

SOLENO THERAPEUTICS INC
Form 424B3
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Table of Contents

**Filed Pursuant to Rule 424(b)(3)
Registration No. 333-222761**

SOLENO THERAPEUTICS, INC.

Up to 14,165,541 Shares of common stock

This prospectus relates to the resale by the selling stockholders identified in this prospectus of up to an aggregate of 14,165,541 shares of our common stock, which consists of:

up to 8,141,116 shares of our common stock that are issued and outstanding, or the Shares; and

up to 6,024,425 shares, or the Warrant Shares, of our common stock that may be purchased upon exercise of issued and outstanding warrants, or the 2017 PIPE Warrants.

We refer to the Shares and the Warrant Shares collectively as the Resale Shares. We sold the Shares and the 2017 PIPE Warrants to the selling stockholders in a private placement in December 2017, which we refer to as the 2017 PIPE Offering, pursuant to a Securities purchase agreement, which we refer to as the Unit Purchase Agreement.

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

Our common stock is listed on the NASDAQ Capital Market under the ticker symbol SLNO. On February 6, 2018, the last reported sale price per share of our common stock was \$1.62 per share.

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

Investing in our securities involves a high degree of risk. See Risk Factors on page 7 of this prospectus.

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

This prospectus is dated February 7, 2018.

Table of Contents

TABLE OF CONTENTS

	Page
<u>Prospectus Summary</u>	1
<u>Risk Factors</u>	7
<u>Cautionary Note Regarding Forward-Looking Statements</u>	40
<u>Use of Proceeds</u>	41
<u>Price Range of Common Stock and Dividend Policy</u>	41
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	43
<u>Business</u>	66
<u>Description of Properties</u>	78
<u>Legal Proceedings</u>	79
<u>Management</u>	80
<u>Executive Compensation</u>	88
<u>Certain Relationships and Related Party Transactions</u>	98
<u>Security Ownership of Certain Beneficial Owners and Management</u>	99
<u>Description of Securities</u>	103
<u>Legal Matters</u>	111
<u>Experts</u>	111
<u>Available Information</u>	111
<u>Indemnification for Securities Act Liabilities</u>	113
<u>Plan of Distribution</u>	114
<u>Selling Stockholders</u>	115
<u>Index to Financial Statements</u>	F-1

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

Table of Contents

PROSPECTUS SUMMARY

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

Recent Developments

On December 4, 2017, we, and our 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 O AHL, 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.

On October 6, 2017, we effected a one-for-five (1:5) reverse stock split of our 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.

Prior to our entry into the joint venture with O AHL, we also completed the sale of stock of our 100% wholly-owned subsidiary, NeoForce, Inc., or NFI, primarily related to our portfolio of neonatology resuscitation business on July 18, 2017, pursuant to a Stock Purchase Agreement, or NFI Purchase Agreement, dated as of July 18, 2017, with NeoForce Holdings, Inc., or NFI Holdings, a 100% owned subsidiary of Flexicare Medical Limited, a privately held United Kingdom company, for \$720,000 and adjustments for inventory and the current cash balances held at NFI.

On May 8, 2017, we 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.

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

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 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. We continue to separately evaluate alternatives for our Serenz portfolio.

Diazoxide Choline Controlled-Release Tablets

DCCR tablets consist of the active ingredient diazoxide choline, a choline salt of diazoxide, which is a benzothiadiazine. Once solubilized from the formulation, diazoxide choline is rapidly hydrolyzed to diazoxide prior to absorption. Diazoxide is a benzothiadiazine that acts by stimulating ion flux through ATP-sensitive K^+ channels (K_{ATP}). In the U.S., diazoxide was first approved in 1973 as an intravenous formulation for the emergency treatment of malignant hypertension. In 1976, immediate-release oral formulations were approved, and there has been nearly 40 years of use of the orally-administered drug in the approved indications.

Table of Contents

A pilot study was conducted between June 2014 and March 2016 to evaluate the safety and preliminary efficacy of DCCR in the treatment of PWS subjects. This study, PC025, was a single-center, randomized withdrawal study and enrolled 13 overweight and obese subjects with genetically-confirmed PWS who were between the ages of 10 and 22. The study showed a statistically significant improvement in hyperphagia, the most important unmet need in PWS, as well as several other parameters.

DCCR is being developed in the U.S. under a current Investigational New Drug, or IND. We have received scientific advice from the U.S. Food and Drug Administration, or FDA, as well as the European Medicines Agency, or EMA, and expect to initiate a Phase III program in the near future.

Table of Contents

CoSense Joint Venture

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. 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.

Risks Associated With Our Business

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

We have a limited commercialization history and have incurred significant losses since our inception, and we anticipate that we will continue to incur substantial losses for the foreseeable future, which makes it difficult to evaluate our business and assess our future viability. As of September 30, 2017, we had an accumulated deficit of \$109.0 million.

Table of Contents

We are significantly dependent upon the success of DCCR, our sole therapeutic product candidate and if we fail to obtain regulatory approval for DCCR in the U.S. and E.U., our business would be harmed. If we are unable to implement our sales, marketing, distribution, training and support strategies or enter into agreements with third parties to perform these functions in markets outside of the U.S. and E.U., we will not be able to effectively commercialize DCCR and may not reach profitability.

The safety and preliminary efficacy results from the pilot study of DCCR conducted in the treatment of PWS subjects may not be indicative of the outcome of the proposed NDA-enabling clinical trial.

The challenges involved in establishing distribution and sales operations may expose us to a higher than usual level of risk with respect to commercializing our products. We may be required to conduct additional clinical trials prior to obtaining additional approval for our products. We may not obtain such approvals for sale on a predictable timeframe, or at all.

We have not manufactured the active drug ingredients contained in DCCR, CoSense or its associated consumables, on a large commercial scale, and there are risks associated with scaling up manufacturing. Our commercial manufacturing partners may not be successful in achieving the levels of production volume, quality, or manufacturing costs necessary to support commercial success.

Our executive officers, directors and principal stockholders may continue to maintain the ability to control all matters submitted to stockholders for approval.

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

Our business depends on our continuing to satisfy the FDA and any other applicable U.S. and international regulatory requirements with respect to medical diagnostics, devices or therapeutics, including requirements which may change or be created in the future.

We need to obtain or maintain patents or other appropriate protection for the intellectual property utilized in our current and planned product offerings, and we must avoid infringement of third-party intellectual property.

Corporate information

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

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

Table of Contents

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of our initial public offering, or IPO, which occurred on November 18, 2014, (2) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.7 billion, (3) the date on which we are deemed to be a large accelerated filer, which means the market value of common stock that is held by non-affiliates exceeds \$700.0 million as of the prior June 30th, and (4) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

Soleno Therapeutics, Serenz, our logo and our other trade names, trademarks and service marks appearing in this prospectus are our property. CoSense, Sensalyze, Capnia, and other trade names, trademarks and service marks relating to the joint venture and appearing in this prospectus are the property of our joint venture with OAH. Other trade names, trademarks and service marks, including NeoForce, appearing in this prospectus are the property of their respective holders.

Table of Contents**The Offering**

Common stock being offered by the selling stockholders	14,165,541 shares
Selling stockholders	Birchview Fund, LLC, Feinberg Family Trust, Oracle Institutional Partners LP, Oracle Partners LP, Oracle Ten Master Fund LP, Jack W. Schuler Living Trust, Tino Hans Schuler Trust, Tanya Eva Schuler Trust, Therese Heidi Schuler Trust, Schuler Grandchildren LLC, Schuler Grandchildren 2010 Continuation Trust, 683 Capital Partners, LP, Vivo Ventures Fund V, L.P., Vivo Ventures V Affiliates Fund, LP., Michael A. Gordon, and Mario 2002 Grandchildren s Trust
Common stock outstanding	19,238,972 (as of January 23, 2018)
Use of proceeds	The selling stockholders will receive all of the proceeds from the sale of the shares offered for sale by them under this prospectus. We will not receive proceeds from the sale of the shares by the selling stockholders.
NASDAQ Symbol	SLNO
Risk Factors	Investing in our securities involves a high degree of risk. You should carefully review and consider the Risk Factors section of this prospectus for a discussion of factors to consider before deciding to invest in shares of our common stock.
	The number of shares of our common stock outstanding excludes 1,072,004 shares of our common stock issuable upon exercise of outstanding stock options, 1,621,585 shares of our common stock available for future issuance under the stock option plans, outstanding warrants exercisable for 120,421 shares of our common stock, 914,200 shares of our common stock issuable upon the conversion of our outstanding Series B Convertible Stock, 485,121 shares of our common stock issuable upon exercise of our outstanding Series A Warrants, 118,083 shares of our common stock issuable upon exercise of our outstanding Series C Warrants, 586,162 shares of our common stock issuable upon exercise of our outstanding Series D Warrants and 6,024,425 outstanding warrants from the 2017 PIPE Offering, each of which securities are outstanding or available for issuance as of January 23, 2018.
<i>Sale of the Units to the Selling Stockholders</i>	
	On December 11, 2017, we entered into a Securities Purchase Agreement, or the Unit Purchase Agreement, with the selling 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 of a share of our common stock at an exercise price of \$2.00 per share, for an aggregate of 8,141,116 shares of our common stock, or the Shares, and corresponding warrants, or the 2017 PIPE Warrants, to purchase 6,024,425 shares of our common stock, or the Warrant Shares. We refer to the Shares and the Warrant Shares collectively as the Resale Shares. We also granted certain registration rights to the selling stockholders pursuant to the Unit Purchase Agreement pursuant to which, among other things, we are preparing and filing this registration statement with the SEC to register for resale the Resale Shares.

Table of Contents

RISK FACTORS

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

Risks related to our financial condition and capital requirements

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

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

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

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

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

obtain a sufficiently broad label that would not unduly restrict patient access;

receipt of marketing approvals for DCCR in the U. S. and E. U.;

building an infrastructure capable of supporting product sales, marketing, and distribution of DCCR in territories where we pursue commercialization directly;

establishing commercial manufacturing arrangements with third party manufacturers;

establishing commercial distribution agreements with third party distributors;

launching commercial sales of DCCR, if and when approved, whether alone or in collaboration with others;

acceptance of DCCR, if and when approved, by patients, the medical community, and third party payors;

the regulatory approval pathway that we pursue for DCCR in the United States;

effectively competing with other therapies;

a continued acceptable safety profile of DCCR following approval;

obtaining and maintaining patent and trade secret protection and regulatory exclusivity;

protecting our rights in our intellectual property portfolio; and

obtaining a commercially viable price for our products.

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

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 September 30, 2017, we had an accumulated deficit of \$109.0 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.

Table of Contents

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.

Table of Contents

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 condensed 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 September 30, 2017, we have incurred significant operating losses since inception and continue to generate losses from operations and has an accumulated deficit of \$109.0 million. These matters raise substantial doubt about our ability to continue as a going concern. The condensed 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 September 30, 2017, our cash balance was \$5.6 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;

Table of Contents

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.

Table of Contents

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 payors will cover and pay for such tests and, if so, whether they will adequately reimburse us.

