Sorrento Therapeutics, Inc.
Form S-3
June 24, 2013
Table of Contents

As filed with the Securities and Exchange Commission on June 21, 2013

Registration No. 333-

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM S-3

REGISTRATION STATEMENT UNDER THE SECURITIES ACT

OF 1933

Sorrento Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	33-0344842
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

6042 Cornerstone Ct. West, Suite B San Diego, California 92121 (858) 210-3700

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Dr. Henry Ji Chief Executive Officer

Sorrento Therapeutics, Inc. 6042 Cornerstone Ct. West, Suite B San Diego, California 92121 (858) 210-3700

(Name, address including zip code, and telephone number, including area code, of agent for service)

With copies to:

Jeffrey J. Fessler, Esq.

Marcelle S. Balcombe, Esq.

Sichenzia Ross Friedman Ference LLP

61 Broadway, 32nd Floor

New York, New York 10006 Telephone: (212) 930-9700

Facsimile: (212) 930-9725

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ¨

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

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

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

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ¨

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ¨

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 the 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 ¨ (Do not check if smaller reporting company)	Non-accelerated filer ¨	Smaller reporting company x

Title of Each Class of Securities to be Registered	**Amount to be Registered[1]**	**Proposed Maximum Offering Price Per Unit**	**Proposed Maximum Aggregate Offering Price[2]**	**Amount of Registration Fee[3]**
Common Stock, $.0001 par value per share				
Preferred Stock, $.0001 par value per share				
Warrants				
Units[4]				
Total			$100,000,000	$13,640

(1) There are being registered under this registration statement such indeterminate number of shares of common stock and preferred stock; such indeterminate number of warrants to purchase common stock, preferred stock, and/or units; and such indeterminate number of units as may be sold by the registrant from time to time, which together shall have an aggregate initial offering price not to exceed $100,000,000. Any securities registered hereunder may be sold separately or as units with other securities registered hereunder. The securities registered hereunder also include such indeterminate number of shares of common stock and preferred stock, and warrants as may be issued upon conversion of or exchange for preferred stock, upon exercise of warrants; or pursuant to the anti-dilution provisions of any such securities. In addition, pursuant to Rule 416 under the Securities Act of 1933, as amended (the Securities Act), the shares being registered hereunder include such indeterminate number of shares of common stock and preferred stock as may be issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends, or similar transactions..

(2) Not required to be included in accordance with General Instruction II.D. of Form S-3 under the Securities Act.

(3) Calculated pursuant to Rule 457(o) under the Securities Act based on the proposed maximum aggregate offering price of all securities listed.

(4) Each unit will represent an interest in two or more other securities, which may or may not be separable from one another.

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

Table of Contents

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PROSPECTUS **SUBJECT TO COMPLETION,** **DATED JUNE 21, 2013**

SORRENTO THERAPEUTICS, INC.

$100,000,000

Common Stock

Preferred Stock

Warrants

Units

We may offer and sell, from time to time in one or more offerings, any combination of common stock, preferred stock, warrants or units having an aggregate initial offering price not exceeding $100,000,000. The preferred stock, warrants, and units may be convertible or exercisable or exchangeable for common stock or preferred stock or other securities of ours. When we decide to sell a particular class or series of securities, we will provide specific terms of the offered securities in a prospectus supplement.

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

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

Our common stock is presently traded on the OTC QB under the symbol SRNE. On June 20, 2013, the last reported sale price of our common stock was $0.35.

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

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

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

The date of this Prospectus is , 2013.

Table of Contents

TABLE OF CONTENTS

Table of Contents

ABOUT THIS PROSPECTUS

This prospectus is part of a shelf registration statement that we filed with the Securities and Exchange Commission (the SEC) using a shelf registration process. Under this shelf registration process, we may sell any combination of the securities described in this prospectus in one or more offerings from time to time having an aggregate initial offering price of $100,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we offer securities, we will provide you with a prospectus supplement that describes the specific amounts, prices and terms of the securities we offer. The prospectus supplement also may add, update or change information contained in this prospectus. You should read carefully both this prospectus and any prospectus supplement together with additional information described below under the caption Where You Can Find More Information.

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

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

OUR BUSINESS

Sorrento Therapeutics, Inc. is referred to throughout this prospectus as we, our or us. The discussion of our business in this section reflects, on a pro forma basis, our anticipated merger with IgDraSol, Inc. pursuant to the option agreement described below. In addition, the IgDraSol option agreement, initial services agreement, asset purchase agreement and development services agreement are collectively referred to in this prospectus as the IgDraSol Transactions.

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 United States, Europe and additional international markets. Our primary therapeutic focus is oncology but we are also developing therapeutic products for other indications, including inflammation, metabolic disorders, and infectious diseases.

Our proprietary G-MAB® fully-human antibody library platform was designed to facilitate the rapid identification and isolation of highly specific antibody therapeutic product candidates that bind to disease targets appropriate for antibody therapy.

On March 7, 2013, we entered into an exclusive option agreement with IgDraSol, Inc., or IgDraSol, a private company focused on developing oncologic agents for the treatment of metastatic breast cancer, or MBC, non-small cell lung cancer, or NSCLC, and other cancers. IgDraSol granted us an irrevocable option to acquire IgDraSol by means of an agreement and plan of merger, and was paid a non-refundable lump sum payment of $200,000 in April 2013. IgDraSol s lead compound is Cynviloq , a micellar diblock copolymeric paclitaxel formulation drug product. Cynviloq is currently approved and marketed in several countries, including South Korea for MBC and NSCLC under the trade name Genexol-PM®.

Table of Contents

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 the fight against cancer, inflammatory and autoimmune diseases and other unmet medical needs.

G-MAB® Fully Human Antibody Library Platform

We believe our proprietary G-MAB® library is one of the industry s most diverse fully human antibody libraries. The theoretical diversity of our library has been calculated to be more than one quadrillion unique antibodies, making it, to our knowledge, the largest fully human antibody library available to pharmaceutical and biotechnology companies for drug discovery and development partnerships. Our objective is to leverage our library to develop both First-in-Class, or FIC, and/or Best-in-Class, or BIC, antibody drug candidates that we expect will possess greater efficacy and fewer side effects as compared to existing drugs.

We have experienced a high success rate when screening our diverse library to identify monoclonal antibodies, or mAbs, that have the potential to be used as drugs. Recently, we have selected several lead drug development candidates to advance into clinical trials in 2015, including anti-PD-L1 and anti-CCR2 mAbs.

The following is a chart of fully human mAbs we ve derived from our G-MAB® library. It includes antibodies that bind to a wide range of targets, from small molecular weight antigens to large protein complexes antigens, such as G-Protein Coupled Receptors, or GPCRs, a difficult class of antigens to raise therapeutic antibodies against.

In addition to employing our G-MAB® library to identify novel therapeutic antibodies, we also plan to: (i) develop potent antibody-formulated drug conjugates, or AfDCs, in therapeutic areas like oncology, auto-immune diseases and infectious diseases, armed using our proprietary TOCOSOL® technology (a tocopheryl polyethelyene glycol succinate (TPGS)-based drug formulation), and / or antibody drug conjugates, or ADCs, and (ii) create recombinant intravenous globulins, or rIVIG, for the treatment of certain auto-immune diseases as well as immunodeficiencies.

Recent Developments IgDraSol Transactions and Cynviloq

On March 7, 2013, we entered into an exclusive option agreement with IgDraSol. IgDraSol granted us an irrevocable option to acquire IgDraSol by means of an agreement and plan of merger, and was paid a non-refundable lump sum payment of $200,000 in April 2013. The option must be exercised by the later of: (i) thirty (30) days after the receipt of the FDA End of Phase II meeting minutes for Cynviloq (the End of Phase II meeting is scheduled in July 2013), or (ii) September 30, 2013. If we exercise our option to acquire IgDraSol, we

Table of Contents

will immediately issue 76,199,198 shares of our common stock to the IgDraSol stockholders. If a specific regulatory milestone is achieved, we will issue an additional 32,656,799 shares of our common stock to the former IgDraSol stockholders. If we do not exercise our option to acquire IgDraSol, we will be required to invest $500,000 in IgDraSol *pari passu* with other new investors of IgDraSol.

IgDraSol s lead compound is Cynviloq , a micellar diblock copolymeric paclitaxel formulation drug product. Cynviloq is currently approved and marketed in several countries, including South Korea for MBC and NSCLC under the trade name Genexol-PM®. IgDraSol obtained exclusive distribution rights for Cynviloq in the United States and 27 countries of the European Union, or EU, from Samyang Biopharmaceuticals Corporation, a South Korean corporation.

