

Sorrento Therapeutics, Inc.  
Form S-8  
April 25, 2014  
Table of Contents

As filed with the Securities and Exchange Commission on April 25, 2014

Registration No. \_\_\_\_\_

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

**FORM S-8**  
**REGISTRATION STATEMENT**  
***UNDER***  
***THE SECURITIES ACT OF 1933***

**Sorrento Therapeutics, Inc.**

**(Exact name of registrant as specified in its charter)**

**Delaware**  
**(State or other jurisdiction of**  
**incorporation or organization)**

**33-0344842**  
**(I.R.S. Employer**  
**Identification No.)**

Edgar Filing: Sorrento Therapeutics, Inc. - Form S-8

**6042 Cornerstone Ct. West, Suite B**

**San Diego, California 92121**

**(Address of principal executive offices) (Zip Code)**

**2008 Equity Compensation Incentive Plan**

**(Full title of the plans)**

**Dr. Henry Ji**

**Chief Executive Officer**

**Sorrento Therapeutics, Inc.**

**6042 Cornerstone Ct. West, Suite B**

**San Diego, CA 92121**

**(Name and Address of agent for service)**

**(858) 210-3700**

**(Telephone number, including area code, of agent for service)**

*With a copy to:*

**Jeffrey Fessler, Esq.**

**Sichenzia Ross Friedman Ference LLP**

**61 Broadway, 32<sup>nd</sup> Floor**

**New York, NY 10006**

**Phone (212) 930-9700**

**Fax (212) 930-9725**

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

Large accelerated filer

Accelerated filer

Table of Contents

2

Non-accelerated filer Smaller Reporting Company **CALCULATION OF REGISTRATION FEE**

<b>Title of Securities</b>	<b>Amount</b>	<b>Proposed</b>	<b>Proposed</b>	<b>Amount of</b>
		<b>Maximum</b>	<b>Maximum</b>	
<b>to be Registered</b>	<b>Registered (1)</b>	<b>Offering Price</b>	<b>Aggregate</b>	<b>Registration Fee</b>
		<b>Per Share</b>	<b>Offering Price</b>	
Common Stock, \$.0001 par value	1,560,000	\$10.07 (2)	\$15,709,200	\$2,023.34
<b>TOTAL</b>	<b>1,560,000</b>		<b>\$15,709,200</b>	<b>\$2,023.34</b>

- (1) Pursuant to Rule 416(a) under the Securities Act of 1933, as amended, this Registration Statement shall also cover any additional shares of the Registrant's common stock that become issuable under the Company's Amended and Restated 2009 Stock Incentive Plan, as amended, by reason of any stock dividend, stock split, recapitalization or other similar transaction that increases the number of the outstanding shares of the Registrant's common stock.
- (2) Estimated solely for purposes of calculating the registration fee in accordance with Rule 457(c) of the Securities Act of 1933, as amended, using the last sale price reported on The NASDAQ Capital Market on April 24, 2014.

---

**Table of Contents**

**EXPLANATORY NOTE**

This registration statement on Form S-8 (the **Registration Statement** ) relates to 1,560,000 shares of the common stock of Sorrento Therapeutics, Inc., a Delaware corporation (the **Registrant**, the **Company**, **we**, **us** or **our** ), \$0.0001 per share par value per share (the **Common Stock** ), which are issuable pursuant to, or upon exercise of, options that may be granted under the Sorrento Therapeutics 2009 Stock Incentive Plan, as amended and restated (the **Plan** ). Under the Plan, a total of 1,560,000 shares of Common Stock have been reserved for issuance upon the grant and exercise of options. In addition, this amount will be automatically increased annually on the first day of each fiscal year, beginning in 2014, by the lesser of: (i) 1% of the aggregate number of shares of our common stock outstanding on the last day of the immediately preceding fiscal year, (ii) 200,000 shares, or (iii) an amount approved by the Plan administrator. However, in no event will the aggregate number of shares available for issuance under the Amended Plan exceed 3,360,000 during the ten-year term of the Plan.

This Registration Statement also includes a reoffer prospectus prepared in accordance with General Instruction C of Form S-8 and in accordance with the requirements of Part I of Form S-3, which may be utilized for reofferings and resales on a continuous or a delayed basis in the future related to the following:

750,900 shares of common stock (the **Shares** ) which are issuable upon exercise of options that have been granted under the Plan, with respect to which the reoffer prospectus relates are being registered for reoffers and resales by certain stockholders listed (the **Selling Stockholders** ), who are our officers and directors and may be deemed to be our **affiliates** , as defined in Rule 405 of the Securities Act. The Selling Stockholders may acquire the Shares upon exercise of options granted under the Plan. We do not know whether any of such Selling Stockholders will use this reoffer prospectus in connection with the offer or sale of the Shares, or, if this reoffer prospectus is so used, how many shares of Common Stock will be offered or sold. Such Selling Stockholders may resell all, a portion, or none of the shares that they may acquire pursuant to the Plan.

The reoffer prospectus does not contain all of the information included in the Registration Statement, certain items of which are contained in schedules and exhibits to the Registration Statement, as permitted by the rules and regulations of the Securities and Exchange Commission (the **SEC** or the **Commission** ). Statements contained in this reoffer prospectus as to the contents of any agreement, instrument or other document referred to herein are not necessarily complete. With respect to each such agreement, instrument or other document filed as an exhibit to the Registration Statement, we refer you to the exhibit for a more complete description of the matter involved, and each such statement shall be deemed qualified in its entirety by this reference.

