

Sorrento Therapeutics, Inc.  
Form 424B5  
April 12, 2017

**Filed pursuant to Rule 424(b)(5)**

**Registration No. 333-199849**

**The information in this preliminary prospectus supplement is not complete and may be changed. A registration statement relating to these securities has been declared effective by the Securities and Exchange Commission. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell these securities, and we are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.**

**Subject to Completion, Dated April 12, 2017**

PRELIMINARY PROSPECTUS SUPPLEMENT  
(To Prospectus dated December 3, 2014)

## **Shares**

### **Common Stock**

---

We are offering \_\_\_\_\_ shares of our common stock in this offering.

Our common stock is listed on the NASDAQ Capital Market under the symbol "SNRE." On April 11, 2017, the last reported sale price of our common stock on the NASDAQ Capital Market was \$2.95 per share.

**Investing in our common stock involves a high degree of risk. See “Risk Factors” beginning on page S-8 of this prospectus supplement and under similar headings in the documents incorporated by reference into this prospectus supplement for a discussion of certain risks you should consider before investing in shares of our common stock.**

	Per Share	Total
Public offering price	\$	\$
Underwriting discounts and commissions <sup>(1)</sup>	\$	\$
Proceeds to us before expenses	\$	\$

(1) We have agreed to reimburse the representative of the underwriters for certain of its expenses. See “Underwriting” for a description of the compensation to be received by the underwriters.

We have granted the underwriters a 30-day option to purchase up to \_\_\_\_\_ additional shares of common stock from us at the public offering price, less underwriting discounts and commissions, to cover over-allotments, if any.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement is truthful or complete. Any representation to the contrary is a criminal offense.**

The underwriters expect to deliver the common stock to the investors in book-entry form through the facilities of The Depository Trust Company on or about April , 2017.

---

*Lead Book-Running Manager Joint Book-Running Manager*

Cantor Fitzgerald & Co.      FBR & Co.

The date of this prospectus supplement is April , 2017

TABLE OF CONTENTS

<b>Prospectus Supplement</b>	<b>Page</b>
<u>About this Prospectus Supplement</u>	S-1
<u>Prospectus Supplement Summary</u>	S-2
<u>Risk Factors</u>	S-8
<u>Cautionary Note Regarding Forward-Looking Statements</u>	S-10
<u>Market and Industry Data</u>	S-11
<u>Use of Proceeds</u>	S-12
<u>Price Range of our Common Stock</u>	S-13
<u>Dividend Policy</u>	S-13
<u>Capitalization</u>	S-14
<u>Dilution</u>	S-15
<u>Underwriting</u>	S-16
<u>Notice to Investors</u>	S-20
<u>Legal Matters</u>	S-23
<u>Experts</u>	S-23
<u>Information Incorporated by Reference: Where You Can Find More Information</u>	S-24

<b>Prospectus</b>	<b>Page</b>
<u>ABOUT THIS PROSPECTUS</u>	1
<u>THE COMPANY</u>	1
<u>RISK FACTORS</u>	2
<u>DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS</u>	28
<u>USE OF PROCEEDS</u>	28
<u>THE SECURITIES WE MAY OFFER</u>	28
<u>DESCRIPTION OF CAPITAL STOCK</u>	29
<u>DESCRIPTION OF WARRANTS</u>	30
<u>PLAN OF DISTRIBUTION</u>	33
<u>LEGAL MATTERS</u>	34
<u>EXPERTS</u>	34
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	34
<u>INCORPORATION OF DOCUMENTS BY REFERENCE</u>	35



## **ABOUT THIS PROSPECTUS SUPPLEMENT**

This prospectus supplement and the accompanying prospectus are part of a “shelf” registration statement on Form S-3 that we filed with the U.S. Securities and Exchange Commission (the “SEC”) using a “shelf” registration process. This prospectus supplement describes the specific terms of this offering. The accompanying prospectus, including the documents incorporated by reference therein, provides general information about us, some of which, such as the section therein entitled “Plan of Distribution,” may not apply to this offering. Generally, when we refer to this prospectus, we are referring to both this prospectus supplement and the accompanying prospectus, combined.

We urge you to carefully read this prospectus supplement, the accompanying prospectus, the documents incorporated by reference herein and therein and the additional information under the heading “Incorporation by Reference; Where You Can Find More Information” before buying any of the securities being offered under this prospectus supplement. These documents contain information you should consider when making your investment decision.

You should rely only on the information contained or incorporated by reference in this prospectus supplement and the accompanying prospectus. We have not, and the underwriters have not, authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus supplement may add, update or change information contained in the accompanying prospectus. To the extent any information in this prospectus supplement is inconsistent with the accompanying prospectus, you should rely on the information in this prospectus supplement. The information in this prospectus supplement will be deemed to modify or supersede the information in the accompanying prospectus and the documents incorporated by reference therein, except for those documents incorporated by reference therein which we file with the SEC after the date of this prospectus supplement.

You should not assume that the information contained or incorporated by reference in this prospectus supplement and the accompanying prospectus is accurate on any date subsequent to the date set forth on the front cover of this prospectus supplement and the accompanying prospectus or on any date subsequent to the date of the document incorporated by reference, as applicable. Our business, financial condition, results of operations and prospects may have changed since those dates.

We are offering to sell, and seeking offers to buy, the securities described in this prospectus supplement only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the offering of the securities in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus supplement outside the United States. This prospectus supplement does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement by any person in any jurisdiction in which it is unlawful for

such person to make such an offer or solicitation.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference into this prospectus supplement or the accompanying prospectus were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

In this prospectus supplement, unless otherwise indicated or required by the context, the terms “Sorrento,” “we,” “our,” “us” and the “Company” refer to Sorrento Therapeutics, Inc. and its consolidated subsidiaries.

S-1

## PROSPECTUS SUPPLEMENT SUMMARY

*This summary contains basic information about us and this offering. This summary highlights selected information contained elsewhere in, or incorporated by reference into, this prospectus supplement. This summary is not complete and may not contain all of the information that is important to you and that you should consider before deciding whether or not to invest in our securities. For a more complete understanding of Sorrento and this offering, you should carefully read this prospectus supplement, including any information incorporated by reference into this prospectus supplement, in its entirety. Investing in our securities involves risks that are described in prospectus supplement under the heading “Risk Factors,” under the heading “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2016, as amended, and in our other filings with the SEC.*

### **Our Company**

#### **Overview**

Sorrento is a clinical stage biotechnology company focused on delivering clinically meaningful therapies to patients and their families, globally. Our primary focus is to transform cancer into a treatable or chronically manageable disease. We also have programs assessing the use of our technologies and products in auto-immune, inflammatory, neurodegenerative, infectious diseases and pain indications with high unmet medical needs.

At our core, we are an antibody-centric company and leverage our proprietary G-MAB™ library to identify, screen and validate fully human antibodies against high impact oncogenic targets and mutations, immune modulators and intracellular targets. To date, we have screened over 100 validated targets and generated a number of fully human antibodies against these targets which are at various stages of preclinical development. These include PD-1, PD-L1, CD38, CD123, CD47, c-MET, VEGFR2, CCR2, OX40, TIGIT and CD137 among others.

Our vision is to leverage these antibodies in conjunction with proprietary targeted delivery modalities to generate the next generation of cancer therapeutics. These modalities include proprietary antibody drug conjugates (“ADCs”), bispecific approaches, as well as T-Cell Receptor (“TCR”)-like antibodies. With LA Cell, Inc. (“LA Cell”), our joint venture with City of Hope, our objective is to become the global leader in the development of antibodies against intracellular targets such as STAT3, mutant KRAS, MYC, p53 and TAU. Additionally, we have acquired and are assessing the regulatory and strategic path forward for our portfolio of late stage biosimilar/biobetter antibodies based on Erbitux®, Remicade®, Xolair®, and Simulect® as these may represent nearer term commercial opportunities.



With each of our programs, we aim to tailor our therapies to treat specific stages in the evolution of cancer, from elimination, to equilibrium and escape. In addition, our objective is to focus on tumors that are resistant to current treatments and where we can design trials based on a genetic signature or biomarker to ensure patients have the best chance of a durable and significant response.

We have several immuno-oncology programs that are in or near entering the clinic. These include cellular therapies, an oncolytic virus, monoclonal antibodies and a palliative care program targeted to treat intractable cancer pain.

Our cellular therapy programs focus on Chimeric Antigen Receptor-T Cell (“CAR-T”) for adoptive cellular immunotherapy to treat both solid and liquid tumors. We have reported early data from Phase I trials of our carcinoembryonic antigen (“CEA”) and PSMA directed CAR-T programs. Our CD38 CAR-T is being evaluated in the context of highly resistant multiple myeloma (“MM”), amyloidosis and graft-versus-host disease (“GvHD”). We are assessing our CD123 CAR-T in the context of highly resistant acute myeloid leukemia (“AML”). Both of the latter programs have successfully demonstrated strong preclinical anti-tumor activity in animal models. Our plan is to submit Investigational New Drug (“IND”) applications with the U.S. Food and Drug Administration (the “FDA”) for at least one of these CAR-T programs in 2017.

Finally, as part of our global aim to provide a wide range of therapeutic products to meet underserved therapeutic markets, we have made investments and developed a separate pain focused franchise which we believe will serve to provide short term upside to our core thesis. Within this franchise, resiniferatoxin (“RTX”) is a non-opioid-based TRPV1 agonist neurotoxin used as an injectable pain treatment. The compound RTX has been granted orphan drug status for the treatment of intractable pain at end-stage disease. We have conducted a Phase I trial with the National Institutes of Health (“NIH”) and are exploring a path to accelerated approval with a Phase II, multicenter trial to be initiated in late 2017.

## Overview

Our primary goal is to deliver clinically meaningful therapies to patients and their families, globally. In immuno-oncology, we aim to deliver next generation therapeutics to transform cancer into a treatable or chronically manageable disease. Across all our programs, we are focused on addressing severe unmet medical needs where our therapies can change the natural course of disease or significantly improve a patient’s quality of life.

Our core strategic objectives and resources are focused on:

Advancing our lead product candidates through the clinic. These include the initiation of Phase I, Phase II and

1. potentially accelerated approval trials for our cellular therapies, oncolytic virus immunotherapy and RTX in oncology and/or hematology indications.

2. Continuing the development of our preclinical programs with the aim of filing several new INDs over the next 5 years. These include moving our checkpoint inhibitors from our core antibody portfolio into the clinic with several of our strategic partners, while internally focusing on advancing our transformational intracellular targeting antibodies (“iTAb”), with LA Cell.

3. Collaborating with key opinion leaders and leading clinical and research institutes to enhance our preclinical and clinical development plans. We currently have such agreements in place with the Karolinska Institute, The Scripps Research Institute (“TRSI”), the NIH, City of Hope, Tufts Medical School and Roger Williams Medical Center, among others.

4. Manufacturing our preclinical and clinical materials in-house. We have established a quality control and quality assurance program, which includes a set of standard operating procedures and specifications designed to ensure that our products are manufactured in accordance with current good manufacturing practices (“cGMPs”), and other applicable domestic and foreign regulations.

5. Exploring strategic relationships to share in the risk reward of our core franchises and to derive near term value from our non-core franchise, such as our pain franchise. Our partnering objectives include generating revenue through license fees, milestone-related development fees and royalties as well as profit shares or joint ventures to generate potential returns from our product candidates and technologies.

S-3

## **Pipeline and Product Candidates**

An overview of our core programs is provided in the table below:

## **Recent Developments**

### ***Yuhan Agreement***

In March 2016, we and Yuhan Corporation, a South Korea company (“Yuhan”), entered into an agreement to form a joint venture company called ImmuneOncia Therapeutics, LLC (“ImmuneOncia”) to develop and commercialize a number of immune checkpoint antibodies against undisclosed targets for both hematological malignancies and solid tumors. In April 2016, Yuhan purchased \$10.0 million of shares of our common stock, \$0.0001 par value per share (“Common Stock”), and warrants as part of our private placement offering. Separately, under the terms of the joint venture agreement, Yuhan contributed an initial investment of \$10.0 million to ImmuneOncia, and we granted ImmuneOncia an exclusive license to one of our immune checkpoint antibodies for specified countries while retaining the rights for the U.S., European and Japanese markets, as well as global rights for ImmuneOncia to two additional antibodies that will be selected by ImmuneOncia from a group of pre-specified antibodies from our immuno-oncology antibody portfolio. Yuhan owns 51% of ImmuneOncia, while we own 49%.

### ***3SBio Agreement***

In June 2016, we and TNK (as defined below) entered into a binding term sheet with Shenyang Sunshine Pharmaceutical Company Ltd (“3SBio”), a China based company, to form a joint venture to develop and commercialize proprietary immunotherapies, including those developed from, including or using TNK’s CAR-T technology targeting CEA positive cancers. Due diligence and negotiations between 3SBio and us for the definitive agreement(s) are currently ongoing. In June 2016, 3SBio purchased \$10.0 million of Common Stock and warrants as part of our private placement offering.

### ***Servier License and Collaboration Agreement***

In July 2016, we announced a license and collaboration agreement with Les Laboratoires Servier, SAS, a corporation incorporated under the laws of France, and Institut de Recherches Internationales Servier, a company duly organized and existing under the laws of France (individually and collectively, “Servier”) for the development, manufacture and commercialization of products using our fully human immuno-oncology anti-PD-1 mAb STI-A1110. The financial terms of the agreement include, among other things, a non-refundable upfront payment to us of €25 million, or \$27.4 million, which we received in July 2016. We may also receive development milestone payments for the initial product and each additional product. We may receive up to €710 million in various payments based on commercial sales milestones related to annual net sales levels for the initial product and then also for each additional product. In addition to the commercial sales milestones, we will be entitled to receive variable royalties on the sales of all commercialized products ranging from high single-digit to double-digit percentages.

S-4

### ***CHA Biotech Agreement***

In August 2016, we announced a binding term sheet to create a joint venture (the “JV”) with CHA Biotech Co., LTD. (“CBT”) of South Korea to develop and commercialize proprietary CAR modified cellular therapies based on CBT’s Activated Killer Cell (“AKC”) technology in combination with five of our CARs for all disease conditions, including oncology and infectious diseases. The JV will cover products on a global basis with the exception of the greater Chinese market, which includes Mainland China, Hong Kong, Macau and Taiwan. In addition, we will obtain an exclusive license to develop and commercialize CBT’s novel investigator-initiated trial stage AKC technology in major territories, including the United States and Europe, and with a co-exclusive license in China. Under the terms of the Term Sheet, we and CBT will make contributions of \$2 million to the JV, and we will grant the JV an exclusive license to five CARs solely for combination with the AKC technology, while CBT will contribute its AKC technology. CBT will initially own 51% of the JV while we will initially hold the remaining 49%. We, under a royalty bearing license, will also gain access to the AKC technology for the use outside the JV alone or with any other of our product candidates. Due diligence and negotiations between CBT and us for the definitive agreement(s) are currently ongoing. However, the binding term sheet is currently terminable by either party at will and no assurances can be made that the transaction will be completed.

### ***Scilex Acquisition***

On November 8, 2016, we entered into a Stock Purchase Agreement with Scilex Pharmaceuticals Inc. (“Scilex”) and a majority of the stockholders of Scilex (the “Scilex Stockholders”) pursuant to which we acquired from the Scilex Stockholders approximately 72% of the outstanding capital stock of Scilex. Scilex’s lead product candidate, ZTlido™, is a next-generation lidocaine patch currently in development for the treatment of PHN, a severe neuropathic pain condition. ZTlido™ is manufactured by our collaboration partner in their state of the art manufacturing facility.

### ***Celularity Transaction***

In November 2016, we entered into a non-binding term sheet between us, our subsidiary, TNK, and Celularity, Inc. (“Celularity”), a research and development company, setting forth the terms and conditions by which we or TNK with one or more third parties would contribute certain assets to Celularity (the “Celularity Transaction”). In addition, at this time, we loaned \$5.0 million to Celularity pursuant to a promissory note issued to us (the “Celularity Note”). Pursuant to the terms of the Celularity Note, the loan will be due and payable in full on the earlier of November 1, 2017 and the occurrence of an event of default under the Celularity Note (the “Maturity Date”). The Celularity Note also provides that, in certain circumstances, we will loan Celularity up to an additional \$5.0 million over the next 12 months. In the event that Celularity meets certain minimum financing conditions prior to the Maturity Date, all outstanding amounts under the Celularity Note will be forgiven.

S-5

### ***Hercules Agreement***

On March 23, 2017, we entered into a fourth amendment to our Hercules Agreement (as defined below) with Hercules Capital, Inc. (“Hercules”). Pursuant to the terms of the fourth amendment, we repaid Hercules, without repayment penalty, \$20.0 million of the outstanding principal and unpaid interest accrued thereon (the “Repayment Amount”) on March 23, 2017. After the payment of the Repayment Amount, our cash position on April 7, 2017 was approximately \$33 million, of which approximately \$24 million qualifies as unrestricted U.S. cash that satisfies our \$20 million U.S. unrestricted cash minimum balance covenant with Hercules. Additionally, under the terms of the Hercules Agreement, we must meet our initial fundraising requirement of \$43.25 million by April 14, 2017. Proceeds from this offering would qualify towards the fundraising requirement. If we do not meet our initial fundraising requirement, an event of default will occur under the Hercules Agreement and the Lenders (as defined below) may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations.

See the section entitled “Risk Factors” in this prospectus supplement for a discussion of some of the risks relating to the execution of our business strategy.