We entered into an initial services agreement dated March 7, 2013 with IgDraSol, wherein IgDraSol has provided certain product development and technology services related to antibody-based nanotherapeutics. In March 2013, IgDraSol was paid a non-refundable payment of $1,000,000 and the related services were completed prior to May 31, 2013. There are no further obligations under the initial services agreement.

In addition, we entered into an asset purchase agreement with IgDraSol whereby we agreed to purchase all documentation, equipment, information and other know-how related to micellar nanoparticle technology encompassing Tocosol® and related technologies for a purchase price of $1,210,000, which was paid in April 2013. Also in April 2013, we entered into a development services agreement with IgDraSol related to the development of Tocosol® and related technologies. We will pay IgDraSol up to $3,000,000 for services provided.

Our Strategy

Assuming the consummation of our planned acquisition of IgDraSol in the third quarter of 2013, our mission is to improve the lives of cancer patients and assist their caretakers by delivering innovative, targeted therapies that improve outcomes while reducing the undesirable side effects of many current therapies. We intend to pursue this initially through the potential approval, launch and marketing of Cynviloq . We believe we have assembled a strong scientific team with in-depth domain knowledge in the nanomedicine and therapeutic antibody fields. We are fostering an integrated, multidisciplinary model for drug discovery, clinical development, manufacturing and commercialization. Our strategy is to discover, acquire, develop, and commercialize proprietary drugs for significant unmet medical needs, with a focus on cancer therapeutics. The key elements to our long-term oncology business strategy are illustrated and described below:

Table of Contents

Cynviloq is our next-generation oncolytic nanomedicine for effective tumor killing. Oncolytic agents are the predominant therapeutics for treating cancer patients, and paclitaxel is one of the most effective and widely used chemotherapeutic agents for multiple solid tumor indications. The first generation paclitaxel formulation, Taxol®, utilizes Cremophor, derived from castor oil, to solubilize paclitaxel. The second generation paclitaxel formulation, Abraxane®, utilizes human serum albumin, or HSA, to solubilize the paclitaxel in an injectable solution. We are developing a third generation injectable nanoparticle paclitaxel, Cynviloq™, that is both Cremophor-free and HSA-free. We believe our formulation offers a higher maximum tolerated dose, or MTD, for potential better efficacy, ease of administration, and may better enable personalized dosing regimens. We believe Cynviloq may provide cancer patients and oncology practitioners with a much needed alternative to the current paclitaxel-based chemotherapies and may offer the potential for improved patient outcomes. We intend to seek a partner to simultaneously develop a companion pharmacokinetic monitoring device to allow for personalized cancer therapy in combination with Cynviloq .

G-MAB® provides us with specific therapeutic antibodies for effective cancer cell targeting and killing. Our proprietary G-MAB® human antibody library has provided us with potent fully human therapeutic mAbs against many valuable cancer targets. The individual mAbs discovered from our G-MAB® library potentially gives us a multitude of therapeutic options to target and attack cancer cells, including, but not limited to, antibody-dependent cellular cytotoxicity, or ADCC for direct cancer cell killing, immunomodulation of T cell activity in the tumor, anti-angiogenesis for cutting off blood supplies to the tumor, and antagonist suppression of cellular processes required for cancer cell proliferation and metastasis. In addition, we intend to utilize our G-MAB® library-derived antibodies as the foundation for the development of companion diagnostics.

Antibody formulated drug conjugates (AfDC) and antibody drug conjugates (ADC) for targeted tumor killing. Combining our proprietary nanotechnology with our proprietary mAbs or biosimilar mAbs, we are in a position to generate proprietary ADCs and/or AfDCs with potentially better efficacy and safety profiles than currently available therapies. We have the exclusive worldwide rights to the TOCOSOL® paclitaxel-nanoparticle formulation, which we believe is well suited for conjugation with a targeting mAb to generate an AfDC candidate. There are few competitors in the oncology space that offer the combination of targeting proprietary mAb warheads with an oncolytic payload, such as TOCOSOL®-paclitaxel. By combining this proprietary nanomedicine formulation encapsulating an oncolytic agent with our mAbs, we are positioning ourselves to become a leader in providing innovative, BIC targeted cancer therapeutics.

Combination therapy of oncolytic agents and therapeutic mAbs for cocktail-based tumor cell killing. There are a plethora of anti-cancer monotherapies available from many drug makers, including chemotherapeutics and therapeutic mAbs. There is a major trend to combine different monotherapeutics to attack cancer using different modes of action (MOA). Such combinations are often referred to as a cocktail treatment approach . We are positioned to develop both oncolytic agents for strong non-specific killing of tumor cells and therapeutic mAbs for specific targeted tumor killing. The mAbs provide an alternative MOA different from the oncolytic agents, such as anti-angiogenesis, in-tumor T cell activation, ADCC, etc. We believe we are well-positioned to provide such solutions by providing both modalities derived from our in-house, proprietary oncolytic and mAb therapeutics as proprietary combination therapies. Many of our competitors may have to collaborate to combine their existing drugs with other company s drugs in order to develop combination therapies. Cynviloq is well suited to be combined with our proprietary anti-angiogenesis mAbs and immunomodulatory mAbs to offer cancer patients with desirable anti-cancer cocktail treatments.

Table of Contents

Assuming the consummation of our planned acquisition of IgDraSol in the third quarter of 2013, we are advancing toward our goal of bringing new therapeutic options to patients and planning to continue to leverage the broad potential of our G-MAB® fully human antibody library. In the near term, we expect to:

- advance IgDraSol s late-stage, oncolytic drug candidate Cynviloq towards registration trials for multiple solid tumor cancer indications,

- progress selected drug development candidates from our proprietary G-MAB® fully human antibody library into clinical trials in 2015, including fully-human anti-PD-L1, anti-PD-1, and anti-CCR2 mAbs,

- develop AfDCs using our nanoparticle formulation (Tocosol® and/or related technologies) or ADCs,

- create rIVIG, using our proprietary G-MAB® fully human antibody library, and

- pursue combination therapies using Cynviloq and our proprietary fully-human mAbs.

Although we intend to retain ownership and control of some product candidates by advancing them further into preclinical or clinical 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.

Product Candidates

We, through IgDraSol, currently have one late-stage oncology drug candidate, Cynviloq , in clinical development for multiple solid tumor indications. We are currently planning for registration trials pending the outcome of our planned End of Phase II meeting with the FDA in July 2013. Additionally, we have multiple mAb product candidates in preclinical development, such as our fully human anti-PD-L1 mAbs, anti-PD-1 mAbs, and anti-CCR2 mAbs, and a discovery effort advancing additional therapeutic mAb drug candidates. We believe these mAb product candidates, individually, as AfDC, as ADC, or as combination therapy, have the potential to address major unmet medical needs.

* Subject to EOP2 meeting with FDA scheduled in July 2013 and subject to FDA approval of Abraxane® for pancreatic cancer.

Table of Contents

Cynviloq

Cynviloq was secured by IgDraSol through an exclusive distribution agreement, as amended, for the United States and 27 countries of the EU, with Samyang Biopharmaceutical Corporation, a South Korean corporation, or Samyang. Cynviloq is currently approved and marketed by Samyang in South Korea for MBC, NSCLC and ovarian cancer, under the trade name Genexol-PM®. Cynviloq is also marketed in the Philippines, Vietnam, and India. Cynviloq consists of paclitaxel encapsulated within a polylactide and polyethylene glycol diblock copolymer micelle. A micelle is an aggregate of surfactant molecules, having hydrophobic and hydrophilic parts, in which the hydrophilic heads form the outside shell of the sphere with the hydrophobic tails at the center of the core. This hydrophobic core is able to effectively encapsulate hydrophobic drugs, such as paclitaxel.

Cynviloq has been clinically tested in over 900 patients in the United States, Russia, and South Korea in Phase I, Phase II, and Phase III clinical trials, and post-marketing surveillance studies in MBC, NSCLC, ovarian, pancreatic and bladder cancer. Cynviloq has demonstrated comparable clinical efficacy and tolerability compared to historical albumin-bound paclitaxel (*nab*-paclitaxel; Abraxane®/Celgene Corporation) clinical data. Samyang is currently conducting an ongoing open-label Phase III MBC study in South Korea, randomizing patients with recurrent or advanced MBC to Cynviloq using a dosing regimen of 260mg/m^2 every 3 weeks, or q3w, as compared to Cremophor-paclitaxel (Taxol®) given at a standard 175 mg/m^2 q3w dose. Interim results have shown statistically significant improvement in the objective response rate (ORR) with Cynviloq when compared to Taxol®. We believe the superior ORR for Cynviloq versus Taxol® is comparable to data generated from the pivotal registration studies submitted for Abraxane® that was the basis for Abraxane® s approval in the United States and in China for the MBC indication.

