SOLENO THERAPEUTICS INC
Form S-1/A
August 18, 2017

As filed with the Securities and Exchange Commission on August 18, 2017
Registration No. 333-215856

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

Post Effective Amendment No. 1
to
FORM S-1
REGISTRATION STATEMENT
Under
The Securities Act of 1933

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

Delaware	3,841	77-0523891
(State of Incorporation)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

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

Anish Bhatnagar
Chief Executive Officer
Soleno Therapeutics, Inc.
1235 Radio Road, Suite 110
Redwood City, CA 94065
(650) 213-8444
(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

Copies to:
Elton Satusky, Esq.
Eric Hsu, Esq.
Wilson Sonsini Goodrich & Rosati,
Professional Corporation
650 Page Mill Road
Palo Alto, CA 94304
(650) 493-9300

Approximate date of proposed sale to the public: From time to time after this Registration Statement becomes effective.

If any securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box: x

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

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. o

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price Per Security(2)	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee(3)
common stock, $0.001 par value	10,000,000	$0.835	$8,350,000.00	$967.77
Total	10,000,000	$0.835	$8,350,000.00	$967.77

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

(2) Pursuant to Rule 457(c), calculated on the basis of the average of the high and low prices per share of the registrant’s Common Stock on the NASDAQ Capital Market on January 31, 2017.

(3) The Registrant previously paid $967.77 in connection with the initial filing of this Registration Statement.

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

EXPLANATORY NOTE

On February 1, 2017, Soleno Therapeutics, Inc. (formerly known as Capnia, Inc.) (the "Company") filed a registration statement with the Securities and Exchange Commission (the "SEC") on Form S-1 (Registration No. 333-215856) which was supplemented by Prospectus Supplement No. 1 filed on March 1, 2017, Prospectus Supplement No. 2 filed on March 9, 2017, Prospectus Supplement No. 3 filed on March 21, 2017, Prospectus Supplement No. 4 filed on May 15, 2017, Prospectus Supplement No. 5 filed on May 15, 2017, Prospectus Supplement No. 6 filed on May 15, 2017, Prospectus Supplement No. 7 filed on July 14, 2017, and Prospectus Supplement No. 8 filed on July 24, 2017, (as supplemented, the "Registration Statement"). The Registration Statement was declared effective by the SEC on February 14, 2017 and registers for resale by the selling stockholders named in the prospectus up to 10,000,000 shares of the Company's Common Stock, par value $0.001 per share (the "Common Stock").

SOLENO THERAPEUTICS, INC.
Up to 10,000,000 Shares of common stock

This prospectus relates to the sale of up to 10,000,000 shares of our common stock by Aspire Capital Fund, LLC. Aspire Capital is also referred to in this prospectus as the selling stockholder. The prices at which the selling stockholder may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive proceeds from the sale of the shares by the selling stockholder. However, we may receive proceeds of up to $17.0 million from the sale of our common stock to the selling stockholder, pursuant to a common stock purchase agreement entered into with the selling stockholder on January 27, 2017, once the registration statement, of which this prospectus is a part, is declared effective.

The selling stockholders are considered as an "underwriter" within the meaning of the Securities Act of 1933, as amended. We will pay the expenses of registering these shares, but all selling and other expenses incurred by the selling stockholders will be paid by the selling stockholders.

Our common stock is listed on the Nasdaq Capital Market under the ticker symbol "SLNO." On August 17, 2017, the last reported sale price per share of our common stock was $0.435 per share.

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

Investing in our securities involves a high degree of risk. See "Risk Factors" on page 8 of this prospectus.

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

This prospectus is dated _____, 2017.

TABLE OF CONTENTS

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

PROSPECTUS SUMMARY

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

Recent Developments

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

Company Overview

On March 7, 2017, we completed our merger, or the Merger, with Essentialis, Inc., a Delaware corporation, or Essentialis. After the Merger, our primary focus is transitioning to the development and commercialization of novel therapeutics for the treatment of rare diseases. Essentialis was a privately held, clinical stage biotechnology company focused on the development of breakthrough medicines for the treatment of rare metabolic diseases where there is increased mortality and risk of cardiovascular and endocrine complications. Prior to the Merger, Essentialis's efforts were focused primarily on developing and testing product candidates that target the ATP-sensitive potassium channel, a metabolically regulated membrane protein whose modulation has the potential to impact a wide range of rare metabolic, cardiovascular, and CNS diseases. Essentialis has tested Diazoxide Choline Controlled Release Tablet, or DCCR, as a treatment for Prader-Willi Syndrome, or PWS, a complex metabolic/neurobehavioral disorder.

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

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

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

pulmonary resuscitation solutions for the neonatal market. We may also license elements of our Sensalyze Technology Platform to other companies that have complementary development or commercial capabilities. Our current research and development efforts are primarily focused on advancing our lead candidate, DCCR tablets for the treatment of PWS into late-stage clinical development.

Diazoxide Choline Controlled-Release Tablets

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

A pilot study was conducted between June 2014 and March 2016 to evaluate the safety and preliminary efficacy of DCCR in the treatment of PWS subjects. This study, PC025, was a single-center, randomized withdrawal study and enrolled 13 overweight and obese subjects with genetically-confirmed PWS who were between the ages of 10 and 22. The first phase of the study was open label during which subjects were initiated on a DCCR dose target and were dose escalated every 14 days at the discretion of the investigator. This open-label treatment phase was followed by randomized double-blind, placebo-controlled withdrawal phase. Changes from baseline in the aggressive, threatening, and destructive behavior subset of the 23-item PWS-associated behaviors questionnaire were evaluated. There was a statistically significant improvement in aggressive, threatening and destructive behaviors.

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

Recent Developments

Merger with Essentialis, Inc.

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

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

On March 7, 2017, we completed the Merger with Essentialis and issued 18,916,940 shares of common stock to stockholders of Essentialis. We held back 913,379 shares of common stock as partial recourse to satisfy indemnification claims, and such shares will be issued to Essentialis stockholders on the 1 year anniversary of the closing of the Merger. We are also obligated to issue an additional 4,566,948 shares of common stock to Essentialis stockholders upon the achievement of a development milestone. Assuming that we issue all of the shares of our common stock held back and the development milestone is achieved, we would issue a total of 24,397,267 shares of common stock to Essentialis stockholders. Additionally, upon the achievement of certain commercial milestones associated with the sale of Essentialis' product in accordance with the terms of the Merger Agreement, we are obligated to make cash earnout payments of up to a maximum of $30 million to Essentialis stockholders. The merger consideration described above will be reduced by any such shares of common stock issuable, or cash earnout payments payable, to Essentialis' management carve-out plan participants and other service providers of Essentialis, in

each case, in accordance with the terms of the Merger Agreement.

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

Risks Associated With Our Business

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

- We have a limited commercialization history and have incurred significant losses since our inception, and we anticipate that we will continue to incur substantial losses for the foreseeable future, which makes it difficult to evaluate our business and assess our future viability. As of June 30, 2017, we had an accumulated deficit of $105.2 million.
- We are significantly dependent upon the success of DCCR, our sole therapeutic product candidate and if we fail to obtain regulatory approval for DCCR in the U.S. and E.U., our business would be harmed. If we are unable to implement our sales, marketing, distribution, training and support strategies or enter into agreements with third parties to perform these functions in markets outside of the U.S. and E.U., we will not be able to effectively commercialize DCCR and may not reach profitability.
- The safety and preliminary efficacy results from the pilot study of DCCR conducted in the treatment of PWS subjects may not be indicative of the outcome of the proposed NDA-enabling clinical trial.
- CoSense may fail to achieve the degree of market acceptance by physicians, patients, caregivers, healthcare payors, and others in the medical community necessary for commercial success.
- The challenges involved in establishing distribution and sales operations may expose us to a higher than usual level of risk with respect to commercializing our products. We may be required to conduct additional clinical trials prior to obtaining additional approval for our products. We may not obtain such approvals for sale on a predictable timeframe, or at all.
- We have not manufactured the active drug ingredients contained in DCCR and there are risks associated with scaling up manufacturing. Our commercial manufacturing partners may not be successful in achieving the levels of production volume, quality, or manufacturing costs necessary to support commercial success.
- Our executive officers, directors and principal stockholders may continue to maintain the ability to control all matters submitted to stockholders for approval.
- We may need additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all, which would force us to delay, reduce, or suspend our research and development programs and other operations or commercialization efforts. Raising additional capital may subject us to unfavorable terms and cause dilution to our existing stockholders.
- Our business depends on our continuing to satisfy the FDA and any other applicable U.S. and international regulatory requirements with respect to medical diagnostics, devices or therapeutics, including requirements which may change or be created in the future.
- We need to obtain or maintain patents or other appropriate protection for the intellectual property utilized in our current and planned product offerings, and we must avoid infringement of third-party intellectual property.