**PART I**

**INFORMATION REQUIRED IN THE SECTION 10(a) PROSPECTUS**

**Item 1. Plan Information.**

The Company will provide each recipient of a grant under the Plan (the **Recipients** ) with documents that contain information related to the Plans, and other information including, but not limited to, the disclosure required by Item 1 of Form S-8, which information is not required to be and are not being filed as a part of this Registration Statement on Form S-8 (the **Registration Statement** ) or as prospectuses or prospectus supplements pursuant to Rule 424 under the Securities Act. The foregoing information and the documents incorporated by reference in response to Item 3 of Part II of this Registration Statement, taken together, constitute a prospectus that meets the requirements of Section 10(a)

of the Securities Act. A Section 10(a) prospectus will be given to each Recipient who receives common stock covered by this Registration Statement, in accordance with Rule 428(b)(1) under the Securities Act.

**Item 2. Registrant Information and Employee Plan Annual Information.**

We will provide to each Recipient a written statement advising of the availability of documents incorporated by reference in Item 3 of Part II of this Registration Statement (which documents are incorporated by reference in this Section 10(a) prospectus) and of documents required to be delivered pursuant to Rule 428(b) under the Securities Act without charge and upon written or oral request by contacting:

**Dr. Henry Ji**

**Chief Executive Officer and President**

**Sorrento Therapeutics, Inc.**

**6042 Cornerstone Ct. West, Suite B**

**San Diego, CA 92121**

**Table of Contents**

**REOFFER PROSPECTUS**

**Sorrento Therapeutics, Inc.**

**750,900 Shares of**

**Common Stock**

This reoffer prospectus relates to the sale of up to 750,900 shares (the "Shares") of our common stock, \$.0001 par value per share (the "Common Stock") on The NASDAQ Capital Market, or such other stock market or exchange on which our common stock may be listed or quoted, in negotiated transactions or otherwise, at market prices prevailing at the time of the sale or at prices otherwise negotiated (see "Plan of Distribution" starting on page 39 of this prospectus). We will receive no part of the proceeds from sales made under this reoffer prospectus. The selling stockholders will bear all sales commissions and similar expenses. Any other expenses incurred by us in connection with the registration and offering and not borne by the selling stockholders will be borne by us.

This reoffer prospectus has been prepared for the purposes of registering the common shares under the Securities Act to allow for future sales by selling stockholders on a continuous or delayed basis to the public without restriction.

Investing in our common stock involves risks. See "Risk Factors" beginning on page 8 of this reoffer prospectus. These are speculative securities.

Our common stock is quoted on The NASDAQ Capital Market under the symbol "SRNE" and the last reported sale price of our common stock on April 24, 2014 was \$10.07 per share.

**NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.**

The date of this prospectus is April 25, 2014

Table of Contents

**SORRENTO THERAPEUTICS, INC.**

**TABLE OF CONTENTS**

	<b>Page</b>
<u>Prospectus Summary</u>	4
<u>Risk Factors</u>	6
<u>Cautionary Note Regarding Forward-Looking Statements</u>	32
<u>Use of Proceeds</u>	32
<u>Selling Stockholders</u>	33
<u>Plan of Distribution</u>	36
<u>Legal Matters</u>	38
<u>Experts</u>	38
<u>Incorporation of Certain Documents by Reference</u>	38
<u>Disclosure of Commission Position on Indemnification For Securities Act Liabilities</u>	38
<u>Additional Information Available to You</u>	39

NO PERSON HAS BEEN AUTHORIZED TO GIVE ANY INFORMATION OR TO MAKE ANY REPRESENTATIONS, OTHER THAN THOSE CONTAINED IN THIS PROSPECTUS, IN CONNECTION WITH THE OFFERING MADE HEREBY, AND, IF GIVEN OR MADE, SUCH INFORMATION OR REPRESENTATION MUST NOT BE RELIED UPON AS HAVING BEEN AUTHORIZED BY THE COMPANY OR ANY OTHER PERSON. NEITHER THE DELIVERY OF THIS PROSPECTUS NOR ANY SALE MADE HEREUNDER SHALL UNDER ANY CIRCUMSTANCES CREATE ANY IMPLICATION THAT THERE HAS BEEN NO CHANGE IN THE AFFAIRS OF THE COMPANY SINCE THE DATE HEREOF. THIS PROSPECTUS DOES NOT CONSTITUTE AN OFFER TO SELL OR A SOLICITATION OF AN OFFER TO BUY ANY SECURITIES OFFERED HEREBY BY ANYONE IN ANY JURISDICTION IN WHICH SUCH OFFER OR SOLICITATION IS NOT AUTHORIZED OR IN WHICH THE PERSON MAKING SUCH OFFER OR SOLICITATION IS NOT QUALIFIED TO DO SO OR TO ANY PERSON TO WHOM IT IS UNLAWFUL TO MAKE SUCH OFFER OR SOLICITATION.