Cynviloq Differentiation versus Taxol® and Abraxane®

Paclitaxel is a water insoluble drug that requires a solvent formulation. The first generation paclitaxel formulation, Taxol®; developed by Bristol-Myers-Squibb, or BMS, utilizes a Cremophor solvent, a castor oil-based emulsion. Known dose-limiting toxicities of Cremophor restrict the overall dose of Taxol® that can be safely administered to patients. Cremophor also causes the entrapment of paclitaxel in the bloodstream, thereby allowing less freely-available paclitaxel to reach the tumor sites. Furthermore, patients receiving Taxol® require pre-medication with steroids and antihistamines to allay the toxic side effects associated with Cremophor.

Abraxane® is a second generation paclitaxel formulation that utilizes a biological polymer, namely donor-derived HSA to encapsulate paclitaxel. Abraxane® does not contain the Cremophor solvent and thus, enables administration of ~50% more paclitaxel than with Taxol®.

Cynviloq is a next generation paclitaxel formulation comprised of paclitaxel encapsulated in a non-biological polymeric micelle composed of a polylactide and polyethylene glycol diblock copolymers resulting in an injectable suspension of paclitaxel. This polymeric micelle formulation of paclitaxel achieves an increased MTD of paclitaxel of potentially greater than 300 mg/m^2. This is significantly greater than the MTDs of Taxol® (175 mg/m^2) and Abraxane® (260 mg/m^2). We believe Cynviloq is easier to prepare and administer for clinical practices, and has no special storage requirements in contrast to Abraxane®. Cynviloq also avoids certain biohazardous safety issues, such as potential prion or viral contamination and subsequent transmission that could be associated with the use of donor-derived HSA required for the Abraxane® formulation.

Clinical Strategy: Basis for bioequivalence

Cynviloq utilizes a proprietary, non-biological, chemical polymeric-micellar nanoparticle technology to solubilize paclitaxel. This is a different formulation from Abraxane®, where paclitaxel is solubilized in HSA nanoparticles. Particle dissociation studies comparing Abraxane® and Cynviloq have shown that both formulations rapidly disintegrate under physiologically-relevant conditions, suggesting that both formulations

Table of Contents

release their paclitaxel payloads shortly after intravenous administration. Our analysis of pharmacokinetic (PK) data (see table below) from three Phase I trials with Cynviloq , suggests Cynviloq is bioequivalent to Abraxane® under the FDAs bioequivalence (BE) guidance. Both paclitaxel formulations showed substantially identical PK parameters at the approved Abraxane® dose range of 100-260 mg/m^2 paclitaxel (administered intravenously over 30 minutes). If we receive the FDA s concurrence, we plan to utilize a 505(b)(2) new drug application, or NDA, submission process to show the BE of Cynviloq as compared to Abraxane®.

We believe the following analysis demonstrates BE between Cynviloq and Abraxane®:

1. Large volume of distribution (suggestive of rapid tissue penetration),

2. Dose proportional PK profile of doses ranging up to 350 mg/m^2,

3. Similar PK parameters at 135 mg/m^2 dose level for Abraxane® (Ibrahim, 2002) and Cynviloq (Study GXLPM-01) both infused over 180 minutes.

Cynviloq vs Abraxane® PKs at 135 mg/m^2 on a 3 hr Infusion Regimen

	Cmax (ng/mL)	AUC inf (ng/mL*h)	T1/2 (hr)	CL (L/hr/m2)
Cynviloq	1357	5473	12.7	25.5
Abraxane®	1392	5654	12.9	27.4

4. Overlapping 95% confidence interval (CI) for AUCinf/D, T1/2, CL, and Vz. There were 78 patients in the Abraxane® dataset, and 32 patients in the Cynviloq dataset.

5. When the Cynviloq infusion was performed over 60 minutes instead of 180 minutes, the ranges for AUCinf/D, T1/2 and Vz overlapped with 95% CI of both Abraxane® and Cynviloq , suggesting that a shorter infusion time does not negatively impact Cynviloq PK properties as predicted by simulation modeling.

Cynviloq vs Abraxane®- Dose Adjusted PK Parameters

	Infusion Time	AUCinf/D (ng/hr/mL/D)	T1/2 (hr)	CL (L/hr/m2)	Vz (L/m2)
		Mean (95% confidence interval)			
Abraxane®	30 min	53	17	22	536
(N=14)		(20-86)	(10-24)	(11-33)	(145-928)
Cynviloq	180 min	48	14	25	631
(N = 9)		(11-84)	(8-19)	(9-40)	(252-1010)
Cynviloq *	60 min				
(N = 7)		(26-61)	(6.0-18.6)		(249-1512)

* Lim, et al, 2009, the AUC, T1/2, CL or Vz were not reported.

6. PK studies were initially conducted using a 180 minute infusion administration of Cynviloq , the same administration schedule as Taxol®, which was the only approved comparator product available when Genexol-PM® was approved (Studies GPMP1 and SAY00101US). The approved dosage administration for Abraxane® is a 30 minute infusion time. A simulation analysis of Cynviloq administered in a 30 minute infusion time is shown in the table below. The simulated data were compared to historical data for Abraxane® to assess similarity (point estimates) for AUC0-t and AUCinf between Cynviloq and Abraxane® (Study Camargo1).

Simulated mean PK Parameter Values after Administration of 260 mg/m^2 Cynviloq in 30 minutes and Summary of Abraxane® s PK Parameter Values

Cmax	**AUC_{inf}**	**Point Estimate for Cmax**	**Point Estimate for AUC_{inf}**
(ng/mL)	**(ng hr/mL)**	**(Difference in %)**	**(Difference in %)**
19486	22198	0.36	9.22
19556	20324		

Table of Contents

Cynviloq Regulatory Strategy

Manufacturers can obtain FDA approval of NDAs for new formulations of approved drugs with the same active pharmaceutical ingredient (API) using an FDA 505(b)(2) BE application process. The 505(b)(2) BE application process relies, in part, on the FDA s findings for a prior approved drug. This avoids costly and time consuming clinical trials. We believe this process might apply to Cynviloq as paclitaxel is the approved API for both of the Abraxane® and Taxol® formulations. According to the Section 505(b)(2) guidelines, an NDA approval can be obtained for a new drug without conducting the full complement of safety and efficacy trials and without a right of reference from the original applicant. In cases where different formulations of the same API are found to be bioequivalent, a BE trial comparing the PK parameters (Cmax and AUC) of both drugs may be sufficient to obtain FDA approval. The Draft Guidance (September 2012) for *nab*-paclitaxel (Abraxane®) states that measurements of both total and unbound paclitaxel should be made to establish BE. Given that both Cynviloq and Abraxane® release free paclitaxel upon intravenous administration, we believe that this is an appropriate method of comparison for marketing approval.

In July 2013, IgDraSol will meet with the FDA to discuss, among other items, using a FDA 505(b)(2) BE application process for Cynviloq on the basis of BE versus Abraxane® as the reference drug. If the FDA concurs with our approach, we plan to initiate a BE trial as well as a Phase III bladder trial. We are also considering other cancer trials. Subject to the FDA s concurrence, a single BE trial is planned to treat MBC patients with Abraxane® in the first cycle and then with Cynviloq (or vice versa) in the next cycle in a cross-over trial designed to use the patients as their own controls to measure the PK parameters between the two drug formulations, and thus establish BE.

Subject to the FDA s concurrence and our conducting the BE trial, an NDA filing under 505(b)(2) is expected to be completed in the first half of 2015, with potential approval in the first half of 2016. If Cynviloq and Abraxane® are found to be bioequivalent and FDA approval is granted, Cynviloq will receive the same label indications as Abraxane®, including MBC and NSCLC, in addition to potentially other future indications for which Abraxane® may be approved, such as advanced pancreatic cancer (upon expiration of Abraxane® s marketing exclusivity). Subject to the FDA s concurrence, a Phase III registration trial for Cynviloq as second-line treatment for bladder cancer as compared to the best supportive care (BSC) is planned as a sNDA application, with approval targeted in 2017.