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

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

We currently have limited sales and distribution personnel, and limited marketing capabilities. If we are unable to develop a sales and marketing and distribution capability on our own or through collaborations or other marketing partners, we will not be successful in commercializing our 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.

Table of Contents

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

Table of Contents

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 payors. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Many of these competitors are attempting to develop therapeutics for our target indications.

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

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 payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of

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

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

Table of Contents

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

Table of Contents

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;

Table of Contents

potential failure by us or our distributors to obtain regulatory approvals for the sale or use of our current products and our planned future products in various countries;

difficulties in managing foreign operations;

complexities associated with managing government payor systems, multiple payor-reimbursement regimes or self-pay systems;

logistics and regulations associated with shipping products, including infrastructure conditions and transportation delays;

limits on our ability to penetrate international markets if our distributors do not execute successfully;

financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable, and exposure to foreign currency exchange rate fluctuations;

reduced protection for intellectual property rights, or lack of them in certain jurisdictions, forcing more reliance on our trade secrets, if available;

natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and

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

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

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

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.

Table of Contents

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 iterations of a product for clinical testing;

collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products;

a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;

collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;

disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our products or that results in costly litigation or arbitration that diverts management attention and resources;

collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable products; and

collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

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

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;

Table of Contents

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

Table of Contents

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 OAH, 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.

Table of Contents

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.

Table of Contents

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;

Table of Contents

Pending patent applications may not lead to issued patents;

Issued patents may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;

Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

We may not develop or in-license additional proprietary technologies that are patentable; and

The patents of others may have an adverse effect on our business.

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

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents or applications will be due to be paid by us to the USPTO and various governmental patent agencies outside of the U.S. in several stages over the lifetime of the patents or applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and this circumstance would have a material adverse effect on our business

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

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

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

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

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.

Table of Contents

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.

Table of Contents

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

Nonclinical Testing

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

Table of Contents***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.

Table of Contents

Once an 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 (i.e., in the U.S., the disease or condition has an incidence of < 200,000 persons; in the E.U., the prevalence of the condition must be not more than 5 in 10,000) can be designated as Orphan

Drugs. In the U.S., orphan-designated drugs are granted up to 7-year market exclusivity. In the E.U., products granted orphan designation are subject to reduced fees for protocol assistance, marketing authorization applications, inspections before authorization, applications for changes to marketing authorizations, and annual fees, access to the centralized authorization procedure, and 10 years of market exclusivity.

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.

Table of Contents

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 enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. The PPACA, among other things:

imposes a tax of 2.3% on the retail sales price of medical devices sold after December 31, 2012;

could result in the imposition of injunctions;

requires collection of rebates for drugs paid by Medicaid managed care organizations; and

requires manufacturers to participate in a coverage gap discount program, under which they must agree to offer

50% point-of-sale discounts off negotiated prices of applicable branded drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under

Medicare Part D.

While the U.S. Supreme Court upheld the constitutionality of most elements of the PPACA in June 2012, other legal challenges are still pending final adjudication in several jurisdictions. In addition, Congress has also proposed a number of legislative initiatives, including possible repeal of the PPACA. In December of 2015, Congress passed a two-year suspension of the 2.3% medical device tax. If after two years, the suspension is not extended, at this time we believe the 2.3% tax on sales of medical devices will be applicable to sales of 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.

Table of Contents

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

our ability to set a price that we believe is fair for our products;

our ability to generate revenue and achieve or maintain profitability; and

the availability of capital.

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

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

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

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

the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation

of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;

indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;

the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities like us which provide coding and billing advice to customers;

federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics and medical supplies to report to the HHS information related to physician payments and other transfers of value and physician ownership and investment interests;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and

Table of Contents

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers. The PPACA, among other things, amends the intent requirement of the Federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

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

Risks related to this offering and ownership of our securities

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

Our stock price has been and is likely to continue to be volatile. The stock market in general, and the market for biotechnology and medical device companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. During the period from January 1, 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 costeffective manner;

announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;

developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;

our ability or inability to raise additional capital and the terms on which we raise it;

the recruitment or departure of key personnel;

changes in the structure of healthcare payment systems;

market conditions in the pharmaceutical and biotechnology sectors;

actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;

Table of Contents

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%.

In addition, 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.

In connection with this offering, subject to certain exceptions, all of our directors and executive officers agreed not to offer, sell or agree to sell, directly or indirectly, any shares without the permission of Piper Jaffray & Co., the placement agent in the 2017 PIPE Offering, for a period of 30 days after the date of this prospectus.

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 \$1.7 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.

Table of Contents

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.

Table of Contents

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

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

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

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

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

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

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

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

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

We have listed our common stock and Series A Warrants on NASDAQ. We might not be able to maintain the listing standards of that exchange, which includes requirements that we maintain our shareholders' equity, total value of shares held by unaffiliated shareholders, market capitalization above certain specified levels and minimum bid requirement of \$1.00 per common share. 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.

Table of Contents

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. 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 acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of our company; and

our Board of Directors are able to issue, without stockholder approval, shares of undesignated preferred stock, which makes it possible for our Board of Directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

Table of Contents

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

On December 11, 2017, we entered into the Unit Purchase Agreement with the selling 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 the selling stockholders, pursuant to which, among other things, we are preparing and filing this registration statement with the SEC to register for resale the Resale Shares.

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.

Table of Contents

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

the timing and the success of additional approvals of any of our products pursuant to our clinical and regulatory efforts;

our ability to successfully build a distribution network and commercial infrastructure for our products;

whether the results of the trials will be sufficient to support domestic or global regulatory approvals for any of our products;

our ability to obtain and/or maintain regulatory approval of our products;

our expectation that our existing capital resources will be sufficient to enable us to successfully meet the capital requirements for all of our current and future products;

the benefits of the use of our products;

the projected dollar amounts of future sales of established and novel diagnostics for neonatal hemolysis;

our ability to successfully commercialize any products;

the rate and degree of market acceptance of our products;

our expectations regarding government and third-party payor coverage and reimbursement;

our ability to manufacture our products in conformity with the applicable regulatory requirements and to scale up manufacturing of our products to commercial scale;

our ability to compete with companies that may enter the market with products that compete with our products;

our reliance on third parties to conduct clinical studies;

our reliance on third-party contract manufacturers to manufacture and supply our products for us;

our reliance on our collaboration partners' performance over which we do not have control;

our ability to retain and recruit key personnel, including development of a sales and marketing function;

our ability to obtain and maintain intellectual property protection for our products;

our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing;

our expectations regarding the time during which we will be an emerging growth company under the Jobs Act;

our ability to identify, develop, acquire and in-license additional products;

our ability to successfully establish and successfully maintain appropriate collaborations and derive significant revenue from those collaborations;

our financial performance; and

developments and projections relating to our competitors or our industry.

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

Table of Contents

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

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

USE OF PROCEEDS

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

PRICE RANGE OF COMMON STOCK AND DIVIDEND POLICY

Our common stock is currently listed on the NASDAQ Capital Market under the symbol **SLNO** and our Series A Warrants are quoted on the NASDAQ Capital Market under the symbol **SLNOW**. Our Series B Warrants, Series C Warrants, Series D Warrants, 2015 Placement Agent Warrants and 2017 PIPE Warrants are not and will not be traded on a national securities exchange.

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

	High	Low
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 January 23, 2018)	\$ 2.05	\$ 1.96

As of February 6, 2018, the last reported sale price of our common stock on the NASDAQ Capital Market was \$1.62.

As of January 23, 2018, there were approximately 81 shareholders of record for our common stock. A substantially greater number of stockholders may be street name or beneficial holders, whose shares are held of record by banks, brokers and other financial institutions. We have never declared or paid, and do not anticipate declaring or paying, any cash dividends on any of our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends in the foreseeable future. Future determination as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors and will depend on then existing conditions, including our operating results, financial conditions, contractual

restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

Table of Contents**SELECTED FINANCIAL DATA**

The following selected consolidated financial data 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 prospectus. The selected consolidated financial data 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, 2016, and 2015, and the balance sheets data as of December 31, 2016, and 2015, from our audited financial statements appearing elsewhere in this filing. We derived the consolidated statements of operations data for the nine months ended September 30, 2016 and 2017 and the consolidated balance sheet data as of September 30, 2017 from unaudited interim consolidated financial statements included elsewhere in this filing. In the opinion of management, the unaudited consolidated financial statements reflect all adjustments, which include normal recurring adjustments, necessary to state fairly our results of operations and financial position. The data should be read in conjunction with the financial statements, related notes, and other financial information included herein.

	Year Ended December 31,		Nine Months Ended	
	2016	2015	September 30,	2016
Statement of Operations Data:				
Operating expenses				
Research and development	\$ 2,247,141	\$	\$ 2,045,961	\$ 1,958,771
Sales and marketing			25,731	
General and administrative	6,076,976	5,991,266	4,900,292	4,532,312
Total Operating expenses	8,324,117	5,991,266	6,971,984	6,491,083
Operating loss	(8,324,117)	(5,991,266)	(6,971,984)	(6,491,083)
Total interest and other income (expense), net	1,586,497	(3,748,800)	(620,854)	1,174,769
Loss from continuing operations	(6,737,620)	(9,740,066)	(7,592,838)	(5,316,314)
Loss from discontinued operations, net of tax effect	(5,327,594)	(6,168,480)	(3,048,821)	(4,135,804)
Net loss	(12,065,214)	(15,908,546)	(10,641,659)	(9,452,117)
Loss on extinguishment of convertible preferred stock	3,651,172			
Net loss applicable to common stockholders	\$ (15,716,386)	\$ (15,908,546)	(10,641,659)	(9,452,117)
Weighted average common shares outstanding				
Basic and diluted	3,101,496	1,885,176	8,936,255	3,072,729
Net loss per common share from continuing operations, basic and diluted	\$ (3.35)	\$ (5.17)	\$ (0.85)	\$ (1.73)

Net loss per common share from discontinued operations, basic and diluted	\$	(1.72)	\$	(3.27)	\$	(0.34)	\$	(1.35)
Net loss per common share, basic and diluted	\$	(5.07)	\$	(8.44)	\$	(1.19)	\$	(3.08)

	December 31		September 30,					
	2016	2015	2017	2016				
Balance Sheet Data								
Cash and cash equivalents	\$	2,725,996	\$	5,494,523	\$	5,647,039	\$	5,414,963
Working capital	\$	2,093,916	\$	3,211,565	\$	4,658,886	\$	4,730,805
Total assets	\$	5,564,852	\$	8,201,195	\$	26,381,996	\$	8,309,310
Total stockholders equity	\$	3,435,197	\$	3,223,816	\$	23,210,162	\$	5,712,442

Table of Contents**MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS****YEARS ENDED DECEMBER 31, 2016 AND 2015**

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

Business Overview

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, products that included temperature probes, scales, surgical tables and patient surfaces.

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 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 we received on March 6, 2017.