Corporate information

We were incorporated in Delaware in August of 1999. Our principal executive offices are located at 1235 Radio Road, Suite 110, Redwood City, CA 94065, and our telephone number is (650) 213-8444. Our website address is www.soleno.life. The information contained on our website is not incorporated by reference into this prospectus, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus, or in deciding whether to purchase our securities. On May 12, 2017, we formally changed our corporate name from "Capnia, Inc." to "Soleno Therapeutics, Inc."

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

executive compensation.

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

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

The Offering	
Common stock being offered by the selling stockholder	10,000,000 shares
Selling Stockholders	Aspire Capital
Common stock outstanding	47,922,838 (as of August 8, 2017)
Use of proceeds	The selling stockholder will receive all of the proceeds from the sale of the shares offered for sale by it under this prospectus. We will not receive proceeds from the sale of the shares by the selling stockholder. However, we may receive up to $17.0 million in proceeds from the sale of our common stock to the selling stockholder under the common stock purchase agreement described below. Any proceeds from the selling stockholder that we receive under the common stock purchase agreement are expected to be used for working capital and general corporate purposes.
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 5,914,016 shares of our common stock issuable upon exercise of outstanding stock options, 7,553,936 shares of our common stock available for future issuance under the stock option plans, outstanding warrants exercisable for 602,109 shares of our common stock, 11,979,000 shares of our common stock issuable upon the conversion of our outstanding Series B Convertible Stock, 2,425,605 shares of our common stock issuable upon exercise of our outstanding Series A Warrants, 590,415 shares of our common stock issuable upon exercise of our outstanding Series C Warrants, 2,930,812 shares of our common stock issuable upon exercise of our outstanding Series D Warrants, each of which securities are outstanding or available for issuance as of August 8, 2017.

Sale of Common Stock to Aspire Capital

On January 27, 2017, we entered into a common stock purchase agreement, or the Purchase Agreement, with Aspire Capital Fund, LLC, an Illinois limited liability company, or Aspire Capital or a selling stockholder, 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 of our shares of common stock over the approximately thirty month term of the Purchase Agreement. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, we issued to Aspire Capital 708,333 shares of our common stock as a commitment fee, or the Commitment Shares. Concurrently with entering into the Purchase Agreement, we also entered into a registration rights agreement with Aspire Capital, or the Registration Rights Agreement, in which we agreed to file one or more registration statements, including the registration statement of which this prospectus is a part, as permissible and necessary to register under the Securities Act of 1933, as amended, or the Securities Act, the sale of the shares of our common stock that have been and may be issued to Aspire Capital under the Purchase Agreement.

As of August 8, 2017, there were 47,922,838 shares of our common stock outstanding (18,926,314 shares held by non-affiliates). If all of such 10,000,000 shares of our common stock issuable to Aspire Capital pursuant to the Purchase Agreement and offered hereby were issued and outstanding as of the date hereof, such shares would represent 17.91% of the total common stock outstanding or 37.25% of the non-affiliate shares of common stock

outstanding as of the date hereof. The aggregate number of shares that we can issue to Aspire Capital under the Purchase Agreement may exceed 3,485,844 shares of our common stock (which is equal to approximately 19.99% of the common stock outstanding on the date of the Purchase Agreement), if (i) shareholder approval is obtained to issue more than 3,485,844 shares of our common stock under the Purchase Agreement, or (ii) shareholder approval has not been obtained and at any time 3,485,844 shares of our common stock have been issued under the Purchase Agreement and at all times thereafter the average price paid for all shares issued under the Purchase Agreement (including the 708,333 Commitment Shares) is equal to or greater than $0.85, the Minimum Price, a price equal to the closing sale price of our common stock on the business date immediately prior to the date of the execution of the Purchase Agreement; provided that at no one point in time shall Aspire Capital (together with its affiliates) beneficially own

more than 19.99% of our common stock. On March 6, 2017, we held a special stockholder meeting and received approval for the issuance of the shares of common stock to Aspire Capital under the Purchase Agreement.

Pursuant to the Purchase Agreement and the Registration Rights Agreement, we have registered 10,000,000 shares of our common stock under the Securities Act, which includes the 708,333 Commitment Shares and 2,083,333 shares of common stock from the completion of the concurrent financing that have already been issued to Aspire Capital and 7,208,334 shares of common stock which we may issue to Aspire Capital. All 10,000,000 shares of common stock are being offered pursuant to this prospectus.

Under the Purchase Agreement, we have the right but not the obligation to issue more than the 10,000,000 shares of common stock included in this prospectus to Aspire Capital. As of the date hereof, we do not have any plans or intent to issue to Aspire Capital any shares of common stock in addition to the 10,000,000 shares of common stock offered hereby.

On February 24, 2017, the conditions necessary for purchases under the Purchase Agreement were satisfied. On any trading day on which the closing sale price of our common stock exceeds $0.25, we have the right, in our sole discretion, to present Aspire Capital with a purchase notice, or each a Purchase Notice, directing Aspire Capital (as principal) to purchase up to 100,000 shares of our common stock per trading day, provided that the aggregate price of such purchase shall not exceed $300,000 per trading day, up to $15.0 million of our common stock in the aggregate at a per share price, or the Purchase Price, calculated by reference to the prevailing market price of our common stock (as more specifically described below).

In addition, on any date on which we submit a Purchase Notice for 100,000 shares to Aspire Capital and the closing sale price of our stock is equal to or greater than $0.25 per share of our common stock, we also have the right, in our sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice, or each, a VWAP Purchase Notice, directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the Company's common stock traded on the NASDAQ on the next trading day, or the VWAP Purchase Date, subject to a maximum number of shares we may determine, or the VWAP Purchase Share Volume Maximum, and a minimum trading price, or the VWAP Minimum Price Threshold (as more specifically described below). The purchase price per Purchase Share pursuant to such VWAP Purchase Notice, or the VWAP Purchase Price, is calculated by reference to the prevailing market price of our common stock.

Merger with Essentialis, Inc.

On March 7, 2017, we completed the Merger with Essentialis and issued 18,916,940 shares of common stock to stockholders of Essentialis. We held back 913,379 shares of common stock as partial recourse to satisfy indemnification claims, and such shares will be issued to Essentialis stockholders on the 1 year anniversary of the closing of the merger. We are also obligated to issue an additional 4,566,948 shares of common stock to Essentialis stockholders upon the achievement of a development milestone. Assuming that we issue all of the shares of our common stock held back and the development milestone is achieved, we would issue a total of 24,397,267 shares of common stock to Essentialis stockholders. Additionally, upon the achievement of certain commercial milestones associated with the sale of Essentialis' product in accordance with the terms of the Merger Agreement, we are obligated to make cash earnout payments of up to a maximum of $30 million to Essentialis stockholders. The merger consideration described above will be reduced by any such shares of common stock issuable, or cash earnout payments payable, to Essentialis' management carve-out plan participants and other service providers of Essentialis, in each case, in accordance with the terms of the Merger Agreement.