Market Opportunity

Cynviloq

According to the 2012 IMS NSP, the taxane market in the United States is estimated to be one billion dollars in 2012, and is comprised of Abraxane®, generic paclitaxel (Taxol®; BMS) and generic docetaxel (Taxotere®; Sanofi-Aventis). Abraxane® had approximately 40% market share in the United States in 2012. In the rest of the world, the taxane market is estimated to be worth at least $2.4 billion, driven primarily by sales of generic paclitaxel and docetaxel, with Abraxane® sales of approximately $90 million. Taxanes are one of the most widely used chemotherapies in the world and play a significant role in the treatment of various solid tumors, including breast, lung, prostrate and ovarian cancers. Taxanes are often the standard of care as monotherapy or in combination with other chemotherapy or biological agents when used in the metastatic setting, although it also being used in the adjuvant/neo-adjuvant settings as well. Historically, taxanes were rarely used in pancreatic cancer. However, the survival benefit seen in the MPACT study combining Abraxane® with gemcitabine is predicted to become the standard of care, replacing gemcitabine monotherapy in this highly aggressive tumor with limited treatment options.

MBC[1]

It is estimated that over 230,000 new cases of invasive breast cancer will be diagnosed among women in the United States during 2013, along with over 2,000 new cases in men. Excluding skin cancers, breast cancer is the most frequently diagnosed cancer in women. An estimated 40,000 breast cancer deaths are expected in 2013. Breast cancer ranks second as a cause of cancer death in women, after lung cancer. Taking into account tumor

Table of Contents

size, extent of spread, and other characteristics, as well as patient preference, treatment usually involves breast-conserving surgery (surgical removal of the tumor and surrounding tissue) or mastectomy (surgical removal of the breast). Treatment may also involve radiation therapy, chemotherapy (before or after surgery), hormone therapy (e.g., selective estrogen response modifiers, aromatase inhibitors, ovarian ablation), and/or targeted therapy. Postmenopausal women, with early stage breast cancer, that test positive for hormone receptors may benefit from treatment with an aromatase inhibitor (e.g., letrozole, anastrozole, or exemestane) or tamoxifen. For women whose cancer tests positive for HER2/neu, approved targeted therapies include trastuzumab (Herceptin®; Genentech), and, for advanced disease, lapatinib (Tykerb®; GSK), and pertuzumab (Perjeta®; Genentech). In February 2013, the United States FDA approved Kadcyla® (ado-trastuzumab emtansine) from Roche-Genentech, a new therapy for patients with HER2-positive, late-stage MBC. Kadcyla® is an ADC product with trastuzumab as the targeting warhead and the anti-tubulin toxin DM1 as the payload. Kadcyla® is intended for patients who were previously treated with trastuzumab, another anti-HER2 therapy, and taxanes. The safety and effectiveness of Kadcyla were evaluated in a clinical study of 991 patients randomly assigned to receive Kadcyla® or lapatinib plus capecitabine (Xeloda®; Roche-Genentech). Results showed that patients treated with Kadcyla® had a median progression-free survival of 9.6 months compared to 6.4 months in patients treated with lapatinib plus capecitabine. The median overall survival was 30.9 months in the Kadcyla group and 25.1 months in the lapatinib plus capecitabine group.

In 2012, approximately 330,000 patients diagnosed with breast cancer were treated with drugs in the United States and the top five (5) EU countries (Germany, France, Italy, Spain, United Kingdom). Half of these patients live in the United States, and approximately 100,000 of these patients were treated in the advanced or metastatic settings in first, second or third-line therapy. The National Comprehensive Cancer Network (NCCN) treatment guidelines list of preferred single agent drugs include paclitaxel & paclitaxel albumin-bound (Abraxane®), among other drugs, for the treatment of patients with Stage IV advanced breast cancer. Preferred combination chemotherapy agents include among others paclitaxel plus Herceptin, paclitaxel plus gemcitabine, Herceptin® plus paclitaxel & carboplatin and Perjeta® plus Herceptin® & paclitaxel. It is estimated that about 25-30% of all patients treated in MBC received a paclitaxel-based regimen. In addition, paclitaxel in combination with other targeted therapies are recommended in neo-/adjuvant breast cancer treatment as well.

Lung cancer[1]

In the United States, lung cancers are expected to represent approximately 14% of new cancer diagnoses, or an estimated 223,000 new cases in 2013. Lung cancer accounts for more deaths than any other cancer in both men and women. An estimated 160,000 deaths, accounting for about 27% of all cancer deaths, are expected in 2013.

Lung cancer is classified as small cell (15%) or non-small cell (84%) for the purposes of treatment. Based on type and stage of cancer, treatments include surgery, radiation therapy, chemotherapy, and targeted therapies such as bevacizumab (Avastin®/Roche-Genentech), erlotinib (Tarceva®), and crizotinib (Xalkori®). Advanced-stage non-small cell lung cancer patients are usually treated with chemotherapy, targeted drugs, or some combination of the two. Approximately 134,000 patients with locally advanced or metastatic Stage IIIB/IV NSCLC were diagnosed in the United States last year. Approximately 70% of these patients were treatment eligible. The NCCN s list of systemic therapy for advanced or metastatic NSCLC includes paclitaxel and Abraxane®, among other recommendations. Paclitaxel is often used in combination with a platinum agent (carboplatin or cisplatin). It is estimated that about a third of patients treated in the first-line and second-line settings received a paclitaxel-based therapy.

Ovarian cancer[1]

Approximately 48,500 women were diagnosed with ovarian cancer last year in the United States and the top 5 EU countries. More than 70% of women diagnosed with ovarian cancer will present with advanced disease, and up to 80% of them will experience disease recurrence and eventually die from this disease. Treatment includes surgery and usually chemotherapy. Among patients with early ovarian cancer, complete surgical staging has been

Table of Contents

associated with better outcomes. For women with advanced disease, surgically removing all abdominal metastases larger than one centimeter (debulking) enhances the effect of chemotherapy and helps improve survival. For women with stage III ovarian cancer that has been optimally debulked, studies have shown that chemotherapy administered both intravenously and directly into the abdomen (intraperitoneally) improves overall survivial, or OS.

In 2012 in the United States and the top 5 EU countries, approximately 36,000 patients were treated with front-line chemotherapy, and approximately17,000 patients were treated with second-line chemotherapy. Paclitaxel in combination with a platinum compound plays a significant role in the treatment of ovarian cancer with the NCCN recommending taxanes plus platinum to be used in both the adjuvant and metastatic settings. It is estimated that 75% of the patients treated in the United States, in 2012, were treated with paclitaxel-based chemotherapy as front-line therapy.

Pancreatic cancer[1]

Even though pancreatic cancer is a relatively uncommon form of cancer making up only 2.1% cancer cases it is one of the leading causes of cancer related deaths, killing around 38,000 people in the United States each year. It is one of the most difficult forms of cancer to treat, especially as it is usually detected at very late stages. It is estimated that around 65,000 patients were diagnosed with pancreatic cancer (mainly adenocarcinoma) in the United States and the top 5 EU countries. In 2013, an estimated 45,000 new cases of pancreatic cancer will be diagnosed in the United States. Pancreatic cancer accounts for about 7% of all cancer deaths and ranks fourth as a cause of cancer death among both men and women in the United States. In 2013, an estimated 38,000 people are expected to die from pancreatic cancer in the United States. The treatment choice is largely determined by whether the tumor can be surgically removed. Surgery remains the only treatment that offers a chance of cure for pancreatic cancer patients. Approximately 20% of all pancreatic cancer patients are candidates for surgery.

Approximately 56,000 of patients with pancreatic cancer were treated in the first-line setting in the United States and top 5 EU countries, with the United States accounting for 27,000 of these patients. Another 26,000 patients were treated in the second-line setting in the United States and top 5 EU countries, with the United States accounting for 15,000 of these patients. Gemcitabine-and fluoro-pyrimidine based therapy are the standard of care both in the adjuvant and metastatic settings. The NCCN recommendation for patients with unresectable, locally advanced or metastatic adenocarcinoma of the pancreas includes Abraxane® plus gemcitabine, gemcitabine (Gemzar®/Lilly) monotherapy, or in combination with erlotinib (Tarceva®/Astellas), folfirinox, capecitabine (Xeloda®/ Roche-Genentech) or fluorouracil (Efudex/Valeant) as a continuous infusion. Last year, before the results of the MPACT study with Abraxane® plus gemcitabine data were reported, approximately 65% of patients were treated with gemcitabine-based regimens in first-line settings, and 30% of patients were treated with gemcitabine-based regimens in second-line settings. With the tolerability issues encountered with FOLFIRINOX, it is expected that Abraxane® plus gemcitabine will rapidly become the new standard of care in the United States.

