Series D warrants to be $203,000. The Company therefore recorded a total of $3.7 million extinguishment loss to net loss applicable to common stockholders.

Common Stock

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 the Company's 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 stockholders, which the Company received on March 6, 2017.

On March 7, 2017, the Company completed the merger with Essentialis and issued 3,783,388 shares of common stock to shareholders of Essentialis. The Company held back 182,676 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. The Company is also obligated to issue an additional 913,389 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 4,879,453 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.

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.

In December 2017, the Company entered into a Securities Purchase Agreement, or the Unit Purchase Agreement, with purchasers of the Company's securities pursuant to which the Company sold and issued 8,141,116 immediately separable units at a price per unit of $1.84 for aggregate gross proceeds of approximately $15,000,000 Each unit consisted of one share of the Company's common stock and a warrant to purchase 0.74 of a share of the Company's common stock at an exercise price of $2.00 per share, for an aggregate of 8,141,116 shares of common stock, and corresponding warrants, or the 2017 PIPE Warrants, to purchase 6,024,425 shares of common stock. Soleno refers to the Shares and the Warrant Shares collectively as the Resale Shares. The Company also granted certain registration rights to the investors pursuant to the Unit Purchase Agreement pursuant to which, among other things, the Company prepared and filed a registration statement with the SEC to register for resale the Resale Shares. The registration statement was declared effective in February 2018.

Stock Option Plan

The Company has adopted the 1999 Incentive Stock Plan, the 2010 Equity Incentive Plan, and the 2014 Equity Incentive Plan (together, the Plans). The 1999 Incentive Stock Plan expired in 2009, and the 2010 Equity

Incentive Plan has been closed to new issuances. Therefore, the Company may issue options to purchase shares of common stock to employees, directors, and consultants only under the 2014 Equity Incentive Plan. Options granted under the 2014 Plan may be incentive stock options ("ISOs") or nonqualified stock options ("NSOs"). ISOs may be granted only to Company employees and directors. NSOs may be granted to employees, directors, advisors, and consultants. The Board of Directors has the authority to determine to whom options will be granted, the number of options, the term, and the exercise price.

Options are to be granted at an exercise price not less than fair value for an ISO or 85% of fair value for an NSO. For individuals holding more than 10% of the voting rights of all classes of stock, the exercise price of an option will not be less than 110% of fair value. The vesting period is normally monthly over a period of 4 years from the vesting date. The contractual term of an option is no longer than five years for ISOs for which the grantee owns greater than 10% of the voting power of all classes of stock and no longer than ten years for all other options.

The Company recognized stock-based compensation expense related to options granted to employees and directors for the fiscal years ended December 31, 2017 and 2016 of $1,000,251 and $871,270, respectively of which $120,220 and $132,038 was recorded in discontinued operations in 2017 and 2016, respectively. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the statements of operations for stock-based compensation arrangements as of December 31, 2017 and December 31, 2016.

Stock compensation expense was allocated between departments as follows.

	Year ended	
	December 31, 2017	December 31, 2016
Research & Development	$ 93,237	$ 63,535
General & Administrative	786,794	675,697
Total	$ 880,031	$ 739,232

The Company granted options to purchase 622,755 and 267,851 of the Company's common stock in 2017 and 2016. The fair value of each award granted was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions.

	Year Ended	
	December 31, 2017	December 31, 2016
Expected life (years)	5.5-6.08	5.5-6.08
Risk-free interest rate	1.9%-2.2%	1.3%-1.7%
Volatility	61%-69%	65%-73%
Dividend rate	— %	— %

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

- *Expected volatility:* The estimated volatility rate based on a peer index of common stock of comparable companies in the Company's industry.
- *Expected term:* The expected life of stock options represents the average of the contractual term of the options and the weighted-average vesting period, as permitted under the simplified method. The Company has elected to use the simplified method, as the Company does not have enough historical exercise experience to provide a reasonable basis upon which to estimate the expected term and the stock option grants are considered "plain vanilla" 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:* The Company has never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. Consequently, the Company used an expected dividend yield of zero.

The following table summarizes stock option transactions for the years ended December 31, 2017 and 2016 as issued under the Plans.