### **Corporate Information**

On September 21, 2009, QuikByte Software, Inc., a Colorado corporation and shell company (“QuikByte”), consummated its acquisition of Sorrento Therapeutics, Inc., a Delaware corporation and private concern (“STI”), in a reverse merger (the “Merger”). Pursuant to the Merger, all of the issued and outstanding shares of STI common stock were converted into an aggregate of 6,775,032 shares of QuikByte common stock and STI became a wholly owned subsidiary of QuikByte. The holders of QuikByte’s common stock immediately prior to the Merger held an aggregate of 2,228,333 shares of QuikByte’s common stock immediately following the Merger.

We were originally incorporated as San Diego Antibody Company in California in 2006 and were renamed “Sorrento Therapeutics, Inc.” and reincorporated in Delaware in 2009, prior to the Merger. QuikByte was originally incorporated in Colorado in 1989. Following the Merger, on December 4, 2009, QuikByte reincorporated under the laws of the State of Delaware (the “Reincorporation”). Immediately following the Reincorporation, on December 4, 2009, we merged with and into QuikByte, the separate corporate existence of STI ceased and QuikByte continued as the surviving corporation (the “Roll-Up Merger”). Pursuant to the certificate of merger filed in connection with the Roll-Up Merger, QuikByte’s name was changed from “QuikByte Software, Inc.” to “Sorrento Therapeutics, Inc.”





The Offering

Common stock offered by us      shares

Common stock to be outstanding immediately after this offering      shares

Option to purchase additional shares      We have granted the underwriters a 30-day option to purchase up to      additional shares of common stock from us at the public offering price, less underwriting discounts and commissions, to cover over-allotments, if any.

Use of proceeds      We estimate the net proceeds from this offering will be approximately \$      million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering for continued investment in our programs, including the resubmission with the FDA of a new drug application for ZTlido®, IND-enabling studies and a Phase I clinical trial for CD38 CAR-T, IND-enabling studies and a Phase I clinical trial for c-MET ADC, preclinical studies for our iTAb product candidates, as well as for general research, development and corporate purposes, to fund potential acquisitions and for working capital. See “Use of Proceeds” beginning on page S-12 of this prospectus supplement for additional detail.

Trading market      Our common stock is listed on the NASDAQ Capital Market under the symbol “SRNE.”

Risk factors      Investing in our securities involves a high degree of risk. See “Risk Factors” beginning on page S-8 of this prospectus supplement.

The number of shares of our common stock that will be outstanding immediately after this offering is based on 50,882,856 shares of common stock outstanding as of December 31, 2016, and excludes:

4,332,876 shares of our common stock issuable upon the exercise of stock options outstanding under our Amended and Restated 2009 Stock Incentive Plan (the “2009 Plan”) as of December 31, 2016, at a weighted-average exercise price of \$7.86 per share;

3,200 shares of our common stock issuable upon the exercise of stock options outstanding under our Non-Employee Director Plan, as of December 31, 2016, at a weighted-average exercise price of \$7.86 per share;

1,414,220 shares of our common stock reserved for issuance under our 2009 Plan as of December 31, 2016; and

5,932,998 shares of our common stock issuable upon the exercise of outstanding warrants as of December 31, 2016, at a weighted-average exercise price of \$7.80 per share.

Except as otherwise indicated, all information in this prospectus supplement assumes no exercise by the underwriters of their option to purchase additional shares to cover over-allotments, if any.

S-7

## RISK FACTORS

*Our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, as amended, which is incorporated by reference into this prospectus supplement, as well as our other filings with the SEC, include material risk factors relating to our business. Those risks and uncertainties and the risks and uncertainties described below are not the only risks and uncertainties that we face. Additional risks and uncertainties that are not presently known to us or that we currently deem immaterial or that are not specific to us, such as general economic conditions, may also materially and adversely affect our business and operations. If any of those risks and uncertainties or the risks and uncertainties described below actually occurs, our business, financial condition or results of operations could be harmed substantially. In such a case, you may lose all or part of your investment. You should carefully consider the risks and uncertainties described below and those risks and uncertainties incorporated by reference into this prospectus supplement, as well as the other information included in this prospectus supplement, before making an investment decision with respect to our common stock.*

### **Risks Related to this Offering**

***Purchasers of common stock in this offering will experience immediate and substantial dilution in the book value of their investment. You may experience further dilution upon exercise of our outstanding options and warrants.***

The public offering price per share of common stock in this offering is substantially higher than the net tangible book value per share of our common stock before giving effect to this offering. Accordingly, if you purchase common stock in this offering, you will incur immediate substantial dilution of approximately \$            per share, representing the difference between the public offering price per share of common stock and our as adjusted net tangible book value as of December 31, 2016. In addition, if outstanding options or warrants are exercised, you could experience further dilution. For a further description of the dilution that you will experience immediately after this offering, see the section in this prospectus supplement entitled “Dilution.”

***Future sales of our common stock, or the perception that such future sales may occur, may cause our stock price to decline.***

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales could occur, following this offering could cause the market price of our common stock to decline. A substantial majority of the outstanding shares of our common stock are, and the shares of common stock sold in this offering upon issuance will be, freely tradable without restriction or further registration under the Securities Act of 1933, as amended.

*We have broad discretion to determine how to use the funds raised in this offering, and may use them in ways that may not enhance our operating results or the price of our common stock.*

Our management will have broad discretion over the use of proceeds from this offering, and we could spend the proceeds from this offering in ways our stockholders may not agree with or that do not yield a favorable return, if at all. We intend to use the net proceeds from this offering for continued investment in our programs, including the resubmission with the FDA of a new drug application for ZTlido®, IND-enabling studies and a Phase I clinical trial for CD38 CAR-T, IND-enabling studies and a Phase I clinical trial for c-MET ADC, preclinical studies for our iTAb product candidates, as well as for general research, development and corporate purposes, to fund potential acquisitions and for working capital. See “Use of Proceeds” beginning on page S-12 of this prospectus supplement for additional detail. However, our use of these proceeds may differ substantially from our current plans. If we do not invest or apply the proceeds from this offering in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline.

#### **Risks Related to our Business and Industry**

*The terms of our secured debt facility require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.*

On November 23, 2016, we and certain of our domestic subsidiaries (together with us, the “Borrowers”) entered into entered into the Hercules Agreement for a term loan of up to \$75.0 million, subject to funding in multiple tranches.

The Hercules Agreement contains customary affirmative and restrictive covenants and representations and warranties, including financial reporting obligations and significant limitations on dividends, indebtedness, liens (including a negative pledge on intellectual property and other assets), collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, deposit accounts and subsidiaries. Additionally, the Hercules Agreement contains covenants requiring the Borrowers (i) to achieve their initial fundraising requirement of \$43.25 million by April 14, 2017, and (ii) to maintain a minimum amount of unrestricted cash prior to achieving their corporate and fundraising milestones. The breach of such covenants, in addition to certain other covenants, would result in the occurrence of an event of default. Upon the occurrence of an event of default and following any applicable cure periods, a default interest rate of an additional 5.00% may be applied to the outstanding loan balances, and the Lenders may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Hercules Agreement.

The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports and maintain insurance coverage. The negative covenants include, among others, restrictions on transferring collateral, changing our business, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments and creating other liens on our assets, in each case subject to customary exceptions. If we default under the Hercules Agreement, the Lenders may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the Lenders' right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. The Lenders could declare a default upon the occurrence of any event that they interpret as a material adverse change as defined under the Hercules Agreement, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by the Lenders of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

### **Risks Related to our Intellectual Property**

*Our position as a relatively small company may cause us to be at a significant disadvantage in defending our intellectual property rights and in defending against infringement claims by third parties.*

Litigation relating to the ownership and use of intellectual property is expensive, and our position as a relatively small company in an industry dominated by very large companies may cause us to be at a significant disadvantage in defending our intellectual property rights and in defending against claims that our technology infringes or misappropriates third party intellectual property rights. However, we may seek to use various post-grant administrative proceedings, including new procedures created under the America Invents Act, to invalidate potentially overly-broad third party rights. Even if we are able to defend our position, the cost of doing so may adversely affect our ability to grow, generate revenue or become profitable. We were recently named as a defendant in the U.S.

District Court for the District of New Jersey in a suit brought by Immunomedics, Inc. (“Immunomedics”) alleging, among other things, patent infringement, improper use and sharing of research material, and breach of contract for failure to provide Immunomedics with the right of first refusal to an exclusive license to certain technologies. This case was dismissed against us for lack of personal jurisdiction but may still pose a risk to our intellectual property and/or licensing rights in certain technologies. In the course of the ongoing litigation or any future additional litigation to which we may subject, we may not be able to protect our intellectual property at a reasonable cost, or at all. The outcome of litigation is always uncertain, and in some cases could include judgments against us that require us to pay damages, enjoin us from certain activities or otherwise affect our legal, contractual or intellectual property rights, which could have a significant adverse effect on our business.

S-9

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement and the documents incorporated herein by reference contain “forward- looking statements” by us within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), including, without limitation, statements as to expectations, beliefs and strategies regarding the future. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These forward-looking statements rely on a number of assumptions concerning future events and include statements relating to:

- risks and uncertainties associated with our research and development activities, including our clinical trials and preclinical studies;

- the timing or likelihood of regulatory filing and approvals or of alternative regulatory pathways for our drug candidates;

- the potential market opportunities for commercializing our product candidates;

- our expectations regarding the potential market size and the size of the patient populations for our product candidates, if approved for commercial use, and our ability to serve such markets;

- estimates of our expenses, future revenue, capital requirements and our needs for additional financing;

- our ability to develop, acquire and advance our product candidates into, and successfully complete, clinical trials and preclinical studies and obtain regulatory approvals;

- the implementation of our business model and strategic plans for our business and product candidates;

- the initiation, cost, timing, progress and results of future preclinical studies and clinical trials, and our research and development programs;

- the terms of future licensing arrangements, and whether we can enter into such arrangements at all;



· timing and receipt or payments of licensing and milestone revenues, if any;

· the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and our ability to operate our business without infringing the intellectual property rights of others;

· regulatory developments in the United States and foreign countries;

· the performance of our third party suppliers and manufacturers;

· our ability to maintain and establish collaborations or obtain additional funding;

· the success of competing therapies that are currently or may become available;

· our use of proceeds from this offering;

· our ability to integrate acquired businesses and assets with our operations, technologies, services, and personnel;

· our planned acquisitions, the terms of any such acquisitions and the expected timing for completing such acquisitions;

· our financial performance; and

· developments and projections relating to our competitors and our industry.

Any forward-looking statements should be considered in light of these factors. Words such as “anticipates,” “believes,” “forecasts,” “potential,” “goal,” “contemplates,” “expects,” “intends,” “plans,” “projects,” “hopes,” “seeks,” “estimates,” “strategies,” “ongoing,” “opportunity,” “could,” “would,” “should,” “likely,” “will,” “may,” “can,” “designed to,” “future,” “foreseeable future,” and other similar expressions and variations, and negatives of these words, identify forward-looking statements. These forward-looking statements are based on the expectations, estimates, projections, beliefs and assumptions of our management based on information currently available to management, all of which are subject to change. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements. Many of the important factors that will determine these results and values are beyond our ability to control or predict. You are cautioned not to put undue reliance on any forward-looking statements. Except as otherwise required by law, we do not assume any obligation to update any forward-looking statements.

In evaluating an investment in shares of our common stock, you should carefully consider the discussion of risks and uncertainties described under the heading “Risk Factors” contained in this prospectus supplement, and under similar headings in other documents, including in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, as amended, and in other filings with the SEC, that are incorporated by reference in this prospectus supplement. You should carefully read this prospectus supplement together with the information incorporated by reference in this prospectus supplement as described under the heading “Incorporation by Reference; Where You Can Find More Information”, completely and with the understanding that our actual future results may be materially different from what we expect.

All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by our cautionary statements. The forward-looking statements included or incorporated by reference herein are made only as of the date of this prospectus supplement (or as of the date of any such document incorporated by reference). We do not intend, and undertake no obligation, to update these forward-looking statements, except as required by law.

## **MARKET AND INDUSTRY DATA**

Unless otherwise indicated, we have based the information concerning our industry contained in this prospectus supplement and incorporated by reference herein on our general knowledge of and expectations concerning the industry, which involve risks and uncertainties and are subject to change based on various factors, including those discussed in the “Risk Factors” section of this prospectus supplement and in the other information contained or incorporated by reference in this prospectus supplement. These and other factors could cause the information concerning our industry to differ materially from those expressed in this prospectus supplement and incorporated by reference herein.

## USE OF PROCEEDS

We estimate that the net proceeds from the sale of the common stock in this offering will be approximately \$       million, or approximately \$       million if the underwriters exercise their option to purchase additional shares to cover over-allotments, if any, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds from this offering as follows:

- approximately \$3 million for the resubmission with the FDA of a new drug application for ZTlido®;
- approximately \$8 million for IND-enabling studies and a Phase I clinical trial for CD38 CAR-T;
- approximately \$8 million for IND-enabling studies and a Phase I clinical trial for c-MET ADC;
- approximately \$5 million for preclinical studies for our iTAbs product candidates; and

the remainder for general research, development and corporate purposes, to fund potential acquisitions and for working capital.

Our expected use of the net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus supplement, we cannot predict with complete certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the actual amounts that we will spend on the uses set forth above. The amount and timing of our actual expenditures will depend upon numerous factors, including the results of our research and development efforts, the timing and success of preclinical studies, our ongoing clinical trials or clinical trials we may commence in the future, the timing of regulatory submissions and the feedback from regulatory authorities. In addition, we might decide to postpone or not pursue clinical trials or preclinical activities if the net proceeds from this offering and the other sources of cash are less than expected, although we currently expect that the net proceeds from this offering will be used in the order set forth above or pro rata across the uses set forth above. Accordingly, our management will have broad discretion in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the net proceeds of this offering. Additionally, our management will have discretion to allocate the net proceeds from this offering for acquisitions of, or investments in, complementary businesses and products or repayment or repurchase of a portion of our indebtedness, in-licensing opportunities and pipeline development. We have no current agreements or commitments to use these proceeds to make any such acquisitions or investments or to repay or repurchase any indebtedness.

Although it is difficult to predict our liquidity requirements, based upon our current operating plan, and assuming successful completion of this offering, we believe we have sufficient cash to meet our projected operating requirements for at least the next 12 months.

Pending use of the proceeds from this offering as described above, we intend to deposit the net proceeds of this offering in our operating cash accounts, including short-term money market accounts.

S-12

**PRICE RANGE OF OUR COMMON STOCK**

Our common stock is listed on the NASDAQ Capital Market under the symbol “SRNE.” On April 11, 2017, the closing price of our common stock on the NASDAQ Capital Market was \$2.95 per share. The following table sets forth, for our fiscal periods indicated, the high and low sale prices of our common stock as reported on the NASDAQ Capital Market.

	<b>High</b>	<b>Low</b>
Fiscal Year ending December 31, 2017		
Second Quarter (through April 11, 2017)	\$3.95	2.85
First Quarter	6.07	3.90
Fiscal Year ended December 31, 2016		
Fourth Quarter	8.35	4.68
Third Quarter	8.00	5.55
Second Quarter	7.80	5.26
First Quarter	8.52	4.25
Fiscal Year ended December 31, 2015		
Fourth Quarter	10.71	7.18
Third Quarter	26.80	7.64
Second Quarter	17.83	8.15
First Quarter	14.30	8.27

**DIVIDEND POLICY**

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on our capital stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as the board of directors may consider relevant. Pursuant to the Hercules Agreement, we are prohibited from paying any dividends without the prior written consent of the Lenders. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if the common stock price appreciates.

**CAPITALIZATION**

The following table sets forth our consolidated cash and cash equivalents, debt, equity and total capitalization as of December 31, 2016:

on an actual basis; and

on an as adjusted basis to give effect to this offering and the application of the estimated net proceeds of this offering as described under “Use of Proceeds”.

The “As Adjusted” column assumes that the underwriters do not exercise their option to purchase additional shares to cover over-allotments, if any.

You should read the data set forth in the table below in conjunction with the section of this prospectus supplement under the caption “Use of Proceeds” as well as our “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and other financial information included or incorporated by reference in this prospectus supplement.

	As of December 31, 2016	
	Actual	As Adjusted (unaudited)
	(in thousands)	
Cash and cash equivalents	\$82,398	\$
Long-term debt	47,107	
Stockholders’ equity:		
Preferred stock, \$0.0001 par value; 100,000,000 shares authorized and no shares issued or outstanding, actual and as adjusted	—	
Common stock, \$0.0001 par value; 750,000,000 shares authorized, actual and as adjusted, and 50,882,856 shares issued and outstanding, actual; and shares issued and outstanding, as adjusted	6	
Additional paid-in capital	303,865	
Accumulated other comprehensive income	(118 )	
Accumulated deficit	(174,252)	
Treasury stock, 7,568,182 shares and no shares at cost at December 31, 2016, and 2015, respectively	(49,464 )	

Total stockholders' equity	80,037
Total capitalization	\$127,144 \$

The above table excludes:

4,332,876 shares of our common stock issuable upon the exercise of stock options outstanding under our 2009 Plan as of December 31, 2016, at a weighted-average exercise price of \$7.86 per share;

3,200 shares of our common stock issuable upon the exercise of stock options outstanding under our Non-Employee Director Plan, as of December 31, 2016, at a weighted-average exercise price of \$7.86 per share;

1,414,220 shares of our common stock reserved for issuance under our 2009 Plan as of December 31, 2016; and

5,932,998 shares of our common stock issuable upon the exercise of outstanding warrants as of December 31, 2016, at a weighted-average exercise price of \$7.80 per share.

**DILUTION**

Purchasers of common stock in this offering will experience immediate dilution to the extent of the difference between the public offering price per share of common stock and the net tangible book value per share of common stock immediately after this offering.