Bladder cancer[1]

According to the American Cancer Society, an estimated 72,000 new cases of bladder cancer will occur in 2013. Bladder cancer incidence is about four times higher in men than in women, and almost two times higher in white men than in African American men. An estimated 15,000 deaths will occur in 2013. Early stage cancers may be treated by administering immunotherapy or chemotherapy directly into the bladder after surgery. More advanced cancers may require removal of the entire bladder. For the 35% of cases that are detected at an early stage, the 5-year survival rate is 70%, compared to just 33% for cases detected after the tumor has metastasized.

Transitional cell carcinoma is the most predominant histological type. Bladder cancer is highly chemo-sensitive. In the metastatic setting, chemotherapy based on cisplatin is considered to be the standard treatment of choice for patients with good performance status (0-1) and good renal function-glomerular filtration rate (GFR) >

Table of Contents

60 mL/min. The standard treatment is based on cisplatin chemotherapy regimens type MVAC, HD-MVAC, gemcitabine plus cisplatin (GC) or dose dense GC. In patients deemed unsuitable, the available options are carboplatin based regimes: gemcitabine plus carboplatin or methotrexate plus carboplatin plus vinblastine (MCAVI).

Patients who recur after first-line therapy have a very poor prognosis. To date, no standard therapy has been established for patients who recur or are refractory to first-line therapy. Second-line vinflunine (VFL), by way of superiority over best supportive care, has shown promise in a Phase III trial. Patients, 370, were randomly assigned to receive vinflunine plus best supportive care, or BSC, or BSC alone. In the eligible population, the median OS was significantly longer for VFL plus BSC than BSC (6.9 v 4.3 months, respectively). The aggressiveness of the disease is underscored by the fact that patients who did not receive the chemotherapy drug, vinflunine, only lived a median of 4 months. Vinflunine is approved in second-line bladder cancer patients who progress or are refractory to first line platinum-based chemotherapy in the EU. Unfortunately, in the United States, there are no approved second-line regimens in patients with transitional cell carcinoma of the bladder.

[1] Sources: US information, SEER Annual Cancer Review 1975-2006; US Census; Mattson Jack; UHC and Medicare Claims; IntrinsiQ; Synovate Tandem. WHO mortality database 2008 http://www.who.int/whosis/whosis/. World Population Prospects. The 2008 Revision. UN Population Division 2009. http://esa.un.org/unpp/. Roche-Genentech Clinical, Patient Chart Audits; Internal estimates; NCCN; Journal of Clinical Oncology (JCO); Curado. M. P., et al (2007), Cancer Incidence in Five Continents, Vol. IX, IARC Scientific Publications No. 160, Lyon, IARC; IMS 2012; NCCN Treatment Guidelines 2013; Cancer Facts and Figures 2013; American Cancer Society.

Therapeutic Drug Monitoring (TDM) for personalized dosing using Cynviloq™

We intend to further expand the Cynviloq™ treatment with innovative personalized dosing regimens of Cynviloq™. We intend to seek a collaboration partner to develop a proprietary device that will allow Therapeutic Drug Monitoring (TDM). This would allow clinicians and patients to measure the blood level of paclitaxel on successive days to determine whether the optimal therapeutic dose of paclitaxel has been achieved for each individual patient. With such a TDM device, patients would benefit from personalized dosing, which would assure the best treatment outcome possible maximum efficacy with lower toxicity. Cynviloq s dose linearity and high MTD (up to 435 mg/m in Phase I studies) makes it the ideal taxane formulation for individualized dosing. TDM has the potential to substantially enhance the commercial viability and competitiveness of Cynviloq versus other chemotherapy agents.

Table of Contents

G-MAB® Fully Human Product Candidates

We have multiple wholly-owned product candidates in preclinical development and a discovery effort advancing additional therapeutic mAb drug candidates, all derived from our G-MAB® library. The following table summarizes the status of our more advanced mAbs product pipeline:

We believe these product candidates, individually, as AfDCs, as ADCs, or as combination therapy, have the potential to address major unmet medical needs.

Fully human anti-PD-1 and anti-PD-L1 antibodies

Overview

In recent early clinical studies performed by competitor pharmaceutical companies, immunomodulatory anti-cancer antibody therapeutics, including mAbs against programmed cell death protein 1 (PD-1), and programmed cell death 1 ligand 1 (PD-L1), have demonstrated great promise for the treatment of solid tumors. PD-1 is a T-cell surface protein while PD-L1 is a tumor-associated surface protein. By blocking immunosuppressive signals originating on cancer cells directed against infiltrating T cells, the patients own anti-tumor immune response may be rejuvenated.

Preclinical Anti-PD-1 and Anti-PD-L1 Data and Development Plan

Each of our mAbs is novel, proprietary, and fully human. Our most advanced preclinical mAb related to our anti-PD-1 antibody is STI-A1110, and our most advanced preclinical mAbs related to anti-PD-L1 antibodies are STI-A1010 (lead candidate), STI-A1011, STI-A1012, and STI-A1014. In four separate cell studies, our mAbs were at least as potent and effective as the anti-PD-1 and anti-PD-L1 mAbs from competitor companies. We are currently developing production quality cell lines for our anti-PD-L1 antibody, STI-A1010, which will lay the foundation for Investigational New Drug, or IND, -enabling studies in the United States in 2014. We anticipate that a Phase I clinical trial for the lead candidate anti-PD-L1 antibody could be initiated in the first half of 2015.

Our anti-PD-1 mAb and other anti-PD-L1 mAbs are expected to reach the cell line development stage in the first half of 2015, and enter into IND-enabling studies in the second half of 2015.

Table of Contents

Anti-C-C chemokine receptor 2 (CCR2) antibodies

Overview

GPCRs, also known as seven-transmembrane domain receptors (7TM receptors), constitute a large protein family of receptors that sense extracellular stimuli and activate intracellular signal transduction pathways leading to cellular tissue and organ responses. The chemokine receptor family of GPCRs is divided into four subfamilies, the CXC chemokine receptors, CC chemokine receptors, CX3C chemokine receptors and XC chemokine receptors that correspond to the 4 distinct subfamilies of chemokines they recognize. Chemokines are important mediators of cell migration during inflammation and immune surveillance. Interaction of a GPCR with its specific chemokine ligand(s) triggers a variety of cellular responses, including a process known as chemotaxis that traffics the cell to a desired location within the body. Dysregulation of chemokine signaling can contribute to or cause many diseases, such as inflammatory diseases and cancer. Thus, there is significant interest in developing specific blocking therapeutics (antagonists) to members of this family of receptors.

Evidence of the Role of CCR2 in Inflammation

It has been shown in animal models that CCR2 is important for host defense, inflammation and immunity mediated through hematopoietic cells including monocytes and basophils. Inflammatory signals, including macrophage chemotactic proteins (MCPs), cause monocytes to leave the bone marrow and be recruited to the site of inflammation. While five MCPs are known to bind to CCR2, MCP-1 is the main ligand for CCR2 and initiates signaling after binding to the receptor. Animal studies have suggested a role for CCR2 in inflammatory bowel disease, or IBD, and CCR2 has been implicated in the accumulation of $CD4^+$ T lymphocytes and $CCR2^+$ lamina propria lymphocytes (LPLs) in the ileum of patients with small bowel Crohn s disease.

Preclinical Anti-CCR2 mAb Data and Development Plan

The fully human anti-CCR2 candidate mAbs STI-B0201 (lead candidate), STI-B0211, STI-B0221, and STI-B0234 were selected from our G-MAB® library or derived from STI-B0201. All mAbs are novel, proprietary, antagonistic and fully human. We are continuing preclinical development of all candidate antagonistic anti-chemokine receptor mAbs and expression cell line generation for the lead candidate mAb is expected to commence in the second half of 2013.

Anti-staphylococcal autoinducing peptide (AIP) antibodies

Overview

Staphylococcus aureus is a Gram-positive bacterium that is commonly found on the skin of humans. But this organism is frequently the cause of infections ranging from minor to serious, including meningitis, endocarditis, toxic shock syndrome and pneumonia. In addition, *S. aureus* is one of the most common causes for nosocomial infections, including post-surgical wound infections. The pathogenicity of *S. aureus* can be attributed to a number of virulence factors, including toxins. Standard treatment of *S. aureus* infections includes the use of antibiotics. However, *S. aureus* has evolved resistance mechanisms that render many antibiotics useless.