	Shares Available for Grant	Number of Options Outstanding	Weighted-Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in years)
Balance at January 1, 2016	1,229	371,768	$ 24.10	8.75
Additional shares authorized	112,143	—	—	
Amendment to plan to authorize additional shares	300,000	—	—	—
Options granted	(267,851)	267,851	$ 6.80	—
Options exercised	—	(11,683)	$ 6.00	—
Options canceled/forfeited	46,249	(46,249)	$ 15.45	—
Balance at December 31, 2016	191,770	581,687	$ 17.10	8.48
Additional shares authorized	134,295	—	—	—
Amendment to plan to authorize additional shares	1,785,837	—	—	—
Options granted	(622,755)	622,755	$ 3.04	
Options exercised	—	—	—	—
Options canceled/forfeited	177,455	(177,455)	$ 8.84	—
Balance at December 31, 2017	1,666,602	1,026,987	$ 9.99	—
Options vested at December 31, 2017		554,763	$ 13.87	7.03
Options vested and expected to vest at December 31, 2017		1,026,987	$ 9.99	7.94

The weighted-average grant date fair value of employee options granted was $1.88 and $4.05 per share for the year ended December 31, 2017 and December 31, 2016, respectively. At December 31, 2017 total unrecognized employee stock-based compensation was $1.2 million, which is expected to be recognized over the weighted-average remaining vesting period of 2.6 years. As of December 31, 2017, the outstanding stock options had an intrinsic value of zero.

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. Stock-based compensation related to its grant of options to non-employees has not been material to date.

In June 2016, the Company granted 11,000 NSOs to sales representatives of Bemes, Inc. Of the 11,000 options granted, 5,499 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, the Company recognized $13,502 in expense for the remaining options during 2016, which vested during the first quarter of 2017. Total expense for the two groups of options reflects the fair value of the Company's common stock on the applicable vesting commencement dates.

2014 Employee Stock Purchase Plan

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

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

As of December 31, 2017, there were no purchases by employees under this plan.

Series D Warrants

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

Accounting Treatment

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

Other Common Stock Warrants

As of December 31, 2017 and 2016, the Company had 96,029 Common Stock warrants outstanding from the 2010/2012 convertible notes, with an exercise price of $24.35 and a term of 10 years expiring in November 2024. The Company also has outstanding 1,851 Common Stock warrants issued in 2009, with an exercise price of $108.00 and a term of 10 years, expiring in January 2019 and 16,500 Common Stock warrants issued to the underwriter in the Company's IPO, with an exercise price of $35.70 and a term of 10 years, expiring in November 2024.

Note 11. Income Taxes

The geographical distribution of loss before income taxes are summarized below.

	December 31,	
	2017	2016
United States	$(13,706,889)	$(6,501,997)
Foreign	(17,429)	(235,623)
Total	$ 13,724,318	$(6,737,620)
Loss resulting from discontinued operations	$ (3,593,575)	$(5,305,894)
Taxes allocated to discontinued operations	—	$ 21,700

The components of the provision for income tax benefit follows.

	December 31,	
	2017	2016
Current:		
Federal	$ —	$ —
State	800	—
Foreign	—	—
	—	—
Deferred		
Federal	(1,578,355)	—
State	(72,912)	—
Foreign	—	—
	(1,651,267)	—
Total provision for income tax benefit	$ (1,650,467)	$ —

The provision for income tax benefit results from accounting for the acquired assets and liabilities of Essentialis resulting in a portion of the Company's valuation allowance in the amount of $1.6 million being released.

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

	December 31,	
	2017	2016
Tax on the loss before income tax expense computed at the federal statutory rate of 34%	$ (4,666,395)	$(2,290,862)
State tax (benefit) at statutory rate, net of federal benefit	(67,321)	(136,982)
Tax reform	10,613,026	—
Foreign rate differential	2,614	35,343
Change in Valuation Allowance	(8,484,728)	2,355,170
Change in research and development credits	(121,382)	(129,974)
Stock Based Compensation—ISO	294,913	274,506
Change in fair value of warrants	343,179	(619,067)
Acquisition costs	203,197	—
Loss on sale of NFI	(677,132)	—
Other	909,562	511,866
Provision for income tax benefit	$ (1,650,467)	—

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities are as follows at December 31, 2017 and 2016.