During the evaluation and negotiation of the merger with Essentialis, the Company commenced to explore 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.

Table of Contents

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 (see Note 5).

On July 24, 2015, we entered into a Common Stock Purchase Agreement with Aspire Capital, or the 2015 Aspire Purchase Agreement, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire is committed to purchase up to an aggregate of \$10.0 million in value of shares of our Common Stock over the 24-month term of the 2015 Aspire Purchase Agreement. Since July 24, 2015, we issued an aggregate of 101,317 shares of Common Stock to Aspire in exchange for approximately \$1.4 million.

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

On June 29, 2016, we entered into the 2016 Sabby Purchase Agreement with Sabby, pursuant to which we agreed to sell to Sabby, in a private placement, an aggregate of up to 13,780 shares of our Series B Convertible Preferred Stock at an aggregate purchase price of \$13,780,000, which shares are convertible into 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 repurchase of the Series A Convertible Preferred Stock and estimated transaction expenses, the Company received approximately \$5.6 million of net proceeds.

During the years ended December 31, 2016 and December 31, 2015, we received \$70,000 and \$294,000, respectively, from the exercise of stock options.

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

As of December 31, 2016, we had an accumulated deficit of \$98.3 million, primarily as a result of research and development and general and administrative expenses. While we may in the future generate revenue from a variety of sources, potentially including sales of our neonatology products, therapeutic products, other diagnostic products, license fees, milestone payments, and research and development payments in connection with potential future strategic partnerships, we have, to date, generated revenue only from the 2013 license agreement pertaining to Serenz, \$1.9 million in revenue from our neonatology products and \$0.2 million in government grants. We may never be

successful in commercializing our 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.

Recent Developments

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.

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.

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.

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, we, and our 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.

Prior to our entry into the joint venture with OAHL, we also completed the sale of stock of our 100% wholly-owned subsidiary, NeoForce, Inc., or NFI, primarily related to our portfolio of neonatology resuscitation business on July 18, 2017, pursuant to a Stock Purchase Agreement, or NFI Purchase Agreement, dated as of July 18, 2017, with NeoForce Holdings, Inc., or NFI Holdings, a 100% owned subsidiary of Flexicare Medical Limited, a privately held United Kingdom company, for \$720,000 and adjustments for inventory and the current cash balances held at NFI.

Table of Contents**Financial overview*****Summary***

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

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.

Table of Contents

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 nor 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 B and Series C stock warrant liabilities.

Critical Accounting Policies and Significant Judgments and Estimates

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

Table of Contents***Series A and Series C Warrants***

We account for the Series A and Series C in accordance with the guidance in ASC 815 *Derivatives and Hedging*. The Series A and Series C Warrants contain standard anti-dilution provisions for stock dividends, stock splits, subdivisions, combinations and similar types of recapitalization events. The Warrants also contain a fundamental transactions provision that permits their settlement in cash at fair value at the option of the holder upon the occurrence of a change in control. Such change in control events include tender offers or hostile takeovers, which are not within the sole control of 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 Series A and Series C Warrants as liabilities at their fair value and will re-measure the warrants at each balance sheet date until they are exercised or expire. Any change in the fair value is recognized as other income (expense) in the Statement of Operations.

Series D Warrants

We account for the Series D Warrants in accordance with the guidance in ASC 815 *Derivatives and Hedging*. The Warrants contain standard anti-dilution provisions for stock dividends, stock splits, subdivisions, combinations and similar types of recapitalization events. They also contain a cashless exercise feature that provides for their net share settlement at the option of the holder in the event that there is no effective registration statement covering the continuous offer and sale of the warrants and underlying shares. We are required to comply with certain requirements to cause or maintain the effectiveness of a registration statement for the offer and sale of these securities. Such change in control events include tender offers or hostile takeovers, which are not within our sole control as the issuer of these warrants. However, the Series D Warrant agreement specifically provides that under no circumstances will we be required to settle any Series D Warrant exercise for cash, whether by net settlement or otherwise. Accordingly, we have classified the value of the Series D Warrants as permanent equity.

Series A and Series B Convertible Preferred Stock

We classified our Series A and Series B Convertible Stock as permanent equity on our balance sheet in accordance with authoritative guidance for the classification and measurement of hybrid securities and distinguishing liability from equity instruments. The preferred stock is not redeemable at the option of the holder.

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

Research and development expense

Research and development costs are expensed as incurred. Research and development expense includes payroll and personnel expenses; consulting costs; 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

Table of Contents

performed. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees to:

contract manufacturers in connection with the production of clinical trial materials;

contract research organizations and other service providers in connection with clinical studies;

investigative sites in connection with clinical studies;

vendors in connection with preclinical development activities; and

professional service fees for consulting and related services.

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

Stock-based compensation expense

For the years ended December 31, 2016 and December 31, 2015 stock-based compensation expense was \$871,270 and \$942,369, respectively of which, stock compensation expense of approximately \$132,000 and \$211,000 was classified in discontinued operations, in 2016 and 2015, respectively. As of December 31, 2016, we had \$1,553,427 of total unrecognized compensation expense, which we expect to recognize over a period of approximately 2.7 years. The intrinsic value of all outstanding stock options as of December 31, 2016, was approximately zero. We expect to continue to grant equity incentive awards in the future as we continue to expand our number of employees and seek to retain our existing employees, and to the extent that we do, our actual stock-based compensation expense recognized in future periods will likely increase.

Stock-based compensation costs related to stock options granted to employees are measured at the date of grant based on the estimated fair value of the award, net of estimated forfeitures. We estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. The grant date fair value

of stock-based awards is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the award. Stock options we grant to employees generally vest over four years.

The fair value of an equity award granted to a non-employee generally is determined in the same manner as an equity award granted to an employee. In most cases, the fair value of the equity securities granted is more reliably determinable than the fair value of the goods or services received. In June 2016, we granted 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, we recognized \$13,502 in expense for the remaining options during 2016, which will vest during the first quarter of 2017. Total expense for the two groups of options reflects the fair value of our common stock on the applicable vesting commencement dates.

Table of Contents

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 267,851 options granted in the year ended December 31, 2016, and there were 191,142 options granted in the year ended December 31, 2015. In addition to the assumptions used in the Black-Scholes option-pricing model, we must also estimate a forfeiture rate to calculate the stock-based compensation expense for our awards. We will continue to use judgment in evaluating the expected volatility, expected terms, and forfeiture rates utilized for our stock-based compensation expense calculations on a prospective basis.

Impairment of Goodwill

Goodwill represents the excess of the purchase price of an acquired enterprise or assets over the fair value of the identifiable assets acquired and liabilities assumed. Goodwill is presumed to have an indefinite life and is not subject to amortization. We test for impairment of goodwill on an annual basis in the fourth quarter and at any other time when events occur or circumstances indicate that the carrying amount of goodwill may not be recoverable.

Circumstances that could trigger an impairment test include, but are not limited to: a significant adverse change in the business climate or legal factors, an adverse action or assessment by a regulator, change in customer, target market and strategy, unanticipated competition, loss of key personnel, or the likelihood that a reporting unit or significant portion of a reporting unit will be sold or otherwise disposed.

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

Under the quantitative test, if the carrying amount of a reporting unit's goodwill exceeds the implied fair value of that goodwill, an impairment loss is recorded in the Consolidated Statements of Operations as Impairment of goodwill.

Measurement of the fair value of a reporting unit is based on one or more of the following fair value measures: amounts at which the unit as a whole could be bought or sold in a current transaction between willing parties, using present value techniques of estimated future cash flows, or using valuation techniques based on multiples of earnings or revenue, or a similar performance measure.

Based on our organizational structure and our financial information during 2016 and 2015, we determined we operate in one segment and two reporting units. The only reporting unit with goodwill was the NeoForce (NFI) unit.

During the fourth quarter of 2016, we tested the NFI reporting unit's goodwill for impairment under the two-step quantitative goodwill impairment test in accordance with authoritative guidance. There were no triggering events during the interim periods of 2016.

Table of Contents

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 2015 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.

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.

Table of Contents**Results of Continuing Operations*****Comparison of the Years Ended December 31, 2016 and 2015***

	Year Ended		Increase (decrease)	
	December 31, 2016	2015	Amount	Percentage
Operating expenses				
Research and development	\$ 2,247,141	\$	\$ 2,247,141	%
General and administrative	6,076,976	5,991,266	85,710	1.4%
Total operating expenses	8,324,117	5,991,266	2,332,851	38.9%
Operating loss	(8,324,117)	(5,991,266)	(2,332,851)	38.9%
Other income (expense), net	1,586,497	(3,748,800)	5,335,297	(142.3)%
Loss from continuing operations	\$ (6,737,620)	\$ (9,740,066)	\$ 3,002,446	(30.8)%

Revenue

The company has not commenced commercialization of DCCR, its current sole novel therapeutic product, and accordingly, through December 31, 2016, has generated no revenue in continuing operations.

Research and development expense

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 discontinued research and development efforts, together with indirect expenses of rent, facilities, and consultants that indirectly support the Company's general research and development efforts. The Company's research and development expenses incurred during the year ended December 31, 2015, were all directly incurred in discontinued operations and no research and development expense was incurred for continuing operations.

Sales and marketing expense

The company has not commenced commercialization of DCCR, its current sole novel therapeutic product, and accordingly, through December 31, 2016, has incurred no sales and marketing activities in continuing operations.

General and administrative expense

General and administrative expense for the year ended December 31, 2016, increased \$86,000 compared to the year ended December 31, 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.

Other income (expense), net

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

Table of Contents**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)	
	2016	2015	Amount	Percentage
Revenue	\$ 1,450,788	\$ 607,472	\$ 843,316	138.8%
Cost of goods sold	1,509,306	352,683	1,156,623	327.9%
Gross profit	(58,518)	254,789	(313,307)	(123.0)%
Operating expenses:				
Research and development	2,937,662	4,536,244	(1,598,582)	(35.2)%
Sales and marketing	1,630,591	1,737,470	(106,879)	(6.2)%
General and administrative	659,227	149,555	509,672	340.8%
Total operating expenses	5,227,480	6,423,269	(1,195,789)	(18.6)%
Income (Loss) from operations	(5,285,998)	(6,168,480)	(882,482)	14.3%
Other income (expense), net	(19,896)		19,896	%
Operating loss from discontinued operations	(5,305,894)	(6,168,480)	862,586	14.0%
Provision for deferred taxes	21,700		21,700	%
Loss from discontinued operations, net of tax effect	\$ (5,327,594)	\$ (6,168,480)	\$ 840,886	13.6%

Revenue

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

Research and development expense

Research and development expense for the year ended December 31, 2016 decreased by \$1.6 million compared to the year ended December 31, 2015, 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 for the year ended December 31, 2016 decreased \$107,000 over the year ended December 31, 2015, due to the decrease of direct sales personnel concurrent with signing a distributor agreement with Bemes.