---

**Table of Contents**

**PROSPECTUS SUMMARY**

*This summary highlights information contained elsewhere or incorporated by reference into this prospectus. This summary does not contain all of the information that you should consider before deciding to invest in our securities. You should read this entire prospectus and the accompanying prospectus carefully, including the Risk Factors section contained in this prospectus and our consolidated financial statements and the related notes and the other documents incorporated by reference into this prospectus and in the accompanying prospectus. Unless we have indicated otherwise or the context otherwise requires, references in this prospectus or the documents incorporated by reference herein and therein to the Company, we, us and our refer to Sorrento Therapeutics, Inc. and its subsidiaries.*

**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 preclinical fully human therapeutic antibodies, including our fully human 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, and recombinant intravenous immunoglobulin, or rIVIG. 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**

On March 31, 2014, we announced that the first patient has been dosed in the pivotal clinical trial designed to support Cynviloq for the treatment of metastatic breast cancer and non-small cell lung cancer. The registration trial is an open-label, randomized, multi-center, single-dose, crossover registration study being conducted at clinical sites across the U.S., EU, and Singapore. A projected 100 patients with metastatic or locally recurrent breast cancer will be administered 260 mg/m<sup>2</sup> of Cynviloq or 260 mg/m<sup>2</sup> of Abraxane<sup>®</sup> using a 30 minute infusion in a crossover design to compare the bioequivalence of both drugs. Based on the End-of-Phase II meeting with the U.S. Food and Drug Administration, or FDA, in July 2013, this trial was designed to gain marketing approval for Cynviloq under the 505(b)(2) regulatory pathway in the U.S. We expect to file a New Drug Application with the FDA in the first half of 2015.



On March 31, 2014, we entered into an amended and restated loan and security agreement with Oxford Finance LLC and Silicon Valley Bank, increasing the September 2013 facility from \$5,000,000 to \$12,500,000, with two banks. The amended and restated loan bears interest at 7.95% per annum. We will make interest only payments on the outstanding amount of the loan on a monthly basis until October 1, 2014, after which equal monthly payments of principal and interest are due until the loan maturity date of September 30, 2017. In the event we raise \$30 million of net equity or proceeds from a collaboration, if any, the interest only period will be extended by six months. Such loan is secured by a security interest in substantially all of our assets, excluding intellectual property, which is subject to a negative pledge. In connection with the amended and restated loan and security agreement, the Lenders received a warrant to purchase an aggregate 34,642 shares of our common stock at an exercise price of \$12.99 per share, which is exercisable for seven years from the date of issuance.

**Table of Contents**

**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.

**Table of Contents**

**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, 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 December 31, 2013 and 2012, we had an accumulated deficit of \$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) conduct our BE registration trial related to Cynviloq and prepare for our New Drug Application filing anticipated in 2015, (ii) advance RTX into clinical 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.

**Table of Contents**

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 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.

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;

**Table of Contents**

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 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.

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 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.



**Table of Contents**

***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 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.

**Table of Contents**

***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.

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 biologics license application, or BLA, or a New Drug Application, 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 FFDCA.***

We are seeking approval for Cynviloq under Section 505(b)(2) of the FFDCA, 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.

---

**Table of Contents**

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 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.

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 and rIVIG is unproven, and we do not know whether we will be able to develop any products of commercial value.***

ADCs and rIVIG 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.

***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.

## **Table of Contents**

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.

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.



**Table of Contents**

***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.

*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.

## **Table of Contents**

***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.

***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.

**Table of Contents**

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;

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 MBC and 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



**Table of Contents**

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;

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

## **Table of Contents**

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.

***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

**Table of Contents**

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 approval prior to commercialization. We do not develop companion diagnostics internally and thus we are 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 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

## **Table of Contents**

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 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.

---

**Table of Contents**

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, Vuong Trieu, Ph.D., Chief Scientific Officer, David Miao, Chief Technology Officer, George Uy, Chief Commercial Officer and Richard Vincent, 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 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.

## **Table of Contents**

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;

the federal Health Insurance Portability and Accountability Act of 1996, or 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

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.

**Table of Contents**

***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.

***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 in 2012. 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.

**Table of Contents**

***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.

***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 have a \$12.5 million loan and security agreement with Oxford Finance LLC, or Oxford, and Silicon Valley Bank, or SVB, that is secured by a lien covering substantially all of our

assets, excluding intellectual property. As of December 31, 2013, under our initial \$5.0 million loan and security agreement with Oxford and SVB entered into in September 2013, we had an outstanding principal balance of \$5.0 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.

## **Table of Contents**

### **Risks Related to the Acquisitions of IgDraSol, Sherrington and Concortis**

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

The success of the acquisitions of IgDraSol, Sherrington and Concortis 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 Concortis 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 Concortis 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. In 2013, we filed 14 antibody family patents. In 2013, we filed three patent application families for the Concortis conjugation chemistry. 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. 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.

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

We do not manage or control the 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.

**Table of Contents**

***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.

***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.

---

**Table of Contents*****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.

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

**Table of Contents**

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.

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.

**Table of Contents**

**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;

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.

**Table of Contents**

***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.

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.

## **Table of Contents**

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 March 31, 2014, our directors, executive officers and principal stockholders beneficially owned, in the aggregate, approximately 36.7% 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.

***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.

---

**Table of Contents**

***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**

**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus, 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, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or 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 supplement.