Our net tangible book value as of December 31, 2016 was approximately \$(19.8) million, or \$(0.39) per share of common stock. Net tangible book value per share is determined by dividing the net of total tangible assets less total liabilities, by the aggregate number of shares of common stock outstanding as of December 31, 2016. After giving effect to the sale by us of            shares of common stock at the public offering price of \$            per share of common stock, and after deducting underwriting discounts and commissions and estimated offering expenses, our net tangible book value as of December 31, 2016 would have been approximately \$            million, or \$            per share of common stock. This represents an immediate increase in net tangible book value of \$            per share to our existing stockholders and an immediate dilution of \$            per share of common stock issued to the new investors purchasing securities in this offering.

The following table illustrates this per share dilution:

Public offering price per share of common stock	\$
Net tangible book value per share as of December 31, 2016	\$(0.39)
Increase in net tangible book value per share attributable to this offering	\$
Net tangible book value per share after this offering	\$
Dilution per share to investors participating in this offering	\$

If the underwriters exercise their option in full to purchase            additional shares of common stock in this offering at the public offering price of \$            per share, the net tangible book value per share after this offering would be \$            per share, the increase in the net tangible book value per share to existing stockholders would be \$            per share and the dilution to new investors purchasing securities in this offering would be \$            per share.

The above table excludes:

4,332,876 shares of our common stock issuable upon the exercise of stock options outstanding under our 2009 Plan as of December 31, 2016, at a weighted-average exercise price of \$7.86 per share;



3,200 shares of our common stock issuable upon the exercise of stock options outstanding under our Non-Employee Director Plan, as of December 31, 2016, at a weighted-average exercise price of \$7.86 per share;

· 1,414,220 shares of our common stock reserved for issuance under our 2009 Plan as of December 31, 2016; and

5,932,998 shares of our common stock issuable upon the exercise of outstanding warrants as of December 31, 2016, at a weighted-average exercise price of \$7.80 per share.

To the extent that options or warrants are exercised, new options are issued under our equity incentive plans, or we issue additional shares of common stock in the future, there may be further dilution to investors participating in this offering. Moreover, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

## UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, dated April , 2017, between us and Cantor Fitzgerald & Co., 499 Park Avenue, New York, New York 10022, as the representative of the underwriters named below, we have agreed to sell to the underwriters, and the underwriters have agreed to purchase from us, the shares of common stock shown opposite its name below:

Underwriter	Number of Shares
Cantor Fitzgerald & Co.	
FBR & Co.	
Total	

The underwriting agreement provides that the obligations of the underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares of common stock if any of them are purchased. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that, following the completion of this offering, they currently intends to make a market in the common stock as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common stock, that you will be able to sell any of the common stock held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the shares of common stock subject to its acceptance of the shares of common stock from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part. In addition, the underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

## Commission and Expenses

The underwriters have advised us that they propose to offer the shares of common stock to the public at the public offering price set forth on the cover page of this prospectus supplement and to certain dealers, which may include the underwriters, at that price less a concession not in excess of \$ per share of common stock. The underwriters may

Edgar Filing: Sorrento Therapeutics, Inc. - Form 424B5

allow a discount from the concession not in excess of \$ per share of common stock to certain brokers and dealers. After the offering, the public offering price, concession and reallowance to dealers may be reduced by the underwriters.

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Per Share		Total	
	Without	With	Without	With
	Option	Option to	Option	Option to
	to	Purchase	to	Purchase
	Purchase	Additional	Purchase	Additional
	Additional	Shares	Additional	Shares
	Shares		Shares	
Public offering price	\$	\$	\$	\$
Underwriting discounts and commissions	\$	\$	\$	\$
Proceeds to us, before expenses	\$	\$	\$	\$

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately \$0. We have also agreed to reimburse the underwriters for up to \$5,000 for their FINRA counsels' fees and expenses. In accordance with FINRA Rule 5110, this reimbursed fee is deemed underwriting compensation for this offering.

### **Listing**

Our common stock is listed on The NASDAQ Capital Market under the trading symbol "SRNE".

### **Stamp Taxes**

If you purchase shares of common stock offered in this prospectus supplement, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus supplement.

### **Option to Purchase Additional Shares**

We have granted the underwriters an option, exercisable for 30 days from the date of this prospectus supplement, to purchase, from time to time, in whole or in part, up to an aggregate of shares from us at the public offering price set forth on the cover page of this prospectus supplement, less underwriting discounts and commissions. This option may be exercised only if the underwriters sell more shares than the total number set forth on the cover page of this prospectus supplement.

### **No Sales of Similar Securities**

We, our officers and our directors have agreed, subject to specified exceptions, not to directly or indirectly:

sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-1(h) under the Securities Exchange Act of 1934, as amended, or

otherwise dispose of any shares of common stock, options or warrants to acquire shares of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock currently or hereafter owned either of record or beneficially, or

publicly announce an intention to do any of the foregoing for a period of 90 days after the date of this prospectus supplement without the prior written consent of the underwriters.

This restriction terminates after the close of trading of the common stock on and including the 90<sup>th</sup> day after the date of this prospectus supplement.

The underwriters may, in their sole discretion and at any time or from time to time before the termination of the 90-day period release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our shareholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

S-17

## **Stabilization**

The underwriter has advised us that it, pursuant to Regulation M under the Securities Exchange Act of 1934, as amended, and certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the common stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either “covered” short sales or “naked” short sales.

“Covered” short sales are sales made in an amount not greater than the underwriters’ option to purchase additional shares of our common stock in this offering. The underwriter may close out any covered short position by either exercising its option to purchase additional shares of our common stock or purchasing shares of our common stock in the open market. In determining the source of shares to close out the covered short position, the underwriter will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which it may purchase shares through the option to purchase additional shares.

“Naked” short sales are sales in excess of the option to purchase additional shares of our common stock. The underwriter must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriter is concerned that there may be downward pressure on the price of the shares of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of common stock on behalf of the underwriter for the purpose of fixing or maintaining the price of the common stock. A syndicate covering transaction is the bid for or the purchase of shares of common stock on behalf of the underwriter to reduce a short position incurred by the underwriter in connection with the offering. Similar to other purchase transactions, the underwriter’s purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriter to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common stock originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we, nor the underwriter make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. The underwriter is not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

The underwriter may also engage in passive market making transactions in our common stock on The NASDAQ Capital Market in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded.

S-18

## **Electronic Distribution**

A prospectus in electronic format may be made available by e-mail or on the web sites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriter may agree with us to allocate a specific number of shares of common stock for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriter on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriter's website and any information contained in any other website maintained by the underwriter is not part of this prospectus supplement, has not been approved and/or endorsed by us or the underwriter and should not be relied upon by investors.

## **Other Activities and Relationships**

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters certain of their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or their affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the common stock offered hereby. Any such short positions could adversely affect future trading prices of the common stock offered hereby. The underwriters and certain of their affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.



## **NOTICE TO INVESTORS**

### **Canada**

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal in accordance with applicable Canadian securities laws, that are "accredited investors", as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are "permitted clients", as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus supplement (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the issuer and the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

### **Australia**

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

You confirm and warrant that you are either:

a “sophisticated investor” under section 708(8)(a) or (b) of the Corporations Act;

a “sophisticated investor” under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant’s certificate to the company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made; or

a “professional investor” within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the shares issued to you pursuant to this prospectus for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

## European Economic Area

In relation to each member state of the European Economic Area which has implemented the Prospectus Directive, each referred to herein as a Relevant Member State, with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, referred to herein as the Relevant Implementation Date, no offer of any securities which are the subject of the offering contemplated by this prospectus has been or will be made to the public in that Relevant Member State other than any offer where a prospectus has been or will be published in relation to such securities that has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the relevant competent authority in that Relevant Member State in accordance with the Prospectus Directive, except that with effect from and including the Relevant Implementation Date, an offer of such securities may be made to the public in that Relevant Member State:

- to any legal entity which is a “qualified investor” as defined in the Prospectus Directive;
- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of securities shall require the Company or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision, the expression an “offer to the public” in relation to any securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe the securities, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression “Prospectus Directive” means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State and the expression “2010 PD Amending Directive” means Directive 2010/73/EU.

## Hong Kong

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or in other circumstances which do not result in the document being a “prospectus” as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32) of Hong Kong. No document, invitation or advertisement relating to the securities has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

## **Japan**

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the underwriter will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means, unless otherwise provided herein, any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

## Singapore

This prospectus has not been and will not be lodged or registered with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or the invitation for subscription or purchase of the securities may not be issued, circulated or distributed, nor may the securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to the public or any member of the public in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person as defined under Section 275(2), or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions, specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of any other applicable provision of the SFA.

Where the securities are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

a corporation (which is not an accredited investor as defined under Section 4A of the SFA) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor,

shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest in that trust shall not be transferable for six months after that corporation or that trust has acquired the Offer Shares under Section 275 of the SFA except:

to an institutional investor under Section 274 of the SFA or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such shares, debentures and units of shares and debentures of that corporation or such rights and interest in that trust are acquired at a consideration of not less than \$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions, specified in Section 275 of the SFA;

where no consideration is given for the transfer; or

where the transfer is by operation of law.

## **Switzerland**

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, the Company or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, or FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

## **Israel**

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this document is being distributed only to, and is directed only at, and any offer of the shares is directed only at, investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and “qualified individuals”, each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors will be required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

## **United Kingdom**

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, referred to herein as the Order, and/or (ii) high net worth entities falling within Article 49(2)(a) to (d) of the

Order and other persons to whom it may lawfully be communicated. Each such person is referred to herein as a Relevant Person.

This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a Relevant Person should not act or rely on this document or any of its contents.

S-22

## **LEGAL MATTERS**

The validity of the securities offered by this prospectus supplement will be passed upon for us by Paul Hastings LLP, Palo Alto, California. Kramer Levin Naftalis & Frankel LLP, New York, New York, is counsel to the underwriters in connection with this offering.

## **EXPERTS**

The consolidated financial statements and the related financial statement schedule, incorporated in this prospectus supplement by reference from the Annual Report on Form 10-K for the year ended December 31, 2016 of Sorrento Therapeutics, Inc. and subsidiaries (the “Company”), and the effectiveness of the Company’s internal control over financial reporting have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their reports (which reports (1) express an unqualified opinion on the consolidated financial statements and financial statement schedule and include an explanatory paragraph referring to the Company’s ability to continue as a going concern and (2) express an adverse opinion on the effectiveness of the Company’s internal control over financial reporting because of a material weakness), which are incorporated herein by reference. Such consolidated financial statements and financial statement schedule have been so incorporated in reliance upon the reports of such firm given upon their authority as experts in accounting and auditing.

The consolidated financial statements of Sorrento Therapeutics, Inc. for each of the years in the two-year period ended December 31, 2015, incorporated by reference in this prospectus supplement have been audited by Mayer Hoffman McCann P.C., an independent registered public accounting firm, as stated in their reports incorporated by reference herein.

The financial statements of Scilex Pharmaceuticals Inc. as of December 31, 2015 and 2014 and for each of the years then ended incorporated by reference in this prospectus supplement have been so included in reliance on the report of BDO USA, LLP, independent auditors (the report on the financial statements contains an emphasis of matter paragraph regarding Scilex Pharmaceuticals Inc.’s ability to continue as a going concern) incorporated by reference herein, given on the authority of said firm as experts in auditing and accounting.



## **INFORMATION INCORPORATED BY REFERENCE; WHERE YOU CAN FIND MORE INFORMATION**

The SEC allows us to incorporate by reference into this prospectus supplement certain information we file with it, which means that we can disclose important information by referring you to those documents. The information incorporated by reference is considered to be a part of this prospectus supplement, and information that we file later with the SEC will automatically update and supersede information contained in this prospectus supplement and any accompanying prospectus supplement. We incorporate by reference the documents listed below that we have previously filed with the SEC:

our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, filed with the SEC on March 22, 2017, as amended by our Amendment No. 1 to Annual Report on Form 10-K/A, filed with the SEC on March 27, 2017;

our Current Reports on Form 8-K filed with the SEC on January 5, 2017 (only with respect to Item 1.02 thereof), March 20, 2017, March 21, 2017 and March 24, 2017;

our Current Report on Form 8-K/A filed with the SEC on January 20, 2017; and

the description of our common stock set forth in our Registration Statement on Form 8-A (File No. 001-36150), filed with the SEC on October 23, 2013, including any amendments or reports filed for the purpose of updating such description.

All documents we file pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act on or after the date of this prospectus supplement and before the later of (1) the completion of the offering of the securities described in this prospectus supplement and (2) if applicable, the date any underwriter stops offering securities pursuant to this prospectus supplement will also be incorporated by reference in this prospectus supplement from the date of filing of such documents. Upon request, we will provide to each person, including any beneficial owner, to whom a prospectus supplement is delivered a copy of any or all of the information that has been incorporated by reference in this prospectus supplement but not delivered with this prospectus supplement.

Notwithstanding the preceding, unless specifically stated to the contrary, none of the information that we disclose under 2.02 or 7.01 or, if related to Items 2.02 or 7.01, Item 9.01 of any Current Report on Form 8-K that we may, from time to time, furnish to the SEC will be incorporated by reference into, or otherwise included in, this prospectus supplement. The information contained in each of the documents incorporated by reference speaks only as of the date of such document. Any statement contained in a document incorporated reference or deemed to be incorporated by

reference herein, or contained in this prospectus supplement, shall be deemed to be modified or superseded for purposes of this prospectus supplement to the extent that a statement contained herein or in any subsequently filed document or report that also is incorporated by reference or is deemed to be incorporated by reference herein modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus supplement.

We file annual, quarterly and other reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at <http://www.sec.gov>. You may also read and copy any document we file at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the Public Reference Room. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K, including any amendments to those reports, and other information that we file with or furnish to the SEC pursuant to Section 13(a) or 15(d) of the Exchange Act can also be accessed free of charge through the Internet. These filings will be available as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

We have filed with the SEC a registration statement under the Securities Act relating to the offering of these securities. The registration statement, including the attached exhibits, contains additional relevant information about us and the securities. This prospectus supplement does not contain all of the information set forth in the registration statement. You can obtain a copy of the registration statement, at prescribed rates, from the SEC at the address listed above. The registration statement and the documents referred to below under "Information Incorporated by Reference" are also available on our corporate website at [www.sorrentotherapeutics.com](http://www.sorrentotherapeutics.com) under the heading "Investors.". Unless specifically listed above, the information contained on the SEC website or our website is not incorporated by reference into this prospectus supplement and you should not consider that information a part of this prospectus supplement. You may obtain a copy of any of these documents at no cost, by writing or telephoning us at the following address:

Sorrento Therapeutics, Inc.  
9380 Judicial Drive,  
San Diego, California  
Attention: Corporate Secretary  
Phone: (858) 210-3700

This prospectus supplement may contain information that updates, modifies or is contrary to information in one or more of the documents incorporated by reference in this prospectus supplement. You should rely only on the information incorporated by reference or provided in this prospectus supplement. We have not authorized anyone else to provide you with different information. You should not assume that the information in this prospectus supplement is accurate as of any date other than the date of this prospectus supplement or the date of the documents incorporated by reference in this prospectus supplement.



**PROSPECTUS**

**\$250,000,000**

**Common Stock**

**Preferred Stock**

**Warrants**

**Units**

We may offer and sell, from time to time in one or more offerings, any combination of common stock, preferred stock, warrants or units having an aggregate initial offering price not exceeding \$250,000,000. The preferred stock, warrants and units may be convertible or exercisable or exchangeable for common stock or preferred stock or other securities of ours. When we decide to sell a particular class or series of securities, we will provide specific terms of the offered securities in a prospectus supplement.

We will provide specific terms of the offerings of our securities in supplements to this prospectus. The prospectus supplement may also add, update or change information in this prospectus. You should read this prospectus and any prospectus supplement, as well as the documents incorporated by reference or deemed to be incorporated by reference into this prospectus, carefully before you invest.

**This prospectus may not be used to offer or sell our securities unless accompanied by a prospectus supplement relating to the offered securities.**

Our common stock is presently traded on The NASDAQ Capital Market under the symbol SRNE. On November 3, 2014, the last reported sale price of our common stock was \$4.55.

These securities may be sold directly by us, through dealers or agents designated from time to time, to or through underwriters, dealers or through a combination of these methods on a continuous or delayed basis. See "Plan of Distribution" in this prospectus. We may also describe the plan of distribution for any particular offering of our securities in a prospectus supplement. If any agents, underwriters or dealers are involved in the sale of any securities in respect of which this prospectus is being delivered, we will disclose their names and the nature of our arrangements with them in a prospectus supplement. The net proceeds we expect to receive from any such sale will also be included in a prospectus supplement.

**Investing in our securities involves various risks. See Risk Factors beginning on page 2 for more information on these risks. Additional risks will be described in the related prospectus supplements under the heading Risk Factors . You should review that section of the related prospectus supplements for a discussion of matters that investors in our securities should consider.**

**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 or any accompanying prospectus supplement. Any representation to the contrary is a criminal offense.**

**The date of this Prospectus is December 3, 2014**

**Table of Contents**

**TABLE OF CONTENTS**

	<b>Page</b>
<u>ABOUT THIS PROSPECTUS</u>	1
<u>THE COMPANY</u>	1
<u>RISK FACTORS</u>	2
<u>DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS</u>	28
<u>USE OF PROCEEDS</u>	28
<u>THE SECURITIES WE MAY OFFER</u>	28
<u>DESCRIPTION OF CAPITAL STOCK</u>	29
<u>DESCRIPTION OF WARRANTS</u>	30
<u>PLAN OF DISTRIBUTION</u>	33
<u>LEGAL MATTERS</u>	34
<u>EXPERTS</u>	34
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	34
<u>INCORPORATION OF DOCUMENTS BY REFERENCE</u>	35

**Table of Contents**

**ABOUT THIS PROSPECTUS**

This prospectus is part of a shelf registration statement that we filed with the Securities and Exchange Commission (the SEC) using a shelf registration process. Under this shelf registration process, we may sell any combination of the securities described in this prospectus in one or more offerings from time to time having an aggregate initial offering price of \$250,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we offer securities, we will provide you with a prospectus supplement that describes the specific amounts, prices and terms of the securities we offer. The prospectus supplement also may add, update or change information contained in this prospectus. You should read carefully both this prospectus and any prospectus supplement together with additional information described below under the caption **Where You Can Find More Information**.