	December 31,	
	2017	2016
Non-Current Deferred Tax Assets:		
Reserves and accruals	$ 144,876	$ 159,163
Assets held for sale	17,428	63,540
Net Operating Loss Carryforwards	25,485,703	30,291,080
Tax credit carryforwards	1,807,163	1,580,253
Capital loss carryover	459,201	
Stock-based compensation—NSO	35,533	
Gross non-current deferred tax assets	27,949,904	32,094,036
Intangible Assets	(4,414,340)	(74,376)
Fixed Assets	(2,397)	(1,764)
Total non-current deferred tax liabilities	(4,416,737)	(76,141)
Total deferred tax assets	23,533,167	32,017,896
Valuation allowance	(23,533,167)	(32,017,895)
Net deferred tax assets	$ —	$ —

The Company has recorded a full valuation allowance against its net deferred tax assets due to the uncertainty as to whether such assets will be realized. The valuation allowance increased by $8,484,728 from December 31, 2016 to December 31, 2017 primarily due to the generation of current year net operating losses and research and development credits claimed.

As of December 31, 2017, the Company had $104.5 million of federal, $50.0 million of state and $253,000 of foreign net operating losses available to offset future taxable income. The federal net operating loss carryforwards begins to expire in 2019, the state net operating loss carryforwards will begin to expire in 2017 and the foreign net operating loss carryforward can be carried forward indefinitely, if not utilized. As of December 31, 2017, the Company also had $1.6 million of federal and $1.3 million of state research and development credit carryforwards. The federal research and development credit carryforward begins to expire in 2024 and the state research and development credit can be carried forward indefinitely.

Utilization of the net operating loss and tax credit carry forwards are subject to an annual limitation due to the ownership percentage change limitations provided by the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of the net operating loss before utilization. The Company completed Section 382 analysis through December 2016 and determined that an ownership change, as defined under Section 382 of the Internal Revenue Code, occurred in June 2016. The Company's tax attributes are subject to an annual limitation of approximately $0.5 million per year for federal purposes.

United States taxes and foreign withholding taxes have not been provided on undistributed earnings for certain non-United States subsidiaries as of December 31, 2017, as the earnings, if any, are intended to be indefinitely reinvested.

The following tables summarize the activities of gross unrecognized tax benefits.

	December 31,	
	2017	2016
Beginning balance	$794,962	$691,697
Decreases related to prior year tax positions	(4,459)	35,804
Increase related to current year tax positions	63,002	67,461
Ending Balance	$853,504	$794,962

There were no unrecognized tax benefits that would impact the effective tax rate as of December 31, 2017 and December 31, 2016. As of December 31, 2017, unrecognized tax benefits of $853,504 would be offset by a change in valuation allowance.

The Company files income tax returns in the U.S. federal jurisdiction, certain state jurisdictions and United Kingdom. In the normal course of business, the Company is subject to examination by federal, state, local and foreign jurisdictions, where applicable. In the U.S federal jurisdiction, tax years 1999 forward remain open to examination, in the state tax jurisdiction, years 2006 forward remain open to examination and in the foreign jurisdiction, years 2015 forward remain open to examination. The Company is currently not under audit by any federal, state, local or foreign jurisdiction.

On December 22, 2017, H.R. 1, also known as the Tax Cuts and Jobs Act, or the "2017 Tax Act", was enacted in the U.S. This enactment resulted in a number of significant changes to U.S. federal income tax law for U.S. corporations. Most notably, the statutory U.S. federal corporate income tax rate was changed from 35% to 21% for corporations. In addition to the change in the corporate income tax rate, the 2017 Tax Act further introduced a number of other changes including a one-time transition tax via a mandatory deemed repatriation of post-1986 undistributed foreign earnings and profits; the introduction of a tax on global intangible low-taxed income ("GILTI") for tax years beginning after December 31, 2017; the limitation of deductible net interest to 30% of adjustable taxable income; the further limitation of the deductibility of share-based compensation of certain highly compensated employees; the ability to elect to accelerate bonus depreciation on certain qualified assets; and the Base Erosion and Anti-Abuse Tax ("BEAT"), amongst other changes.

Additionally, on December 22, 2017, the SEC staff also issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the 2017 Tax Act. Specifically, SAB 118 provides a measurement period for companies to evaluate the impacts of the 2017 Tax Act on their financial statements. This measurement period begins in the reporting period that includes the enactment date and ends when an entity has obtained, prepared, and analyzed the information that was needed in order to complete the accounting requirements, and cannot exceed one year.