Table of Contents***General and administrative expense***

General and administrative expense for the year ended December 31, 2016, increased \$509,000 compared to the year ended December 31, 2015, 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

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 July 24, 2015, we entered into the 2015 Aspire Purchase Agreement with Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$10.0 million in value of shares of our Common Stock over the 24-month term of the purchase agreement. During the quarter ended September 30, 2015, we issued an aggregate of 101,317 shares of Common Stock to Aspire Capital in exchange for approximately \$1.4 million.

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

On June 29, 2016, we entered into the 2016 Sabby Purchase Agreement with Sabby, pursuant to which we agreed to sell to Sabby, in a private placement, an aggregate of up to 13,780 shares of our Series B Convertible Preferred Stock at an aggregate purchase price of \$13,780,000, which shares are convertible into 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.

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 (see Note 14).

On January 27, 2017, we entered into the 2017 Aspire Purchase Agreement with Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$17.0 million in value of shares of our Common Stock over the 30-month term of the 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. On March 7, 2017, we received the \$2.0 million from Aspire Capital (see Note 14). The 2017 Aspire Purchase Agreement was terminated upon the closing of the 2017 PIPE.

Table of Contents

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.

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

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

We expect to incur substantial expenditures in the foreseeable future for the 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.

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.

Table of Contents**Cash flows**

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

	Year Ended December 31,	
	2016	2015
Cash Flows		
Net cash used in continuing operating activities	\$ (7,260,708)	\$ (5,568,804)
Net cash used in discontinued operating activities	(6,237,272)	(4,730,526)
Net cash used in operating activities	(13,497,980)	(10,299,330)
Net cash used in continuing investing activities	(14,795)	(59,019)
Net cash used in discontinued investing activities	(23,885)	(1,261,758)
Net cash used in investing activities	(38,680)	(1,320,777)
Net cash provided by continuing by continuing financing activities	10,768,133	9,157,920
Net cash provided by financing activities	10,768,133	9,157,920
Net increase in cash and cash equivalents from continuing operations	3,492,630	3,530,097
Net decrease in cash and cash equivalents from discontinued operations	(6,261,157)	(5,992,284)
Net decrease in cash and cash equivalents	\$ (2,768,527)	\$ (2,462,187)

Cash used in continuing operating activities

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.

During the year ended December 31, 2015, net cash used in continuing operating activities was \$5.6 million, resulting primarily from the net loss from continuing operations of \$9.7 million, adjusted for the non-cash loss of \$516,000 from the change in fair value of warrants, the non-cash expense for the Series C Warrants inducement charge of \$3.0 million, \$731,000 of non-cash stock based compensation expense, and the use of cash for the increase in accounts payable of \$435,000.

Cash used in continuing investing activities

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

In the year ended December 31, 2015, cash was for the increase in restricted cash for collateral of credit card purchase activity and for purchases of equipment for continuing investing activities.

Cash provided by continuing financing activities

During the year ended December 31, 2016, cash provided by financing activities was \$10.8 million, consisting primarily of \$5.1 million, net of 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.

During the year ended December 31, 2015 cash provided by financing activities was \$9.2 million, consisting primarily of \$4.2 million in proceeds from issuance of Series A Convertible Preferred stock, \$3.9 million from the issuance of Common Stock resulting from the exercise of Series A and B Warrants, issuance of Common Stock to Aspire Capital for \$1.4 million and the \$294,000 proceeds from the sale of common stock for exercised stock options, all of which were partially offset by payment of \$575,000 for IPO and Series B transaction costs of and the \$102,000 repayment of the outstanding balance on our line of credit.

Table of Contents

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

Cash used in discontinued operating activities

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.

During the year ended December 31, 2015, the Company used \$4.7 million net cash in discontinued operating activities, resulting primarily from the net loss of \$6.2 million, adjusted for the \$1.1 million non-cash increase in accrued compensation and other current liabilities and for \$211,000 of non-cash stock-based compensation expense.

Cash used in discontinued investing activities

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

In the year ended December 31, 2015, the company used cash for discontinued investing activities in the amount of \$1.0 million to acquire NeoForce and \$250,000 to acquire certain patents.

Discontinued Financing activities

The Company had no financing activities related to discontinued operations in 2016 or 2015.

Contractual obligations and commitments

As of December 31, 2016, we had net lease obligations totaling \$1.7 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 July of 2019. We had previously signed a sublease for our prior operating facilities at 3 Twin Dolphins Drive in Redwood City, with an expiration date of June 2018.

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

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

We are obligated to make future payments to third parties under in-license agreements, including sublicense fees, royalties, and payments that become due and payable on the achievement of certain development and commercialization milestones. As the amount and timing of sublicense fees and the achievement and timing of these

milestones are not probable and estimable, such commitments have not been included on our balance sheet or in the contractual obligations tables above. We are also obligated to make certain payments of deferred compensation to management upon completion of certain types of transactions. As the amount and timing of such payments are not probable and estimable, such commitments have not been included on our balance sheet or in the contractual obligations tables above.

Table of Contents

On February 28, 2017, we settled the Lawsuit (see Note 14) 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, 2016, we had no off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K as promulgated by the SEC.

Accounting Guidance Update

Recently Issued Accounting Guidance

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

Table of Contents

Management's Discussion and Analysis of Financial Condition and Results of Operation

Nine Months Ended September 30, 2017 and 2016

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

Overview

On March 7, 2017, we completed our merger, or the Merger, with Essentialis, Inc., a Delaware corporation, or Essentialis. After the Merger with Essentialis, our primary focus is on the development and commercialization of novel therapeutics for the treatment of rare diseases. Essentialis was a privately-held, clinical stage biotechnology company focused on the development of breakthrough medicines for the treatment of rare metabolic diseases where there is increased mortality and risk of cardiovascular and endocrine complications. Essentialis has been developing Diazoxide Choline Controlled Release, or DCCR, tablets as a treatment for Prader-Willi syndrome, or PWS, a complex neurobehavioral/metabolic disorder.

We sold CoSense, which measures end-tidal carbon monoxide, or ETCO, and aids in the detection of excessive hemolysis, a condition in which red blood cells degrade rapidly. When present in neonates with jaundice, excessive hemolysis is a dangerous condition which can lead to adverse neurological outcomes. CoSense is 510(k) cleared for sale in the U.S. and received CE Mark certification for sale in the E.U. (see Note 5).

On December 4, 2017, we, and our 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.

Our current research and development efforts are primarily focused on advancing our lead candidate, DCCR tablets for the treatment of PWS, into late-stage clinical development.

DCCR tablets consist of the active ingredient diazoxide choline, a choline salt of diazoxide, which is a benzothiadiazine. Once solubilized from the formulation, diazoxide choline is rapidly hydrolyzed to diazoxide prior to absorption. Diazoxide acts by stimulating ion flux through ATP-sensitive K⁺ (K_{ATP}) channels. The K_{ATP} channel links the cellular energy status to the membrane potential. Diazoxide appears to act on signs and symptoms of PWS in a variety of ways. Agonizing the K_{ATP} channels 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 approved indications for Proglycem, there is also a long history of its chronic use in neonates, infants and children with congenital hyperinsulinism, or CHI, persistent hyperinsulinemic hypoglycemia of infancy, and in adults with insulinoma, which is a tumor of the pancreas that produces excessive amounts of insulin. Insulinoma patients tend to be older, with 50% of them over 70 years old. The average duration of use of Proglycem in CHI and insulinoma patients is 5 years and 7 years, respectively.

DCCR tablets were formulated with the goals of improving the safety and bioavailability of orally-administered diazoxide and reducing the frequency of daily dosing required by current diazoxide formulations. Diazoxide choline is formulated into a controlled-release tablet that lowers peak plasma concentration compared to diazoxide oral suspension and slows release of diazoxide from DCCR, making it suitable for once-a-day dosing.

PWS is a rare, complex neurobehavioral/metabolic disorder which is due to the absence of normally active paternally expressed genes from the chromosome 15q11-q13 region. PWS is an imprinted condition with 70-75% of the cases due to a *de novo* deletion in the paternally inherited chromosome 15 11-q13 region, 20-30% from maternal uniparental disomy 15, or UPD, and the remaining 2-5% from either microdeletions or epimutations of the imprinting center (i.e., imprinting defects; IDs). The committee on genetics of the American Academy of Pediatrics states PWS affects both genders equally and occurs in people from all geographic regions; its estimated incidence is 1 in 15,000 to 1 in 25,000 live births. The mortality rate among PWS patients is 3% a year across all ages 3 years and older 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).

Table of Contents

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

Other complications in PWS patients include greater risk for autistic symptomatology, psychosis, sleep disorders, distress, mood lability, food stealing, withdrawal, sulking, nail-biting, hoarding and overeating, and more pronounced attention-deficit hyperactivity disorder symptoms, 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.

In May of 2017 we had a scientific advice meeting with the FDA . The FDA supported change in hyperphagia score (without a change in weight) compared to placebo as the primary endpoint for the planned Phase III study. The dosing paradigm proposed for the Phase III study was acceptable. The FDA proposed and we agreed that the duration of the randomized double-blind placebo controlled study should be shorter (3-4 months). Safety information about DCCR could be obtained in a long-term, safety extension study. There was agreement on several other aspects of the study and the overall development program, and additional regulatory input is being sought on others.

In September 2017, we received scientific advice from the European Medicines Agency (EMA). The EMA, like the FDA, supported the use of change in hyperphagia compared to placebo as the primary endpoint for the study as well as the proposed dosing paradigm.

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

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

On March 7, 2017, we completed the Merger with Essentialis and issued 3,783,388 shares of Common Stock to stockholders of Essentialis. We 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. We are 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.

Table of Contents

In addition, 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.

During the year ended December 31, 2016 and the nine months ended September 30, 2017, we received \$0.1 million and zero, respectively, from the exercise of stock options.

As of September 30, 2017, we had an accumulated deficit of \$109.0 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 therapeutic products, license fees, milestone payments, and research and development payments in connection with potential future strategic partnerships, we have, to date, generated revenue only from the 2013 license agreement pertaining to Serenz, \$2.2 million in revenue from our neonatology products and \$0.2 million in government grants. We may never be successful in commercializing our neonatology products, therapeutic products or in developing additional products. Accordingly, we expect to incur significant losses from operations for the foreseeable future, and there can be no assurance that we will ever generate significant revenue or profits.

Recent Developments

On December 4, 2017, we, and our 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 O AHL, with the purpose of developing and commercializing medical monitors, including CoSense.

Prior to our entry into the joint venture with O AHL, we also completed the sale of stock of our 100% wholly-owned subsidiary NFI, which was primarily related to our portfolio of neonatology resuscitation business on July 18, 2017, pursuant to a Stock Purchase Agreement, or NFI Purchase Agreement, dated as of July 18, 2017, with NeoForce Holdings, Inc., or NFI Holdings, a 100% owned subsidiary of Flexicare Medical Limited, a privately held United Kingdom company, for \$720,000 and adjustments for inventory and the current cash balances held at NFI.

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 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.

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.

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.

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.

Management does not believe that we have sufficient capital resources to sustain operations through at least the next twelve months.