This prospectus does not contain all the information provided in the registration statement we filed with the SEC. You should read both this prospectus, including the section titled **Risk Factors**, and the accompanying prospectus supplement, together with the additional information described under the heading **Where You Can Find More Information**.

You should rely only on the information contained or incorporated by reference in this prospectus or a prospectus supplement. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus is not an offer to sell securities, and it is not soliciting an offer to buy securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus or any prospectus supplement, as well as information we have previously filed with the SEC and incorporated by reference, is accurate as of the date on the front of those documents only. Our business, financial condition, results of operations and prospects may have changed since those dates.

**THE COMPANY**

**Business Overview**

We are a biopharmaceutical company engaged in the discovery, acquisition, development and commercialization of proprietary drug therapeutics for addressing significant unmet medical needs in the U.S., Europe and additional international markets. Our primary therapeutic focus is oncology, including the treatment of chronic cancer pain, but we are also developing therapeutic products for other indications, including immunology and infectious diseases. We currently have two clinical development programs underway: (i) our lead oncology drug product candidate Cynviloq, a micellar diblock copolymeric paclitaxel formulation, and (ii) resiniferatoxin, a non-opiate, ultra potent and selective agonist of the TRPV-1 receptor for intractable pain in end-stage disease.

Our pipeline also includes a number of preclinical fully human therapeutic antibodies, including our anti-PD-L1 and anti-PD-1 monoclonal antibodies, or Abs, derived from our proprietary G-MAB<sup>®</sup> library platform, antibody drug conjugates, or ADCs. Our objective is to develop two classes of antibody drug products, therapeutic antibodies and ADCs: (i) First in Class, or FIC, and/or (ii) Best in Class, or BIC, which may offer greater efficacy and/or fewer adverse events or side effects as compared to existing drugs.

Although we intend to retain ownership and control of some product candidates by advancing their development, we will also consider partnerships with pharmaceutical or biopharmaceutical companies in order to balance the risks associated with drug discovery and development and maximize our stockholders' returns. Our partnering objectives include generating revenue through license fees, milestone-related development fees and royalties by licensing rights to our product candidates.

Our goal is to deliver innovative, highly effective and safe treatment options to patients throughout the world. By working closely with scientists, doctors, patient organizations and other health care specialists, we are committed to improving the lives of patients and assisting their caregivers in their fight against serious diseases.

## **Recent Developments**

### *Cynviloq*

On October 14, 2014, we issued a press release announcing positive results from recently analyzed pharmacokinetic, or PK, data from the first eight patients enrolled in our ongoing TRIBECA (TRIAL establishing BE between Cynviloq and Albumin-bound paclitaxel) registrational trial. The TRIBECA trial is expected to be completed in the first quarter of 2015 with an NDA submission in 2015.

### *License Agreement with Lee's Pharmaceutical Holdings Limited*

On October 3, 2014, we entered into a license agreement with Lee's Pharmaceutical Holdings Limited, or Lee's Pharma, pursuant to which Lee's Pharma licensed our fully human immune-oncology anti-PD-L1 monoclonal antibody STI-A1014. Under the terms of the agreement, Lee's Pharma received exclusive rights to develop and commercialize the STI-A1014 for the greater Chinese market, including Mainland China, Hong Kong, Macau, and Taiwan. In turn, we will receive an up-front payment, potential future milestone payments and high single digit to double digit royalties on future net sales. In total, we have the potential to receive more than \$46 million upon the successful attainment of key milestones, excluding royalties, and retains all the rights to use data generated by Lee's Pharma for territories outside of the greater Chinese market. Additionally, Lee's Pharma purchased 400,000 shares of our common stock at a price of \$9.00 per share, or an aggregate of \$3.6 million.



## **Table of Contents**

### *Collaboration Agreement with Esai / Morphotek.*

On June 25, 2014, we entered into a collaboration agreement to generate novel ADCs based on a Morphotek antibody linked to chemotherapeutic agents using proprietary ADC Technology. Under the terms of the agreement, we will receive research fees, an up-front payment, milestone payments and royalties on future net sales. Additionally, we have the potential to receive up to \$50 million upon the successful attainment of key milestones.

### *License and Development Agreement with Ark Animal Health, Inc., our wholly-owned subsidiary*

On June 18, 2014, we entered into a License and Development Agreement, or LDA, with our wholly-owned subsidiary Ark Animal Health, Inc., or Ark, whereby we granted Ark a license to develop and commercialize RTX for animal use only, in exchange for the issuance to us of 10,000,000 shares of Ark common stock valued at \$13.1 million representing 100% of the outstanding shares of Ark.

## **Corporate Information**

On September 21, 2009, QuikByte Software, Inc., a shell company, or QuikByte, acquired Sorrento Therapeutics, Inc., a privately held Delaware corporation, or STI, in a reverse merger, or Merger. Pursuant to the Merger, all of the issued and outstanding shares of STI common stock were exchanged into shares of QuikByte common stock and STI became a wholly owned subsidiary of QuikByte. STI and QuikByte reincorporated in Delaware in December 2009, and on December 4, 2009, STI merged with and into QuikByte, the separate corporate existence of STI ceased and QuikByte continued as the surviving corporation. Contemporaneously, QuikByte Software, Inc. changed its name to Sorrento Therapeutics, Inc. Our principal executive office is located at 6042 Cornerstone Ct. West, Suite B, San Diego, California 92121. Our telephone number is (858) 210-3700 and our website address is [www.sorrentotherapeutics.com](http://www.sorrentotherapeutics.com). The information on our website is not a part of, and should not be construed as being incorporated by reference into, this prospectus supplement or the accompanying prospectus.

## **RISK FACTORS**

*You should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones we face. Additional risks we are not presently aware of or that we currently believe are immaterial may also impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained or incorporated by reference into this prospectus and any accompanying prospectus supplement, including our financial statements and related notes.*

### **Risks Related to Our Financial Position and Capital Requirements**

*We are a development-stage company subject to all of the risks and uncertainties of a new business, including the risk that we or our partners may never develop, complete development or market any of our product candidates or generate product related revenues.*

We are a development-stage biopharmaceutical company that began operating and commenced research and development activities in 2009. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. There is no assurance that our libraries of fully-human mAbs will be suitable for diagnostic or therapeutic use, or that we will be able to identify and isolate therapeutics product candidates, or develop, market and commercialize these candidates. We do not expect any of our fully-human mAb, ADC, RTX, Cynviloq or related companion diagnostic product candidates to be commercially available for a few years, if at all.

Even if we are able to commercialize our product candidates, there is no assurance that these candidates would generate revenues or that any revenues generated would be sufficient for us to become profitable or thereafter maintain profitability.

***We do not have any products that are approved for commercial sale and therefore do not expect to generate any revenues from product sales in the foreseeable future, if ever.***

We have not generated any product related revenues to date, and do not expect to generate any such revenues for at least the next several years, if at all. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing products with commercial potential. We may never succeed in these activities, and we may not generate sufficient revenues to continue our business operations or achieve profitability.

***We have incurred significant losses since inception and anticipate that we will incur continued losses for the foreseeable future.***

As of September 30, 2014, December 31, 2013 and 2012, we had an accumulated deficit of \$59.0 million, \$32.9 million and \$11.0 million, respectively. We have incurred operating losses since our inception, expect to continue to incur significant operating losses for the foreseeable future, and we expect these losses to increase as we: (i) complete our bioequivalence, or BE, registration trial related to Cynviloq and prepare for our New Drug Application, or NDA, filing anticipated in 2015, (ii) advance RTX into clinical

**Table of Contents**

trials and potentially pursue other human or veterinary indications, (iii) continue to identify and advance a number of potential mAb and ADC drug candidates into preclinical and clinical development activities, (iv) continue our development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products, and (v) expand our corporate infrastructure, including the costs associated with being a NASDAQ public company. As such, we are subject to all risks incidental to the development of new biopharmaceutical products and related companion diagnostics, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

***We will require substantial additional funding which may not be available to us on acceptable terms, or at all. If we fail to raise the necessary additional capital, we may be unable to complete the development and commercialization of our product candidates, or continue our development programs.***

Our operations have consumed substantial amounts of cash since inception. We expect to significantly increase our spending to advance the preclinical and clinical development of our product candidates and launch and commercialize any product candidates for which we receive regulatory approval, including building our own commercial organizations to address certain markets. We will require additional capital for the further development and commercialization of our product candidates, as well as to fund our other operating expenses and capital expenditures.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. We may also seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available. Any of these events could significantly harm our business, financial condition and prospects.

Our future capital requirements will depend on many factors, including:

the progress of the development of our fully-human mAb, ADC, RTX, Cynviloq or related companion diagnostic product candidates;

the number of product candidates we pursue;

the time and costs involved in obtaining regulatory approvals;

the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims;

our plans to establish sales, marketing and/or manufacturing capabilities;

the effect of competing technological and market developments;

the terms and timing of any collaborative, licensing and other arrangements that we may establish;

general market conditions for offerings from biopharmaceutical companies;

our ability to establish, enforce and maintain selected strategic alliances and activities required for product commercialization; and

our revenues, if any, from successful development and commercialization of our product candidates.

In order to carry out our business plan and implement our strategy, we anticipate that we will need to obtain additional financing from time to time and may choose to raise additional funds through strategic collaborations, licensing arrangements, public or private equity or debt financing, bank lines of credit, asset sales, government grants, or other arrangements. We cannot be sure that any additional funding, if needed, will be available on terms favorable to us or at all. Furthermore, any additional equity or equity-related financing may be dilutive to our stockholders, and debt or equity financing, if available, may subject us to restrictive covenants and significant interest costs. If we obtain funding through a strategic collaboration or licensing arrangement, we may be required to relinquish our rights to certain of our product candidates or marketing territories.

Further, there is uncertainty related to future National Institute of Health, or NIH, grant funding, and the NIH plans for new grants or cooperative agreements may be re-scoped, delayed, or canceled depending on the nature of the work and the availability of resources. As a result, we cannot assure you that we will receive any additional funding under our existing NIH grants, and we may not be successful in securing additional grants from the NIH in the future.

## **Table of Contents**

Our inability to raise capital when needed would harm our business, financial condition and results of operations, and could cause our stock price to decline or require that we wind down our operations altogether.

### **Risks Related to Our Business and Industry**

*We are heavily dependent on the success of our technologies and product candidates, and we cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized.*

To date, we have invested a significant portion of our efforts and financial resources in the acquisition and development of our product candidates. We have not demonstrated our ability to perform the functions necessary for the successful acquisition, development or commercialization of the technologies we are seeking to develop. As an early stage company, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. Our future success is substantially dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize such product candidates. Our product candidates are currently in preclinical development or in clinical trials. Our business depends entirely on the successful development and commercialization of our product candidates, which may never occur. We currently generate no revenues from sales of any drugs, and we may never be able to develop or commercialize a marketable drug.

The successful development, and any commercialization, of our technologies and any product candidates would require us to successfully perform a variety of functions, including:

developing our technology platform;

identifying, developing, manufacturing and commercializing product candidates;

entering into successful licensing and other arrangements with product development partners;

participating in regulatory approval processes;

formulating and manufacturing products; and

conducting sales and marketing activities.

Our operations have been limited to organizing our company, acquiring, developing and securing our proprietary technology and identifying and obtaining early preclinical data or clinical data for various product candidates. These operations provide a limited basis for you to assess our ability to continue to develop our technology, identify product candidates, develop and commercialize any product candidates we are able to identify and enter into successful collaborative arrangements with other companies, as well as for you to assess the advisability of investing in our securities. Each of these requirements will require substantial time, effort and financial resources.

Each of our product candidates will require additional preclinical or clinical development, management of preclinical, clinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, building of a commercial organization, and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the U.S. Food and Drug Administration, or FDA, or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. In addition, our product development programs contemplate the development of companion diagnostics by our third-party collaborators. Companion diagnostics are subject to regulation as medical devices and must themselves be pre-cleared or approved for marketing by the FDA or certain other foreign regulatory agencies before we may commercialize our product candidates.

***Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.***

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure 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. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. It is not uncommon for companies in the biopharmaceutical industry to suffer significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trial results may not be successful.

## **Table of Contents**

This drug candidate development risk is heightened by any changes in the planned clinical trials compared to the completed clinical trials. As product candidates are developed through preclinical to early and late stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and methods of administration, are altered along the way in an effort to optimize processes and results. While these types of changes are common and are intended to optimize the product candidates for late stage clinical trials, approval and commercialization, such changes do carry the risk that they will not achieve these intended objectives.

We have not previously initiated or completed a corporate-sponsored clinical trial. Consequently, we may not have the necessary capabilities, including adequate staffing, to successfully manage the execution and completion of any clinical trials we initiate, including our planned clinical trials of Cynviloq and RTX, in a way that leads to our obtaining marketing approval for our product candidates in a timely manner, or at all.

In the event we are able to conduct a pivotal clinical trial of a product candidate, the results of such trial may not be adequate to support marketing approval. Because our product candidates are intended for use in life-threatening diseases, in some cases we ultimately intend to seek marketing approval for each product candidate based on the results of a single pivotal clinical trial. As a result, these trials may receive enhanced scrutiny from the FDA. For any such pivotal trial, if the FDA disagrees with our choice of primary endpoint or the results for the primary endpoint are not robust or significant relative to control, are subject to confounding factors, or are not adequately supported by other study endpoints, including possibly overall survival or complete response rate, the FDA may refuse to approve a biologics license application, or BLA, based on such pivotal trial. The FDA may require additional clinical trials as a condition for approving our product candidates.

In some of our future trials, we may combine Cynviloq with other therapies such as chemotherapy or immunotherapy. We have not yet tested these combinations.

### ***Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.***

Although we are planning for certain clinical trials relating to Cynviloq and RTX, there can be no assurance that the FDA will accept our proposed trial designs. We may experience delays in our clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

obtaining regulatory approval to commence a trial;

reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

obtaining institutional review board, or IRB, approval at each site;

recruiting suitable patients to participate in a trial;

clinical sites deviating from trial protocol or dropping out of a trial;

having patients complete a trial or return for post-treatment follow-up;

developing and validating companion diagnostics on a timely basis, if required;

adding new clinical trial sites; or

manufacturing sufficient quantities of product candidate for use in clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, 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' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we intend to have agreements governing their committed activities, we will have limited influence over their actual performance.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial



## **Table of Contents**

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 drug, 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, the commercial prospects of our product candidates will 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 harm our business, financial condition and prospects significantly. 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.

***Competition for patients in conducting clinical trials may prevent or delay product development and strain our limited financial resources.***

Many pharmaceutical companies are conducting clinical trials in patients with the disease indications that our potential drug products target. As a result, we must compete with them for clinical sites, physicians and the limited number of patients who fulfill the stringent requirements for participation in clinical trials. Also, due to the confidential nature of clinical trials, we do not know how many of the eligible patients may be enrolled in competing studies and who are consequently not available to us for our clinical trials. Our clinical trials may be delayed or terminated due to the inability to enroll enough patients. Patient enrollment depends on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites and the eligibility criteria for the study. The delay or inability to meet planned patient enrollment may result in increased costs and delays or termination of the trial, which could have a harmful effect on our ability to develop products.

***The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.***

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;

we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;

the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;

the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;

the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;

the FDA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing with partners; and

the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

## **Table of Contents**

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

We have not previously submitted a BLA or NDA to the FDA, or similar drug approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenues will be dependent, in part, upon our collaborators' ability to obtain regulatory approval of the companion diagnostics to be used with our product candidates, as well as the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patients that we are targeting for our product candidates are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval to commercialize our product candidates both in the U.S., the European Union and in additional foreign countries. While the scope of regulatory approval is similar in other countries, to obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions.

### ***Our most rapid and cost effective access to market approval for Cynviloq depends on meeting the conditions for approval under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA.***

We are seeking approval for Cynviloq under Section 505(b)(2) of the FDCA, enacted as part of the Drug Price Competition and Patent Restoration Act of 1984, otherwise known as the Hatch-Waxman Act, which permits applicants to rely in part on preclinical and clinical data generated by third parties.

Specifically, with respect to Cynviloq, we are relying in part on third party data on paclitaxel, which is the active ingredient in Cynviloq and the previously approved products Abraxane<sup>®</sup> and Taxol. There can be no assurance that the FDA will not require us to conduct additional preclinical or clinical studies or otherwise obtain new supplementary data with respect to some or all of the data upon which we may rely prior to approving a Cynviloq NDA. For instance, if bioequivalence, or BE, is not established between Abraxane and Cynviloq, then clinical trials to assess the safety and/or efficacy of our formulation may be needed.

Our NDA also relies on prior FDA findings of safety and effectiveness of previously approved products, and we will make certifications in our NDA under Section 505(b)(2) requirements based on the listed patents in the FDA publication Approved Drug Products with Therapeutics Equivalence Evaluations, or the Orange Book, for certain of these referenced products. In the event that one or more patents is listed in the Orange Book for the referenced product after our submission of additional information in support of our NDA for Cynviloq, we may also be required to

evaluate the applicability of these patents to Cynviloq and submit additional certifications. A paragraph III certification, stating that a listed patent has not expired, but will expire on a particular date, may delay the approval of Cynviloq until the expiration of the patent. A paragraph IV certification, stating that a listed patent is invalid, unenforceable, or not infringed by Cynviloq may require us to notify the patent owner and the holder of the NDA for the referenced product of the existence of the Cynviloq NDA, and may result in patent litigation against us and the entry of a 30-month stay of FDA ability to issue final approval of the 505(b)(2) NDA for Cynviloq.