The re-measurement of U.S. deferred tax assets/liabilities were approximately $10.6 million with corresponding offset to valuation allowance. The Company estimated a negative earning & profit for all its foreign entities including FIN 48 liabilities and therefore did not record for any transition tax pursuant to IRC Section 965.

The Company uses the "more likely than not" criterion for recognizing the tax benefit of uncertain tax positions and to establish measurement criteria for income tax benefits. The Company has determined it has no material unrecognized assets or liabilities related to uncertain tax positions as of December 31, 2017. The Company does not anticipate any significant changes in such uncertainties and judgments during the next 12 months. In the event the Company should need to recognize interest and penalties related to unrecognized tax liabilities, this amount will be recorded as a component of other expense.

Note 12. Net loss per share

Basic net loss per share is computed by dividing net loss by the weighted-average number of Common Stock actually outstanding during the period. Diluted net loss per share is computed by dividing net loss by the weighted-average number of Common Stock outstanding and dilutive potential Common Stock that would be issued upon the exercise of Common Stock warrants and options. For the year ended December 31, 2017 and 2016, the effect of issuing the potential common stock is anti-dilutive due to the net losses in those periods and the number of shares used to compute basic and diluted earnings per share are the same in each of those periods.

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

	As of December 31,	
	2017	2016
Convertible preferred stock	914,200	2,556,000
Warrants issued to 2010/2012 convertible note holders to purchase common stock	102,070	102,070
Options to purchase common stock	1,026,987	581,686
Warrants issued in 2009 to purchase common stock	1,851	1,851
Warrants issued to underwriter to purchase common stock	16,500	16,500
Series A warrants to purchase common stock	485,121	485,121
Series C warrants to purchase common stock	118,083	118,083
Series D warrants to purchase common stock	586,182	586,162
2017 PIPE warrants	6,024,425	—
Total	9,275,419	4,447,473

Note 13. Compensation Plan for Board Members

The Compensation Committee of the Board of Directors of the Company recommended, and the Board approved a new compensation plan for the payment of quarterly Board fees. At the election of each Board member, beginning with the third quarter of 2016, they had the option to either receive cash payments or to be paid in common stock of the Company. For the third quarter of 2016, two of the Board members elected to be paid in common stock of the Company resulting in the issuance of 5,084 shares of common stock.

In 2017, the Compensation Committee of the Board of Directors recommended, and the Board approved a revised compensation plan pursuant to which all board fees are paid in Common Stock of the Company. Payment to the Board of Directors in shares of the Company's Common Stock is made after the close of the quarter in which the compensation is earned. During the year ended December 31, 2017, the Company issued 90,306 shares of Common Stock to its Board members for fees earned during the first, second and third quarters. he Company issued 47,766 shares of Common Stock to directors in the fourth quarter of 2017 were issued in February 2018 (see Note 15).

Note 14. Defined Contribution Plan

The Company sponsors a 401(k) Plan, which stipulates that eligible employees can elect to contribute to the 401(k) Plan, subject to certain limitations of eligible compensation. The Company may match employee contributions in amounts to be determined at the Company's sole discretion. To date, the Company has not made any matching contributions.

Note 15. Subsequent Events

(i) Sabby conversion of Series B convertible stock

In January 2018, a fund managed by Sabby converted an aggregate of 1,000 shares of their Series B Convertible Stock into 200,000 shares of Common Stock.

(ii) Common shares issued to directors in payment of quarterly board of director fees

On February 2, 2018, the Company issued 47,766 shares of Common Stock to members of its Board of Directors as compensation for Board of Directors fees earned during the quarter ended December 31, 2017.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

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

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

Internal Control over Financial Reporting

Management's Annual Report on Internal Control over Financial Reporting

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

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

Management conducted an evaluation of the effectiveness of our control over financial reporting based on the 2013 framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2017.

Changes in Internal Controls

There have been no changes to our internal control over financial reporting that occurred during our last fiscal quarter ended December 31, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our 2018 Annual Meeting of Stockholders. The Definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our 2018 Annual Meeting of Stockholders. The Definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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

The information required by this item to our Definitive Proxy Statement for our 2018 Annual Meeting of Stockholders. The Definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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

The information required by this item to our Definitive Proxy Statement for our 2018 Annual Meeting of Stockholders. The Definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our 2017 Annual Meeting of Stockholders. The Definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

1. Financial Statements: See “Index to Financial Statements” in Part II, Item 8 of this Annual Report on Form 10-K
2. Financial Schedules: All schedules have been omitted because the information called for is not required or is shown either in the financial statements or in the notes thereto.
3. Exhibits: The exhibits listed in the accompanying index to exhibits are filed or incorporated by reference as part of this Annual Report on Form 10-K.