Critical Accounting Policies and Significant Judgments and Estimates

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

Table of Contents**Results of Operations****Comparison of the nine months ended September 30, 2017, and 2016, from continuing operations**

	Nine Months Ended September 30,		Increase (decrease)	
	2017	2016	Amount	Percentage
	(in thousands)			
Operating expenses:				
Research and development	\$ 2,046	\$ 1,959	\$ 87	4%
Sales and marketing	26		26	
General and administrative	4,900	4,532	368	8%
Total	6,972	6,491	481	7%
Loss from operations	(6,972)	(6,491)	(481)	7%
Interest Income	7		7	%
Change in fair value of warrants	(29)	1,295	(1,324)	(102)%
Cease-use expense	3	(94)	97	(103)%
Other income (expense)	(602)	(26)	(576)	2,215%
Interest and other income (expense), net	(621)	1,175	(1,803)	(153)%
Loss from continuing operations	(7,593)	(5,316)	(2,284)	43%
Loss from discontinued operations:				
Operating	(2,841)	(4,136)	1,295	(31)%
Non-operating	(208)		(208)	%
Total	(3,049)	(4,136)	1,087	(26)%
Net loss	\$ (10,642)	\$ (9,452)	\$ (1,190)	13%

Revenue

During the quarter, the business component associated with sales of Serenz was determined to meet the criteria as a discontinued operations and, accordingly, operating activities for the Serenz product component is reported in Discontinued Operations for the nine months ended September 30, 2017, and 2016.

Cost of product revenue

During the quarter, the business component associated with sales of Serenz was determined to meet the criteria as a discontinued operations and, accordingly, operating activities for the Serenz product component is reported in Discontinued Operations for the nine months ended September 30, 2017, and 2016.

Research and development expense

Research and development expense in the nine months ended September 30, 2017, increased \$87,000 as compared to the nine months ended September 30, 2016. The decrease was primarily due to reduction in headcount.

Sales and marketing expense

Sales and marketing expense, which consisted primarily of costs incurred in the United Kingdom, in the nine months ended September 30, 2017, increased \$26,000 over the nine months ended September 30, 2016, primarily due to the cessation of sales of Serenz in the United Kingdom.

General and administrative expense

General and administrative expense in the nine months ended September 30, 2017, increased \$368,000 compared to the nine months ended September 30, 2016, due primarily to expense for amortizing intangible assets acquired in the Essentialis acquisition.

Table of Contents***Interest and other income (expense), net***

Interest and other income/(expense) in the nine months ended September 30, 2017, decreased \$1.8 million to net interest and other expense of \$602,000 in the nine months ended September 30, 2017, compared to net interest and other income of approximately \$1.2 million in the nine months ended September 30, 2016, due primarily to the \$1.324 million decline in the fair value of warrants between the two comparative periods and from the expense of \$600 resulting from the value assigned to the commitment shares issued to Aspire Capital in January 2017 (see Note 7).

Comparison of the three months ended September 30, 2017, and 2016 from continuing operations

	Three Months Ended September 30,		Increase (decrease)	
	2017	2016	Amount	Percentage
	(in thousands)			
Operating expenses:				
Research and development	\$ 982	\$ 708	\$ 274	39%
General and administrative	1,707	1,260	447	35%
Total	2,689	1,968	721	37%
Loss from operations	(2,689)	(1,968)	(721)	37%
Interest Income	4		4	%
Change in fair value of warrants	130	200	(70)	(35)%
Other income (expense)	4	(9)	13	(144)%
Interest and other income (expense), net	138	191	(53)	(28)%
Loss from continuing operations	(2,551)	(1,777)	(774)	44%
Loss from discontinued operations:				
Operating	(1,027)	(973)	(54)	6%
Non-operating	(208)		(208)	%
Total	(1,235)	(973)	(262)	27%
Net loss	\$ (3,786)	\$ (2,750)	\$ (1,036)	38%

Revenue

During the quarter, the business component associated with sales of Serenz was determined to meet the criteria as a discontinued operations and, accordingly, operating activities for the Serenz product component is reported in Discontinued Operations for the three months ended September 30, 2017, and 2016.

Cost of product revenue

During the quarter, the business component associated with sales of Serenz was determined to meet the criteria as a discontinued operations and, accordingly, operating activities for the Serenz product component is reported in Discontinued Operations for the three months ended September 30, 2017, and 2016.

Research and development expense

Research and development expense in the three months ended September 30, 2017 increased \$274,000 compared to the three months ended September 30, 2016. The increase was due primarily to expenditures for clinical services to advance DCCR development and legal fees associated with intellectual property related to DCCR.

Sales and marketing expense

No sales and marketing expenses were reported in continuing operations during the three months ended September 30, 2017, and 2016 as the Company's remaining sales operations are related to the Serenz product, which is included in discontinued operations.

Table of Contents

General and administrative expense

General and administrative expense in the three months ended September 30, 2017 increased \$447,000 compared to the three months ended September 30, 2016, due primarily to the expense of amortizing intangible assets acquired in the Essentialis merger completed in March 2017.

Interest and other income (expense), net

Interest and other expense, net in the three months ended September 30, 2017 decreased \$53,000 compared to the three months ended September 30, 2016, due primarily to the change in the fair value of the Series A warrants.

Comparison of the three and nine months ended September 30, 2017, and 2016, from discontinued operations

Revenue

During the nine months ended September 30, 2017, and 2016, the Company's revenues were generated by product sales for the CoSense, Precision Sampling Sets, Serenz, and NFI, whose product portfolio consists of neonatology resuscitation devices. These medical device products are associated with operations discontinued by the Company and sales have declined as the Company has focused its efforts sell or otherwise monetize these operations. Sales by the Company of the NFI products ceased in July 2017 when the Company sold NFI to Holdings (see Note 5).

Cost of product revenue

Cost of product revenue has declined in relation to the decrease in sales activity, and resulting decrease in revenue, for the CoSense, Precision Sampling Sets, Serenz, and NFI products for which sales have declined as the Company has focused effort sell or otherwise monetize these discontinued operations.

Research and development expense

Research and development expense related to the CoSense, Precision Sampling Sets and NFI products, whose products are has declined as development efforts have been redirected by the Company to its therapeutic product, DCCR, into late-stage clinical development.

Sales and marketing expense

Sales and marketing expense, which consisted primarily of expenses incurred in the United Kingdom with efforts associated with the Company's sales effort for its discontinued Serenz products rimirly due to the cessation of sales of Serenz in the United Kingdom and the reduction of sales of all medical device products in the United States.

General and administrative expense

General and administrative expense associated with discontinued development and sale of medical device products reflects additional legal and professional expenses associated with efforts to reduce operations of medical device products and actively focus on efforts to sell or otherwise monetize thse operations..

Other income and (expense)

Other income and expense associated with discontinued operations has been nominal in the periods reported.

Loss on sale of assets

In July 2017 the Company completed the sale of stock of its wholly-owned subsidiary, NFI. The Company recorded a loss on the sale in the amount of \$208,000 as the net book value of assets sold in the amount of \$1.185 million exceeded the total proceeds of \$977,000 (see Note 5).

Table of Contents**Liquidity and Capital Resources**

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

	Nine Months Ended September 30, 2017 2016 (in thousands)	
Cash Flows		
Net cash used in continuing operating activities	\$ (4,641)	\$ (5,956)
Net cash used in discontinued operating activities	(2,577)	(4,853)
Net cash used in operating activities	(7,218)	(10,809)
Net cash used in continuing investing activities	(577)	(22)
Net cash used in discontinued investing activities	716	(17)
Net cash used in investing activities	139	(39)
Net cash provided by continuing financing activities	10,000	10,768
Net cash provided by discontinued financing activities		
Net cash provided by financing activities	10,000	10,768
Net increase (decrease) in cash and cash equivalents		
Continuing operations	4,783	4,790
Discontinued operations	(1,862)	(4,870)
Net increase (decrease) in cash and cash equivalents	\$ 2,921	\$ (80)

Continuing Operations***Cash used in operating activities***

During the nine months ended September 30, 2017, operating activities used net cash of approximately \$4.6 million, which was primarily due to the use of funds resulting in the operating loss of \$7.6 million, partially offset by non-cash expenses which were primarily \$1.0 million of non-cash amortization and depreciation, approximately \$855,000 of non-cash stock compensation expense, approximately \$600,000 of non-cash expense for issuing shares to Aspire Capital, and approximately \$200 thousand non-cash expense for board member fees paid with shares of the Company's stock.

During the nine months ended September 30, 2016, net cash used in operating activities was \$6.0 million, which was due primarily to the use of funds resulting in the operating loss of approximately \$5.3 million, including costs incurred to launch Serenz in the E.U. and excluding the non-cash income of \$1.3 million from change in fair value of warrants, all of which were partially offset by approximately \$560,000 of non-cash expense for stock-based compensation

expense.

Cash used in investing activities

During the nine months ended September 30, 2017, we used \$577,000 for investing activities resulting from \$573,000 expenses incurred resulting from our merger with Essentialis and for the purchase of property and equipment in the amount of \$4,000.

Cash provided by financing activities

During the Nine months ended September 30, 2017, cash provided by financing activities was \$10 million resulting from the completion of the concurrent financing associated with the Essentialis merger.

During the nine months ended September 30, 2016, cash provided by financing activities was \$10.8 million resulting from the second close under the 2015 Sabby Purchase Agreement and from the first and second close under the 2016 Sabby Purchase Agreement.

Table of Contents

On March 7, 2017, the Company completed the merger with Essentialis. Concurrently, the Company 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.

As of September 30, 2017, The Company had cash and cash equivalents of approximately \$5.6 million.

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

Discontinued Operations

Cash used in operating activities

Net cash used in operating activities for the nine months ended September 30, 2017 totaled \$2.6 million compared to \$4.9 million for the nine months ended September 30, 2016 representing a decrease of \$2.3 million. The decrease was primarily due to the lower comparative level of operating activities for the discontinued operations which resulted in lower cash requirements during the first half of 2017.

Cash used in investing activities

Net cash provided by investing activities for the nine months ended September 30, 2017 totaled \$716,000 compared to net cash used of \$17,000 for investing activities in the nine months ended September 30, 2016, resulting primarily from the sale of the NFI operations in July 2017 which eliminated operating expenditures from that activity and for cash proceeds of \$862,000 from the sale collected prior to September 30, 2017.

Cash provided by financing activities

There were no financing activities related to discontinued operations during either period.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Table of Contents**BUSINESS****Company Overview**

Our primary focus is on the development and commercialization of novel therapeutics for the treatment of rare diseases. We are developing DCCR as a treatment for Prader Willi Syndrome, or PWS, a complex metabolic/neurobehavioral disorder. Our current research and development efforts are primarily focused on advancing our DCCR tablets into late-stage clinical development.