Many bacteria utilize intercellular communication via small, diffusible molecules called autoinducers to coordinate a number of microbial processes, including expression of virulence factors. One such process is known as quorum sensing . Autoinducer concentration increases as a function of cell density. In *S. aureus*, binding of autoinducing peptides (AIP) to their cognate receptors activates the transcription of certain genes, including RNAIII, a master regulator of toxins and other virulence factors. By neutralizing these AIPs, quorum sensing signaling and subsequent virulence factor production is inhibited, which reduces the potential toxicity of a *S. aureus* infection while it is treated with antibiotics.

With the rise of antibiotic-resistant bacteria, such as methicillin-resistant *Staphylococcus aureus* (MRSA), and given the escalation in antibiotic limitations, alternative approaches to combat infections are needed. Therefore, we are developing human mAbs aimed at the inhibition of quorum sensing signaling.

Table of Contents

Our Preclinical Anti-AIP mAb Data and Development Plan

We exclusively licensed the anti-quorum sensing technology from The Scripps Research Institute in La Jolla, California or TSRI. We have identified a number of fully human lead anti-AIP2 mAbs, which are currently being developed preclinically. In addition, the licensed murine anti-AIP1 mAb AP1-15B4 antibody from TSRI is currently being humanized at our facility. Our anti-MRSA program is currently funded by a STTR Fast Track grant from the National Institutes of Health (NIH)/National Institute for Allergy and Infectious Diseases (NIAID). This grant will cover most of the preclinical development costs of the antibodies. The lead mAbs, including STI-C0205, are currently being optimized and are expected to enter cell line development in H2 2015 with IND-enabling studies commencing in 2016. We anticipate that a Phase I clinical trial for the lead anti-MRSA antibodies could be initiated in the first half of 2017.

Antibody formulated drug conjugates (AfDC)

In April 2013, we purchased IgDraSol s nanoparticle technology IG-004 (formerly clinically developed as TOCOSOL® -paclitaxel), a TPGS-based drug formulation, which could serve as the foundation for our next-generation, targeted AfDC competitive against current ADCs.

Classical ADCs consist of an anti-cancer antibody covalently conjugated via a synthetic linker to an oncolytic agent. Due to the nature of ADC constructs, they typically require binding and internalization of the ADC by the tumor cells in order to cleave the linker and release the activated drug into the cell. The potential advantages of our AfDC technology over ADCs might include flexibility in combining multiple targeting mAb warheads and drug payloads, as well as the release of the active oncolytic agent at the tumor site rather than relying on internalization for agent activation. We also plan to explore using our AfDC candidates to treat non-oncology indications, including autoimmune and inflammatory diseases.

Fully human candidate mAbs derived from our G-MAB® library for use as potential targeting warheads for AfDC candidates including anti-c-Met, anti-EGFR, and anti-ErbB3 antibodies are currently being preclinically developed. The use of biosimilar mAbs, such as anti-Her2 or anti-CD20 antibodies, is also under development. We expect to have in vivo proof-of-concept for the AfDC technology in the first half of 2014.

Fully human anti-c-Met antibodies for AfDC generation

Overview

The c-Met protein, encoded by the proto-oncogene *c-Met*, is a membrane receptor tyrosine kinase. Physiologically, it is a receptor that is essential for embryonic development and wound healing. The paracrine factor hepatocyte growth factor (HGF) is the only known ligand of the c-Met receptor. Stimulation of c-Met by HGF activates several biological responses that lead to a programmed invasive growth necessary for wound healing in normal adults. However, mutations can lead to overexpression of c-Met resulting in malignancies and eventual metastasis. Such c-Met activating mutations have been identified in a number of human cancers including kidney, ovarian, breast, liver, stomach, lung, and brain cancers. Abnormal c-Met activation in cancer appears to correlate with poor prognosis, where aberrant c-Met activation triggers tumor growth, formation of new blood vessels, and spread to other organs.

Preclinical Anti-c-Met mAb Data and Development Plan

The anti-c-Met candidate mAbs STI-A0601, STI-A0602, and STI-A0603 were selected from our G-MAB® library while STI-A0604 and STI-A0610 were derived from STI-A0601 via antibody engineering. Each of our mAbs is novel, proprietary, and fully human. Our most advanced preclinical mAbs have shown in vitro and in vivo anti-tumor activity.

We are continuing preclinical development of all candidate anti-c-Met mAbs and expression cell line generation for the lead candidate mAb is expected to commence in the second half of 2013.

Table of Contents

Combination therapy Cynviloq + G-MAB® Antibody

Our oncology product pipeline includes Cynviloq™ as well as therapeutic mAbs for treating cancer. Recent clinical testing utilizing Abraxane®, an albumin-bound paclitaxel formulation, in combination with the anti-angiogenic mAb Avastin® (Roche-Genentech) demonstrated potentially synergistic anti-tumor efficacy in solid tumor indications. Based on these findings, we are currently planning on developing a combination of Cynviloq and an anti-angiogenesis mAb targeting the vascular endothelial growth factor receptor 2 (VEGFR2). This combination could potentially be a powerful anti-tumor cancer therapy strategy.

Fully human anti-Vascular Endothelial Growth Factor Receptor 2 (VEGFR2) mAb for combination therapy with Cynviloq™

Overview

The vascular endothelial growth factor receptor 2, or VEGFR2, also known as kinase insert domain receptor , or KDR, is a receptor tyrosine kinase for the soluble vascular endothelial growth factor, or VEGF that induces the growth of new blood vessels (neo-angiogenesis) upon stimulation. Solid tumors take advantage of this activity by secreting VEGF to stimulate local angiogenesis and subsequent infiltration of vasculature into the tumor, thus providing nutrients as well as means to metastasize. Importantly, the VEGF/VEGFR2 pathway has been validated as a potent intervention target, especially in metastatic colon cancer and NSCLC. Additionally, anti-VEGF/VEGFR2 therapies (single agent or combination) are also currently being evaluated for therapeutic efficacy in gastric, pancreatic, and ovarian cancers.

Preclinical Anti-VEGFR2 mAb Data and Development Plan

The fully human anti-VEGFR2 lead candidate mAb STI-A0168 has been selected from our G-MAB® library. It is a novel, proprietary, fully human monoclonal antibody and is currently in preclinical development. We are currently performing cell line development activities for the lead candidate antibody STI-A0168, which will lay the foundation for IND-enabling studies in the United States in 2014. We anticipate that a Phase I clinical trial could be initiated in 2015.

Recombinant Intravenous Immunoglobulin (rIVIG)

Antibodies derived from the extracted plasma of over 1,000 donors delivered to patients for the treatment of a broad range of conditions are referred to as intravenous immunoglobulin (IVIG). Global sales of IVIG exceeded $6 billion in 2012. Medical applications for IVIG include treatment for immune deficiencies, autoimmune diseases, specific pathogens, as well as other uses. Although its clinical utility is well accepted, broader use of IVIG is severely constrained by a number of critical factors including limitations of human donor supply, cost, batch-to-batch variability, contamination risk, and limited specificity.

We have assembled several key technologies and capabilities enabling the effective production of rIVIG. We anticipate that rIVIG would not only recapitulate most of the relevant attributes of plasma-derived IVIG, but may allow for refinements enabling novel and more effective treatments, including those for several conditions not currently addressable by IVIG or other means. Our rIVIG products would also have distinct advantages over traditional IVIG as our production would not be limited by donor supply, disease contamination risk could be removed, and batch-to-batch variability would potentially be much better controlled.

Our goal is to leverage our G-MAB® library platform technology and other key intellectual property with the specific clinical development focus of a dedicated team to commercialize rIVIG products. Our rIVIG not only has the potential to supplant plasma derived IVIG due to its many advantages, but may also address important diseases, which neither donor IVIG nor mAb strategies are able to adequately treat. Using the G-MAB® library platform with novel production methods, rIVIG can be purposefully designed with potentially superior binding profiles and effector functions.

Table of Contents

We anticipate obtaining manufacturing as well as in vitro and in vivo proof-of-concept in the first half of 2014. We intend to pursue partnering or strategic options for the further development of rIVIG.

mAb Competition

We compete in an industry characterized by intense competition and rapid technological change. We face, and will continue to face, competition in both the discovery and development of any of our G-MAB® library derived product opportunities. New discoveries and developments occur and are expected to continue to occur at a rapid pace. There are many companies, including major pharmaceutical and specialized biotechnology companies, engaged in activities similar to ours. Universities, governmental agencies and other public and private research organizations also conduct research and may market commercial products on their own or through joint ventures.