You should read this prospectus supplement and any accompanying prospectus and the documents that we reference herein and therein and have filed as exhibits to the registration statement, of which this prospectus supplement 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 supplement and any accompanying prospectus is accurate as of the date on the front cover of this prospectus supplement. Because the risk factors referred to above, as well as the risk factors referred to on page of this prospectus supplement 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 supplement and the accompanying prospectus, and particularly our forward-looking statements, by these cautionary statements.

**USE OF PROCEEDS**

This prospectus relates to sale of shares of common stock that may be offered and sold from time to time by the selling stockholders. We will not receive any proceeds from the sale of shares by the selling stockholders.

**Table of Contents**

**SELLING STOCKHOLDERS**

The selling stockholders named in this prospectus (the Selling Stockholders ) are offering 750,900 shares of our common stock including shares of stock which are issuable to the Selling Stockholders directly by options, stock awards or indirectly through exercise of options pursuant to our 2009 Stock Incentive Plan, as amended and restated. The selling stockholders are our officers and directors, and may be deemed to be our affiliates, as defined in Rule 405 of the Securities Act, who may acquire such shares upon exercise of options granted under the Plan. We do not know whether any of such individuals will be granted additional options under the Plan, whether any of such Selling Stockholders will use this prospectus in connection with the offer or sale of any shares of Common Stock, or, if this prospectus is so used, how many shares of Common Stock will be offered or sold. The selling stockholders may resell all, a portion, or none of the shares that they may acquire pursuant to the Plan. The Selling Stockholders named in this prospectus were granted the options in consideration of services and such shares are issuable upon exercise of stock options at various exercise prices, depending on the dates of grant.

The following table provides, as of March 31, 2014, information regarding the beneficial ownership of our common shares held by each of the selling stockholders, including:

1. the total number of common shares owned by each selling stockholder prior to this offering;
2. the total number of common shares that are to be offered by each selling stockholder;
3. the total number of common shares that will be owned by each selling stockholder upon completion of the offering; and
4. the percentage owned by each selling stockholder, prior to and upon completion of the offering.

Information with respect to beneficial ownership is based upon information obtained from the Selling Stockholders. Information with respect to Shares Beneficially Owned Prior to the Offering includes the shares issuable upon exercise of the stock options held by the selling stockholders to the extent these options are exercisable within 60 days of March 31, 2014. Information with respect to Shares Beneficially Owned After the Offering assumes the sale of all of the common shares offered by this prospectus and no other purchases or sales of our common shares by the selling stockholders. Except as described below and to our knowledge, the named selling shareholder beneficially owns and has sole voting and investment power over all common shares or rights to these common shares.

Because the Selling Stockholders may offer all or part of the shares of common stock, which they own pursuant to the offering contemplated by this reoffer prospectus, and because its offering is not being underwritten on a firm commitment basis, no estimate can be given as to the amount of shares that will be held upon termination of this offering. The shares of common stock currently owned offered by this reoffer prospectus may be offered from time to time by the Selling Stockholders named below. However, information with respect to Shares Beneficially Owned Upon Completion the Offering assumes the sale of all of the shares of common stock offered by this prospectus and no other purchases or sales of our shares of common stock by the selling stockholders. Except as described below and to our knowledge, the named selling stockholder beneficially owns and has sole voting and investment power over all common shares or rights to these common shares.



**Table of Contents**

<b>Name</b>	<b>Shares Beneficially Owned prior to this Offering (1) Number</b>	<b>Number of Shares Being Offered</b>	<b>Shares Beneficially Owned Upon Completion of the Offering (1) Number Percent (2)</b>	
Cam Gallagher (3)	12,667	35,000	6,667	*
David (Zhenwei) Miao (4)	599,390	36,000	599,390	2.6
George Uy (5)	199,496	47,000	199,496	1.0
Henry Ji (6)	2,349,162	117,000	2,349,162	9.9
Jaism Shah (7)	110,442	140,000	110,442	*
Kim Janda (8)	32,567	56,900	32,567	*
Mark Durand (9)	2,166	13,000	2,166	*
Richard Vincent (10)	115,625	220,000	115,625	*
Vuong Trieu (11)	1,786,019	36,000	1,786,019	7.8
William S. Marth (12)	4,333	50,000	4,333	*

\* Less than one percent (1%).

- (1) The number and percentage of shares beneficially owned is determined in accordance with Rule 13d-3 of the Securities Exchange Act of 1934, as amended, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rule, beneficial ownership includes any shares as to which the selling stockholder has sole or shared voting power or investment power and also any shares which the selling stockholder has the right to acquire within 60 days.
- (2) Percentage is based upon 23,053,101 shares of common stock outstanding as of March 31, 2014.
- (3) The shares offered by the selling shareholder represent: (i) 16,000 options exercisable at a price of \$3.50 of which 1/48th of the total number of shares subject to the option (rounded down to the nearest whole share) shall vest on the first day of each month after the vesting commencement date, so that all of the shares subject to the option shall be vested on the 4th year anniversary for such grant (ii) 9,000 options exercisable at a price of \$8.40 per share, 1/12 of the options shall vest and become exercisable following each one-month period of service commencing on September 6, 2013, subject to the selling shareholder's continued service on the Company's board of directors on each such date, and (iii) 10,000 options exercisable at a price of \$9.82 per share of which 3,333 options shall vest and become exercisable on January 23, 2015 and 2016 and 3,334 shall vest and become exercisable on January 23, 2017, subject to the selling shareholder's continued service on the Company's board of directors on each such date.
- (4) The shares offered by the selling shareholder represent 36,000 options exercisable at a price of \$13.53 per share, 9,000 of which shall vest and become exercisable on March 10, 2015 and 1/48 of the remainder shall vest following each one month period of service thereunder subject to the selling shareholder's continued service to the Company through such vesting date.
- (5) The shares offered by the selling shareholder represent 47,000 options exercisable at a price of \$8.40 per share of which: (i) 20,000 options vested on grant, and (ii) with respect to the remainder, 1/4 of the options shall vest on October 1, 2014 and 1/48 of the original number of shares subject to the option shall vest following each one month period of service thereafter, subject to the selling shareholder's continued service to the Company through each such vesting date. The remaining 20,000 options vest immediately upon grant.
- (6) The shares offered by the selling shareholder represent: (i) 6,000 options exercisable at a price of \$1.75 per share of which all such options are currently vested and exercisable, (ii) 10,000 options exercisable at a price of \$4.00 per share of which 5,000 are currently vested and exercisable, and 2,500 of which shall vest on each of