EXHIBIT INDEX

Exhibit Number	Description of Document	Incorporated by Reference from			Filed Herewith
		Registrant's Form	Date Filed with the SEC	Exhibit Number	
2.1	Stock Purchase Agreement, dated as of July 18, 2017, and between Soleno Therapeutics, Inc., a Delaware corporation, and NeoForce Holdings, Inc. a Delaware corporation	8-K	July 24, 2017	2.1	
2.2	Joint Venture Agreement, dated as of December 4, 2017, by and among Soleno Therapeutics, Inc., Capnia, Inc., and OptAsia Healthcare Limited	8-K	December 8, 2017	2.1	
2.3	PRC IP Purchase Agreement, dated as of December 4, 2017, by and between OptAsia Healthcare Limited and Capnia, Inc.	8-K	December 8, 2017	2.2	
2.4	Transition Services Agreement, dated as of December 4, 2017, by and among Soleno Therapeutics, Inc., a Delaware corporation, Capnia, Inc. and OptAsia Healthcare, Ltd., a Hong Kong company	8-K	December 8, 2017	2.3	
3.1	Amended and Restated Certificate of Incorporation of Soleno Therapeutics, Inc.	S-1/A	August 7, 2014	3.2	
3.2	Amended and Restated Bylaws of Soleno Therapeutics, Inc.	S-1/A	July 1, 2014	3.4	
3.3	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock.	8-K	October 15, 2015	3.1	
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock	8-K	July 6, 2016	3.1	
3.5	Certificate of Amendment	8-K	May 11, 2017	3.1	
3.6	Certificate of Amendment to the Certificate of Incorporation	8-K	October 6, 2017	3.1	
4.1	Form of the common stock certificate.	S-1/A	August 5, 2014	4.1	
4.2	Amended And Restated Investors' Rights Agreement, dated March 20, 2008, by and among Soleno Therapeutics, Inc. and certain holders of the Soleno Therapeutics, Inc.'s capital stock named therein.	S-1/A	July 1, 2014	4.2	
4.3	Form of Series A Warrant Agreement.	S-1/A	August 5, 2014	4.3	
4.4	Form of the Series A Warrant certificate.	S-1/A	August 5, 2014	4.4	
4.5	Form of Underwriters' Compensation Warrant.	S-1/A	August 5, 2014	4.5	
4.6	Form of Convertible Promissory Note issued in February 2010 and March 2010 in connection with the 2010 convertible note financing.	S-1	June 10, 2014	4.6	
4.7	Form of Warrant to Purchase Shares issued in February 2010 and March 2010 in connection with the 2010 convertible note financing.	S-1	June 10, 2014	4.7	