In addition, we issued 8,333,333 shares of our common stock for an investment of $8 million and issued 2,083,333 shares of our common stock for an investment of $2 million from Aspire Capital, both from the completion of the concurrent financing. Concurrently with entering into the Merger Agreement and stock purchase agreements entered into for the concurrent financing, we agreed to file one or more registration statements as permissible and necessary to register under the Securities Act of 1933, as amended, or the Securities Act, the sale of the shares of our common stock that have been issued under the Merger Agreement and stock purchase agreements. Pursuant to the Merger Agreement and the terms of the stock purchase agreements entered into for the concurrent financing, 7,250,273 shares of common stock have already been issued and an additional 913,379 shares of common stock could be issued to Essentialis stockholders on the 1 year anniversary of the closing of the Merger and 4,566,948 shares of common stock

could be issued to Essentialis stockholders upon the achievement of a development milestone.
On April 21, 2017, we filed a registration statement on Form S-1 covering the shares issued under the Merger Agreement and stock purchase agreements, which was declared effective by the SEC on August 10, 2017.

RISK FACTORS

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

Risks related to our financial condition and capital requirements

We have a limited commercialization history and have incurred significant losses since our inception, and we anticipate that we will continue to incur substantial losses for the foreseeable future. We have generated limited commercial sales to date, which, together with our limited operating history, makes it difficult to evaluate our business and assess our future viability.

We are a developer of therapeutics and 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 medical product development is highly speculative, because it entails substantial upfront capital expenditures and significant risk that any planned product will fail to demonstrate adequate accuracy or clinical utility. We have incurred significant operating losses in each year since our inception, and expect that we will not be profitable for an indefinite period of time. As of June 30, 2017, we had an accumulated deficit of $105.2 million.

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

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

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

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

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

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

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

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

- the cost and risk of initiating sales and marketing activities;
- the timing and cost of, and level of investment in, research and development activities relating to our planned products, which will change from time to time;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- the cost of manufacturing our products may vary depending on FDA and other regulatory requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional planned products and technologies;
- the design, timing and outcomes of clinical studies;
- changes in the competitive landscape of our industry, including consolidation among our competitors or potential partners;
- any delays in regulatory review or approval in the U.S., or, if applicable, globally, of any of our planned products;
- the level of demand for our products may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our future products, if approved, and existing and potential future drugs that compete with our planned products;
- competition from existing and potential future offerings that compete with our products;
- our ability to commercialize our products inside and outside of the U.S., either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also 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 June 30, 2017, we have incurred significant operating losses since inception and continue to generate losses from operations and has an accumulated deficit of $105.2 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 June 30, 2017, our cash balance was $7.5 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.

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

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

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

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

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

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

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

Risks Relating to the Company after the Merger with Essentialis

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

The Merger and concurrent financing resulted in the issuance of a significant amount of our common stock. The common stock issued in the Merger and concurrent financing represents an increase in the outstanding our common stock as of the date of the completion of the Merger of up to approximately 172% of the common stock currently outstanding. The issuance of such

10

a significant amount of our common stock could depress the trading price of our common stock and you may lose all or a part of your investment.

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

Our executive officers, directors and principal stockholders own a majority of our outstanding common stock. Entities associated with Vivo Ventures, Forward Ventures, Technology Partners and our Chairman, Ernest Mario, as of June 30, 2017, own approximately 58.9% of our common stock. As a result, the forgoing group of stockholders are able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders will control the election of directors and the approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

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

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

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

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

We will now be significantly dependent upon the success of DCCR, our sole therapeutic product candidate.

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

Any delay or impediment in our ability to obtain regulatory approval 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 E.U. and U.S.;
- building an infrastructure capable of supporting product sales, marketing, and distribution of DCCR in territories where we pursue commercialization directly;
- establishing commercial manufacturing arrangements with third party manufacturers;
- establishing commercial distribution agreements with third party distributors;
- launching commercial sales of DCCR, if and when approved, whether alone or in collaboration with others;

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

- the regulatory approval pathway that we pursue for DCCR in the United States;
- effectively competing with other therapies;
- a continued acceptable safety profile of DCCR following approval;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity;
- protecting our rights in our intellectual property portfolio; and
- obtaining a commercially viable price for our products.

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

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

We 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, and demonstrating efficacy with statistical significance and safety in humans. The results of our current and future clinical trials may not meet the FDA, the European Medicines Agency, or EMA, or other regulatory agencies' requirements to approve DCCR for marketing under any specific indication, and these regulatory agencies may otherwise determine that our manufacturing processes or facilities are insufficient to support approval. As such, we may need to conduct more clinical trials than we currently anticipate and upgrade our manufacturing processes and facilities, which may require significant additional time and expense, and may delay or prevent approval. If we fail to obtain regulatory approval in a timely manner, our commercialization of DCCR would be delayed and our business would be harmed.

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

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

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

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

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

If we are unable to establish our own sales, marketing, distribution, training and support capabilities and instead enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, are likely to be lower than if we were to market, sell and distribute DCCR ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute DCCR or may be unable to do

so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to commercialize DCCR effectively. If we do not establish sales, marketing, distribution, training and support

capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing DCCR and achieving profitability, and our business would be harmed.

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

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

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

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

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

We may experience delays in our clinical trials. We do not know whether future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of patients 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 preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- obtain regulatory approval, or feedback on trial design, to commence a trial;
- identify, recruit and train suitable clinical investigators;
- reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- obtain and maintain IRB approval at each clinical trial site;
- identify, recruit and enroll suitable patients to participate in a trial;
- have a sufficient number of patients complete a trial or return for post-treatment follow-up;
- ensure clinical investigators observe trial protocol or continue to participate in a trial;
- address any patient safety concerns that arise during the course of a trial;
- address any conflicts 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 appropriate for use in clinical trials; or
- raise sufficient capital to fund a trial.

Patient enrollment is a significant factor in the timing of clinical trials and is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of

the clinical trial, competing clinical trials and clinicians' and patients' or caregivers' perceptions as to the potential advantages of the drug candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating.

We could also encounter delays if a clinical trial is suspended or terminated by us, by 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 following the merger. The denial or delay of any such approval would delay commercialization and have a material adverse effect on our potential to generate revenue, our business and our results of operations.

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

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

Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA may grant approval contingent on the performance of costly additional post-approval clinical

trials. The FDA may also approve our product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. To the extent we seek regulatory approval in foreign countries, we may face challenges similar to those

described above with regulatory authorities in applicable jurisdictions. Any delay in obtaining, or inability to obtain, applicable regulatory approval for any of our product candidates would delay or prevent commercialization of our product candidates and would materially adversely impact our business, results of operations and prospects.

Even if DCCR receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third party payors and others in the medical community necessary for commercial success.

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

- the efficacy and potential advantages compared to alternative treatments;
- the prevalence and severity of any side effects;
- the ability to offer our product candidates for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments; and
- sufficient third party coverage or reimbursement.

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

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

We are the sole owner of patents and patent applications in the U.S. with claims covering the compounds underlying our primary product candidate, DCCR. Foreign counterparts of these patents and applications have been issued in the E.U., Japan, China, Canada, Australia, 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.

Risks related to the development and commercialization of our products

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

We will derive substantially all of our revenues from sales of CoSense devices and consumables globally for the foreseeable future. If we cannot generate sufficient revenues from sales, we may be unable to finance our continuing operations.

We may not be successful in commercializing our approved products

15

Our efforts to launch CoSense into the neonatology marketplace and Serenz are subject to a variety of risks, any of which may prevent or limit sales of CoSense. Furthermore, commercialization of products into the medical marketplace is subject to a variety of regulations regarding the manner in which potential customers may be engaged, the manner in which products may be lawfully advertised, and the claims that can be made for the benefits of the product, among other things. Our lack of experience with product launches may expose us to a higher than usual level of risk of non-compliance with these regulations, with consequences that may include fines or the removal of our approved products from the marketplace by regulatory authorities.

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

Although we believe that DCCR 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.

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 CoSense justifies payment for the device and consumables at adequate pricing levels. We need to hire additional commercial, scientific, technical and other personnel to support this process.

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

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

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

16

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

If we cannot compete successfully with other testing modalities, we may be unable to increase or sustain our revenues or achieve and sustain profitability.