Edgar Filing: Sorrento Therapeutics, Inc. - Form S-8

December 31, 2014, and December 31, 2015, and (iii) 101,000 options exercisable at a price of \$8.40 per share 1/4th of the original number of shares subject to the option shall vest on the first anniversary of the vesting commencement date of October 29, 2013 and 1/48th of the original number of shares subject to the option shall vest following each one-month period of service following the vesting commencement date, subject to selling shareholder's continued service or employment with the Company through each such vesting date.

- (7) The shares offered by the selling shareholder represent: (i) 60,000 options exercisable at a price of \$4.00 per share of which 15,000 options vest on September 22, 2013 and 1,250 per month thereafter, and (ii) 80,000 options exercisable at a price of

**Table of Contents**

\$8.40 per share of which 20,000 options vest immediately upon grant, the remaining 60,000 options, are subject to the closing of one or more strategic partnering out-license or sale transactions by December 31, 2014, and shall be eligible to vest as follows: (i) 20,000 shares upon the closing of one or more strategic transactions with a total transaction value greater than \$500,000,000, (ii) 20,000 shares subject upon the closing of one or more strategic transactions with a cumulative total transaction value greater than \$1,000,000,000 but less than \$1,500,000,000, and (iii) 20,000 shares subject upon the closing of one or more strategic transactions with a cumulative total transaction value greater than \$1,500,000,000.

- (8) The shares offered by the selling shareholder represent: (i) 8,000 options exercisable at a price of \$1.75 per share, (ii) 1,900 options exercisable at a price of \$3.50 per share, (iii) 8,000 options exercisable at a price of \$3.50 per share, (iv) 3,000 options exercisable at a price of \$4.00 per share, (v) 1,000 options exercisable at a price of \$4.00 per share, (vi) 16,000 options exercisable at a price of \$4.00 per share, (vii) 9,000 options exercisable at a price of \$8.40 per share of which 1/12 of the options shall vest and become exercisable following each one-month period of service commencing on September 6, 2013, subject to the selling shareholder's continued service on the Company's board of directors on each such date, and (viii) 10,000 options exercisable at a price of \$9.82 per share of which 3,333 options shall vest and become exercisable on each of January 23, 2015 and January 23, 2016, and 3,334 shall vest and become exercisable on January 23, 2017, subject to the selling shareholder's continued service on the Company's board of directors on each such date.
- (9) The shares offered by the selling shareholder represent 13,000 options exercisable at a price of \$13.53 per share, of which 1/12 of such option shall vest and become exercisable following each one-month period of service commencing on March 7, 2014, subject to the selling shareholder's continued service on Company's board of directors on each such date.
- (10) The shares offered by the selling shareholder represent: (i) 4,000 options exercisable at a price of \$1.75 per share which are fully vested and currently exercisable, (ii) 20,000 options exercisable at a price of \$3.50 per share, of which 15,000 are vested and 5,000 shall become exercisable on December 31, 2014, (iii) 5,000 options exercisable at a price of \$4.00 per share of which 2,500 are vested and the remainder of which shall vest equally on December 31, 2014 and December 31, 2015, (iv) 91,000 options exercisable at a price of \$4.00 per share of which 28,438 have vested and are exercisable with 1/48th of the original number of shares subject to the option shall vest following each one-month period of service following the vesting commencement date, subject to selling shareholder's continued service or employment with the Company on each such date, and (v) 100,000 options exercisable at a price of \$8.40 per share of which 40,000 options vested immediately upon grant, 20,000 shares vested upon the closing of a strategic transaction prior to March 31, 2014, and of the remaining 40,000 shares, 1/4 of the original number of shares subject to the option shall vest on October 1, 2014 and 1/48 of the original number of shares subject to the option shall vest following each one month period of service thereafter, subject to the reporting person's continued service to the Company through each such vesting date.
- (11) The shares being offered by the selling shareholder represent 36,000 options exercisable at a price of \$8.40 per share of which 1/4 of the options shall vest on October 1, 2014 and 1/48 of the original number of shares subject to the option shall vest following each one month period of service thereafter, subject to the selling shareholder's continued service to the Company through each such vesting date.
- (12) The shares offered by the selling shareholder represent: (i) 13,000 options exercisable at a price of \$8.20 per share of which 1/12th of the total number of shares subject to the option (rounded down to the nearest whole share) shall vest on the first day of each month after the vesting commencement date, so that all of the shares subject to the option shall be vested on the one year anniversary for the grant, and (ii) 37,000 options exercisable at a price of \$9.82 per share of which 12,333 options shall vest and become exercisable on January 23, 2015 and 2016, and 12,334 shall vest and become exercisable on January 23, 2017, subject to the selling shareholder's continued service on the Company's board of directors on each such date.