Exhibit Number	Description of Document	Incorporated by Reference from			Filed Herewith
		Registrant's Form	Date Filed with the SEC	Exhibit Number	
4.8	Form of Convertible Promissory Note issued in November 2010 in connection with the 2010 convertible note financing.	S-1	June 10, 2014	4.8	
4.9	Form of Warrant to Purchase Shares issued in November 2010 in connection with the 2010 convertible note financing.	S-1	June 10, 2014	4.9	
4.10	Form of Convertible Promissory Note issued in January 2012 in connection with the 2012 convertible note financing.	S-1	June 10, 2014	4.10	
4.11	Form of Warrant to Purchase Shares issued in January 2012 in connection with Soleno Therapeutics, Inc.'s 2012 convertible note financing.	S-1	June 10, 2014	4.11	
4.12	Form of Convertible Promissory Note issued in July 2012 and August 2012 in connection with the 2012 convertible note financing.	S-1	June 10, 2014	4.12	
4.13	Form of Warrant to Purchase Shares issued in July 2012 and August 2012 in connection with the 2012 convertible note financing.	S-1	June 10, 2014	4.13	
4.14	Form of Convertible Promissory Note issued in April, August and October 2014 in connection with the 2014 convertible note financing.	S-1	June 10, 2014	4.14	
4.15	Form of Warrant to Purchase Shares issued in April, August and October 2014 in connection with the 2014 convertible note financing.	S-1	June 10, 2014	4.15	
4.16	Form of unit certificate.	S-1/A	August 5, 2014	4.16	
4.17	Form of Series B Warrant Agreement.	S-1/A	November 4, 2014	4.17	
4.18	Form of the Series B Warrant certificate.	S-1/A	November 4, 2014	4.18	
4.19	Form of the Series C Warrant Agreement.	S-4	April 1, 2015	4.19	
4.20	Form of the Series C Warrant certificate.	S-4	April 1, 2015	4.20	
4.21	Form of Series D Common Stock Purchase Warrant.	8-K	October 15, 2015	4.1	
4.22	Form of Placement Agent Warrant.	8-K	October 15, 2015	4.2	
4.23	Form of Series D common stock Warrant Certificate.	8-K	October 15, 2015	4.3	
4.24	Form of Series A Convertible Preferred Stock Certificate.	8-K	October 15, 2015	4.4	
4.25	Form of Placement Agent Warrant.	8-K	July 6, 2016	4.1	
4.26	Form of Series B Convertible Preferred Stock Certificate.	8-K	July 6, 2016	4.2	
4.27	Form of Common Stock Purchase Warrant	8-K	December 13, 2017	4.1	

Exhibit Number	Description of Document	Incorporated by Reference from			Filed Herewith
		Registrant's Form	Date Filed with the SEC	Exhibit Number	
9.10	Form of Voting Agreement.	8-K	October 15, 2015	9.1	
9.20	Form of Voting Agreement.	8-K	July 6, 2016	9.1	
9.30	Form of Voting Agreement.	8-K	December 27, 2016	10.1	
10.1	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.	S-1/A	June 10, 2014	10.1	
10.2	1999 Incentive Stock Plan and forms of agreements thereunder.	S-1/A	June 10, 2014	10.2	
10.3	2010 Equity Incentive Plan and forms of agreements thereunder.	S-1/A	June 10, 2014	10.3	
10.4	2014 Equity Incentive Plan and forms of agreements thereunder.	S-1/A	July 1, 2014	10.4	
10.5	2014 Employee Stock Purchase Plan and forms of agreements thereunder.	S-1/A	July 1, 2014	10.5	
10.6	Offer Letter, dated June 22, 2007, by and between Soleno Therapeutics, Inc. and Ernest Mario, Ph.D.	S-1	June 10, 2014	10.6	
10.7	Employment Agreement, dated April 6, 2010, by and between Soleno Therapeutics, Inc. and Anish Bhatnagar.	S-1	June 10, 2014	10.7	
10.8	Offer Letter, dated May 29, 2013, between Soleno Therapeutics, Inc. and Anthony Wondka.	S-1	June 10, 2014	10.8	
10.9	Offer Letter, dated April 17, 2014, by and between Soleno Therapeutics, Inc. and Antoun Nabhan.	S-1	June 10, 2014	10.9	
10.10	Asset Purchase Agreement dated May 11, 2010, by and between Soleno Therapeutics, Inc. and BioMedical Drug Development Inc.	S-1	June 10, 2014	10.10	
10.11	Convertible Note and Warrant Purchase Agreement, dated February 10, 2010, by and among Soleno Therapeutics, Inc. and the investors named therein.	S-1	June 10, 2014	10.11	
10.12	Amendment No. 1 to Convertible Note and Warrant Purchase Agreement, Convertible Promissory Notes and Warrants to Purchase Shares, dated November 10, 2010, by and among Soleno Therapeutics, Inc. and the investors named therein.	S-1	June 10, 2014	10.12	
10.13	Amendment No. 2 to Convertible Note and Warrant Purchase Agreement, Convertible Promissory Notes and Warrants to Purchase Shares, dated January 17, 2012, by and among Soleno Therapeutics, Inc. and the investors named therein.	S-1	June 10, 2014	10.13	
10.14	Convertible Note and Warrant Purchase Agreement, dated January 16, 2012, by and among Soleno Therapeutics, Inc. and the investors named therein.	S-1	June 10, 2014	10.14	