Many of these entities are significantly larger and have greater financial resources, technical staff, manufacturing, research and development resources, including personnel and technology, expertise in prosecution and enforcement of intellectual property rights and marketing capabilities than us, and many have significant experience in preclinical testing, human clinical trials, product manufacturing, marketing, sales and distribution and other regulatory approval and commercial procedures. They may also have a greater number of patents and greater legal resources to seek remedies for cases of alleged infringement of their patents, which may have the effect of blocking, delaying or compromising our own drug development process.

A number of biotechnology and pharmaceutical companies are developing new products for the treatment of the same diseases being targeted by us; in some instances, these products have already entered clinical trials or are already being marketed. Discoveries or commercial developments by our competitors may render some or all of our technologies or potential products obsolete or non-competitive.

Government Regulation

Government authorities in the United States (including federal, state and local authorities) and in other countries, extensively regulate, among other things, the manufacturing, research and clinical development, marketing, labeling and packaging, storage, distribution, post-approval monitoring and reporting, advertising and promotion, pricing and export and import of pharmaceutical products, such as those we are developing. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Moreover, failure to comply with applicable regulatory requirements may result in, among other things, warning letters, clinical holds, civil or criminal penalties, recall or seizure of products, injunction, disbarment, partial or total suspension of production or withdrawal of the product from the market. Any agency or judicial enforcement action could have a material adverse effect on us.

U.S. Government Regulations

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- submission to the FDA of an IND which must become effective before human clinical trials may begin and must be updated annually;

- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA s Good Laboratory Practice, or GLP, regulations. Preclinical testing generally includes evaluation of our products in the laboratory or in animals to characterize the product and determine safety and efficacy;

Table of Contents

performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;

submission to the FDA of a Biologics License Application (BLA) or an NDA after completion of all pivotal clinical trials;

a determination by the FDA within 60 days of its receipt of a BLA or an NDA to file the NDA for review;

satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the active pharmaceutical ingredient, or API, and finished drug product are produced and tested to assess compliance with cGMP regulations; and

FDA review and approval of a BLA or an NDA prior to any commercial marketing or sale of the drug in the United States.

In addition, we are subject to regulation under state, federal, and international laws and regulations regarding occupational safety, laboratory practices, environmental protection and the use and handling of hazardous substance control, and other regulations. Our clinical trial and research and development activities involve the controlled use of hazardous materials and chemicals compounds. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our financial resources. In addition, disposal of radioactive materials used in our clinical trials and research efforts may only be made at approved facilities. We believe that we are in material compliance with all applicable laws and regulations including those relating to the handling and disposal of hazardous and toxic waste.

An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. The IND also includes results of animal studies or other human studies, as appropriate, as well as manufacturing information, analytical data and any available clinical data or literature to support the use of the investigational new drug. An IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical trials. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before clinical trials can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical trials to commence.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators in accordance with Good Clinical Practices, or GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical trial site s IRB before the trials may be initiated, and the IRB must monitor the study until completed. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

The clinical investigation of a drug is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined. The three phases of an investigation are as follows:

Phase I. Phase I includes the initial introduction of an investigational new drug into humans. Phase I clinical trials are typically closely monitored and may be conducted in patients with the target disease or condition or in healthy volunteers. These studies are designed to evaluate the safety, dosage

Table of Contents

tolerance, metabolism and pharmacologic actions of the investigational drug in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness. During Phase I clinical trials, sufficient information about the investigational drug s pharmacokinetics and pharmacological effects may be obtained to permit the design of well-controlled and scientifically valid Phase II clinical trials. The total number of participants included in Phase I clinical trials varies, but is generally in the range of 20 to 80.

Phase II. Phase II includes controlled clinical trials conducted to preliminarily or further evaluate the effectiveness of the investigational drug for a particular indication(s) in patients with the disease or condition under study, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the drug. Phase II clinical trials are typically well-controlled, closely monitored, and conducted in a limited patient population, usually involving no more than several hundred participants.

Phase III. Phase III clinical trials are generally controlled clinical trials conducted in an expanded patient population generally at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug product, and to provide an adequate basis for product approval. Phase III clinical trials usually involve several hundred to several thousand participants.

A pivotal study is a clinical study which adequately meets regulatory agency requirements for the evaluation of a drug candidate s efficacy and safety such that it can be used to justify the approval of the product. Generally, pivotal studies are also Phase III studies but may be Phase II studies if the trial design provides a well-controlled and reliable assessment of clinical benefit, particularly in situations where there is an unmet medical need.

The FDA, the IRB or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the study. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational drug product information is submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications.

The application includes all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product s chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA.

Once the NDA submission has been accepted for filing, the FDA s goal is to review applications within ten months of submission or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months from submission. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations.

Table of Contents

After the FDA evaluates the NDA and conducts inspections of manufacturing facilities where the drug product and/or its API will be produced, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase III clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA could also approve the NDA with a Risk Evaluation and Mitigation Strategies, or REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase IV clinical trials and surveillance to further assess and monitor the product s safety and effectiveness after commercialization. Regulatory approval of oncology products often requires that patients in clinical trials be followed for long periods to determine the overall survival benefit of the drug.

After regulatory approval of a drug product is obtained, we are required to comply with a number of post-approval requirements. As a holder of an approved NDA, we would be required to report, among other things, certain adverse reactions and production problems to the FDA, to provide updated safety and efficacy information, and to comply with requirements concerning advertising and promotional labeling for any of our products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval to ensure and preserve the long term stability of the drug product. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural, substantive and record keeping requirements. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. Newly discovered or developed safety or effectiveness data may require changes to a product s approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA s policies may change, which could delay or prevent regulatory approval of our products under development.

Europe/Rest of World Government Regulations

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the

Table of Contents

submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application, or CTA, must be submitted to each country s national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country s requirements, clinical trial development may proceed.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug under European Union regulatory systems, we must submit a marketing authorization application. The application used to file the NDA in the United States is similar to that required in Europe, with the exception of, among other things, country-specific document requirements.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Available Special Regulatory Procedures

Formal Meetings

We are encouraged to engage and seek guidance from health authorities relating to the development and review of investigational drugs, as well as marketing applications. In the United States, there are different types of official meetings that may occur between us and the FDA. Each meeting type is subject to different procedures. Conclusions and agreements from each of these meetings are captured in the official final meeting minutes issued by the FDA.

The EMA also provides the opportunity for dialogue with us. This is usually done in the form of Scientific Advice, which is given by the Scientific Advice Working Party of the Committee for Medicinal Products for Human Use, or CHMP. A fee is incurred with each Scientific Advice meeting.

Advice from either the FDA or EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical studies, and pharmacovigilance plans and risk-management programs. Such advice is not legally binding on the sponsor. To obtain binding commitments from health authorities in the United States and the European Union, SPA or Protocol Assistance procedures are available. An SPA is an evaluation by the FDA of a protocol with the goal of reaching an agreement with the sponsor that the protocol design, clinical endpoints and statistical analyses are acceptable to support regulatory approval of the product candidate with respect to effectiveness in the indication studied. The FDA s agreement to an SPA is binding upon the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining the safety or effectiveness of the product after clinical studies begin, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA. There is no guarantee that a study will ultimately be adequate to support an approval even if the study is subject to an SPA.

Orphan Drug Designation

The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the

Table of Contents

United States, there is no reasonable expectation that the cost of developing and making the drug for this type of disease or condition will be recovered from sales in the United States. In the European Union, the EMA s Committee for Orphan Medicinal Products, or COMP, grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than 5 in 10,000 persons in the European Union Community. Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of 7 years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity.

In the European Union, orphan drug designation also entitles a party to financial incentives such as reduction of fees or fee waivers and 10 years of market exclusivity is granted following drug or biological product approval. This period may be reduced to 6 years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Authorization Procedures in the European Union

Medicines can be authorized in the European Union by using either the centralized authorization procedure or national authorization procedures.

Centralized procedure. The EMA implemented the centralized procedure for the approval of human medicines to facilitate marketing authorizations that are valid throughout the European Union. This procedure results in a single marketing authorization issued by the EMA that is valid across the European Union, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human medicines that are: derived from biotechnology processes, such as genetic engineering, contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, and officially designated orphan medicines.

For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.

National authorization procedures. There are also two other possible routes to authorize medicinal products in several countries, which are available for investigational drug products that fall outside the scope of the centralized procedure:

Decentralized procedure. Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one European Union country of medicinal products that have not yet been authorized in any European Union country and that do not fall within the mandatory scope of the centralized procedure.