**Table of Contents**

**PLAN OF DISTRIBUTION**

**Timing of Sales**

The selling stockholders may offer and sell the shares covered by this prospectus at various times. The selling stockholders will act independently of our company in making decisions with respect to the timing, manner and size of each sale.

**No Known Agreements to Resell the Shares**

To our knowledge, no selling stockholder has any agreement or understanding, directly or indirectly, with any person to resell the common shares covered by this prospectus.

**Offering Price**

The sales price offered by the selling stockholders to the public may be:

1. the market price prevailing at the time of sale;
2. a price related to such prevailing market price; or
3. such other price as the selling stockholders determine from time to time.

**Manner of Sale**

The common shares may be sold by means of one or more of the following methods:

1. a block trade in which the broker-dealer so engaged will attempt to sell the common shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
2. Purchases by a broker-dealer as principal and resale by that broker-dealer for its account pursuant to this prospectus;
3. ordinary brokerage transactions in which the broker solicits purchasers;
4. through options, swaps or derivatives;
5. in transactions to cover short sales;

6. privately negotiated transactions; or

7. in a combination of any of the above methods.

The selling stockholders may sell their common shares directly to purchasers or may use brokers, dealers, underwriters or agents to sell their common shares. Brokers or dealers engaged by the selling stockholders may arrange for other brokers or dealers to participate. Brokers or dealers may receive commissions, discounts or concessions from the selling stockholders, or, if any such broker-dealer acts as agent for the purchaser of common shares, from the purchaser in amounts to be negotiated immediately prior to the sale. The compensation received by brokers or dealers may, but is not expected to, exceed that which is customary for the types of transactions involved.

Broker-dealers may agree with a selling stockholder to sell a specified number of common shares at a stipulated price per common share, and, to the extent the broker-dealer is unable to do so acting as agent for a selling stockholder, to purchase as principal any unsold common shares at the price required to fulfill the broker-dealer commitment to the selling stockholder.

Broker-dealers who acquire common shares as principal may thereafter resell the common shares from time to time in transactions, which may involve block transactions and sales to and through other broker-dealers, including transactions of the nature described above, on The NASDAQ Capital Market or otherwise at prices and on terms then prevailing at the time of sale, at prices then related to the then-current market price or in negotiated transactions. In connection with resales of the common shares, broker-dealers may pay to or receive from the purchasers of shares commissions as described above.



## **Table of Contents**

If our selling stockholders enter into arrangements with brokers or dealers, as described above, we are obligated to file a post-effective amendment to this registration statement disclosing such arrangements, including the names of any broker-dealers acting as underwriters.

The selling stockholders and any broker-dealers or agents that participate with the selling stockholders in the sale of the common shares may be deemed to be underwriters within the meaning of the Securities Act. In that event, any commissions received by broker-dealers or agents and any profit on the resale of the common shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act.

We will make copies of this prospectus available to the selling stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act.

## **Sales Pursuant to Rule 144**

Any common shares covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than pursuant to this prospectus.

## **Regulation M**

The selling stockholders must comply with the requirements of the Securities Act and the Exchange Act in the offer and sale of the common stock. In particular we will advise the selling stockholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of common shares in the market and to the activities of the selling stockholders and their affiliates. Regulation M under the Exchange Act prohibits, with certain exceptions, participants in a distribution from bidding for, or purchasing for an account in which the participant has a beneficial interest, any of the securities that are the subject of the distribution.

Accordingly, during such times as a selling stockholder may be deemed to be engaged in a distribution of the common stock, and therefore be considered to be an underwriter, the selling stockholder must comply with applicable law and, among other things:

1. may not engage in any stabilization activities in connection with our common stock;
2. may not cover short sales by purchasing shares while the distribution is taking place; and
3. may not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities other than as permitted under the Exchange Act.

## **State Securities Laws**

Under the securities laws of some states, the common shares may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the common shares may not be sold unless the shares have been registered or qualified for sale in the state or an exemption from registration or qualification is available and is complied with.

## **Expenses of Registration**

Edgar Filing: Sorrento Therapeutics, Inc. - Form S-8

We are bearing all costs relating to the registration of the common stock. These expenses are estimated to be \$5,000, including, but not limited to, legal, accounting, printing and mailing fees. The selling stockholders, however, will pay any commissions or other fees payable to brokers or dealers in connection with any sale of the common stock.

**Table of Contents**

**LEGAL MATTERS**

The validity of the common stock has been 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.

**INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE**

The Securities and Exchange Commission ( Commission ) allows us to incorporate by reference certain of our publicly filed documents into this prospectus, which means that such information is considered part of this prospectus. As such, the following documents filed with the Commission are incorporated herein by reference:

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

Proxy Statement on Schedule 14A filed on April 16, 2013;

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 April 1, 2014 and April 4, 2014; and

The description of our common stock contained in our Form 8-A filed on October 23, 2013. All documents subsequently filed with the Commission by the Registrant pursuant to Sections 13(a), 13(c), 14, and 15(d) of the Exchange Act, prior to the filing of a post-effective amendment which indicates that all securities offered hereunder have been sold or which deregisters all securities then remaining unsold under this Registration Statement, shall be deemed to be incorporated by reference in this Registration Statement and to be part hereof from the date of filing of such documents. Any statement contained herein or in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes of this Registration Statement to the extent that a statement contained herein or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such earlier statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this Registration Statement.

We will provide without charge to each person to whom a copy of this prospectus has been delivered, on written or oral request, a copy of any or all of the documents incorporated by reference in this prospectus, other than exhibits to such documents. Written or oral requests for such copies should be directed to Richard Vincent, the Company's Chief Financial Officer.

**DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION  
FOR SECURITIES ACT LIABILITIES**

As permitted by the Delaware General Corporation Law, we have adopted provisions in our certificate of incorporation and by-laws to be in effect at the closing of this offering that limit or eliminate the personal liability of our directors. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

any breach of the director's duty of loyalty to us or our stockholders;

any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;

any unlawful payments related to dividends or unlawful stock repurchases, redemptions or other distributions;  
or

**Table of Contents**

any transaction from which the director derived an improper personal benefit. These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our by-laws provide that:

we will indemnify our directors, officers and, in the discretion of our board of directors, certain employees to the fullest extent permitted by the Delaware General Corporation Law; and

we will advance expenses, including attorneys' fees, to our directors and, in the discretion of our board of directors, to our officers and certain employees, in connection with legal proceedings, subject to limited exceptions.

We also maintain general liability insurance that covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act.

These provisions may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. These provisions may also have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit us and our stockholders. Furthermore, a stockholder's investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. We believe that these provisions, the indemnification agreements and the insurance are necessary to attract and retain talented and experienced directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Company pursuant to the foregoing provisions, or otherwise, the Company has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Company of expenses incurred or paid by a director, officer or controlling person of the Company in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Company will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

**ADDITIONAL INFORMATION AVAILABLE TO YOU**

This prospectus is part of a Registration Statement on Form S-8 that we filed with the SEC. Certain information in the Registration Statement has been omitted from this prospectus in accordance with the rules of the SEC. We file annual, quarterly and special reports, proxy statements and other information with the SEC. You can inspect and copy the Registration Statement as well as reports, proxy statements and other information we have filed with the SEC at the public reference room maintained by the SEC at 100 F Street N.E. Washington, D.C. 20549. You can obtain copies from the public reference room of the SEC at 100 F Street N.E. Washington, D.C. 20549, upon payment of certain fees. You can call the SEC at 1-800-732-0330 for further information about the public reference room. We are also required to file electronic versions of these documents with the SEC, which may be accessed through the SEC's World

Wide Web site at <http://www.sec.gov>.

**Table of Contents**

**SORRENTO THERAPEUTICS, INC.**

**750,900 SHARES OF COMMON STOCK**

**PROSPECTUS**

**April 25, 2014**

Table of Contents

**PART II**

**INFORMATION NOT REQUIRED IN THE PROSPECTUS**

**Item 3. Incorporation of Documents by Reference.**

The following documents filed by the Registrant with the Commission pursuant to the Securities Act and the Securities Exchange Act of 1934, as amended (the Exchange Act ) are incorporated herein by reference:

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

Proxy Statement on Schedule 14A filed on April 16, 2013;

Current Report on Form 8-K (excluding any reports or portions thereof that are deemed to be furnished and not filed) filed with the SEC on April 1, 2014 and April 4, 2014; and

The description of our common stock contained in our Form 8-A filed on October 23, 2013.

All documents subsequently filed with the Commission by the Registrant pursuant to Sections 13(a), 13(c), 14, and 15(d) of the Exchange Act, prior to the filing of a post-effective amendment which indicates that all securities offered hereunder have been sold or which deregisters all securities then remaining unsold under this Registration Statement, shall be deemed to be incorporated by reference in this Registration Statement and to be part hereof from the date of filing of such documents. Any statement contained herein or in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes of this Registration Statement to the extent that a statement contained herein or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such earlier statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this Registration Statement.

**Item 4. Description of Securities.**

Not applicable.

**Item 5. Interests of Named Experts and Counsel.**

No expert or counsel named in this Registration Statement as having prepared or certified any part of this Registration Statement or having given an opinion upon the validity of the securities being registered or upon other legal matters in connection with the registration or offering of the common stock was employed on a contingency basis or had, or is to receive, in connection with the offering, a substantial interest, directly or indirectly, in the registrant or any of its parents or subsidiaries.

**Item 6. Indemnification of Directors and Officers.**



Section 145 ( Section 145 ) of the Delaware General Corporation Law, as amended (the DGCL ), permits indemnification of directors, officers, agents and controlling persons of a corporation under certain conditions and subject to certain limitations. Section 145 empowers a corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding whether civil, criminal, administrative or investigative, by reason of the fact that he or she is or was a director, officer or agent of the corporation or another enterprise if serving at the request of the corporation. Depending on the character of the proceeding, a corporation may indemnify against expenses (including attorneys fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding if the person indemnified acted in good faith and in a manner he or she reasonably believed to be in or not opposed to, the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. In the case of an action by or in the right of the corporation, no indemnification may be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine that despite the adjudication of liability such person is fairly and reasonably entitled to indemnity for such expenses which the court shall deem proper. Section 145 further provides that to the extent a present or former director or officer of a corporation has been successful in the defense of any action, suit

**Table of Contents**

or proceeding referred to above or in the defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith. The foregoing is only a summary of the described sections of the Delaware General Corporation Law and is qualified in its entirety by reference to such sections.