Since December 2017, we have, through our joint venture with OAHL, continued to operate Capnia for the development and commercialization of Capnia's Sensalyze technology, which includes the CoSense ETCO monitor that assists in the detection of excessive hemolysis in neonates, and other related products. We continue to separately evaluate options for our Serenz product 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 (K_{ATP}). The K_{ATP} channel links the cellular energy status to the membrane potential. Diazoxide appears to act on signs and symptoms of PWS in a variety of ways. Agonizing the K_{ATP} channel in the hypothalamus has the potential to address hyperphagia, which is an abnormally increased appetite for food. Agonizing the channel in GABAergic neurons improves GABA signaling and may reduce aggressive behaviors.

In the U.S., diazoxide was first approved in 1973 as an intravenous formulation for the emergency treatment of malignant hypertension. In 1976, immediate-release oral formulations, including Proglycem[®] Oral Suspension and Capsules, or Proglycem, were approved 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.

Table of Contents

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 improves activity and stamina. The behavioral and cognitive symptoms rated by respondents as very or most important were: 85.2% indicated reduction of obsessive/compulsive behavior, 84.6% 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 of DCCR in the treatment of PWS subjects. This study, PC025, was a single-center, randomized withdrawal study and enrolled 13 overweight and obese subjects with genetically-confirmed PWS who were between the ages of 11 and 21. The first phase of the study was open label during which subjects were initiated on a DCCR dose that was escalated every 14 days at the discretion of the investigator. Any subject who showed an increase in resting energy expenditure and/or a reduction in hyperphagia from baseline at certain study visits would be designated a responder, whereas all others would be designated non-responders. This 10-week open-label treatment phase was followed by randomized double-blind, placebo-controlled, withdrawal phase. Responders were randomized in a 1:1 ratio either to continue on active treatment at the dose they were treated with, or to the placebo equivalent of that dose for an additional 4 weeks. Of the 13 subjects who enrolled, 11 were designated as responders; the remaining two subjects had discontinued prematurely.

Key efficacy results included a statistically significant reduction was seen 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 was seen. 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.

Table of Contents

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. On September 25, 2017 we announced the receipt of scientific advice from the European Medicines Agency, or EMA. 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.

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.

Table of Contents

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. 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.

On May 8, 2017, we 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.

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.

Table of Contents

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 K_{ATP} 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.

Table of Contents

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 can be tested in humans, it must be studied in laboratory experiments and in animals to generate data to support the drug candidate's potential benefits and/or safety. Additional nonclinical testing may be required during the clinical development process such as reproductive toxicology and juvenile toxicology studies. Carcinogenicity studies in 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 I. 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 health 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.

Table of Contents

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.

Table of Contents

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 FFDC. 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

Table of Contents

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.

Table of Contents

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.

Table of Contents

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

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

U.S. Healthcare Reform

In March 2010, the PPACA was enacted, which includes measures that have or will significantly change the way healthcare is financed by both governmental and private insurers. Beginning in August 2013, the PPACA and its implementing regulations requires medical device manufacturers to track certain financial arrangements with physicians and teaching hospitals, including any transfer of value made or distributed to such entities, as well as any investment interests held by physicians and their immediate family members. Manufacturers are required to report this information to Centers for Medicare & Medicaid Services, or CMS, beginning in 2014. Various states have also implemented regulations prohibiting certain financial interactions with healthcare professionals or mandating public disclosure of such financial interactions. We may incur significant costs to comply with such laws and regulations now or in the future.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Recent Developments

On December 11, 2017, we entered into the Unit Purchase Agreement with the selling 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 the selling stockholders, pursuant to which, among other things, we are preparing and filing this registration statement with the SEC to register for resale the Resale Shares.

On December 8, 2017, we announced that we and our previously wholly-owned subsidiary Capnia entered into a joint venture agreement with 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. 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.

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.

On October 12, 2017 we announced that the European Medicines Agency's (EMA) Committee for Orphan Medicinal Products (COMP) issued a positive opinion recommending diazoxide choline for designation as an orphan medicinal product for the treatment of Prader-Willi Syndrome (PWS). The designation has subsequently been granted as EU/3/17/1941.

Table of Contents

On October 11, 2017, we announced the issuance of a new patent (9,782,416) from the U.S. Patent and Trademark Office related to the use of pharmaceutical formulations of diazoxide to treat hyperphagia in a subject with PWS. The treatment of hyperphagia is the highest priority unmet need in PWS according to parents and caregivers of PWS patients.

On September 25, 2017, we announced that we had received scientific 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 September 13, 2017, we announced the issuance of a new patent (9,757,384) from the U.S. Patent and Trademark Office related to the use of pharmaceutical formulations of diazoxide and its salts, such as diazoxide choline, to reduce one or more aggressive behaviors in a subject with PWS or Smith-Magenis syndrome (SMS). This issuance extends protection of the associated claims to 2035.

On July 24, 2017, we announced the sale of our entire interest in NFI, a previously wholly-owned non-strategic subsidiary, which manufactures and promotes a range of innovative pulmonary resuscitation solutions in the neonatal market, to Flexicare, Inc., a privately-held, leading UK based manufacturer of airway management, anesthesia and critical care medical devices. The sale occurred on July 18, 2017.

On July 5, 2017, we announced the receipt of minutes from an FDA scientific guidance meeting. 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.

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.

Table of Contents

DESCRIPTION OF PROPERTIES

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

Table of Contents

LEGAL PROCEEDINGS

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

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

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

Table of Contents**MANAGEMENT****Directors and Executive Officers**

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

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

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

* resigned on September 11, 2017.

** transitioned from Soleno Therapeutics to Capnia on or about December 4, 2017.

*** resigned from the Board on December 31, 2017.

Executive Officers

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

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

David D. O Toole. Mr. O Toole was appointed as our Chief Financial Officer in July 2014. He has more than 30 years of experience in the accounting and finance sectors, and for the past 14 years has focused on the medical device, tools, and diagnostics industry. From September 2012 to June 2014 Mr. O Toole was Senior Vice President and Chief Financial Officer at Codexis, Inc., a public company focused on developing biocatalysts. From May 2010 to August 2012 Mr. O Toole was Vice President and Chief Financial Officer at Response Genetics, Inc., and served from May 2008 to August 2010 as Executive Vice President and Chief Financial Officer of Abraxis Bioscience, Inc. From 1992 to 2008, Mr. O Toole worked at Deloitte &

Table of Contents

Touche LLP, where he served for 12 of those years as a partner. He worked at Arthur Anderson & Co., from 1984 to 1992, as an international tax manager. Mr. O Toole received his Bachelor of Science, Accounting from the University of Arizona and is a certified public accountant.

We believe Mr. OToole was able to make valuable contributions as an executive officer of our company as a result of his prior financial experience in related industries that are applicable to us. Mr. O Toole resigned effective September 11, 2017.

Anthony Wondka. Mr. Wondka was appointed as Senior Vice President of Research and Development of Capnia, Inc. in connection with a joint venture agreement entered into on December 4, 2017 with OptAsia Healthcare Limited. Prior to that, he was our Vice President of Research and Development since June 2013 and was a consultant for us from May 2011 to June 2013. He has held management and executive positions in the medical device industry for over 20 years, in large and small companies. From April 2006 to March 2011, Mr. Wondka served as VP of R&D and then VP of Technology and Clinical Affairs for Breathe Technologies, where he invented and co-invented ventilation products that address large unmet needs in chronic obstructive pulmonary disease, or COPD, and obstructive sleep apnea. From July 1997 to April 2006, Mr. Wondka was Director of R&D and VP of Manufacturing at Pulmonx, where he co-invented and led the early development of the Chartist diagnostic system and procedure that is used to guide endobronchial lung volume reduction for the treatment of COPD, and is currently being sold in the E.U. Prior to Pulmonx, Mr. Wondka worked at Pfizer subsidiary Shiley (acquired by Covidien) and Bear Medical (acquired by Carefusion), where he held lead roles in engineering and quality assurance, supporting commercialization activities for market leading ear, nose and throat, or ENT, and respiratory products. He holds over 40 issued or pending patents and has a B.S. in Bioengineering from University of California San Diego.

We believe Mr. Wondka was able to make valuable contributions as an executive officer of our company as a result of his prior technical experience in our industry and related industries.

Non-Employee Directors

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

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

Edgar G. Engleman, M.D. Dr. Engleman was a member of our board of directors from June 2001 until December 2017. He is a founding member of Vivo Ventures, LLC (formerly BioAsia Investments) and since 1990 has served as Professor of Pathology and Medicine at Stanford University School of Medicine, where he oversees the Stanford Blood Center as well as his own immunology research group. An editor of numerous scientific journals and the inventor of multiple patented technologies, Dr. Engleman has authored more than 250 publications in medical and scientific journals and has trained more than 200 graduate students and postdoctoral fellows. Dr. Engleman has co-founded a number of biopharmaceutical companies including Cetus Immune Corporation (acquired by Chiron Corporation), Genelabs Technologies, Inc., (acquired by GlaxoSmithKline plc), National Medical Audit, and Dendreon Corporation. He is the lead inventor of the technology

Table of Contents

underlying Provenge, Dendreon's cancer vaccine, which was approved in 2010 to treat asymptomatic or minimally symptomatic metastatic hormone-refractory prostate cancer. Dr. Engleman currently serves on the boards of several private biotechnology companies, including Gryphon Therapeutics, Inc., Naryx Pharma, Inc., Eiger BioPharma, Inc., Nuveta, Inc. and Semnur Pharmaceuticals, Inc. He received his M.D. from Columbia University School of Medicine and his B.A. from Harvard University.

We believe Dr. Engleman was able to make valuable contributions to our board of directors due to his extensive knowledge of the healthcare industry, his medical expertise, his service on other company boards of directors, and his understanding of our company.

Steinar J. Engelsen, M.D., M.Sc., CEFA. Dr. Engelsen was a member of our board of directors from April 2004 until December 2017. Since November 1996, Dr. Engelsen has been a partner of Teknoinvest AS, a venture capital firm based in Norway. From June 1989 until October 1996, Dr. Engelsen held various management positions within Hafslund Nycomed AS, a pharmaceutical company based in Europe, and affiliated companies. He was responsible for therapeutic research and development, most recently serving as Senior Vice President, Research and Development of Nycomed Pharma AS from January 1994 until October 1996. He currently serves on the board of directors of Insmmed, Inc. In addition, from January to November 2000, Dr. Engelsen was acting Chief Executive Officer of Centaur Pharmaceuticals, Inc., a biopharmaceutical company. Dr. Engelsen also served as Chairman of the board of directors of Centaur. Dr. Engelsen received his M.Sc. in Nuclear Chemistry and his M.D. from the University of Oslo, and is a Certified European Financial Analyst from The Norwegian School of Economics.