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

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

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

17

- 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.

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

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

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

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

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

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

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

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

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

We face significant competition in seeking appropriate strategic partners, and the negotiation process to secure favorable terms is time-consuming and complex. In addition, the termination of our license agreement for Serenz with our former partner, may negatively impact the perception of Serenz held by other potential partners for the program. We may not be successful in our efforts to establish such a strategic partnership for any future products and programs on terms that are acceptable to us, or at all.

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

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

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

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

19

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

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

Alternatives exist for our products and we will likely face competition with respect to any planned products that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies, medical device companies, and biotechnology companies worldwide. There are several large pharmaceutical and biotechnology companies that currently market and sell AR therapies to our target patient group. These companies may reduce prices for their competing drugs in an effort to gain or retain market share, and undermine the value our products might otherwise be able to offer to payors. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Many of these competitors are attempting to develop therapeutics for our target indications. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified technical and management personnel, establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs.

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

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

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

In the U.S., while we expect payments for CoSense to be part of a diagnosis-related group, or DRG (also known as a bundled payment), we may have to obtain reimbursement for it from payors directly. There may be significant delays in obtaining reimbursement for CoSense, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced

by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the U.S. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies.

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

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

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

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

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

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

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

The loss of a key employee, the failure of a key employee to perform in his or her current position or our inability to attract and retain skilled employees could result in our inability to continue to grow our business or to implement our business strategy.

In addition, we rely on collaborators, consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our collaborators, consultants and advisors are

21

generally employed by employers other than us and may have commitments under agreements with other entities that may limit their availability to us.

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

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

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

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

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

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

As part of our business strategy, we may pursue acquisitions or licenses of assets or acquisitions of businesses, including the Merger with Essentialis pursuant to the Merger Agreement. We completed the Merger with Essentialis on March 7, 2017, and concurrently with the closing of the Merger, completed financing transaction with total aggregate proceeds of approximately $10 million from current stockholders and new investors. We also may pursue strategic alliances and joint ventures that leverage our core technology and industry experience to expand our product offerings or sales and distribution

resources. Our company has limited experience with acquiring other companies, acquiring or licensing assets or forming strategic alliances and joint ventures. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. Integration of an acquired company also may disrupt ongoing operations and require management resources that would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a material negative effect on our results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, license, strategic alliance or joint venture. To finance such a transaction we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

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

We have distribution partners for CoSense in China, India, Qatar and Saudi Arabia. Our business strategy contemplates international expansion, including partnering with medical device distributors, and introducing our current products and other planned products outside the U.S. Doing business internationally involves a number of risks, including:

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

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

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

The accuracy of CoSense depends, in part, on the function of software run by the microprocessors embedded in the device. This software is proprietary to us. While we have made efforts to test the software extensively, it is potentially subject to malfunction. It may be vulnerable to physical break-ins, hackers, improper employee or contractor access, computer viruses, programming errors, or similar problems. Any of these might result in confidential medical, business or other information of other persons or of ourselves being revealed to unauthorized persons.

23

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

Risks related to the operation of our business

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

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

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

- collaborators have significant discretion in determining the efforts and resources that they will apply to any such collaborations;
- collaborators may not pursue development and commercialization of our products, or may elect not to continue or renew efforts based on clinical study results, changes in their strategic focus for a variety of reasons, potentially including the acquisition of competitive products, availability of funding, and mergers or acquisitions that divert resources or create competing priorities;
- collaborators may delay clinical studies, provide insufficient funding for a clinical study program, stop a clinical study, abandon a product, repeat or conduct new clinical studies or require a new engineering iterations of a product for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate

our intellectual property or proprietary information or expose us to potential liability;

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

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable products; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

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

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 June 30, 2017, we had 20 employees and 3 full-time or part-time consultants. Over the next several years, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, quality assurance, engineering, product development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Future growth would impose significant added responsibilities on members of management, including:

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

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

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

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

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

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

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

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

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

Risks related to intellectual property

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

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

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

misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business to the infringement claims discussed above.

Even if we are successful in defending against intellectual property claims, litigation or other legal proceedings relating to such claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim

proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of litigation or other intellectual property related proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

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

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

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

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

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

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

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

Competitors may infringe or otherwise violate the patents we rely on, or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. In addition, in an infringement proceeding, a court may decide that a patent we are asserting is invalid or unenforceable, or may refuse to stop the other party from using the technology

at issue on the grounds that the patents we are asserting do not cover the technology in question. An adverse result in any litigation proceeding could put one or more patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

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

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

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

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

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

Filing, prosecuting and defending patents on all of our planned products throughout the world would be prohibitively expensive to us. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as in the U.S. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing

products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

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

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

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

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

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

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

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

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

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

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

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

Risks related to government regulation

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

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of medical devices are subject to extensive regulation by the FDA in the U.S. and other regulatory authorities in other countries, which regulations differ from country to country. We are not permitted to market our planned products in the U.S. until we received the requisite approval or clearance from the FDA. We have not submitted an application or received marketing approval for any planned products. Obtaining PMA or 510(k) clearance for a medical device from the FDA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions, including the following:

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

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

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

- a planned product may not be deemed safe or effective;

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

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

Even if we receive 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. The current clearance for CoSense, as well as any additional regulatory approval that we receive for any planned products may be subject to limitations on the indicated uses for which the product may be marketed. Future approvals may contain requirements for potentially costly post-marketing follow-up studies to monitor the safety and effectiveness of the approved product. In addition, we are subject to extensive and ongoing regulatory requirements by the FDA and other regulatory authorities with regard to the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for our products. In addition, we are required to comply with cGMP regulations regarding the manufacture of our drugs, which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory authorities must approve these manufacturing facilities before they can be used to manufacture drug products, and these facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we or a third party discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturer or us, including requiring withdrawal of the product from the market or suspension of manufacturing.

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

We intend to seek distribution and marketing partners for our current products outside the U.S. and may market planned products in international markets. We have 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 CoSense devices and may be applicable to CoSense consumables and Serenz devices. We cannot assure you that after the two-year suspension, the reinstatement of the 2.3% medical device tax would not adversely affect our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

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

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

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

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

Given the serious public health risks of high-profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk evaluation and mitigation strategies, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling,

expedited reporting of certain adverse events, preapproval of promotional materials and restrictions on direct-to-consumer advertising.

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

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

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

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

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

Risks related to ownership of our securities

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

Our stock price has been and is likely to continue to be volatile. The stock market in general, and the market for biotechnology and medical device companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. During the period from June 30, 2016 through June 30, 2017, the reported high and low prices of our common stock ranged from $1.18 to $0.50. 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;

33

- 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;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders;
- general economic, industry and market conditions; and
- the other risks described in this “Risk Factors” section.

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

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

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

We have issued 13,780 shares of Series B Convertible Preferred Stock, which are convertible into 13,780,000 shares of our common stock, based on a fixed conversion price of $1.00 per share on an as-converted basis. Under the terms of the Series B Convertible Preferred Stock, in no event shall shares of Common stock be issued to Sabby upon conversion of the Series B Convertible Preferred Stock to the extent such issuance of shares of common stock would result in Sabby having ownership in excess of 4.99%.

In connection with the sale and issuance of Series B Convertible Preferred Stock to Sabby pursuant to the 2016 Sabby Purchase Agreement, we also amended the Series D Common Stock Purchase Warrants that were issued to Sabby under the

2015 Sabby Purchase Agreement. The per share exercise price of the common stock underlying the Series D Common Stock Purchase Warrants was reduced from $2.46 per share to $1.75 per share, which, if exercised, may result in sales of substantial amounts of the underlying common stock in the public market, or the perception that these sales may occur, and which could materially and adversely affect the price of our common stock and could impair our ability to raise capital through the sale of additional equity securities.