Our success also relies, in part, on obtaining Hatch-Waxman marketing exclusivity in connection with any approval of our NDA for Cynviloq. Such exclusivity protection would preclude the FDA from approving a marketing application for a duplicate of Cynviloq, a product candidate that the FDA views as having the same conditions of approval as Cynviloq (for example, the same indication, the same route of delivery and/or other conditions of use), or a 505(b)(2) NDA submitted to the FDA with Cynviloq as the reference product, for a period of three years from the date of Cynviloq approval, although the FDA may accept and commence review of such applications. This form of exclusivity may not prevent FDA approval of an NDA that relies only on its own data to support the change or innovation. Similarly, if, prior to approval of the Cynviloq NDA, another company obtains approval for a product candidate under, in the view of the FDA, the same conditions of approval that we are seeking for Cynviloq, Cynviloq could be blocked until the other company's three-year Hatch-Waxman marketing exclusivity expires.

***Our approach to the discovery and development of product candidates that target ADCs is unproven, and we do not know whether we will be able to develop any products of commercial value.***

ADCs are emerging technologies and, consequently, it is conceivable that such technologies may ultimately fail to identify commercially viable drugs to treat human patients with cancer or other diseases.

## Table of Contents

***Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.***

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. To date, patients treated with Cynviloq have experienced drug-related side effects such as neutropenia, leukopenia, anemia, thrombocytopenia, peripheral neuropathy, myalgia nausea, vomiting, diarrhea, alopecia, rash, pruritus and hypersensitivity reactions. The clinical evaluation of Cynviloq is still in the early stages, but as is the case with all oncology drugs, it is likely that there may be side effects associated with its use. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

regulatory authorities may withdraw approvals of such product;

regulatory authorities may require additional warnings on the label;

we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;

we could be sued and held liable for harm caused to patients; and

our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate or for particular indications of a product candidate, if approved, and could significantly harm our business, results of operations and prospects.

***We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully perform their contractual legal and regulatory duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.***

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is

conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with current good clinical practices, or cGCP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all of our products in clinical development.

Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the European Medicines Agency, or EMA, or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with cGCP regulations. In addition, our clinical trials must be conducted with product produced under current good manufacturing practices, or cGMP, regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going clinical, nonclinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

## **Table of Contents**

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

***We expect to rely on third parties to manufacture our clinical drug supplies and we intend to rely on third parties to produce commercial supplies of any approved product candidate, and our commercialization of any of our product candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of drug product or fail to do so at acceptable quality levels or prices.***

We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our clinical drug supplies for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the cGMP regulatory requirements for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

***Material necessary to manufacture our product candidates may not be available on commercially reasonable terms, or at all, which may delay the development and commercialization of our product candidates.***

We rely on our manufacturers to produce or purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our drugs and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Except for the manufacture and supply of Cynviloq, we currently do not have any agreements for the commercial production of these raw materials. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

We expect to continue to depend on third-party contract manufacturers for the foreseeable future. We have not entered into long-term agreements with all of our current contract manufacturers or with any alternate fill/finish suppliers, and though we intend to do so prior to commercial launch in order to ensure that we maintain adequate supplies of finished drug product, we may be unable to enter into such an agreement or do so on commercially reasonable terms, which could have a material adverse impact upon our business. We currently obtain our supplies of finished drug product through individual purchase orders.

***We may not be able to manufacture our product candidates in commercial quantities, which would prevent us from commercializing our product candidates.***

We are dependent on our third party manufacturers to conduct process development and scale-up work necessary to support greater clinical development and commercialization requirements for our product candidates. Carrying out these activities in a timely manner, and on commercially reasonable terms, is critical to the successful development and commercialization of our product candidates. We expect our third-party manufacturers are capable of providing sufficient quantities of our product candidates to meet anticipated clinical and full-scale commercial demands, however if third parties with whom we currently work are unable to meet our supply requirements, we will need to secure alternate suppliers. While we believe that there are other contract manufacturers having the technical capabilities to manufacture our product candidates, we cannot be certain that identifying and establishing relationships with such sources would not result in significant delay or material additional costs.

***We currently have no sales and marketing organization. If we are unable to establish a direct sales force in the U.S. to promote our products, the commercial opportunity for our products may be diminished.***

We currently have no sales and marketing organization. If any of our product candidates are approved by the FDA, we intend to market that product through our own sales force. We will incur significant additional expenses and commit significant additional management resources to establish our sales force. We may not be able to establish these capabilities despite these additional expenditures. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire and train sales and marketing personnel. If we elect to rely on third parties to sell our product candidates in the U.S., we may receive less revenue than if we sold our products directly. In addition, although we would intend to use due diligence in monitoring their activities, we may have little or no control over the sales efforts of those third parties. In the event we are unable to develop our own sales force or collaborate with a third party to sell our product candidates, we may not be able to commercialize our product candidates which would negatively impact our ability to generate revenue.



## Table of Contents

*We may need others to market and commercialize our product candidates in international markets.*

In the future, if appropriate regulatory approvals are obtained, we may commercialize our product candidates in international markets. However, we have not decided how to commercialize our product candidates in those markets. We may decide to build our own sales force or sell our products through third parties. If we decide to sell our product candidates in international markets through a third party, we may not be able to enter into any marketing arrangements on favorable terms or at all. In addition, these arrangements could result in lower levels of income to us than if we marketed our product candidates entirely on our own. If we are unable to enter into a marketing arrangement for our product candidates in international markets, we may not be able to develop an effective international sales force to successfully commercialize those products in international markets. If we fail to enter into marketing arrangements for our products and are unable to develop an effective international sales force, our ability to generate revenue would be limited.

*Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.*

Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and cGCPs for any clinical trials that we conduct post-approval. The future discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;

fines, warning letters or holds on clinical trials;

refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;

product seizure or detention, or refusal to permit the import or export of products; and

injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

***We will need to obtain FDA approval of any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business.***

A pharmaceutical product cannot be marketed in the U.S. or other countries until we have completed rigorous and extensive regulatory review processes, including approval of a brand name. Any brand names we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office, or the PTO. The FDA typically conducts a review of proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if we believe the name inappropriately implies medical claims. If the FDA objects to any of our proposed product brand names, we may be required to adopt an alternative brand name for our product candidates. If we adopt an alternative brand name, we would lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

**Table of Contents**

***Our failure to successfully discover, acquire, develop and market additional product candidates or approved products would impair our ability to grow.***

As part of our growth strategy, we intend to develop and market additional products and product candidates. We are pursuing various therapeutic opportunities through our pipeline. We may spend several years completing our development of any particular current or future internal product candidate, and failure can occur at any stage. The product candidates to which we allocate our resources may not end up being successful. In addition, because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select, discover and acquire promising pharmaceutical product candidates and products. Failure of this strategy would impair our ability to grow.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;

incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;

higher than expected acquisition and integration costs;

difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;

increased amortization expenses;

impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership;

inability to motivate key employees of any acquired businesses; and

assumption of known and unknown liabilities.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities.

***Our commercial success depends upon us attaining significant market acceptance of our product candidates, if approved for sale, among physicians, patients, healthcare payors and major operators of cancer and other clinics.***

Even if we obtain regulatory approval for our product candidates, the product may not gain market acceptance among physicians, health care payors, patients and the medical community, which are critical to commercial success. Market acceptance of any product candidate for which we receive approval depends on a number of factors, including:

the efficacy and safety as demonstrated in clinical trials;

the timing of market introduction of such product candidate as well as competitive products;

the clinical indications for which the drug is approved;

acceptance by physicians, major operators of cancer clinics and patients of the drug as a safe and effective treatment;

**Table of Contents**

the safety of such product candidate seen in a broader patient group, including its use outside the approved indications;

the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs;

the availability of adequate reimbursement and pricing by third-party payors and government authorities;

the relative convenience and ease of administration of Cynviloq for clinical practices;

the product labeling or product insert required by the FDA or regulatory authority in other countries;

the approval, availability, market acceptance and reimbursement for a companion diagnostic, if any;

the prevalence and severity of adverse side effects; and

the effectiveness of our sales and marketing efforts.

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as, or is perceived as being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and sell any approved products will also depend on pricing and cost-effectiveness, including our ability to produce a product at a competitive price and our ability to obtain sufficient third-party coverage or reimbursement. If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, patients and third-party payors, our ability to generate revenues from that product would be substantially reduced. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, may be constrained by FDA rules and policies on product promotion, and may never be successful.

***If we fail to develop Cynviloq for additional indications, our commercial opportunity will be limited.***

To date, our initial focus has been on the development of Cynviloq for the treatment of metastatic breast cancer, or MBC, and non-small cell lung cancer, or NSCLC. A key element of our strategy is to pursue clinical development of Cynviloq for bladder cancer and ovarian cancer, and potentially for other indications. Although we believe there is large commercial opportunity for the treatment of MBC and NSCLC alone, our ability to generate and grow revenues will be highly dependent on our ability to successfully develop and commercialize Cynviloq for the treatment of additional indications. The development of Cynviloq for additional indications is prone to the risks of failure inherent in drug development and we cannot provide you any assurance that we will be able to successfully advance any of these programs through the development process. Even if we receive FDA approval to market Cynviloq for the treatment of any additional indications, we cannot assure you that any such indications will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize Cynviloq for additional indications, our commercial

opportunity will be limited and our business prospects will suffer.

***If we cannot compete successfully against other biotechnology and pharmaceutical companies, we may not be successful in developing and commercializing our technology and our business will suffer.***

The biotechnology and pharmaceutical industries are characterized by intense competition and rapid technological advances, both in the U.S. and internationally. In addition, the competition in the oncology market is intense. For example, our late-stage product candidate, Cynviloq, may compete directly with a marketed product, Abraxane, for certain cancer indications. Abraxane is already approved for MBC, NSCLC and pancreatic cancer, and approval is being pursued for and melanoma cancer. Even if we are able to develop our proprietary platform technology and additional antibody libraries, each will compete with a number of existing and future technologies and product candidates developed, manufactured and marketed by others. Specifically, we will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have validated technologies with products already FDA-approved or in various stages of development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs and have substantially greater financial resources than we do, as well as significantly greater experience in:

developing product candidates and technologies generally;

**Table of Contents**

undertaking preclinical testing and clinical trials;

obtaining FDA and other regulatory approvals of product candidates;

formulating and manufacturing product candidates; and

launching, marketing and selling product candidates.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early-stage companies or generic pharmaceutical manufacturers may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products that are more effective or less costly than any drug candidate that we are currently developing or that we may develop. If approved, our product candidates will face competition from commercially available drugs as well as drugs that are in the development pipelines of our competitors and later enter the market.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA, EMA or other regulatory approval or discovering, developing and commercializing medicines before we do, which would have a material adverse impact on our business. If our technologies fail to compete effectively against third party technologies, our business will be adversely impacted.

We expect that our ability to compete effectively will depend upon our ability to:

successfully and rapidly complete clinical trials and submit for and obtain all requisite regulatory approvals in a cost-effective manner;

maintain a proprietary position for our products and manufacturing processes and other related product technology;

attract and retain key personnel;

develop relationships with physicians prescribing these products; and

build an adequate sales and marketing infrastructure for our product candidates.

Because we will be competing against significantly larger companies with established track records, we will have to demonstrate that, based on experience, clinical data, side-effect profiles and other factors, our products, if approved, are competitive with other products.

***If approved, Cynviloq will face competition from less expensive generic products of competitors and, if we are unable to differentiate the benefits of Cynviloq over these less expensive alternatives, we may never generate meaningful product revenues.***

Generic paclitaxel therapies are typically sold at lower prices than branded paclitaxel therapies and are generally preferred by hospital formularies and managed care providers of health services. We anticipate that, if approved, Cynviloq will face increasing competition in the form of generic versions of branded products of competitors that have lost or will lose their patent exclusivity. For example, Cynviloq if approved, will initially face competition from the less expensive generic forms of paclitaxel that are currently available such as Taxol, and, in the future, would face additional competition from a generic form of Abraxane when the patents covering it begin to expire in approximately 2022, or earlier if the patents are successfully challenged. If we are unable to demonstrate to physicians and payers that the key differentiating features of Cynviloq translate to overall clinical benefit or lower cost of care, we may not be able to compete with generic alternatives.



**Table of Contents**

***Reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our products profitably.***

There is significant uncertainty related to the third-party coverage and reimbursement of newly approved drugs. We intend to seek approval to market our product candidates in the U.S., Europe and other selected foreign jurisdictions. Market acceptance and sales of our product candidates in both domestic and international markets will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for any of our product candidates and may be affected by existing and future health care reform measures. Government and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new drugs and, as a result, they may not cover or provide adequate payment for our product candidates. These payors may conclude that our product candidates are less safe, less effective or less cost-effective than existing or future introduced products, and third-party payors may not approve our product candidates for coverage and reimbursement or may cease providing coverage and reimbursement for these product candidates.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

In some foreign countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our product candidates is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability of our products in such country.

***Healthcare reform measures could hinder or prevent our product candidates' commercial success.***

In both the U.S. and certain foreign jurisdictions, there have been and we expect there will continue to be a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. The U.S. government and other governments have shown significant interest in pursuing healthcare reform. In particular, the Medicare Modernization Act of 2003 revised the payment methodology for many products under the Medicare program in the U.S. This has resulted in lower rates of reimbursement. In 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Healthcare Reform Law, was enacted. The Healthcare Reform Law substantially changes the way healthcare is financed by both governmental and private insurers. Such government-adopted reform measures may adversely impact the pricing of healthcare products and services in the U.S. or internationally and the amount of reimbursement available from governmental agencies or other third-party payors.

There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect the demand for any drug products for which we may obtain regulatory approval, as well as our ability to set satisfactory prices for our products, to generate revenues, and to achieve and maintain profitability.

***Certain of our potential product candidates are in early stages of development and any product candidates that we develop will require extensive preclinical and clinical testing before they are approved by the appropriate regulatory agency, if at all.***

The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of biopharmaceutical products. We are in the early stages of developing potential product candidates, and any candidates that we develop will require extensive preclinical and clinical testing before they will be approved by the FDA or another regulatory authority in a jurisdiction outside the U.S., if at all. We have not yet developed any product candidate; if we were to do so there are a number of requirements that we would be required to satisfy in order to begin conducting preclinical trials and there can be no assurance that we will develop product candidates or complete the steps necessary to allow us to commence these trials. We cannot predict with any certainty the results of preclinical testing or whether such trials would yield sufficient data to permit us, or those with whom we collaborate, to proceed with clinical development and ultimately submit an application for regulatory approval of our product candidates in the U.S. or abroad, or whether such applications would be approved by the appropriate regulatory agency. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

***Failure to successfully validate, develop and obtain regulatory approval for companion diagnostics could harm our long-term drug development strategy.***

As one of the key elements of our clinical development strategy, we seek to identify patients within a disease category or indication who may derive selective and meaningful benefit from the product candidates we are developing. In collaboration with partners, we plan to develop companion diagnostics to help us to more accurately identify patients within a particular category or indication, both during our clinical trials and in connection with the commercialization of certain of our product candidates. Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate regulatory pre-clearance or approval prior to commercialization. We do not develop companion diagnostics internally and thus we are

## **Table of Contents**

dependent on the sustained cooperation and effort of our third-party collaborators in developing and obtaining approval for these companion diagnostics. We and our collaborators may encounter difficulties in developing and obtaining pre-clearance or approval for the companion diagnostics, including issues relating to selectivity, specificity, analytical validation, reproducibility, or clinical validation. Any delay or failure by our collaborators to develop or obtain regulatory approval of the companion diagnostics could delay or prevent approval of our product candidates. In addition, our collaborators may encounter production difficulties that could constrain the supply of the companion diagnostics, and both they and we may have difficulties gaining acceptance of the use of the companion diagnostics in the clinical community. If such companion diagnostics fail to gain market acceptance, it would have an adverse effect on our ability to derive revenues from sales of our products. In addition, the diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

### ***Our product development efforts may not be successful.***

Our product development efforts for our FIC therapeutic antibodies, ADC and rIVIG technologies are designed to focus on novel therapeutic approaches and technologies that have not been widely studied. We are applying these approaches and technologies in our attempt to discover new treatments for conditions that are also the subject of research and development efforts of many other companies. These approaches and technologies may never be successful.

### ***Our failure to find third party collaborators to assist or share in the costs of product development could materially harm our business, financial condition and results of operations.***

Our strategy for the development and commercialization of our proprietary product candidates may include the formation of collaborative arrangements with third parties. Potential third parties include biopharmaceutical, pharmaceutical and biotechnology companies, academic institutions and other entities. Third-party collaborators may assist us in:

funding research, preclinical development, clinical trials and manufacturing;

seeking and obtaining regulatory approvals; and

successfully commercializing any future product candidates.

If we are not able to establish further collaboration agreements, we may be required to undertake product development and commercialization at our own expense. Such an undertaking may limit the number of product candidates that we will be able to develop, significantly increase our capital requirements and place additional strain on our internal resources. Our failure to enter into additional collaborations could materially harm our business, financial condition and results of operations.

In addition, our dependence on licensing, collaboration and other agreements with third parties may subject us to a number of risks. These agreements may not be on terms that prove favorable to us and may require us to relinquish certain rights in our product candidates. To the extent we agree to work exclusively with one collaborator in a given area, our opportunities to collaborate with other entities could be curtailed. Lengthy negotiations with potential new collaborators may lead to delays in the research, development or commercialization of product candidates. The decision by our collaborators to pursue alternative technologies or the failure of our collaborators to develop or commercialize successfully any product candidate to which they have obtained rights from us could materially harm our business, financial condition and results of operations.