The Registrant's Certificate of Incorporation eliminates the personal liability of directors to the fullest extent permitted by the Delaware General Corporation Law and, together with the Registrant's Bylaws, provides that the Registrant shall indemnify and hold harmless, to the fullest extent permitted by applicable law as it may be amended or supplemented, any person who was or is made or is threatened to be made a party or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that such person, or a person for whom such person is the legal representative, is or was a director or officer of the Registrant or, while a director or officer of the Registrant, is or was serving at the request of the Registrant as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust, enterprise or nonprofit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys' fees) reasonably incurred by such person. The Registrant has also obtained liability insurance for its officers and directors.

We have an insurance policy that insures our directors and officers, within the limits and subject to the limitations of the policy, against certain expenses in connection with the defense of actions, suits or proceedings, and certain liabilities that might be imposed as a result of such actions, suits or proceedings, to which they are parties by reason of being or having been directors or officers.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to the Company's directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, the Company has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

**Item 7. Exemption from Registration Claimed.**

Not applicable.

**Item 8. Exhibits.**

<b>Exhibit Number</b>	<b>Description</b>
5.1	Opinion of Sichenzia Ross Friedman Ference LLP
10.1	Amended and Restated 2009 Stock Incentive Plan (Incorporated by reference to Appendix A to the Company's definitive Proxy Statement pursuant to Section 14(a) filed with the Securities and Exchange Commission on April 16, 2013)

Edgar Filing: Sorrento Therapeutics, Inc. - Form S-8

- 23.1 Consent of Mayer Hoffman McCann P.C.
- 23.2 Consent of Sichenzia Ross Friedman Ference LLP (included in Exhibit 5.1)
- 24.1 Powers of Attorney (included on signature page)

II-2

---

**Table of Contents**

**Item 9. Undertakings.**

A. The undersigned Registrant hereby undertakes:

1. To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the Registration Statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the Registration Statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective Registration Statement.

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the Registration Statement or any material change to such information in the Registration Statement;

*Provided, however,* that paragraphs (A)(1)(i) and (A)(1)(ii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the Registrant pursuant to section 13 or section 15(d) of the Exchange Act that are incorporated by reference in the Registration Statement.

2. That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered herein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

3. To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

B. The undersigned Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the Registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Exchange Act) that is incorporated by reference in the Registration Statement shall be deemed to be a new registration statement relating to the securities offered herein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

C. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate

jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

II-3

Table of Contents

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-8 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in San Diego, California, on the 25<sup>th</sup> day of April 2014.

*SORRENTO THERAPEUTICS INC.*

By: /s/ Henry Ji  
Henry Ji  
Chief Executive Officer and President

By: /s/ Richard G. Vincent  
Richard G. Vincent  
Chief Financial Officer

**Table of Contents****POWER OF ATTORNEY**

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Henry Ji and Richard G. Vincent, his true and lawful attorney-in-fact and agent with full power of substitution and re-substitution, for him/her and in his name, place and stead, in any and all capacities to sign any or all amendments (including, without limitation, post-effective amendments) to this Registration Statement, any related Registration Statement filed pursuant to Rule 462(b) under the Securities Act of 1933 and any or all pre- or post-effective amendments thereto, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming that said attorney-in-fact and agent, or any substitute or substitutes for him, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, the following persons in the capacities and on the dates indicated have signed this Registration Statement below.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Henry Ji	Director, Chief Executive Officer and President	April <u>25</u> , 2014
Henry Ji	(Principal Executive Officer)	
/s/ Richard G. Vincent	Chief Financial Officer	April <u>25</u> , 2014
Richard G. Vincent	(Principal Financial and Accounting Officer)	
/s/ William S. Marth	Director and Chairman	April <u>25</u> , 2014
William S. Marth		
/s/ Vuong Trieu	Director and Chief Scientific Officer	April <u>25</u> , 2014
Vuong Trieu		
/s/ Jaisim Shah	Director	April <u>25</u> , 2014
Jaisim Shah		
/s/ Cam Gallagher	Director	April <u>25</u> , 2014
Cam Gallagher		
/s/ Kim D. Janda	Director	April <u>25</u> , 2014
Kim D. Janda		

/s/ Mark Durand

Director

April 25, 2014

Mark Durand



**Table of Contents**

EXHIBIT INDEX

<b>Exhibit Number</b>	<b>Description</b>
5.1	Opinion of Sichenzia Ross Friedman Ference LLP
10.1	Amended and Restated 2009 Stock Incentive Plan (Incorporated by reference to Appendix A to the Company's definitive Proxy Statement pursuant to Section 14(a) filed with the Securities and Exchange Commission on April 16, 2013)
23.1	Consent of Mayer Hoffman McCann P.C.
23.2	Consent of Sichenzia Ross Friedman Ference LLP (included in Exhibit 5.1)
24.1	Powers of Attorney (included on signature page)