In addition, on March 7, 2017, we issued 8,333,333 shares of common stock for an investment of $8 million from the completion of the concurrent financing, which shares may, in the future, be available for resale upon the filing of a registration statement that covers such shares and which has been declared effective by the SEC, and issued 2,083,333 shares of common stock for an investment of $2 million from Aspire Capital pursuant to the 2017 Aspire Purchase Agreement. Aspire Capital may ultimately purchase all, some or none of the $17.0 million worth of common stock, of which $2 million was sold on March 7, 2017, issuable under the 2017 Aspire Purchase Agreement, including the 708,333 commitment shares. All the shares issued under the 2017 Aspire Purchase Agreement are eligible for future resale under a registration statement on Form S-1 on February 1, 2017 that was declared effective by the SEC on February 15, 2017.

Furthermore, concurrently with entering into the Merger Agreement and stock purchase agreements entered into for the concurrent financing, we agreed to file one or more registration statements as permissible and necessary to register under the Securities Act of 1933, as amended, or the Securities Act, the sale of the shares of our common stock that have been issued under the Merger Agreement and stock purchase agreements. Pursuant to the Merger Agreement and the terms of the stock purchase agreements entered into for the concurrent financing, 7,250,273 shares of common stock have already been issued and an additional 913,379 shares of common stock could be issued to Essentialis stockholders on the 1 year anniversary of the closing of the Merger and 4,566,948 shares of common stock could be issued to Essentialis stockholders upon the achievement of a development milestone. On April 21, 2017, we filed a registration statement on Form S-1 covering the shares issued under the Merger Agreement and stock purchase agreements, which was declared effective by the SEC on August 10, 2017.

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

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, which was enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering, or IPO, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.0 billion, (3) the date on which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may suffer or be more volatile.

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

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

Our executive officers, directors and stockholders own a majority of our outstanding common stock. Entities associated with Vivo Ventures, Forward Ventures, Technology Partners and our Chairman, Ernest Mario, as of June 30, 2017, own approximately 58.9% of our common stock. As a result, the forgoing group of stockholders are able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders will control the election of directors and the approval of any merger, consolidation or sale of all or substantially all of our assets. This

concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

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

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

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, or Section 404, beginning with our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, which was filed March 13, 2015. In addition, we will be required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting beginning with our annual report on Form 10-K following the date on which we are no longer an emerging growth company. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge.

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

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

Our ability to utilize our federal net operating loss, carryforwards and federal tax credit will be limited under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code. The limitations apply if an “ownership change,” as defined by Section 382, occurs. Generally, an ownership change occurs if the percentage of the value of the stock that is owned by one or more direct or indirect “five percent shareholders” increases by more than 50% over their lowest ownership percentage at any time during the applicable testing period (typically three years). During the year ended December 31, 2016, we experienced an “ownership change”, which will limit our ability to utilize our existing net

operating losses and other tax attributes to offset taxable income. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other tax attributes to offset U.S. federal taxable income will be subject to limitations, which could potentially result in increased future tax liability to us.

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

As of June 30, 2017, we had Series A Warrants outstanding exercisable for an aggregate of 2,425,605 shares of common stock, Series C Warrants outstanding exercisable for an aggregate of 590,415 shares of common stock, Series D Warrants outstanding exercisable for an aggregate of 2,930,812 shares of common stock and other warrants exercisable for an aggregate of 571,906 shares of common stock. As of December 31, 2016, we had 12,780 shares of Series B Convertible Preferred Stock outstanding exercisable for an aggregate of 12,780,000 shares of common stock. As of March 31, 2017, 2,934,847 options to purchase shares of our common stock were issued and outstanding with a weighted average exercise price of $3.35 per share. The sale or even the possibility of sale of the shares of common stock, or the exercise of options or warrants to purchase shares of our common stock and subsequent sale thereof could substantially reduce the market price for our common stock or our ability to obtain future financing.

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

In addition, on March 7, 2017, we issued 8,333,333 shares of common stock for an investment of $8 million from the completion of the concurrent financing, which shares may, in the future, be available for resale upon the filing of a registration statement that covers such shares and which has been declared effective by the SEC, and issued 2,083,333 shares of common stock for an investment of $2 million from Aspire Capital pursuant to the 2017 Aspire Purchase Agreement. Aspire Capital may ultimately purchase all, some or none of the $17.0 million worth of common stock, of which $2 million was sold on March 7, 2017, issuable under the 2017 Aspire Purchase Agreement, including the 708,333 commitment shares. All the shares issued under the 2017 Aspire Purchase Agreement are eligible for future resale under a registration statement on Form S-1 on February 1, 2017 that was declared effective by the SEC on February 15, 2017.

Furthermore, concurrently with entering into the Merger Agreement and stock purchase agreements entered into for the concurrent financing, we agreed to file one or more registration statements as permissible and necessary to register under the Securities Act of 1933, as amended, or the Securities Act, the sale of the shares of our common stock that have been issued under the Merger Agreement and stock purchase agreements. Pursuant to the Merger Agreement and the terms of the stock purchase agreements entered into for the concurrent financing, 7,250,273 shares of common stock have already been issued and an additional 913,379 shares of common stock could be issued to Essentialis stockholders on the 1 year anniversary of the closing of the Merger and 4,566,948 shares of common stock could be issued to Essentialis stockholders upon the achievement of a development milestone. On April 21, 2017, we filed a registration statement on Form S-1 covering the shares issued under the Merger Agreement and stock purchase agreements, which was declared effective by the SEC on August 10, 2017.

As our warrant holders exercise their warrants into shares of our common stock, our stockholders will be diluted. The exercise of some or all of our warrants results in issuance of common stock that dilute the ownership interests of existing stockholders. Any sales of the common stock issuable upon exercise of the warrants could adversely affect prevailing market prices of our common stock.

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

If there is significant downward pressure on the price of our common stock, it may encourage holders of our warrants, or other parties, to sell shares by means of short sales or otherwise. Short sales involve the sale, usually with a future delivery date, of common stock the seller does not own. Covered short sales are sales made in an amount not greater than the number of shares subject to the short seller’s right to acquire common stock, such as upon exercise of warrants. A holder of warrants may close out any covered short position by exercising all, or a portion, of its warrants,

or by purchasing shares in the open market. In determining the source of shares to close out the covered short position, a holder of warrants will likely consider, among other things, the price of common stock available for purchase in the open market as compared to the exercise price of the warrants. The existence of a significant number of short sales generally causes the price of common stock to decline, in part because it indicates that a number of market participants are taking a position that will be profitable only if the price of the common stock declines.

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

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

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

We have listed our common stock and Series A Warrants on NASDAQ. We might not be able to maintain the listing standards of that exchange, which includes requirements that we maintain our shareholders' equity, total value of shares held by unaffiliated shareholders, market capitalization above certain specified levels and minimum bid requirement of $1.00 per common share. On October 24, 2016, we received a letter from the Listing Qualifications Department of NASDAQ indicating that, based upon the closing bid price of our common stock for the last 30 consecutive business days, we did not meet the minimum bid price of $1.00 per share required for continued listing on NASDAQ pursuant to Nasdaq Listing Rule 5550(a)(2). The letter also indicated that we will be provided with a compliance period of 180 calendar days, or until April 24, 2017, in which to regain compliance pursuant to NASDAQ Listing Rule 5810(c)(3)(A). In addition, we do not expect to become profitable for some time and there is a risk that our shareholders' equity could fall below the $2.5 million level required by NASDAQ. If we do not regain compliance with the minimum bid requirement or our shareholders' equity falls below $2.5 million, it will cause us to fail to conform to the NASDAQ listing requirements on an ongoing basis, which in turn could cause our common stock to cease to trade on the NASDAQ exchange, and be required to move to the Over the Counter Bulletin Board or the "pink sheets" exchange maintained by OTC Markets Group, Inc. The OTC Bulletin Board and the "pink sheets" are generally considered to be markets that are less efficient, and to provide less liquidity in the shares, than the NASDAQ market.

On April 24, 2017, we received a letter from Nasdaq indicating that we were eligible for an additional 180-day period, or until October 23, 2017, to regain compliance with the minimum bid requirement.