***Adverse economic conditions may have material adverse consequences on our business, results of operations and financial condition.***

Unpredictable and unstable changes in economic conditions, including recession, inflation, increased government intervention, or other changes, may adversely affect our general business strategy. We rely upon our ability to generate additional sources of liquidity and we may need to raise additional funds through public or private debt or equity financings in order to fund existing operations or to take advantage of opportunities, including acquisitions of complementary businesses or technologies. Any adverse event would have a material adverse impact on our business, results of operations and financial condition.

***Because our development activities are expected to rely heavily on sensitive and personal information, an area which is highly regulated by privacy laws, we may not be able to generate, maintain or access essential patient samples or data to continue our research and development efforts in the future on reasonable terms and conditions, which may adversely affect our business.***

We may have access to very sensitive data regarding patients whose tissue samples are used in our studies. This data will contain information that is personal in nature. The maintenance of this data is subject to certain privacy-related laws, which impose upon us administrative and financial burdens, and litigation risks. For instance, the rules promulgated by the Department of Health and Human Services under the Health Insurance Portability and Accountability Act, or HIPAA, create national standards to protect patients' medical records and other personal information in the U.S. These rules require that healthcare providers and other covered

---

**Table of Contents**

entities obtain written authorizations from patients prior to disclosing protected health care information of the patient to companies. If the patient fails to execute an authorization or the authorization fails to contain all required provisions, then we will not be allowed access to the patient's information and our research efforts can be substantially delayed. Furthermore, use of protected health information that is provided to us pursuant to a valid patient authorization is subject to the limits set forth in the authorization (i.e., for use in research and in submissions to regulatory authorities for product approvals). As such, we are required to implement policies, procedures and reasonable and appropriate security measures to protect individually identifiable health information we receive from covered entities, and to ensure such information is used only as authorized by the patient. Any violations of these rules by us could subject us to civil and criminal penalties and adverse publicity, and could harm our ability to initiate and complete clinical studies required to support regulatory applications for our proposed products. In addition, HIPAA does not replace federal, state, or other laws that may grant individuals even greater privacy protections. We can provide no assurance that future legislation will not prevent us from generating or maintaining personal data or that patients will consent to the use of their personal information, either of which may prevent us from undertaking or publishing essential research. These burdens or risks may prove too great for us to reasonably bear, and may adversely affect our ability to achieve profitability or maintain profitability in the future.

***Our therapeutic product candidates for which we intend to seek approval as biological products may face competition sooner than expected.***

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, as part of the Health Care Reform Law, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The new abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as interchangeable. The FDA defines an interchangeable biosimilar as a product that, in terms of safety or diminished efficacy, presents no greater risk when switching between the biosimilar and its reference product than the risk of using the reference product alone. Under the BPCIA, an application for a biosimilar product cannot be submitted to the FDA until four years, or approved by the FDA until 12 years, after the original brand product identified as the reference product was approved under a BLA. The new law is complex and is only beginning to be interpreted by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. While it is uncertain when any such processes may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that if any of our product candidates were to be approved as biological products under a BLA, such approved products should qualify for the 12-year period of exclusivity. However, there is a risk that the U. S. Congress could amend the BPCIA to significantly shorten this exclusivity period as proposed by President Obama, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. In addition, a competitor could decide to forego the biosimilar route and submit a full BLA after completing its own preclinical studies and clinical trials. In such cases, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its product as soon as it is approved.

***We may be exposed to liability claims associated with the use of hazardous materials and chemicals.***

Our research and development activities may involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for using, storing, handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental injury or

contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations. We do not currently maintain hazardous materials insurance coverage. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially harm our business.

***If we are unable to retain and recruit qualified scientists and advisors, or if any of our key executives, key employees or key consultants discontinues his or her employment or consulting relationship with us, it may delay our development efforts or otherwise harm our business.***

We may not be able to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Diego, California area. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the successful development of any product candidates, our ability to raise additional capital and our ability to implement our overall business strategy.

We are highly dependent on key members of our management and scientific staff, especially Henry Ji, Ph.D, Chief Executive Officer and President, Mike Royal, Executive Vice President of Clinical and Regulatory Affairs, David Miao, Chief Technology Officer, George Uy, Executive Vice President and Chief Commercial Officer and Richard Vincent, Executive Vice President and Chief Financial Officer. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level, and senior managers as well as junior, mid-level, and senior scientific and medical personnel. The loss of any of our executive officers, key employees or key consultants and our inability to find suitable replacements could impede the achievement of our research and development objectives, potentially harm our business, financial condition and prospects. Furthermore, recruiting and retaining qualified scientific personnel to perform research and development work in the future is critical to our success. We may be

## **Table of Contents**

unable to attract and retain personnel on acceptable terms given the competition among biotechnology, biopharmaceutical and health care companies, universities and non-profit research institutions for experienced scientists. Certain of our current officers, directors, scientific advisors and/or consultants or certain of the officers, directors, scientific advisors and/or consultants hereafter appointed may from time to time serve as officers, directors, scientific advisors and/or consultants of other biopharmaceutical or biotechnology companies. We do not maintain key man insurance policies on any of our officers or employees. All of our employees are employed at will and, therefore, each employee may leave our employment at any time.

We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical, biotechnology, pharmaceutical and other businesses. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we have to offer. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize product candidates will be limited.

We plan to grant stock options or other forms of equity awards in the future as a method of attracting and retaining employees, motivating performance and aligning the interests of employees with those of our stockholders. If we are unable to implement and maintain equity compensation arrangements that provide sufficient incentives, we may be unable to retain our existing employees and attract additional qualified candidates. If we are unable to retain our existing employees, including qualified scientific personnel, and attract additional qualified candidates, our business and results of operations could be adversely affected.

***Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.***

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state health-care fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

***We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.***

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the U.S., our operations may be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;

HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and



**Table of Contents**

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. 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 of which could adversely affect our ability to operate our business and our results of operations.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.***

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates, if approved. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

decreased demand for our product candidates or products that we may develop;

injury to our reputation;

withdrawal of clinical trial participants;

initiation of investigations by regulators;

costs to defend the related litigation;

a diversion of management's time and our resources;

substantial monetary awards to trial participants or patients;

product recalls, withdrawals or labeling, marketing or promotional restrictions;

loss of revenues from product sales; and

the inability to commercialize our product candidates.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop.

***We will need to increase the size of our company and may not effectively manage our growth.***

Our success will depend upon growing our business and our employee base. Over the next 12 months, we plan to add additional employees to assist us with research and development. Our future growth, if any, may cause a significant strain on our management, and our operational, financial and other resources. Our ability to manage our growth effectively will require us to implement and improve our operational, financial and management systems and to expand, train, manage and motivate our employees. These demands may require the hiring of additional management personnel and the development of additional expertise by management. Any increase in resources devoted to research and product development without a corresponding increase in our operational, financial and management systems could have a material adverse effect on our business, financial condition, and results of operations.

## **Table of Contents**

***Any disruption in our research and development facilities could adversely affect our business, financial condition and results of operations.***

Our principal executive offices, which house our research and development programs, are located in San Diego, California. Our facilities may be affected by natural or man-made disasters. Earthquakes are of particular significance since our facilities are located in an earthquake-prone area. We are also vulnerable to damage from other types of disasters, including power loss, attacks from extremist organizations, fire, floods and similar events. In the event that our facilities were affected by a natural or man-made disaster, we may be forced to curtail our operations and/or rely on third-parties to perform some or all of our research and development activities. Although we believe we possess adequate insurance for damage to our property and the disruption of our business from casualties, such insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all. In the future, we may choose to expand our operations in either our existing facilities or in new facilities. If we expand our worldwide manufacturing locations, there can be no assurance that this expansion will occur without implementation difficulties, or at all.

***International operations may expose us to foreign currency exchange rate fluctuations for all foreign currencies in which we do business and we may be materially adversely affected by these fluctuations.***

We formed Sorrento Hong Kong effective December 4, 2012. Sorrento Hong Kong had no operations from formation through September 2014. In the event Sorrento Hong Kong becomes operational, we may have an international subsidiary that operates in a foreign currency which would expose us to foreign currency exchange rate fluctuations. We intend to hedge any foreign currency risks associated with potential transactions by entering into forward contracts. Although we may enter into such forward contracts, they may not be adequate to eliminate the risk of foreign currency exchange rate exposures. International operations may also expose us to currency fluctuations as we translate the financial statements of our international subsidiary to U.S. Dollars.

***Our business and operations would suffer in the event of system failures.***

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

***If we acquire companies or technologies in the future, they could prove difficult to integrate, disrupt our business, dilute stockholder value, and adversely affect our operating results and the value of our common stock.***

As part of our business strategy, we may acquire, enter into joint ventures with, or make investments in complementary or synergistic companies, services, and technologies in the future. Acquisitions and investments involve numerous risks, including:

difficulties in identifying and acquiring products, technologies, or businesses that will help our business;

difficulties in integrating operations, technologies, services, and personnel;

diversion of financial and managerial resources from existing operations;

the risk of entering new development activities and markets in which we have little to no experience;

risks related to the assumption of known and unknown liabilities; and

risks related to our ability to raise sufficient capital to fund additional operating activities.

As a result, if we fail to properly evaluate acquisitions or investments, we may not achieve the anticipated benefits of any such acquisitions, we may incur costs in excess of what we anticipate, and management resources and attention may be diverted from other necessary or valuable activities.

---

**Table of Contents**

***The terms of our secured debt facility require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.***

Effective in March 2014, as amended and restated, we entered into a \$12.5 million loan and security agreement with Oxford Finance and Silicon Valley Bank that is secured by a lien covering substantially all of our assets, excluding intellectual property. As of September 30, 2014, we had an outstanding principal balance of \$12.5 million. The amended and restated loan and security agreement contains customary affirmative and negative covenants and events of default. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports and maintain insurance coverage. The negative covenants include, among others, restrictions on transferring collateral, changing our business, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments and creating other liens on our assets, in each case subject to customary exceptions. If we default under the loan agreement, the lenders may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the lender's right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. The lenders could declare a default upon the occurrence of any event that they interpret as a material adverse change as defined under the loan agreement, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by the lenders of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

**Risks Related to the Acquisitions of IgDraSol, Sherrington and Concertis**

***We may fail to realize the anticipated benefits of the acquisitions of IgDraSol, Sherrington and Concertis.***

The success of the acquisitions of IgDraSol, Sherrington and Concertis will depend on, among other things, our ability to combine our businesses in a manner that does not materially disrupt existing relationships and that allows us to achieve development and operational synergies. If we are unable to achieve these objectives, the anticipated benefits of the acquisition may not be realized fully or at all or may take longer to realize than expected. In particular, the acquisition may not be accretive to our stock value or development pipeline in the near or long term.

It is possible that the integration process could result in the loss of key employees; the disruption of our ongoing business or the ongoing business of the acquired companies; or inconsistencies in standards, controls, procedures, or policies that could adversely affect our ability to maintain relationships with third parties and employees or to achieve the anticipated benefits of the acquisition. Integration efforts between the two companies will also divert management's attention from our core business and other opportunities that could have been beneficial to our shareholders. An inability to realize the full extent of, or any of, the anticipated benefits of the acquisition, as well as any delays encountered in the integration process, could have an adverse effect on our business and results of operations, which may affect the value of the shares of our common stock after the completion of the acquisition. If we are unable to achieve these objectives, the anticipated benefits of the acquisition may not be realized fully or at all or may take longer to realize than expected. In particular, the acquisition may not be accretive to our stock value or development pipeline in the near or long term.

***We expect to incur significant additional costs in connection with the acquisition of IgDraSol, Sherrington and Concertis and integrating the companies into a single business.***

During 2013, we incurred significant legal and professional fees in connection with such acquisitions. We expect to incur additional costs integrating the companies' operations, higher development and regulatory costs, and personnel, which cannot be estimated accurately at this time. If the total costs of the integration of our companies and advancement of the Cynviloq, RTX or Concartis assets exceed the anticipated benefits of the acquisition, our financial results could be adversely affected.

### **Risks Related to Our Intellectual Property**

*Our ability to protect our intellectual property rights will be critically important to the success of our business, and we may not be able to protect these rights in the U.S. or abroad.*

Our success, competitive position and future revenues will depend in part on our ability to obtain and maintain patent protection for our product candidates, methods, processes and other technologies, to prevent third parties from infringing on our proprietary rights and to operate without infringing upon the proprietary rights of third parties. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. We attempt to protect our proprietary position by maintaining trade secrets and by filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We have one issued U.S. patent covering our G-MAB<sup>®</sup> which expires in 2022 and the examination of its European equivalent is currently in progress. In 2011, several improvement patent applications were filed for our proprietary antibody library technology. However, due to the difficulties of enforcing such antibody library technology, we filed a key patent application in the U.S. only and requested nonpublication. In 2013 and 2014, we filed 18 antibody family patents. The first of the antibody family patents applications issued on October 14, 2014 as U.S. Patent 8,859,740. In 2013 and 2014, we filed five patent application families for the Concartis conjugation chemistry associated with ADCs.

We have also filed two patent applications protecting improvements we found for Cynviloq. Those two patent applications, once issued as patents, if ever, will protect the Cynviloq product until 2034 or 2035.

We have commenced generating a patent application portfolio of patents to protect each product candidate in our pipeline. However, the patent position of biopharmaceutical companies involves complex legal and factual questions, and therefore we cannot predict with certainty whether any patent applications that we have filed or that we may file in the future will be approved or any resulting patents will be enforced. In addition, third parties may challenge, seek to invalidate or circumvent any of our patents, once they are issued. Thus, any patents that we own or license from third parties may not provide any protection against competitors. Any patent applications that we have filed or that we may file in the future, or those we may license from third parties, may not result in patents being issued. Also, patent rights may not provide us with adequate proprietary protection or competitive advantages against competitors with similar technologies.

## **Table of Contents**

In addition, the laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the U.S. If we fail to apply for intellectual property protection or if we cannot adequately protect our intellectual property rights in these foreign countries, our competitors may be able to compete more effectively against us, which could adversely affect our competitive position, as well as our business, financial condition and results of operations.

***The original intellectual property protection for Cynviloq is being managed and controlled by Samyang, the manufacturer.***

We do not manage or control the original intellectual property protection for Cynviloq. Therefore we cannot provide any assurance that the 3 patent applications in the U.S. or the AU will ever issue or be granted. Moreover, there cannot be any assurances that the families of patent applications that could provide product protection for Cynviloq will ever issue or be granted, or even provide meaningful protection to prevent generic Cynviloq protection.

***If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.***

Our success also depends upon the skills, knowledge and experience of our scientific and technical personnel and our consultants and advisors, as well as our licensors. To help protect our proprietary know-how and our inventions for which patents may be unobtainable or difficult to obtain, we rely on trade secret protection and confidentiality agreements. Unlike some of our competitors, we maintain our proprietary libraries for ourselves as we believe they have proven to be superior in obtaining strong binder product candidates. To this end, we require all of our employees, consultants, advisors and contractors to enter into agreements which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. These agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

Third party competitors may seek to challenge the validity of our patents, thereby rendering them unenforceable or we may seek to challenge third party competitor patents if such third parties seek to interpret or enforce a claim scope going well beyond the actual enabled invention.

***Claims that we infringe upon the rights of third parties may give rise to costly and lengthy litigation, and we could be prevented from selling products, forced to pay damages, and defend against litigation.***

Third parties may assert patent or other intellectual property infringement claims against us or our strategic partners or licensees with respect to our technologies and potential product candidates. If our products, methods, processes and other technologies infringe upon the proprietary rights of other parties, we could incur substantial costs and we may have to:

obtain licenses, which may not be available on commercially reasonable terms, if at all, and may be non-exclusive, thereby giving our competitors access to the same intellectual property licensed to us;

redesign our products or processes to avoid infringement;

stop using the subject matter validly claimed in the patents held by others;

pay damages; and

defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our valuable management resources.

Even if we were to prevail, any litigation could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. Furthermore, as a result of a patent infringement suit brought against us or our strategic partners or licensees, we or our strategic partners or licensees may be forced to stop or delay developing, manufacturing or selling technologies or potential products that are claimed to infringe a third party's intellectual property unless that party grants us or our strategic partners or licensees rights to use its intellectual property. Ultimately, we may be unable to develop some of our technologies or potential products or may have to discontinue development of a product candidate or cease some of our business operations as a result of patent infringement claims, which could severely harm our business.



---

**Table of Contents*****The potential commercial launch of Cynviloq could be delayed in the event that the manufacturer of Abraxane files a lawsuit against us.***

We plan to file an NDA for Cynviloq under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act and as a result we will be required to file a subparagraph (iv) certification for the Orange Book-listed patents for Abraxane. The Orange Book listed patents for Abraxane require a paclitaxel formulation having human serum albumin coating its particles (*Cynviloq* does not have human serum albumin in its formulation). The commercial manufacturer of Abraxane may file a lawsuit against us for which we believe there is not merit. In the event a lawsuit is filed against us the potential commercial launch of Cynviloq could be delayed up to a maximum of 30 months which would have a material adverse effect on our business.

***Our position as a relatively small company may cause us to be at a significant disadvantage in defending our intellectual property rights and in defending against infringement claims by third parties.***

Litigation relating to the ownership and use of intellectual property is expensive, and our position as a relatively small company in an industry dominated by very large companies may cause us to be at a significant disadvantage in defending our intellectual property rights and in defending against claims that our technology infringes or misappropriates third party intellectual property rights. However, we may seek to use various post-grant administrative proceedings, including new procedures created under the America Invents Act, to invalidate potentially overly-broad third party rights. Even if we are able to defend our position, the cost of doing so may adversely affect our ability to grow, generate revenue or become profitable. Although we have not yet experienced patent litigation, we may in the future be subject to such litigation and may not be able to protect our intellectual property at a reasonable cost, or at all, if such litigation is initiated. The outcome of litigation is always uncertain, and in some cases could include judgments against us that require us to pay damages, enjoin us from certain activities or otherwise affect our legal or contractual rights, which could have a significant adverse effect on our business.