Exhibit Number	Description of Document	Incorporated by Reference from			Filed Herewith
		Registrant's Form	Date Filed with the SEC	Exhibit Number	
10.15	Omnibus Amendment to Convertible Note and Warrant Purchase Agreement, Convertible Promissory Notes and Warrants to Purchase Shares, dated July 31, 2012, by and among Soleno Therapeutics, Inc. and the investors named therein.	S-1	June 10, 2014	10.15	
10.16	Omnibus Amendment to Convertible Promissory Notes and Warrants to Purchase Shares, dated April 28, 2014, by and among Soleno Therapeutics, Inc. and the investors named therein.	S-1	June 10, 2014	10.16	
10.17	Convertible Note and Warrant Purchase Agreement, dated April 28, 2014, by and among Soleno Therapeutics, Inc. and the investors named therein.	S-1	June 10, 2014	10.17	
10.18	Omnibus Amendment to Convertible Note and Warrant Purchase Agreement, Convertible Promissory Notes and Warrants to Purchase Shares, dated May 5, 2014, by and among Soleno Therapeutics, Inc. and the investors named therein.	S-1	June 10, 2014	10.18	
10.19	Sublease, dated May 20, 2014, by and among Soleno Therapeutics, Inc. and Silicon Valley Finance Group.	S-1/A	July 1, 2014	10.19	
10.20	Offer Letter, dated June 24, 2014, by and between Soleno Therapeutics, Inc. and David D. O'Toole.	S-1/A	July 22, 2014	10.20	
10.21	Loan Agreement by and between Soleno Therapeutics, Inc. and the investors named therein, dated September 29, 2014.	S-1/A	September 29, 2014	10.21	
10.22	Revised Second Tranche Closing Notice and Letter Amendment dated August 18, 2014 relating to the August 2014 Notes.	S-1/A	November 4, 2014	10.22	
10.23	Second Tranche Subsequent Closing Notice and Letter Amendment dated October 22, 2014 relating to the October 2014 Notes.	S-1/A	November 4, 2014	10.23	
10.24	Form of Warrant Exercise Agreement.	8-K	March 5, 2015	10.1	
10.25	Advisory Agreement by and between Soleno Therapeutics, Inc. and Maxim Group LLC, dated March 4, 2015.	S-4	April 1, 2015	10.25	
10.26	Agreement and First Amendment to Asset Purchase Agreement between the Company, BDDI and affiliate of BDDI, dated June 30, 2015.	8-K	July 7, 2015	10.1	
10.27	Common Stock Purchase Agreement between the Company and an affiliate of BDDI, dated June 30, 2015.	8-K	July 7, 2015	10.2	
10.28	Registration Rights Agreement between the Company and Aspire Capital Fund, LLC, dated July 24, 2015.	8-K	July 27, 2015	4.1	

Exhibit Number	Description of Document	Incorporated by Reference from			Filed Herewith
		Registrant's Form	Date Filed with the SEC	Exhibit Number	
10.29	Common Stock Purchase Agreement between the Company and Aspire Capital Fund, LLC, dated July 24, 2015.	8-K	July 27, 2015	10.1	
10.30	Engagement Letter dated September 17, 2015, between Soleno Therapeutics, Inc. and Maxim Group, LLC.	8-K	October 15, 2015	1.1	
10.31	Securities Purchase Agreement dated October 12, 2015.	8-K	October 15, 2015	10.1	
10.32	Form of Registration Rights Agreement.	8-K	October 15, 2015	10.2	
10.33	Form of Lock-Up Agreement.	8-K	October 15, 2015	10.3	
10.34	Amendment No. 1 to Securities Purchase Agreement dated October 29, 2015.	S-1/A	December 22, 2015	10.33	
10.35	Transfer and Distribution Agreement: United States: by and between Soleno Therapeutics, Inc. and Bemes, Inc. signed January 26, 2016.	8-K	January 28, 2016	10.1	
10.36	Engagement Letter dated June 26, 2016, between Soleno Therapeutics, Inc. and Maxim Group, LLC.	8-K	July 6, 2016	1.1	
10.37	Securities Purchase Agreement dated June 29, 2016.	8-K	July 6, 2016	10.1	
10.38	Form of Registration Rights Agreement dated June 29, 2016.	8-K	July 6, 2016	10.2	
10.39	Amendment No. 1 to Securities Purchase Agreement dated September 20, 2016.	S-1/A	September 20, 2016	10.39	
10.40	Agreement and Plan of Merger and Reorganization, dated as of December 22, 2016, by and among Soleno Therapeutics, Inc., a Delaware corporation, Essentialis, Inc., a Delaware corporation, Company E Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of Soleno Therapeutics, and Neil Cowen as the stockholders' representative.	8-K	December 27, 2016	2.1	
10.41	Registration Rights Agreement between the Company and Aspire Capital Fund, LLC, dated January 27, 2017.	S-1	February 1, 2017	10.51	
10.42	Common Stock Purchase Agreement between the Company and Aspire Capital Fund, LLC, dated January 27, 2017.	S-1	February 1, 2017	10.52	
10.43	Stock Purchase Agreement made by and between the Company and NeoForce Holdings, Inc. a Delaware corporation dated July 18, 2017	8-K	July 24, 2017	2.1	