On May 8, 2017, we received stockholder approval for a reverse stock split of our common stock at a ratio between one-for-two (1:2) and one-for-ten (1:10), or the Reverse Split, to be determined by our Board of Directors and to be effected at the sole discretion of the Board at any time time within six months, pursuant to the proxy statement filed with the SEC on March 29, 2017. If the Board implements the stock split within the next 6 months, we expect that the market price of the common stock will be in excess of the $1.00 minimum closing bid price as required by the Nasdaq Marketplace Rules.

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

The warrants we have issued and outstanding do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, holders of Series A Warrants may exercise their right to acquire the common stock and pay an exercise price of $6.50 per share prior to the expiration of the five-year term on November 12, 2019, after which date any unexercised Series A Warrants will expire and have no further value. Holders of Series C Warrants may exercise their right to acquire common stock and pay an exercise price of $6.25 per share prior to the expiration of the five-year term on March 4, 2020. Following amendment of the Series D Common Stock Purchase Warrants, the holders may exercise their right to acquire common stock and pay an amended exercise price of $1.75 per share prior to the expiration of the five-year term on October 15, 2020. In certain circumstances, the Series A Warrants, Series C Warrants, and Series D Warrants may be exercisable on a cashless

basis. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the warrants, and, consequently, whether it will ever be profitable for holders of the warrants to exercise the warrants.

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

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

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

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

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

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

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

Certain of our executive officers are parties to employment agreements that contain change in control and severance provisions providing for aggregate cash payments of up to approximately $1.4 million for severance and other benefits and acceleration of vesting of stock options with a value of approximately $1.1 million, in the event of a termination of employment in connection with a change in control of us. The accelerated vesting of options could result in dilution

to our existing stockholders and harm the market price of our common stock. The payment of these severance benefits could harm our

financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

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

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

The sale of our common stock to Aspire Capital and Sabby and issuance of shares in connection with the Essentialis merger may cause substantial dilution to our existing stockholders and the sale of common stock by Aspire Capital, Sabby and the holders of shares of common stock received as part of the Essentialis transaction could cause the price of our common stock to decline.

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

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

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

Furthermore, concurrently with entering into the Merger Agreement and stock purchase agreements entered into for the concurrent financing, we agreed to file one or more registration statements as permissible and necessary to register under the Securities Act of 1933, as amended, or the Securities Act, the sale of the shares of our common stock that have been issued under the Merger Agreement and stock purchase agreements. Pursuant to the Merger Agreement and the terms of the stock purchase agreements entered into for the concurrent financing, 7,250,273 shares of common stock have already been issued and an additional 913,379 shares of common stock could be issued to Essentialis stockholders on the 1 year anniversary of the closing of the Merger and 4,566,948 shares of common stock could be issued to Essentialis stockholders upon the achievement of a development milestone. On April 21, 2017, we filed a registration statement on Form S-1 covering the shares issued under the Merger Agreement and stock purchase agreements, which was declared effective by the SEC on August 10, 2017.

Risks Associated with a proposed Reverse Stock Split

On May 8, 2017, we received stockholder approval for a reverse stock split of our common stock at a ratio between one-for-two (1:2) and one-for-ten (1:10), or the Reverse Split, pursuant to the proxy statement filed with the SEC on March 29, 2017. The Reverse Split could result in a significant devaluation of our market capitalization and trading price of the common stock. Our board of directors expects that the Reverse Split of the outstanding common stock will increase the market price of the common stock. However, we cannot be certain whether the Reverse Split would lead to a sustained increase in the trading

price or the trading market for our common stock. The history of similar stock split combinations for companies in like circumstances is varied. There is no assurance that:

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

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

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

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

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

SALE OF COMMON STOCK TO ASPIRE CAPITAL

General

On January 27, 2017, we entered into the Purchase Agreement 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 of our shares of common stock over the term of the Purchase Agreement. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, we issued to Aspire Capital the 708,333 Commitment Shares. Concurrently with entering into the Purchase Agreement, we also entered into the Registration Rights Agreement, in which we agreed to file one or more registration statements as permissible and necessary to register under the Securities Act, the sale of the shares of our common stock that have been and may be issued to Aspire Capital under the Purchase Agreement.

As of August 8, 2017, there were 47,922,838 shares of our common stock outstanding (18,926,314 shares held by non-affiliates). If all of such 10,000,000 shares of our common stock issuable to Aspire Capital pursuant to the Purchase Agreement and offered hereby were issued and outstanding as of the date hereof, such shares would represent 17.91% of the total common stock outstanding or 37.25% of the non-affiliate shares of common stock outstanding as of the date hereof.

Pursuant to the Purchase Agreement and the Registration Rights Agreement, we have registered 10,000,000 shares of our common stock under the Securities Act, which includes the 708,333 Commitment Shares that have already been issued to Aspire Capital and 9,291,667 shares of common stock which we may issue to Aspire Capital. All 10,000,000 shares of common stock are being offered pursuant to this prospectus. Under the Purchase Agreement, we have the right but not the obligation to issue more than the 10,000,000 shares of common stock included in this prospectus to Aspire Capital. As of the date hereof, and other than the financing we closed on March 7, 2017 with Aspire Capital pursuant to the Purchase Agreement in connection with the contemplated merger with Essentialis, Inc., a Delaware corporation, pursuant to the Agreement and Plan of Merger dated December 22, 2016, which is described in further detail below, we do not have any plans or intent to issue to Aspire Capital any shares of common stock in addition to the 10,000,000 shares of common stock issuable to Aspire Capital pursuant to the Purchase Agreement and offered hereby.

On February 24, 2017, the conditions necessary for purchases under the Purchase Agreement were satisfied. On any trading day on which the closing sale price of our common stock is not less than $0.25 per share, we have the right, in our sole discretion, to present Aspire Capital with a Purchase Notice, directing Aspire Capital (as principal) to purchase up to 100,000 shares of our common stock per business day, up to $17.0 million of our common stock in the aggregate at a Purchase Price calculated by reference to the prevailing market price of our common stock over the preceding 10-business day period (as more specifically described below). However, in no event shall the purchase amount exceed $300,000 per business day.

In addition, on any date on which we submit a Purchase Notice to Aspire Capital for 100,000 Purchase Shares and our stock price is not less than $0.25 per share, we also have the right, in our sole discretion, to present Aspire Capital with a VWAP Purchase Notice directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the Company’s common stock traded on the NASDAQ on the next trading day, subject to the VWAP Purchase Share Volume Maximum and the VWAP Minimum Price Threshold. The VWAP Purchase Price is calculated by reference to the prevailing market price of our common stock (as more specifically described below).

On the date of the closing of the Financing (as defined in that certain Agreement And Plan Of Merger dated as of December 22, 2016 by and among us and the parties thereto, or the Merger Agreement, filed as Exhibit 2.1 to the Current Report on Form 8-K filed by the Company on December 27, 2016), we sold to Aspire Capital, and Aspire Capital purchased from us, an aggregate of $2.0 million of our common stock, with the per share purchase price equal to the per share price in the Financing paid to us by the Financing Investors (as defined in the Merger Agreement), however, in no event shall the per share purchase price exceed $0.96.

The Purchase Agreement provides that the Company and Aspire Capital shall not effect any sales under the Purchase Agreement on any purchase date where the closing sale price of our common stock is less than $0.25. There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Aspire Capital. Aspire Capital has no right to require any sales by us, but is

obligated to make purchases from us as we direct in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. Aspire Capital may not assign its rights or obligations under the Purchase Agreement. The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us.

Purchase Of Shares Under The Purchase Agreement

Under the Purchase Agreement, on any trading day selected by us on which the closing sale price of our common stock exceeds $0.25 per share, we may direct Aspire Capital to purchase up to 100,000 shares of our common stock per trading day. The Purchase Price of such shares is equal to the lesser of:

- the lowest sale price of our common stock on the purchase date; or
- the arithmetic average of the three lowest closing sale prices for our common stock during the ten consecutive trading days ending on the trading day immediately preceding the purchase date.