***Third-party claims of intellectual property infringement may prevent or delay our drug discovery and development efforts.***

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including Patent Office administrative proceedings, such as inter parties reviews, and reexamination proceedings before the U.S. PTO or oppositions and revocations and other comparable proceedings in foreign jurisdictions. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

Despite safe harbor provisions, third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents, of which we are currently unaware, with claims to materials, formulations, methods of doing research or library screening, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent published applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtain a license under the applicable patents, or until such patents expire or they are

finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtain a license, limit our uses, or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, limit our uses, pay royalties or redesign our infringing product candidates, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly.

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

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. 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 enforcement is not as strong as that 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.

## **Table of Contents**

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.

***Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.***

Because we operate in the highly technical field of research and development of small molecule drugs, we rely in part on trade secret protection in order to protect our proprietary trade secrets and unpatented know-how. However, trade secrets are difficult to protect, and we cannot be certain that others will not develop the same or similar technologies on their own. We have taken steps, including entering into confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, to protect our trade secrets and unpatented know-how. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. We also typically obtain agreements from these parties which provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

***If we breach any of the agreements under which we license commercialization rights to our product candidates from third parties, we could lose license rights that are important to our business.***

We license the use, development and commercialization rights for all of our product candidates, and may enter into similar licenses in the future. Under each of our existing license agreements we are subject to commercialization and development, diligence obligations, milestone payment obligations, royalty payments and other obligations. If we fail to comply with any of these obligations or otherwise breach our license agreements, our licensing partners may have the right to terminate the license in whole or in part.

Generally, the loss of any one of our three current licenses or other licenses in the future could materially harm our business, prospects, financial condition and results of operations.

***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 compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.

We or our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed.

We or our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions.

Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.

It is possible that our pending patent applications will not lead to issued patents.

Issued patents that we own or have exclusively licensed 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 additional proprietary technologies that are patentable.

## **Table of Contents**

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.

*From time to time we may need to license patents, intellectual property and proprietary technologies from third parties, which may be difficult or expensive to obtain.*

We may need to obtain licenses to patents and other proprietary rights held by third parties to successfully develop, manufacture and market our drug products. As an example, it may be necessary to use a third party's proprietary technology to reformulate one of our drug products in order to improve upon the capabilities of the drug product. If we are unable to timely obtain these licenses on reasonable terms, our ability to commercially exploit our drug products may be inhibited or prevented.

## **Risks Related to Ownership of Our Common Stock**

*The market price of our common stock may fluctuate significantly, and investors in our common stock may lose all or a part of their investment.*

The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. The market price of our common stock may fluctuate significantly in response to numerous factors, some of which are beyond our control, such as:

actual or anticipated adverse results or delays in our clinical trials;

our failure to commercialize our product candidates, if approved;

unanticipated serious safety concerns related to the use of any of our product candidates;

adverse regulatory decisions;

changes in laws or regulations applicable to our product candidates, including but not limited to clinical trial requirements for approvals;

legal disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our product candidates, government investigations and the results of any proceedings or lawsuits, including patent or stockholder litigation;

our decision to initiate a clinical trial, not initiate a clinical trial or to terminate an existing clinical trial;

our dependence on third parties, including CROs;

announcements of the introduction of new products by our competitors;

market conditions in the pharmaceutical and biotechnology sectors;

announcements concerning product development results or intellectual property rights of others;

future issuances of common stock or other securities;

the addition or departure of key personnel;

failure to meet or exceed any financial guidance or expectations regarding development milestones that we may provide to the public;

**Table of Contents**

actual or anticipated variations in quarterly operating results;

our failure to meet or exceed the estimates and projections of the investment community;

overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;

conditions or trends in the biotechnology and biopharmaceutical industries;

introduction of new products offered by us or our competitors;

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

issuances of debt or equity securities;

sales of our common stock by us or our stockholders in the future;

trading volume of our common stock;

ineffectiveness of our internal controls;

publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;

general political and economic conditions;

effects of natural or man-made catastrophic events; and

other events or factors, many of which are beyond our control.

Further, the equity markets in general have recently experienced extreme price and volume fluctuations. Continued market fluctuations could result in extreme volatility in the price of our common stock, which could cause a decline in the value of our common stock. Price volatility of our common stock might worsen if the trading volume of our common stock is low. The realization of any of the above risks or any of a broad range of other risks, including those

described in these Risk Factors, could have a dramatic and material adverse impact on the market price of our common stock.

***We have not paid cash dividends in the past and do not expect to pay cash dividends in the foreseeable future. Any return on investment may be limited to the value of our common stock.***

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on our capital stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as the board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if the common stock price appreciates.

***A sale of a substantial number of shares of the common stock may cause the price of our common stock to decline.***

If our stockholders sell, or the market perceives that our stockholders intend to sell for various reasons, substantial amounts of our common stock in the public market, including shares issued in connection with the exercise of outstanding options or warrants, the market price of our common stock could fall. Sales of a substantial number of shares of our common stock may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate. We may become involved in securities class action litigation that could divert management's attention and harm our business.



## **Table of Contents**

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biotechnology and biopharmaceutical companies. These broad market fluctuations may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of our securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business.

### ***Our quarterly operating results may fluctuate significantly.***

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

variations in the level of expenses related to our development programs;

the addition or termination of clinical trials;

any intellectual property infringement lawsuit in which we may become involved;

regulatory developments affecting our product candidates;

our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements; and

if Cynviloq receives regulatory approval, the level of underlying demand for that product and wholesalers buying patterns.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially.

***Existing stockholders' interest in us may be diluted by additional issuances of equity securities and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.***

We may issue additional equity securities to fund future expansion and pursuant to employee benefit plans. We may also issue additional equity for other purposes. These securities may have the same rights as our common stock or, alternatively, may have dividend, liquidation or other preferences to our common stock. The issuance of additional equity securities will dilute the holdings of existing stockholders and may reduce the share price of our common stock.

If we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates, potential products or proprietary technologies, or grant

licenses on terms that are not favorable to us. If adequate funds are not available, our ability to achieve profitability or to respond to competitive pressures would be significantly limited and we may be required to delay, significantly curtail or eliminate the development of our product candidates.

***Directors, executive officers, principal stockholders and affiliated entities own a significant percentage of our capital stock, and they may make decisions that you do not consider to be in your best interests or those of our other stockholders.***

As of November 4, 2014, our directors, executive officers and principal stockholders beneficially owned, in the aggregate, approximately 42.8% of our outstanding voting securities. As a result, if some or all of them acted together, they would have the ability to exert substantial influence over the election of our board of directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may also have the effect of delaying or preventing a change in control of our company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

***Our ability to use our net operating loss carry forwards may be subject to limitation.***

Generally, a change of more than 50% in the ownership of a company's stock, by value, over a three-year period constitutes an ownership change for U.S. federal income tax purposes. An ownership change may limit our ability to use our net operating loss carryforwards attributable to the period prior to the change. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liability for us. At December 31, 2013, we had net operating loss carryforwards aggregating approximately \$28.1 million.

## **Table of Contents**

***Our certificate of incorporation, as amended, and bylaws provide for indemnification of officers and directors at our expense and limits their liability, which may result in a major cost to us and hurt the interests of our stockholders because corporate resources may be expended for the benefit of our officers and/or directors.***

Our certificate of incorporation, as amended, bylaws and applicable Delaware law provide for the indemnification of our directors, officers, employees, and agents, under certain circumstances, against attorney's fees and other expenses incurred by them in any litigation to which they become a party arising from their association with or activities on our behalf. We will also bear the expenses of such litigation for any of our directors, officers, employees, or agents, upon such person's promise to repay us, therefore if it is ultimately determined that any such person shall not have been entitled to indemnification. This indemnification policy could result in substantial expenditures by us, which we will be unable to recover.

***Our corporate documents and Delaware law contain provisions that could discourage, delay or prevent a change in control of our company, prevent attempts to replace or remove current management and reduce the market price of our common stock.***

Provisions in our certificate of incorporation, as amended, and bylaws may discourage, delay or prevent a merger or acquisition involving us that our stockholders may consider favorable. For example, our certificate of incorporation, as amended, authorizes our board of directors to issue up to 100,000,000 shares of "blank check" preferred stock. As a result, without further stockholder approval, the board of directors has the authority to attach special rights, including voting and dividend rights, to this preferred stock. With these rights, preferred stockholders could make it more difficult for a third party to acquire us.

We are also subject to the anti-takeover provisions of the Delaware General Corporation Law. Under these provisions, if anyone becomes an "interested stockholder," we may not enter into a "business combination" with that person for three years without special approval, which could discourage a third party from making a takeover offer and could delay or prevent a change in control of us. An "interested stockholder" means, generally, someone owning 15% or more of our outstanding voting stock or an affiliate of ours that owned 15% or more of our outstanding voting stock during the past three years, subject to certain exceptions as described in the Delaware General Corporation Law.

We have adopted a shareholder rights plan, the purpose of which is, among other things, to enhance our board's ability to protect shareholder interests and to ensure that shareholders receive fair treatment in the event any coercive takeover attempt of our company is made in the future. The shareholder rights plan could make it more difficult for a third party to acquire, or could discourage a third party from acquiring, our company or a large block of our common stock.

***Compliance with changing regulations concerning corporate governance and public disclosure may result in additional expenses.***

There have been changing laws, regulations and standards relating to corporate governance and public disclosure, including the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley, new regulations promulgated by the SEC and rules promulgated by the national securities exchanges. The Dodd-Frank Act, enacted in July 2010, expands federal regulation of corporate governance matters and imposes requirements on public companies to, among other things, provide stockholders with a periodic advisory vote on executive compensation and also adds compensation committee reforms and enhanced pay-for-performance disclosures. While some provisions of the Dodd-Frank Act are effective upon enactment, others will be implemented upon the SEC's adoption of related rules and regulations. The scope and timing of the adoption of such rules and regulations is uncertain and, accordingly, the cost of compliance with the Dodd-Frank Act is also

uncertain.

These new or changed laws, regulations and standards are, or will be, subject to varying interpretations in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. As a result, our efforts to comply with evolving laws, regulations and standards are likely to continue to result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. Members of our board of directors and our principal executive officer and principal financial officer could face an increased risk of personal liability in connection with the performance of their duties. As a result, we may have difficulty attracting and retaining qualified directors and executive officers, which could harm our business. If the actions we take in our efforts to comply with new or changed laws, regulations and standards differ from the actions intended by regulatory or governing bodies, we could be subject to liability under applicable laws or our reputation may be harmed.

***If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to accounting controls and procedures, or, if we discover material weaknesses and deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult.***

Sarbanes-Oxley specifically requires, among other things, that we maintain effective internal controls for financial reporting and disclosure of controls and procedures. In particular, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of Sarbanes-Oxley. Our testing, or the subsequent testing by our independent registered public accounting firm, if and when required, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. 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. Moreover, 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 identifies deficiencies in our internal controls 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 the SEC or other regulatory authorities, which would require additional financial and management resources.

**Table of Contents**

**DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus and any accompanying prospectus supplement, including the documents that we incorporate by reference, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Exchange Act. Such forward-looking statements include those that express plans, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. These forward-looking statements are based on our current expectations and projections about future events and they are subject to risks and uncertainties known and unknown that could cause actual results and developments to differ materially from those expressed or implied in such statements.

In some cases, you can identify forward-looking statements by terminology, such as expects, anticipates, intends, estimates, plans, believes, seeks, may, should, could or the negative of such terms or other similar expressions. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this prospectus.

You should read this prospectus and any accompanying prospectus supplement and the documents that we reference herein and therein and have filed as exhibits to the registration statement, of which this prospectus is part, completely and with the understanding that our actual future results may be materially different from what we expect. You should assume that the information appearing in this prospectus and any accompanying prospectus supplement is accurate as of the date on the front cover of this prospectus or such prospectus supplement only. Because the risk factors referred to above, as well as the risk factors referred to on page 2 of this prospectus and incorporated herein by reference, could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor 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 qualify all of the information presented in this prospectus and any accompanying prospectus supplement, and particularly our forward-looking statements, by these cautionary statements.

**USE OF PROCEEDS**

Except as otherwise provided in the applicable prospectus supplement, we intend to use the net proceeds from the sale of the securities offered by this prospectus for general corporate purposes, which may include working capital, capital expenditures, research and development expenditures, regulatory affairs expenditures, clinical trial expenditures, acquisitions of new technologies and investments, and the repayment, refinancing, redemption or repurchase of future indebtedness or capital stock.

The intended application of proceeds from the sale of any particular offering of securities using this prospectus will be described in the accompanying prospectus supplement relating to such offering. The precise amount and timing of the application of these proceeds will depend on our funding requirements and the availability and costs of other funds.

**THE SECURITIES WE MAY OFFER**

The descriptions of the securities contained in this prospectus, together with the applicable prospectus supplements, summarize all the material terms and provisions of the various types of securities that we may offer. We will describe

in the applicable prospectus supplement relating to any securities the particular terms of the securities offered by that prospectus supplement. If we indicate in the applicable prospectus supplement, the terms of the securities may differ from the terms we have summarized below. We will also include in the prospectus supplement information, where applicable, about material United States federal income tax considerations relating to the securities, and the securities exchange, if any, on which the securities will be listed.

We may sell from time to time, in one or more offerings:

shares of our common stock;

shares of our preferred stock;

warrants to purchase any of the securities listed above; and/or

The terms of any securities we offer will be determined at the time of sale. We may issue securities that are exchangeable for or convertible into common stock or any of the other securities that may be sold under this prospectus. When particular securities are offered, a supplement to this prospectus will be filed with the SEC, which will describe the terms of the offering and sale of the offered securities.

**Table of Contents**

**DESCRIPTION OF CAPITAL STOCK**

**General**

The following description of common stock and preferred stock, together with the additional information we include in any applicable prospectus supplements, summarizes the material terms and provisions of the common stock and preferred stock that we may offer under this prospectus but is not complete. For the complete terms of our common stock and preferred stock, please refer to our certificate of incorporation, as amended, which may be further amended from time to time, any certificates of designation for our preferred stock, and our bylaws, as amended from time to time. Delaware General Corporation Law (the "DGCL") may also affect the terms of these securities. While the terms we have summarized below will apply generally to any future common stock or preferred stock that we may offer, we will describe the particular terms of any series of these securities in more detail in the applicable prospectus supplement. If we so indicate in a prospectus supplement, the terms of any common stock or preferred stock we offer under that prospectus supplement may differ from the terms we describe below.

As of November 4, 2014, our authorized capital stock consisted of 750,000,000 shares of common stock, \$0.0001 par value per share, and 100,000,000 shares of preferred stock, \$0.0001 par value per share. Our board of directors may establish the rights and preferences of the preferred stock from time to time. As of November 4, 2014, there are 28,932,850 shares of our common stock issued and outstanding and no shares of preferred stock issued and outstanding.

**Common Stock**

Holders of our common stock are entitled to one vote per share. Our Certificate of Incorporation does not provide for cumulative voting. Holders of our common stock are entitled to receive ratably such dividends, if any, as may be declared by our board of directors (the "Board") out of legally available funds. However, the current policy of our Board is to retain earnings, if any, for the operation and expansion of the Company. Upon liquidation, dissolution or winding-up, the holders of our common stock are entitled to share ratably in all of our assets which are legally available for distribution, after payment of or provision for all liabilities. The holders of our common stock have no preemptive, subscription, redemption or conversion rights.

**Preferred Stock**

As of the date of this prospectus, no shares of preferred stock are issued and outstanding. Our Certificate of Incorporation provides that our Board may by resolution, without further vote or action by the stockholders, establish one or more classes or series of preferred stock having the number of shares and relative voting rights, designation, dividend rates, liquidation, and other rights, preferences, and limitations as may be fixed by them without further stockholder approval. Once designated by our Board, each series of preferred stock will have specific financial and other terms that will be described in a prospectus supplement. The description of the preferred stock that is set forth in any prospectus supplement is not complete without reference to the documents that govern the preferred stock. These include our Certificate of Incorporation and any certificates of designation that the Board may adopt. Prior to the issuance of shares of each series of preferred stock, the Board is required by the DGCL and the Certificate of Incorporation to adopt resolutions and file a certificate of designation with the Secretary of State of the State of Delaware. The certificate of designation fixes for each class or series the designations, powers, preferences, rights, qualifications, limitations and restrictions, including, but not limited to, some or all of the following:

- (a) The distinctive designation of such series and the number of shares which shall constitute such series, which number may be increased (except where otherwise provided by the Board in creating such series) or decreased (but not below the number of shares thereof then outstanding) from time to time by resolution of the Board;
- (b) The rate and manner of payment of dividends payable on shares of such series, including the dividend rate, date of declaration and payment, whether dividends shall be cumulative, and the conditions upon which and the date from which such dividends shall be cumulative;
- (c) Whether shares of such series shall be redeemed, the time or times when, and the price or prices at which, shares of such series shall be redeemable, the redemption price, the terms and conditions of redemption, and the sinking fund provisions, if any, for the purchase or redemption of such shares;
- (d) The amount payable on shares of such series and the rights of holders of such shares in the event of any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Company;
- (e) The rights, if any, of the holders of shares of such series to convert such shares into, or exchange such shares for, shares of common stock, other securities, or shares of any other class or series of preferred stock and the terms and conditions of such conversion or exchange;
- (f) The voting rights, if any, and whether full or limited, of the shares of such series, which may include no voting rights, one vote per share, or such higher number of votes per share as may be designated by the Board; and



**Table of Contents**

- (g) The preemptive or preferential rights, if any, of the holders of shares of such series to subscribe for, purchase, receive, or otherwise acquire any part of any new or additional issue of stock of any class, whether now or hereafter authorized, or of any bonds, debentures, notes, or other securities of the Company, whether or not convertible into shares of stock with the Company.