Exhibit Number	Description of Document	Incorporated by Reference from			Filed Herewith
		Registrant's Form	Date Filed with the SEC	Exhibit Number	
10.44	Joint Venture Agreement dated as of December 4, 2017 by and among Soleno Therapeutics, Inc., Capnia, Inc., and OptAsia Healthcare Limited	8-K	December 8, 2017	2.1	
10.45	Securities Purchase Agreement, dated as of December 11, 2017	8-K	December 13, 2017	10.1	
21.1	Subsidiaries				X
23.1	Consent of Marcum LLP				X
24.1	Power of Attorney (incorporated by reference to the signature page to this registration statement)				
31.1	Certification of Principal Executive Officer and Principal Financial and Accounting Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended				X
32.1	Certification of Principal Executive Officer and Principal Financial and Accounting Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350				X
101.INS	XBRL Instance Document.				X
101.SCH	XBRL Taxonomy Extension Schema Document.				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.				X

SIGNATURES

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

Soleno Therapeutics, Inc. (formerly Capnia, Inc.)

Date: April 2, 2018

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

POWER OF ATTORNEY

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

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

Signature	Title	Date
/S/ ANISH BHATNAGAR Anish Bhatnagar	President, Chief Executive Officer and Director (Principal Executive Officer and Principal Financial and Accounting Officer)	April 2, 2018
/S/ ERNEST MARIO Ernest Mario	Chairman	April 2, 2018
/S/ RAJEN DALAL Rajen Dalal	Director	April 2, 2018
/S/ WILLIAM G. HARRIS William G. Harris	Director	April 2, 2018
/S/ MAHENDRA SHAH Mahendra Shah	Director	April 2, 2018
/S/ JAMES GLASHEEN James Glasheen	Director	April 2, 2018
/S/ STUART COLLINSON Stuart Collinson	Director	April 2, 2018

Exhibit 21.1

Subsidiaries of Capnia, Inc.

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

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of Soleno Therapeutics, Inc. (formerly known as Capnia, Inc.) on Form S-8 (File Nos. 333-200175, 333-210563 and 333-220056) of our report which includes an explanatory paragraph as to the Company's ability to continue as a going concern dated April 2, 2018 with respect to our audits of the consolidated financial statements of Soleno Therapeutics, Inc. (formerly known as Capnia, Inc.) as of December 31, 2017 and 2016 and for each of the two years in the period ended December 31, 2017, which report is included in this Annual Report on Form 10-K of Soleno Therapeutics, Inc. (formerly known as Capnia, Inc.) for the year ended December 31, 2017.

/s/ Marcum LLP

Marcum LLP
San Francisco, CA
April 2, 2018

Exhibit 31.1

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

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

1. I have reviewed this annual report on Form 10-K of Soleno Therapeutics, Inc. (formerly Capnia, Inc.);

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

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

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

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

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

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

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

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

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

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

Date: April 2, 2018

/S/ Anish Bhatnagar
Anish Bhatnagar
President, Chief Executive Officer
(principal executive officer and principal financial and
accounting officer)

Exhibit 32.1

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

In connection with the Annual Report of Soleno Therapeutics, Inc. (formerly Capnia, Inc.) , Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2017, as filed with the Securities and Exchange Commission (the "Report"), Anish Bhatnagar, President, Chief Executive Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: April 2, 2018

/S/ Anish Bhatnagar
Anish Bhatnagar
President, Chief Executive Officer
(principal executive officer and principal financial and accounting officer)