In addition, on any date on which we submit a Purchase Notice to Aspire Capital for purchase of 100,000 shares, we also have the right to direct Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of our common stock traded on the NASDAQ on the next trading day, subject to the VWAP Purchase Share Volume Maximum and the VWAP Minimum Price Threshold, which is equal to the greater of (a) 80% of the closing price of the Company's common stock on the business day immediately preceding the VWAP Purchase Date or (b) such higher price as set forth by the Company in the VWAP Purchase Notice. The VWAP Purchase Price of such shares is the lower of:

- the Closing Sale Price on the VWAP Purchase Date; or
- 97% of the volume-weighted average price for our common stock traded on the NASDAQ :
  - on the VWAP Purchase Date, if the aggregate shares to be purchased on that date have not exceeded the VWAP Purchase Share Volume Maximum or
  - during that portion of the VWAP Purchase Date until such time as the sooner to occur of (i) the time at which the aggregate shares traded on the NASDAQ exceed the VWAP Purchase Share Volume Maximum or (ii) the time at which the sale price of the Company's common stock falls below the VWAP Minimum Price Threshold.

The purchase price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the trading day(s) used to compute the purchase price. We may deliver multiple Purchase Notices and VWAP Purchase Notices to Aspire Capital from time to time during the term of the Purchase Agreement, so long as the most recent purchase has been completed.

Minimum Share Price

Under the Purchase Agreement, we and Aspire Capital may not effect any sales of shares of our common stock under the Purchase Agreement on any trading day that the closing sale price of our common stock is less than $0.25 per share.

Events of Default

Generally, Aspire Capital may terminate the Purchase Agreement upon the occurrence of any of the following events of default:

- the effectiveness of any registration statement that is required to be maintained effective pursuant to the terms of the Registration Rights Agreement between us and Aspire Capital lapses for any reason (including, without limitation, the issuance of a stop order) or is unavailable to Aspire Capital for sale of our shares of common stock, and such lapse or unavailability continues for a period of ten consecutive business days or for more than an aggregate of thirty business days in any 365-day period, which is not in connection with a post-effective amendment to any such registration statement; in connection with any post-effective amendment to such registration statement that is required to be declared effective by the SEC such lapse or unavailability may continue for a period of no more than 40 consecutive business days;
- the suspension from trading or failure of our common stock to be listed on our principal market for a period of ten consecutive business days;
- the delisting of our common stock from the NASDAQ, provided however, that in the event the Company's common stock is not immediately thereafter listed and traded on the New York Stock Exchange, the NYSE MKT, the Nasdaq Global Select Market, the Nasdaq Global Market, the Over-The-Counter Bulletin Board interdealer quotation system or either one of the OTCQB or the OTCQX market places of the OTC Markets Group, Inc.;
- our transfer agent's failure to issue to Aspire Capital shares of our common stock which Aspire Capital is entitled to receive under the Purchase Agreement within five business days after an applicable purchase date;
- any breach by us of the representations or warranties or covenants contained in the Purchase Agreement or any related agreements which could have a material adverse effect on us, subject to a cure period of five business days;
- if we become insolvent or are generally unable to pay our debts as they become due; or

- any participation or threatened participation in insolvency or bankruptcy proceedings by or against us.

Our Termination Rights

The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us.

No Short-Selling or Hedging by Aspire Capital

Aspire Capital has agreed that neither it nor any of its agents, representatives and affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the Purchase Agreement.

Effect of Performance of the Purchase Agreement on Our Stockholders

The Purchase Agreement does not limit the ability of Aspire Capital to sell any or all of the 10,000,000 shares that may be sold to Aspire Capital and registered in this offering. It is anticipated that shares registered in this offering will be sold over a period of up to approximately thirty months from the date of this prospectus. The sale by Aspire Capital of a significant amount of shares registered in this offering at any given time could cause the market price of our common stock to decline and/or to be highly volatile. Aspire Capital may ultimately purchase all, some or none of the 10,000,000 shares of common stock not yet issued but registered in this offering. After it has acquired such shares, it may sell all, some or none of such shares. Therefore, sales to Aspire Capital by us pursuant to the Purchase Agreement also may result in substantial dilution to the interests of other holders of our common stock. However, we have the right to control the timing and amount of any sales of our shares to Aspire Capital and the Purchase Agreement may be terminated by us at any time at our discretion without any penalty or cost to us.

PERCENTAGE OF OUTSTANDING SHARES AFTER GIVING EFFECT TO THE PURCHASED SHARES ISSUED TO ASPIRE CAPITAL

In connection with entering into the Purchase Agreement, we authorized the sale to Aspire Capital of up to $17.0 million of our shares of common stock. However, we estimate that we will sell no more than 10,000,000 shares to Aspire Capital under the Purchase Agreement (including the 708,333 Commitment Shares and the 2,083,333 shares of common stock issued in the concurrent financing), all of which are included in this offering. Subject to any required approval by our board of directors, we have the right but not the obligation to issue more than the 10,000,000 shares included in this prospectus to Aspire Capital under the Purchase Agreement. In the event we elect to issue more than 10,000,000 shares under the Purchase Agreement, we will be required to file a new registration statement and have it declared effective by the SEC. The number of shares ultimately offered for sale by Aspire Capital in this offering is dependent upon the number of shares purchased by Aspire Capital under the Purchase Agreement. The following table sets forth the number and percentage of outstanding shares to be held by Aspire Capital after giving effect to the sale of shares of common stock issued to Aspire Capital at varying purchase prices:

Assumed Average Purchase Price	Proceeds from the Sale of Shares to Aspire Capital Under the Purchase Agreement Registered in this Offering	Number of Shares to be Issued in this Offering at the Assumed Average Purchase Price(1)	Percentage of Outstanding Shares After Giving Effect to the Purchased Shares Issued to Aspire Capital(2)
$0.25	$871,461	3,485,844	12.21%
$1.00	$2,500,000	2,500,000	10.49%
$1.75	$5,250,000	3,000,000	11.37%
$2.00	$7,000,000	3,500,000	12.24%
$4.00	$14,400,000	3,600,000	12.41%
$5.00	$15,000,000	3,000,000	11.37%

(1) Excludes 708,333 Commitment Shares issued under the Purchase Agreement between the Company and Aspire Capital and the 2,083,333 shares of common stock issued to Aspire Capital from the completion of the concurrent financing.

(2) The denominator is based on 47,922,838 shares outstanding as of August 8, 2017, which includes the 708,333 commitment shares and the 2,083,333 shares of common stock previously issued to Aspire Capital and the number of shares set forth in the adjacent column which we would have sold to Aspire Capital at the corresponding assumed purchase price set forth in the adjacent column. The numerator is based on the number of shares which we may issue to Aspire Capital under the Purchase Agreement (that are the subject of this offering) at the corresponding assumed

purchase price set forth in the adjacent column and 708,733 Commitment Shares and the 2,083,333 shares issued in the concurrent financing.

USE OF PROCEEDS

We may receive proceeds up to $17.0 million under the Purchase Agreement with Aspire Capital. The proceeds received from the sale of the shares under the Purchase Agreement will be used for working capital and general corporate purposes. This anticipated use of net proceeds from the sale of our common stock to Aspire Capital under the Purchase Agreement represents our intentions based upon our current plans and business conditions. In addition, this prospectus also relates to shares of our common stock that may be offered and sold from time to time by the selling stockholders. We will not receive any proceeds upon the sale of shares by the selling stockholders.

PRICE RANGE OF COMMON STOCK AND DIVIDEND POLICY

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

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

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

As of August 17, 2017, the last reported sale price of our common stock on the NASDAQ Capital Market was $0.435. As of August 3, there were approximately 70 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.

DESCRIPTION OF PROPERTIES

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

LEGAL PROCEEDINGS

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

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

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

MANAGEMENT

Directors and Executive Officers

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

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

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

Executive Officers

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

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

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

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

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

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

Non-Employee Directors

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

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

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

Columbia University School of Medicine and his B.A. from Harvard University.