All shares of preferred stock offered hereby will, when issued, be fully paid and nonassessable, including shares of preferred stock issued upon the exercise of preferred stock warrants or subscription rights, if any.

Although our Board has no intention at the present time of doing so, it could authorize the issuance of a series of preferred stock that could, depending on the terms of such series, impede the completion of a merger, tender offer or other takeover attempt.

**Anti-Takeover Effects of Certain Provisions of our Certificate of Incorporation, Bylaws and the DGCL**

Certain provisions of our Certificate of Incorporation and Bylaws, which are summarized in the following paragraphs, may have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. Such provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. In particular, the Certificate of Incorporation and Bylaws and Delaware law, as applicable, among other things:

provide the board of directors with the ability to alter the bylaws without stockholder approval;

place limitations on the removal of directors; and

provide that vacancies on the board of directors may be filled by a majority of directors in office, although less than a quorum.

These provisions are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control of our company to first negotiate with its board. These provisions may delay or prevent someone from acquiring or merging with us, which may cause the market price of our common stock to decline.

*Blank Check Preferred.* The Board is authorized to create and issue from time to time, without stockholder approval, up to an aggregate of 100,000,000 shares of preferred stock in one or more series and to establish the number of shares of any series of preferred stock and to fix the designations, powers, preferences and rights of the shares of each series and any qualifications, limitations or restrictions of the shares of each series.

The authority to designate preferred stock may be used to issue series of preferred stock, or rights to acquire preferred stock, that could dilute the interest of, or impair the voting power of, holders of the common stock or could also be used as a method of determining, delaying or preventing a change of control.

*Advance Notice Bylaws.* The Bylaws contain an advance notice procedure for stockholder proposals to be brought before any meeting of stockholders, including proposed nominations of persons for election to the Board. Stockholders at any meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the Board or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given the Company's corporate

secretary timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. Although the Bylaws do not give the Board the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, the Bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of the Company.

*Interested Stockholder Transactions.* We are subject to Section 203 of the Delaware General Corporation Law which, subject to certain exceptions, prohibits business combinations between a publicly-held Delaware corporation and an interested stockholder, which is generally defined as a stockholder who becomes a beneficial owner of 15% or more of a Delaware corporation's voting stock for a three-year period following the date that such stockholder became an interested stockholder.

### **Transfer Agent and Registrar**

The Transfer Agent and Registrar for our common stock is Philadelphia Stock Transfer, Inc.

### **DESCRIPTION OF WARRANTS**

The following description, together with the additional information we may include in any applicable prospectus supplements, summarizes the material terms and provisions of the warrants that we may offer under this prospectus and the related warrant agreements and warrant certificates. While the terms summarized below will apply generally to any warrants that we may offer, we will describe the particular terms of any series of warrants in more detail in the applicable prospectus supplement. If we indicate in the prospectus supplement, the terms of any warrants offered under that prospectus supplement may differ from the terms described

## **Table of Contents**

below. If there are differences between that prospectus supplement and this prospectus, the prospectus supplement will control. Thus, the statements we make in this section may not apply to a particular series of warrants. Specific warrant agreements will contain additional important terms and provisions and will be incorporated by reference as an exhibit to the registration statement which includes this prospectus.

### **General**

We may issue warrants for the purchase of common stock and/or preferred stock in one or more series. We may issue warrants independently or together with common stock and/or preferred stock, and the warrants may be attached to or separate from these securities.

We will evidence each series of warrants by warrant certificates that we may issue under a separate agreement. We may enter into the warrant agreement with a warrant agent. Each warrant agent may be a bank that we select which has its principal office in the United States and a combined capital and surplus of at least \$50,000,000. We may also choose to act as our own warrant agent. We will indicate the name and address of any such warrant agent in the applicable prospectus supplement relating to a particular series of warrants.

We will describe in the applicable prospectus supplement the terms of the series of warrants, including:

the offering price and aggregate number of warrants offered;

the currency for which the warrants may be purchased;

if applicable, the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each such security or each principal amount of such security;

if applicable, the date on and after which the warrants and the related securities will be separately transferable;

in the case of warrants to purchase common stock or preferred stock, the number of shares of common stock or preferred stock, as the case may be, purchasable upon the exercise of one warrant and the price at which these shares may be purchased upon such exercise;

the warrant agreement under which the warrants will be issued;

the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreement and the warrants;

anti-dilution provisions of the warrants, if any;

the terms of any rights to redeem or call the warrants;

any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;

the dates on which the right to exercise the warrants will commence and expire or, if the warrants are not continuously exercisable during that period, the specific date or dates on which the warrants will be exercisable;

the manner in which the warrant agreement and warrants may be modified;

the identities of the warrant agent and any calculation or other agent for the warrants;

federal income tax consequences of holding or exercising the warrants;

the terms of the securities issuable upon exercise of the warrants;

any securities exchange or quotation system on which the warrants or any securities deliverable upon exercise of the warrants may be listed; and

any other specific terms, preferences, rights or limitations of or restrictions on the warrants.

Before exercising their warrants, holders of warrants will not have any of the rights of holders of the securities purchasable upon such exercise, including in the case of warrants to purchase common stock or preferred stock, the right to receive dividends, if any, or, payments upon our liquidation, dissolution or winding up or to exercise voting rights, if any.

## **Table of Contents**

### **Exercise of Warrants**

Each warrant will entitle the holder to purchase the securities that we specify in the applicable prospectus supplement at the exercise price that we describe in the applicable prospectus supplement. Unless we otherwise specify in the applicable prospectus supplement, holders of the warrants may exercise the warrants at any time up to 5:00 P.M. eastern time on the expiration date that we set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

Holders of the warrants may exercise the warrants by delivering the warrant certificate representing the warrants to be exercised together with specified information, and paying the required amount to the warrant agent in immediately available funds, as provided in the applicable prospectus supplement. We will set forth on the reverse side of the warrant certificate, and in the applicable prospectus supplement, the information that the holder of the warrant will be required to deliver to the warrant agent.

Until the warrant is properly exercised, no holder of any warrant will be entitled to any rights of a holder of the securities purchasable upon exercise of the warrant.

Upon receipt of the required payment and the warrant certificate properly completed and duly executed at the corporate trust office of the warrant agent or any other office indicated in the applicable prospectus supplement, we will issue and deliver the securities purchasable upon such exercise. If fewer than all of the warrants represented by the warrant certificate are exercised, then we will issue a new warrant certificate for the remaining amount of warrants. If we so indicate in the applicable prospectus supplement, holders of the warrants may surrender securities as all or part of the exercise price for warrants.

### **Enforceability of Rights By Holders of Warrants**

Any warrant agent will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A single bank or trust company may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action its right to exercise, and receive the securities purchasable upon exercise of, its warrants in accordance with their terms.

### **Warrant Agreement Will Not Be Qualified Under Trust Indenture Act**

No warrant agreement will be qualified as an indenture, and no warrant agent will be required to qualify as a trustee, under the Trust Indenture Act. Therefore, holders of warrants issued under a warrant agreement will not have the protection of the Trust Indenture Act with respect to their warrants.

### **Governing Law**

Each warrant agreement and any warrants issued under the warrant agreements will be governed by New York law.

### **Calculation Agent**

Calculations relating to warrants may be made by a calculation agent, an institution that we appoint as our agent for this purpose. The prospectus supplement for a particular warrant will name the institution that we have appointed to

act as the calculation agent for that warrant as of the original issue date for that warrant. We may appoint a different institution to serve as calculation agent from time to time after the original issue date without the consent or notification of the holders.

The calculation agent's determination of any amount of money payable or securities deliverable with respect to a warrant will be final and binding in the absence of manifest error.

### **DESCRIPTION OF UNITS**

We may issue units comprised of one or more of the other securities described in this prospectus in any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date.

The applicable prospectus supplement will describe:

the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;

any unit agreement under which the units will be issued;

any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units; and

whether the units will be issued in fully registered or global form.

**Table of Contents**

The applicable prospectus supplement will describe the terms of any units. The preceding description and any description of units in the applicable prospectus supplement does not purport to be complete and is subject to and is qualified in its entirety by reference to the unit agreement and, if applicable, collateral arrangements and depositary arrangements relating to such units.

**PLAN OF DISTRIBUTION**

We may sell the securities being offered pursuant to this prospectus through underwriters or dealers, through agents, or directly to one or more purchasers or through a combination of these methods. The applicable prospectus supplement will describe the terms of the offering of the securities, including:

the name or names of any underwriters, if any, and if required, any dealers or agents;

the purchase price of the securities and the proceeds we will receive from the sale;

any underwriting discounts and other items constituting underwriters' compensation;

any discounts or concessions allowed or reallocated or paid to dealers; and

any securities exchange or market on which the securities may be listed.

We may distribute the securities from time to time in one or more transactions at:

a fixed price or prices, which may be changed;

market prices prevailing at the time of sale;

prices related to such prevailing market prices; or

negotiated prices.

Only underwriters named in the prospectus supplement are underwriters of the securities offered by the prospectus supplement.

If underwriters are used in an offering, we will execute an underwriting agreement with such underwriters and will specify the name of each underwriter and the terms of the transaction (including any underwriting discounts and other terms constituting compensation of the underwriters and any dealers) in a prospectus supplement. The securities may be offered to the public either through underwriting syndicates represented by managing underwriters or directly by one or more investment banking firms or others, as designated. If an underwriting syndicate is used, the managing

underwriter(s) will be specified on the cover of the prospectus supplement. If underwriters are used in the sale, the offered securities will be acquired by the underwriters for their own accounts and may be resold from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. Any public offering price and any discounts or concessions allowed or reallocated or paid to dealers may be changed from time to time. Unless otherwise set forth in the prospectus supplement, the obligations of the underwriters to purchase the offered securities will be subject to conditions precedent and the underwriters will be obligated to purchase all of the offered securities if any are purchased.

We may grant to the underwriters options to purchase additional securities to cover over-allotments, if any, at the public offering price, with additional underwriting commissions or discounts, as may be set forth in a related prospectus supplement. The terms of any over-allotment option will be set forth in the prospectus supplement for those securities.

If we use a dealer in the sale of the securities being offered pursuant to this prospectus or any prospectus supplement, we will sell the securities to the dealer, as principal. The dealer may then resell the securities to the public at varying prices to be determined by the dealer at the time of resale. The names of the dealers and the terms of the transaction will be specified in a prospectus supplement.

We may sell the securities directly or through agents we designate from time to time. We will name any agent involved in the offering and sale of securities and we will describe any commissions we will pay the agent in the prospectus supplement. Unless the prospectus supplement states otherwise, any agent will act on a best-efforts basis for the period of its appointment.

We may authorize agents or underwriters to solicit offers by institutional investors to purchase securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. We will describe the conditions to these contracts and the commissions we must pay for solicitation of these contracts in the prospectus supplement.

In connection with the sale of the securities, underwriters, dealers or agents may receive compensation from us or from purchasers of the common stock for whom they act as agents in the form of discounts, concessions or commissions. Underwriters may sell the securities to or through dealers, and those dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters or commissions from the purchasers for whom they may act as agents. Underwriters, dealers and



## **Table of Contents**

agents that participate in the distribution of the securities, and any institutional investors or others that purchase common stock directly and then resell the securities, may be deemed to be underwriters, and any discounts or commissions received by them from us and any profit on the resale of the common stock by them may be deemed to be underwriting discounts and commissions under the Securities Act.

We may provide agents and underwriters with indemnification against particular civil liabilities, including liabilities under the Securities Act, or contribution with respect to payments that the agents or underwriters may make with respect to such liabilities. Agents and underwriters may engage in transactions with, or perform services for, us in the ordinary course of business.

In addition, we may enter into derivative transactions with third parties (including the writing of options), or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement indicates, in connection with such a transaction, the third parties may, pursuant to this prospectus and the applicable prospectus supplement, sell securities covered by this prospectus and the applicable prospectus supplement. If so, the third party may use securities borrowed from us or others to settle such sales and may use securities received from us to close out any related short positions. We may also loan or pledge securities covered by this prospectus and the applicable prospectus supplement to third parties, who may sell the loaned securities or, in an event of default in the case of a pledge, sell the pledged securities pursuant to this prospectus and the applicable prospectus supplement. The third party in such sale transactions will be an underwriter and will be identified in the applicable prospectus supplement or in a post-effective amendment.

To facilitate an offering of a series of securities, persons participating in the offering may engage in transactions that stabilize, maintain, or otherwise affect the market price of the securities. This may include over-allotments or short sales of the securities, which involves the sale by persons participating in the offering of more securities than have been sold to them by us. In those circumstances, such persons would cover such over-allotments or short positions by purchasing in the open market or by exercising the over-allotment option granted to those persons. In addition, those persons may stabilize or maintain the price of the securities by bidding for or purchasing securities in the open market or by imposing penalty bids, whereby selling concessions allowed to underwriters or dealers participating in any such offering may be reclaimed if securities sold by them are repurchased in connection with stabilization transactions. The effect of these transactions may be to stabilize or maintain the market price of the securities at a level above that which might otherwise prevail in the open market. Such transactions, if commenced, may be discontinued at any time. We make no representation or prediction as to the direction or magnitude of any effect that the transactions described above, if implemented, may have on the price of our securities.

Any common stock sold pursuant to a prospectus supplement will be eligible for quotation and trading on The NASDAQ Capital Market. Any underwriters to whom securities are sold by us for public offering and sale may make a market in the securities, but such underwriters will not be obligated to do so and may discontinue any market making at any time without notice.

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

## **LEGAL MATTERS**

The validity of the issuance of the securities offered hereby will be passed upon for us by Sichenzia Ross Friedman Ference LLP, New York, New York.

## **EXPERTS**

The consolidated balance sheets as of December 31, 2013 and 2012, and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended and for the period from January 25, 2006 (Inception) through December 31, 2013 have been incorporated in reliance on the report of Mayer Hoffman McCann P.C., an independent registered public accounting firm, incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

## **WHERE YOU CAN FIND MORE INFORMATION**

This prospectus constitutes a part of a registration statement on Form S-3 filed under the Securities Act. As permitted by the SEC's rules, this prospectus and any prospectus supplement, which form a part of the registration statement, do not contain all the information that is included in the registration statement. You will find additional information about us in the registration statement. Any statements made in this prospectus or any prospectus supplement concerning legal documents are not necessarily complete and you should read the documents that are filed as exhibits to the registration statement or otherwise filed with the SEC for a more complete understanding of the document or matter.

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read, without charge, and copy the documents we file at the SEC's public reference rooms in Washington, D.C. at 100 F Street, NE, Room 1580, Washington, DC 20549, or in New York, New York and Chicago, Illinois. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for further information on the public reference rooms. Our SEC filings are also available to the public at no cost from the SEC's website at <http://www.sec.gov>.

**Table of Contents**

**INCORPORATION OF DOCUMENTS BY REFERENCE**

We have filed a registration statement on Form S-3 with the Securities and Exchange Commission under the Securities Act. This prospectus is part of the registration statement but the registration statement includes and incorporates by reference additional information and exhibits. The Securities and Exchange Commission permits us to incorporate by reference the information contained in documents we file with the Securities and Exchange Commission, which means that we can disclose important information to you by referring you to those documents rather than by including them in this prospectus. Information that is incorporated by reference is considered to be part of this prospectus and you should read it with the same care that you read this prospectus. Information that we file later with the Securities and Exchange Commission will automatically update and supersede the information that is either contained, or incorporated by reference, in this prospectus, and will be considered to be a part of this prospectus from the date those documents are filed. We have filed with the Securities and Exchange Commission, and incorporate by reference in this prospectus:

Annual Report on Form 10-K for the year ended December 31, 2013 filed with the SEC on April 1, 2014;

Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2014 filed with the SEC on May 14, 2014;

Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2014 filed with the SEC on August 6, 2014;

Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2014 filed with the SEC on May 14, 2014;

Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014 filed with the SEC on November 4, 2014;

Proxy Statement on Schedule 14A filed with the SEC on April 29, 2014;

Current Reports on Form 8-K (excluding any reports or portions thereof that are deemed to be furnished and not filed) filed with the SEC on January 9, 2014, February 3, 2014, March 3, 2014, March 11, 2014, March 25, 2014, April 1, 2014, April 4, 2014, May 13, 2014, May 15, 2014, May 30, 2014, June 23, 2014, June 25, 2014, July 1, 2014, July 21, 2014, July 31, 2014, August 8, 2014, August 18, 2014, August 21, 2014, October 6, 2014 and October 15, 2014; and

The description of our common stock contained in our Form 8-A filed with the SEC on October 23, 2014. We also incorporate by reference all additional documents that we file with the Securities and Exchange Commission under the terms of Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act that are made after the initial filing date of

the registration statement of which this prospectus is a part until the offering of the particular securities covered by a prospectus supplement or term sheet has been completed. We are not, however, incorporating, in each case, any documents or information that we are deemed to furnish and not file in accordance with Securities and Exchange Commission rules.

You may request, and we will provide you with, a copy of these filings, at no cost, by calling us at (858) 210-3700 or by writing to us at the following address:

Sorrento Therapeutics, Inc.

6042 Cornerstone Ct. West, Suite B

San Diego, California 92121

Attn.: Corporate Secretary

Shares

Common Stock

---

Prospectus Supplement

**Cantor Fitzgerald & Co. FBR & Co.**

, 2017