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

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

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

Stephen Kirnon, Ed.D. Dr. Kirnon was a member of our board of directors from July 2002 until December 2017. He has over 20 years of operational experience in biomedical organizations. Since January 2009, he has served as the Co-founder and CEO of PharmaPlan LLC. From January 2012 until July 2013 he served as Vice President, Co-Lead Life Science Practice at Witt/Kieffer, Ford, Hadelman, Lloyd Corp. Prior to that, Dr. Kirnon was the President and Chief Executive Officer of Pepgen Corporation, a biopharmaceutical company based in Alameda, California, specializing in autoimmune diseases. He was formerly the President and CEO of Target Protein Technologies, Inc., a pharmaceutical company based in San Diego and specializing in the development of pharmaceutical compounds targeted to specific tissues and organs of the human body. Prior to TPT, he was the President and COO and a member of the board of Yamanouchi Pharma Technologies, Inc., which is responsible for developing and commercializing Yamanouchi's proprietary drug delivery technologies as well as the U.S. development and manufacture of

Yamanouchi's pharmaceuticals. Previously, Dr. Kirnon was the President of the Drug Delivery Division of Cygnus, Inc., successfully leading that Division into profitability and subsequently through sale of its business. Dr. Kirnon has also held various business development, sales, and marketing positions at Cygnus, Biogenex Laboratories, Inc., and GlaxoSmithKline plc. Dr. Kirnon received his doctorate in organization change and transformational leadership from as well as his M.B.A. from Pepperdine University, where he is an Adjunct Professor. He received a B.A. degree in Biochemistry from Harvard University. He is also a trustee of the New England College of Optometry.

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

Rajen Dalai. Mr. Dalai joined our Board of Directors in April 2016. Mr. Dalal has served as the CEO and board member of several medical device companies including from 2011-2015, ReLIA Diagnostic Systems, Inc., a point-of-care diagnostics company selling blood tests used in emergency medicine. Mr. Dalal also served from 2008 to 2010 on the board of Singapore based A-Bio Pharma and Dx Assays, from 2006 to 2008 as CEO and director of Aviiir, a medical device company which commercialized multi-protein biomarker test for detecting risk of acute myocardial infarction, from 2003 to 2008 on the board of directors for Vermillion, a public ovarian cancer diagnostics company, from 2002 to 2005 as CEO and a director of Guava Technologies, which commercialized a low cost bench top flow cytometer for HIV/AIDS testing (US FDA cleared), and from 2000 to 2002 on the HHS Committee for Blood Safety and Availability. Mr. Dalal was previously with Chiron as President of its Blood Testing division (HIV/HCV/retroviral nucleic acid and immune testing) as well as its Vice President, Corporate Development. Prior to working in biotech, Mr. Dalai was at McKinsey & Co in New York and Cleveland. He is a graduate of the University of Chicago, MIT and St. Xavier's College, Bombay with degrees in business, biochemical engineering and chemistry respectively.

Table of Contents

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

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

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

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

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

James Glasheen. Dr. Glasheen has been a member of our Board of Directors since March 2017. Since 2002, Dr. Glasheen has served as a general partner with Technology Partners, a venture capital firm that focuses on clean tech and life science companies. Prior to his work at Technology Partners, he served as Managing Director of CIT Venture Capital. From 1996 to 2000, he was a leader within McKinsey & Company's Pharmaceutical and Medical Products Practice. Dr. Glasheen holds a B.S. from Duke University and an M.A. and Ph.D. from Harvard University.

We believe Dr. Glasheen is able to make valuable contributions to our Board of Directors due to his experience facilitating the growth of venture-backed companies, his experiences with McKinsey & Company and his consumer medical company expertise.

Table of Contents

Board Composition

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

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

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

The Class II director is Dr. Glasheen, and the terms will expire at our annual meeting of stockholders to be held in 2019; and

The Class III directors are Drs. Bhatnagar, Collinson and Mario and Mr. Harris, and their terms will expire at our annual meeting of stockholders to be held in 2020.

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

Director Independence

Under the listing requirements and rules of The NASDAQ Capital Market, or NASDAQ, independent directors must comprise a majority of a listed company's board of directors, subject to certain phase-ins.

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

Board Leadership Structure

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

Table of Contents

Board Committees

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

Audit committee

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

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

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

Compensation committee

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

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

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

Nominating and corporate governance committee

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

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

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

Role in Risk Oversight

Our board of directors oversees an enterprise-wide approach to risk management, designed to support the achievement of business objectives, including organizational and strategic objectives, to improve long-term organizational performance and enhance stockholder value. The involvement of our board of directors in setting our business strategy is a key part of its

Table of Contents

assessment of management's plans for risk management and its determination of what constitutes an appropriate level of risk for our company. The participation of our board of directors in our risk oversight process includes receiving regular reports from members of senior management on areas of material risk to our company, including operational, financial, legal and regulatory, and strategic and reputational risks.

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

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

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

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

Code of Business Conduct and Ethics

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

Compensation Committee Interlocks and Insider Participation

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

Non-Employee Director Compensation

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

The following table sets forth information regarding compensation earned by our non-employee directors during the fiscal year ended December 31, 2017.

Name	Cash Compensation	Option Awards(1)	Stock Awards	Total
Edgar G. Engleman(2)	\$ 8,750	\$ 19,707	\$ 26,250	\$ 54,707
Ernie Mario(3)	\$ 15,000	\$ 19,707	\$ 45,000	\$ 79,707
Steinar J. Engelsen(4)	\$ 14,000	\$ 19,707	\$ 42,000	\$ 75,707
Stephen Kirnon(5)	\$ 13,625	\$ 19,707	\$ 40,875	\$ 74,207
William G. Harris(6)	\$ 13,750	\$ 19,707	\$ 41,250	\$ 74,707

Table of Contents

Rajen Dalal(7)	\$ 9,625	\$ 19,707	\$ 28,875	\$ 58,207
James Glasheen (8)	\$ 2,375	\$ 27,207	\$ 30,000	\$ 59,582
Stuart Collinson (9)	\$ 2,363	\$ 27,207	\$ 28,875	\$ 58,445
Mahendra Shah (10)		\$ 27,207	\$ 26,250	\$ 53,457

- (1) The amounts in this column reflect the aggregate grant date fair value of each option award granted during the fiscal year, computed in accordance with FASB ASC Topic 718. The valuation assumptions used in determining such amounts are described in Note 6 and Note 9 to our financial statements included in this prospectus. The table below lists the aggregate number of shares and additional information with respect to the outstanding option awards held by each of our non-employee directors.
- (2) Dr. Engleman joined our Board in June 2001. During 2017, Dr. Engelman was granted 9,027 shares of our common stock, of which 100% of the shares vest on the earlier of the 12 month anniversary of the date of grant or the day before the next annual meeting of stockholders. Dr. Engleman resigned from our Board effective December 31, 2017.
- (3) Dr. Mario joined our Board in August 2007. During 2017, Dr. Mario was granted 9,027 shares of our common stock, of which 100% of the shares vest on the earlier of the 12 month anniversary of the date of grant or the day before the next annual meeting of stockholders.
- (4) Dr. Engelsen joined our Board in April 2004. During 2017, Dr. Engelsen was granted 9,027 shares of our common stock, of which 100% of the shares vest on the earlier of the 12 month anniversary of the date of grant or the day before the next annual meeting of stockholders. Dr. Engelsen resigned from our Board effective December 31, 2017.
- (5) Dr. Kirnon joined our Board in July 2002. During 2017, Dr. Kirnon was granted 9,027 shares of our common stock, of which 100% of the shares vest on the earlier of the 12 month anniversary of the date of grant or the day before the next annual meeting of stockholders. Dr. Kirnon resigned from our Board effective December 31, 2017.
- (6) Mr. Harris joined our Board in June 2014. During 2017, Mr. Harris was granted 9,027 shares of our common stock, of which 100% of the shares vest on the earlier of the 12 month anniversary of the date of grant or the day before the next annual meeting of stockholders.
- (7) Mr. Dalal joined our Board in April 2016. During 2017, Mr. Dalal was granted 9,027 shares of our common stock, of which 100% of the shares vest on the earlier of the 12 month anniversary of the date of grant or the day before the next annual meeting of stockholders.
- (8) Dr. Glasheen joined our Board in March 2017. During 2017, Dr. Glasheen was granted an option to purchase 9,027 shares, of which 100% of the shares vest on the earlier of the 12 month anniversary of the date of grant or the day before the next annual meeting of stockholders, and an option to purchase 4,000 shares, which vests as to 1/48th of the shares each month, in each case subject to continued service through each such date.
- (9) Dr. Collinson joined our Board in March 2017. During 2017, Dr. Collinson was granted an option to purchase 9,027 shares, of which 100% of the shares vest on the earlier of the 12 month anniversary of the date of grant or the day before the next annual meeting of stockholders, and an option to purchase 4,000 shares, which vests as to 1/48th of the shares each month, in each case subject to continued service through each such date.
- (10) Dr. Shah joined our Board in March 2017. During 2017, Dr. Shah was granted an option to purchase 9,027 shares, of which 100% of the shares vest on the earlier of the 12 month anniversary of the date of grant or the day before the next annual meeting of stockholders, and an option to purchase 4,000 shares, which vests as to 1/48th of the shares each month, in each case subject to continued service through each such date.

Our board of directors has adopted a non-employee director compensation policy pursuant to which we will compensate our non-employee directors with a combination of cash and equity. Each such director will receive an annual base cash retainer of \$35,000 for such service, to be paid quarterly in the form of shares of our common stock. Each non-employee director will receive an annual stock option grant to purchase that number of shares representing,

as of the date of grant, \$32,500 of value, which shall be granted effective as of the date of each annual stockholder meeting, and share vest as to 100% of the shares on the earlier of the 12 month anniversary of the date of grant or the day before the next annual stockholder meeting. New members elected to the board of directors shall receive a stock option grant to purchase 20,000 shares of common stock, which shall vest monthly over four years. The policy also provides that we compensate certain members of our Board of Directors for service on our committees as follows:

The chair or executive chair of our board of directors will receive an annual cash retainer of \$25,000 for such service, paid quarterly;

The chairperson of our audit committee will receive an annual cash retainer of \$15,000 for such service and each other member of the audit committee will receive an annual cash retainer of \$7,500 for such service, paid quarterly;

The chairperson of our compensation committee will receive an annual cash retainer of \$10,000 for such service and each other member of the compensation committee will receive an annual cash retainer of \$5,000 for such service, paid quarterly; and

The chairperson of our nominating and corporate governance committee will receive an annual cash retainer of \$7,000 for such service and each other member of the nominating and corporate governance committee will receive an annual cash retainer of \$3,500, paid quarterly.

Table of Contents**EXECUTIVE COMPENSATION**

As an emerging growth company, we have opted to comply with the executive compensation disclosure rules applicable to smaller reporting companies, as such term is defined in the rules promulgated under the Securities Act, which require compensation disclosure for our principal executive officer and the two most highly compensated executive officers other than our principal executive officer. Our named executive officers for the year ended December 31, 2017 are:

Anish Bhatnagar, M.D., our Chief Executive Officer, President and Chief Operating Officer;

David D. O Toole, our Senior Vice President, Chief Financial Officer; and

Anthony Wondka, our Senior Vice President, Research & Development.

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

2017 Summary Compensation Table

The Summary Compensation Table below sets forth information regarding the compensation awarded to or earned by our named executive officers during the years ended December 31, 2017, 2016, and 2015.