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

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

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

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

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

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

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

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

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

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

Stuart J.M Collinson, Ph.D. Dr. Collinson has been a member of our board of directors since March 2017. He currently serves as a partner at Forward Ventures, a venture capital firm. Previously he was Chairman and CEO of Aurora Biosciences. Dr. Collinson is currently a Board member of Tioga Pharmaceuticals from 2005 and Arcturus Therapeutics from 2014. He was a Board member for Affinium Pharmaceuticals from 2007 to 2014, Oxagen from 2001 to 2012 and VertexPharmaceuticals from 2002 to 2011. Dr. Collinson held senior management positions with Glaxo Wellcome from December 1994 to June 1998, most recently serving as Co-Chairman, Hospital and Critical Care Therapy Management Team and Director of Hospital and Critical Care. Dr. Collinson received his Ph.D. in physical chemistry from the University of Oxford, England and his M.B.A. from Harvard University.
We believe Dr. Collinson is able to make valuable contributions to our board of directors due to his significant financial experience and his expertise in our industry.
Mahendra G. Shah, Ph.D. Dr. Shah has been a member of our board of directors since March 2017. Dr. Shah has been with at Vivo Capital, LLC, a healthcare focused investment firm, since March 2010, and is currently serving as its managing director. Dr. Shah is the founder and executive chairman of Semnur Pharmaceuticals. Dr. Shah previously served as chairman of the board of Essentialis, as a board member of Bolt Therapeutics, Impel Neuropharma, Fortis Inc., Crinetic Pharmaceuticals, Verona Pharma and a member of the board of trustees of St. John's University. He is also a board member and charter member of EPPIC and a charter member of TIE. From September 2005 to December 2009, he was the founder, chairman and CEO of NextWave Pharmaceuticals, a pediatric focused specialty pharmaceutical company, which was acquired by Pfizer. From 1993 to May 2003, he was the chairman and CEO of First Horizon Pharmaceuticals, a publicly traded specialty pharmaceutical company before it was sold to Shionogi Pharmaceuticals. From 1991 to October 1999, he was vice president of E. J. Financial Enterprises, Inc., a healthcare fund management company. He previously served on the boards of Biotie therapies (BITI), Unimed Pharmaceuticals (UMED), Introgen Therapeutics (INGN), Inpharmakon, Protomed, Structural Bioinformatics, and Zarix. From 1987 to 1991 he was the senior director of new business development with Fujisawa USA (Astellas). Prior to that time he worked in various scientific and management positions with Schering-Plough and Bristol Myers-Squibb. Dr. Shah received his Ph.D. in industrial pharmacy from St. John's University and his Bachelor's and Master's Degree in Pharmacy from L.M. College of Pharmacy in Gujarat, India.
We believe Dr. Shah is able to make a valuable contribution to our board of directors due to his vast experience as a finance professional in the biomedical and pharmaceutical industries.
James Glasheen, Ph.D. Dr. Glasheen has been a member of our Board of Directors since March 2017. Since 2002, Dr. Glasheen has served as a general partner with Technology Partners, a venture capital firm that focuses on clean tech and life science companies. Prior to his work at Technology Partners, he served as Managing Director of CIT Venture Capital. From 1996 to 2000, he was a leader within McKinsey & Company's Pharmaceutical and Medical Products Practice. Dr. Glasheen also serves as an advisor to the National Science Foundation's (NSF) SBIR program in Washington D.C. Dr. Glasheen currently serves as a member of the board of directors of several privately-held biotechnology, consumer medical and medical device companies. Dr. Glasheen holds a B.S. from Duke University and an M.A. and Ph.D. from Harvard University.
We believe Dr. Glasheen is able to make valuable contributions to our Board of DDirectors due to his experience facilitating the growth of venture-backed companies, his experiences with McKinsey & Company and his consumer medical company expertise.
Board Composition
Our business and affairs are managed under the direction of our board of directors, which currently consists of ten members. The members of our board of directors were elected in compliance with the provisions of our amended and restated certificate of incorporation and a voting agreement among certain of our stockholders, as amended. The voting agreement terminated upon the closing of our IPO, and none of our stockholders have any special rights regarding the election or designation of members of our board of directors.

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

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

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

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

Director Independence

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

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

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

Board Leadership Structure

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

Board Committees

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

55

Audit committee

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

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

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

Compensation committee

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

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

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

Nominating and corporate governance committee

Our nominating and corporate governance committee consists of Steinar J. Engelsen, Stephen Kirnon, Rajen Dalal and Stuart Collinson, each of whom our board of directors has determined to be independent under NASDAQ listing standards. The chairperson of our nominating and corporate governance committee is Dr. Kirnon.

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

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

Role in Risk Oversight

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

from members of senior management on areas of material risk to our company, including operational, financial, legal and regulatory, and strategic and reputational risks.

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

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

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

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

Code of Business Conduct and Ethics

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

Compensation Committee Interlocks and Insider Participation

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

Non-Employee Director Compensation

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

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

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

(1) The amounts in this column reflect the aggregate grant date fair value of each option award granted during the fiscal year, computed in accordance with FASB ASC Topic 718. The valuation assumptions used in determining such amounts are described in Note 6 and Note 9 to our financial statements included in this prospectus. The table below lists the aggregate number of shares and additional information with respect to the outstanding option awards held by each of our non-employee directors.

(2) Dr. Engelman joined our Board in June 2001. During 2016, Dr. Engelman was granted one option to purchase 27,083 shares outstanding. This option vests as to 100% of the shares on the earlier of the 12 month anniversary of the date of grant or the day before the next annual meeting of stockholders, subject to continued service through each such date.

(3) Dr. Mario joined our Board in August 2007. During 2016, Dr. Mario was granted one option to purchase 27,083 shares outstanding. This option vests as to 100% of the shares on the earlier of the 12 month anniversary of the date of grant or the day before the next annual meeting of stockholders, subject to continued service through each such date.

(4) Dr. Engelsen joined our Board in April 2004. During 2016, Dr. Engelsen was granted one option to purchase 27,083 shares outstanding. This option vests as to 100% of the shares on the earlier of the 12 month anniversary of the date of grant or the day before the next annual meeting of stockholders, subject to continued service through each such date.

(5) Dr. Kirnon joined our Board in July 2002. During 2016, Dr. Kirnon was granted one option to purchase 27,083 shares outstanding. This option vests as to 100% of the shares on the earlier of the 12 month anniversary of the date of grant or the day before the next annual meeting of stockholders, subject to continued service through each such date.

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

(7) Mr. Harris joined our Board in June 2014. During 2016, Mr. Harris was granted one option to purchase 27,083 shares outstanding. This option vests as to 100% of the shares on the earlier of the 12 month anniversary of the date of grant or the day before the next annual meeting of stockholders, subject to continued service through each such date.

(8) Mr. Dalal joined our Board in April 2016. During 2016, Mr. Dalal was granted two options to purchase an aggregate of 47,083 shares of our common stock outstanding, comprised of an option to purchase 27,083 shares, which vests as to 100% of the shares on the earlier of the 12 month anniversary of the date of grant or the day before the next annual meeting of stockholders, and an option to purchase 20,000 shares, which vests as to 1/48th of the shares each month, in each case subject to continued service through each such date in June 2001.

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

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

an annual cash retainer of $3,500, paid quarterly.

EXECUTIVE COMPENSATION

As an emerging growth company, we have opted to comply with the executive compensation disclosure rules applicable to "smaller reporting companies," as such term is defined in the rules promulgated under the Securities Act, which require compensation disclosure for our principal executive officer and the two most highly compensated executive officers other than our principal executive officer. Our named executive officers for the year ended December 31, 2016 are:

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

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

2016 Summary Compensation Table

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

Summary Compensation Table

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

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

Employment offer letters and Employment Agreements

We have entered into employment agreements with our named executive officers. The employment agreements provide for "at-will" employment and set forth the terms and conditions of employment, including annual base salary,

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

Agreement with Anish Bhatnagar

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

Agreement with David D. O’Toole

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

Agreement with Anthony Wondka

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

Potential payments and benefits upon termination or change of control

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

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

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

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

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

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

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

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

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

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

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

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

Outstanding Equity Awards at December 31, 2016

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

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