Summary Compensation Table

Name and Position	Year Ended December 31,	Salary	Bonus(1)	Non-qualified Incentive Compensation			Total
				Stock Awards	Option Awards	Deferred Compensation	
Anish Bhatnagar Chief Executive Officer, President and Chief Operating Officer	2017	\$ 446,000	230,000	\$ 612,000			\$ 1,288,000
	2016	\$ 460,000		\$ 499,243			\$ 959,243
	2015	\$ 435,156	\$ 185,000	\$ 570,100			\$ 1,190,256
David D. O Toole Senior Vice President, Chief Financial Officer	2017	\$ 229,000		\$ 129,000			\$ 358,000
	2016	\$ 300,000		\$ 125,133			\$ 425,133
	2015	\$ 265,000	\$ 47,950	\$ 108,732			\$ 421,682
Anthony Wondka Senior Vice President, Research & Development	2017	\$ 270,000		\$			\$ 270,000
	2016	\$ 266,500		\$ 73,346			\$ 339,846
	2015	\$ 262,375	\$ 45,500	\$ 111,476			\$ 419,351

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

accrued.

- (2) The amounts in this column reflect the aggregate grant date fair value of each option award granted during the fiscal years ended December 31, 2017, 2016 and 2015, as applicable, computed in accordance with FASB ASC Topic 718. The valuation assumptions used in determining such amounts are described in the Notes to our audited financial statements for the year ended December 31, 2017, 2016 and 2015.

Employment offer letters and Employment Agreements

We have entered into employment agreements with our named executive officers. The employment agreements provide for at-will employment and set forth the terms and conditions of employment, including annual base salary, target bonus opportunity, equity compensation, severance benefits and eligibility to participate in our employee benefit plans and programs. In connection with their employment, our named executive officers were each also required to execute our standard proprietary information and inventions agreement. The material terms of these employment agreements are summarized below. These summaries are qualified in their entirety by reference to the actual text of the employment agreements, which were filed as exhibits to the Current Report on Form 8-K that was filed with the SEC on May 20, 2015.

Table of Contents

Agreement with Anish Bhatnagar

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

Agreement with David D. O Toole

We entered into an employment agreement with Mr. O Toole, dated May 15, 2015, pursuant to which Mr. O Toole serves as our Senior Vice President, Chief Financial Officer. The agreement provides for at-will employment and sets forth certain agreed upon terms and conditions of employment. Mr. O Toole's annual base salary was \$300,000. Mr. O Toole resigned effective September 11, 2017.

Agreement with Anthony Wondka

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

Potential payments and benefits upon termination or change of control

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

If Dr. Bhatnagar's termination or resignation occurs prior to six (6) months before a Change in Control (as defined in Dr. Bhatnagar's employment agreement) of the Company: (i) continuing payments of severance pay at a rate equal to Dr. Bhatnagar's base salary rate for fifteen (15) months from the date of such termination without Cause or resignation for Good Reason; (ii) if Dr. Bhatnagar elects continuation coverage pursuant to the Consolidated Budget Reconciliation Act of 1985 (COBRA), then the Company will reimburse Dr. Bhatnagar on the last day of each month for a period ending fifteen (15) months after Dr. Bhatnagar's termination date for the COBRA premiums paid during such period for such coverage (at the coverage levels in effect immediately prior to Dr. Bhatnagar's termination); and (iii) twenty-five percent (25%) of any unvested equity awards held by Dr. Bhatnagar as of the date of such termination without Cause or resignation for Good Reason shall immediately vest and become fully exercisable;

If such termination or resignation occurs within six (6) months prior to, or twelve (12) months following, a Change in Control of the Company: (i) continuing payments of severance pay at a rate equal to Dr. Bhatnagar's base salary rate for eighteen (18) months from the date of such termination without Cause or resignation for Good Reason; (ii) if Dr. Bhatnagar elects continuation coverage pursuant to COBRA, then the Company will reimburse Dr. Bhatnagar on the last day of each month for a period ending eighteen (18) months after Dr. Bhatnagar's termination date for the COBRA premiums paid during such period for

such coverage (at the coverage levels in effect immediately prior to Dr. Bhatnagar's termination); (iii) a payment equal to one hundred fifty percent (150%) the annual target bonus opportunity for the year in which Dr. Bhatnagar is terminated without Cause or resigns for Good Reason; and (iv) one hundred percent (100%) of any unvested equity awards held by Dr. Bhatnagar as of the date of such termination without Cause or resignation for Good Reason shall immediately vest and become fully exercisable; and

If Dr. Bhatnagar is terminated without Cause or resigns for Good Reason during the term of Dr. Bhatnagar's employment agreement, then Dr. Bhatnagar shall have one year following such termination without Cause or resignation for Good Reason to exercise any then vested options.

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

if Mr. O Toole's termination or resignation occurred prior to three (3) months before a Change in Control (as defined in Mr. O Toole's employment agreement) of the Company: (i) continuing payments of severance pay at a rate equal to Mr. O Toole's base salary rate for six (6) months from the date of such termination without Cause or resignation for Good

Table of Contents

Reason; and (ii) if Mr. O Toole elected continuation coverage pursuant to COBRA, then the Company will reimburse Mr. O Toole on the last day of each month for a period ending six (6) months after Mr. O Toole's termination date for the COBRA premiums paid during such period for such coverage (at the coverage levels in effect immediately prior to Mr. O Toole's termination); and

If Mr. O Toole's termination or resignation occurred within three (3) months prior to, or six (6) months following, a Change in Control of the Company: (i) continuing payments of severance pay at a rate equal to Mr. O Toole's base salary rate for twelve (12) months from the date of such termination without Cause or resignation for Good Reason; (ii) if Mr. O Toole elected continuation coverage pursuant to COBRA, then the Company will reimburse Mr. O Toole on the last day of each month for a period ending twelve (12) months after Mr. O Toole's termination date for the COBRA premiums paid during such period for such coverage (at the coverage levels in effect immediately prior to Mr. O Toole's termination); (iii) a payment equal to one hundred percent (100%) the annual target bonus opportunity for the year in which Mr. O Toole was terminated without Cause or resigned for Good Reason; and (iv) one hundred percent (100%) of any unvested equity awards held by Mr. O Toole as of the date of such termination without Cause or resignation for Good Reason shall immediately vest and become fully exercisable.

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

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

If Mr. Wondka's termination or resignation occurred within three (3) months prior to, or six (6) months following, a Change in Control of the Company: (i) continuing payments of severance pay at a rate equal to Mr. Wondka's base salary rate for twelve (12) months from the date of such termination without Cause or resignation for Good Reason; (ii) if Mr. Wondka elected continuation coverage pursuant to COBRA, then the Company will reimburse Mr. Wondka on the last day of each month for a period ending twelve (12) months after Mr. Wondka's termination date for the COBRA premiums paid during such period for such coverage (at the coverage levels in effect immediately prior to Mr. Wondka's termination); (iii) a payment equal to one hundred percent (100%) the annual target bonus opportunity for the year in which Mr. Wondka was terminated without Cause or resigned for Good Reason; and (iv) one hundred percent (100%) of any unvested equity awards held by Mr. Wondka as of the date of such termination without Cause or resignation for Good Reason shall immediately vest and become fully exercisable.

Table of Contents**Outstanding Equity Awards at December 31, 2017**

The following table provides information regarding outstanding equity awards held by our named executive officers as of December 31, 2017.

Name	Grant Date	Number of Securities Underlying Unexercised Options		Option Exercise Price	Option Expiration Date
		Exercisable	Unexercisable		
Anish Bhatnagar					
	6/27/2008	2,333(1)		\$ 17.40	9/25/2018
	10/15/2008	1,666(1)		\$ 17.40	10/15/2018
	11/12/2014	76,191(2)	9,858	\$ 35.70	11/12/2024
	1/11/2015	37,199(2)	5,825	\$ 9.00	1/11/2025
	5/15/2015	22,032(4)	7,967	\$ 23.30	5/15/2025
	1/10/2016	28,750(3)	31,250	\$ 8.05	1/10/2026
	6/8/2016	41,410(2)	18,824	\$ 6.00	6/8/2026
	4/19/2017	128,926(4)	207,861	\$ 2.95	4/19/2027
David O Toole					
	11/12/2014	19,871(4)		\$ 35.70	11/12/2024
	1/11/2015	4,866(4)		\$ 9.00	1/11/2025
	5/15/2015	3,375(3)		\$ 23.30	5/15/2025
	1/10/2016	5,250(3)		\$ 8.05	1/10/2026
	6/8/2016	8,800(4)		\$ 6.00	6/8/2026
	4/19/2017	22,184(4)		\$ 2.95	4/19/2027
Anthony Wondka					
	6/3/2013	2,183(5)		\$ 9.00	6/3/2023
	11/12/2014	11,087(4)	2,301	\$ 35.70	11/12/2024
	1/11/2015	2,670(4)	676	\$ 9.00	1/11/2025
	5/15/2015	4,780(3)	2,619	\$ 23.30	5/15/2025
	1/10/2016	3,831(3)	4,168	\$ 8.05	1/10/2026
	6/8/2016	4,978(4)	4,394	\$ 6.00	6/8/2026

- (1) The options listed are fully vested or are subject to an early exercise right and may be exercised in full prior to vesting of the shares underlying such options. Vesting of all options is subject to continued service on each vesting date.
- (2) The shares subject to the stock option vest over a four-year period as follows: 50% of the shares underlying the options vest immediately on the vesting commencement date, and thereafter 1/48th of the shares vest each month, subject to the officer's continued service to us through each vesting date.
- (3) The shares subject to the stock option vest over a four-year period as follows: 1/48th of the shares vest each month beginning on the vesting commencement date, subject to the officer's continued service to us through each vesting date.
- (4) The shares subject to the stock option vest over a four-year period as follows: 25% of the shares underlying the option vest immediately on the vesting commencement date and thereafter 1/48th of the shares vest each month,

subject to the officer's continued service to us through each vesting date.

- (5) The shares subject to the stock option vest over a four-year period as follows: 25% of the shares underlying the option vest on the one-year anniversary of the vesting commencement date, and thereafter 1/36th of the shares vest each month, subject to the officer's continued service to us through each vesting date.

Securities Authorized for Issuance under Equity Compensation Plans

2014 Equity Incentive Plan

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

Table of Contents

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

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

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

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

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

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

Table of Contents

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

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

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

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

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

2014 Employee Stock Purchase Plan

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

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

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

immediately after the grant would own stock possessing 5% or more of the total combined voting power or value of all classes of our capital stock; or

hold rights to purchase stock under all of our employee stock purchase plans that accrue at a rate that exceeds \$25,000 worth of stock for each calendar year.

Table of Contents

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

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

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

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

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

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

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

Employee benefit plans

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

1999 Stock Plan

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

Table of Contents

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

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

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

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

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

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

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

Table of Contents

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

2010 Stock Plan

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

Plan administration. Our board of directors, or a duly authorized committee of our board of directors, may administer our 2010 Plan. Subject to the terms of our 2010 Plan, the administrator will have the power to administer the 2010 Plan, including but not limited to the power to interpret