Table of Contents

Mutual recognition procedure. In the mutual recognition procedure, a medicine is first authorized in one European Union Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other European Union countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

Priority Review/Standard Review (United States) and Accelerated Review (European Union)

Based on results of the Phase III clinical trial(s) submitted in an NDA, upon the request of an applicant, the FDA may grant the NDA a priority review designation, which sets the target date for FDA action on the application at six months. Priority review is granted where preliminary estimates indicate that a product, if approved, has the potential to provide a safe and effective therapy where no satisfactory alternative therapy exists, or a significant improvement compared to marketed products is possible. If criteria are not met for priority review, the NDA is subject to the standard FDA review period of 10 months. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Under the Centralized Procedure in the European Union, the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, defined by three cumulative criteria: the seriousness of the disease (e.g. heavy disabling or life-threatening diseases) to be treated; the absence or insufficiency of an appropriate alternative therapeutic approach; and anticipation of high therapeutic benefit. In this circumstance, EMA ensures that the opinion of the CHMP is given within 150 days, excluding clock stops.

There can be no assurance that we or any of our partners would be able to satisfy one or more of these requirements to conduct preclinical or clinical trials or receive any regulatory approvals.

Patents and Proprietary Rights

We are able to protect our technology from unauthorized use by third parties only to the extent that it is covered by valid and enforceable patents or is effectively maintained as a trade secret or is protected by confidentiality agreements. Accordingly, patents or other proprietary rights are an essential element of our business.

As of June 14, 2013 we have four issued United States patents related to two of our five platform groups (nanomedicine/formulations and G-MAB). The five platform groups are: (1) Nanomedicine/formulations, (2) G-MAB®, (3) rIVIG, (4) Quorum Quenching, and (5) AfDC.

(1) Nanomedicine/formulations related to Tocosol®. Contains four issued U.S. patents for formulation of highly insoluble drugs such as paclitaxel (6,458,373 (expiring 2018); 7,030,155 (expiring 2019); 6,982,282 (expiring 2018); and 6,727,280 (expiring 2018). There are also four patent applications pending relating to various processes and particle stability.

(2) G-MAB® has one issued U.S. patent which expires in 2022 and two additional patent families relating to the G-MAB library technology. The third patent family is being maintained as a trade secret as it was filed only in the United States without publication. Given the difficult ability to enforce such patent rights, we will decide at a later date whether to issue this invention as a U.S. patent with publication. In addition, there are ten (10) separate filed patent application families relating to therapeutic products with lead candidates that include the PD-L1, PD-1, CCR2, VEGFR2 and c-Met projects described herein and five additional patent families with lead candidates.

(3) rIVIG is a platform that includes a patent application patent family that will be published by the end of June 2013.

Table of Contents

(4) Quorum Quenching is a platform including a patent family exclusively licensed from the TSRI and includes the MRSA project. In addition, there is a separately filed patent application family for a lead anti-MRSA product.

(5) AfDC is a platform that is protected by one patent application family. No product patent application families have been filed yet. There is also a U.S. patent application relating to a mammalian cell manufacturing process for antibodies.

Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country.

While trade secret protection is an essential element of our business and we have taken security measures to protect our proprietary information and trade secrets, we cannot give assurance that our unpatented proprietary technology will afford us significant commercial protection. We seek to protect our trade secrets by entering into confidentiality agreements with third parties, employees and consultants. Our employees and consultants also sign agreements requiring that they assign to us their interests in intellectual property arising from their work for us. All employees sign an agreement not to engage in any conflicting employment or activity during their employment with us and not to disclose or misuse our confidential information. However, it is possible that these agreements may be breached or invalidated, and if so, there may not be an adequate corrective remedy available. Accordingly, we cannot ensure that employees, consultants or third parties will not breach the confidentiality provisions in our contracts, infringe or misappropriate our trade secrets and other proprietary rights or that measures we are taking to protect our proprietary rights will be adequate.

In the future, third parties may file claims asserting that our technologies or products infringe on their intellectual property. We cannot predict whether third parties will assert such claims against us or against the licensors of technology licensed to us, or whether those claims will harm our business. If we are forced to defend ourselves against such claims, whether they are with or without merit and whether they are resolved in favor of, or against, our licensors or us, we may face costly litigation and the diversion of management s attention and resources. As a result of such disputes, we may have to develop costly non-infringing technology or enter into licensing agreements. These agreements, if necessary, may be unavailable on terms acceptable to us, or at all.

Manufacturing and Raw Materials

We currently use, and expect to continue the use of, contract manufacturers for the manufacture of our product candidates. Our contract manufacturers are subject to extensive governmental regulation. Regulatory authorities in our markets require that pharmaceutical products be manufactured, packaged and labeled in conformity with current Good Manufacturing Practices (cGMPs). We intend to establish a quality control and quality assurance program, which will include a set of standard operating procedures and specifications designed to ensure that our products are manufactured in accordance with cGMPs, and other applicable domestic and foreign regulations.

Under the terms of our agreement with Samyang, we purchase from Samyang all of our required supplies of the product for the United States and certain European Union countries. Cynviloq (Genexol-PM) is formulated, encapsulated and packaged for us by Samyang in South Korea, in a facility that is in compliance with the regulatory standards of each country in which our product is intended for use. The price we pay Samyang is fixed during the initial term of the agreement, which expires in October 2022. Unless terminated by either party as allowed for in the agreement, the agreement is automatically extended for a period of two (2) years each time thereafter.

Table of Contents

We currently do not have any clinical or commercial antibody-based therapeutic manufacturing capabilities. We may or may not manufacture the products we develop, if any. We intend to use contract manufacturers for the manufacture of our product candidates.

Sales and Marketing

We intend to build the commercial infrastructure in the United States necessary to effectively support the commercialization of Cynviloq , if and when we believe regulatory approval of the first indication appears imminent. The commercial infrastructure for oncology products typically consists of a targeted, specialty sales force that calls on a limited and focused group of physicians supported by sales management, internal sales support, an internal marketing group and distribution support. Additional capabilities important to the oncology marketplace include the management of key accounts such as managed care organizations, group-purchasing organizations, specialty pharmacies, oncology group networks, and government accounts. To develop the appropriate commercial infrastructure, we will have to invest significant amounts of financial and management resources, some of which will be committed prior to any confirmation that Cynviloq will be approved.

Outside of the United States, we may elect in the future to utilize strategic partners, distributors, or contract sales forces to assist in the commercialization of our products, if any.

We intend to license to, or enter into strategic alliances with, larger companies in the biopharmaceutical businesses, which are equipped to manufacture, market and/or sell our products, if any, through their well-developed manufacturing capabilities and distribution networks. We intend to license some or all of our worldwide patent rights to more than one third party to achieve the fullest development, marketing and distribution of any products we develop.

Third-Party Reimbursement and Pricing Controls

In order to raise sufficient financial resources to continue to advance our product candidates, we will need to address pricing pressures and potential third-party reimbursement coverage for our product candidates. In the United States and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payors, such as government and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. It is and will continue to be time-consuming and expensive for us or our strategic collaborators to go through the process of seeking reimbursement from Medicare and private payors. Our products may not be considered cost effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

In many foreign markets, including the countries in the European Union, pricing of pharmaceutical products is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental pricing control.

Corporate Information

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. 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 supplement and the accompanying prospectus, including our financial statements and related notes. The risks described below are reflected on a pro forma basis to include our anticipated merger with IgDraSol pursuant to the option agreement described above.

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, AfDC, 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, 2012 and March 31, 2013, we had an accumulated deficit of $10,950,299 and $13,472,638, respectively. We continue to incur significant research and development and other expenses related to our ongoing and acquired operations. 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) continue to identify and advance a number of potential drug candidates into preclinical and clinical development activities, (ii) potentially acquire IgDraSol and continue to fund its operations, (iii) continue our development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products, and (iv) expand our corporate infrastructure, including the costs associated with being a public company. As such, we are subject to all of the 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.

Table of Contents

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing.

Our consolidated financial statements as of December 31, 2012 were prepared under the assumption that we will continue as a going concern for the next twelve months. Our independent registered public accounting firm has issued a report that included an explanatory paragraph referring to our recurring losses from operations and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

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

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

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

- the progress of the development of our fully-human mAb, AfDC, 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

Table of Contents

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, the NIH has notified all grant recipients that due to the current Congressional budget sequestration, the NIH may not be able to issue continuation awards, or it may be required to negotiate a reduction in the scope of existing awards to meet the constraints imposed. Additionally, 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 the funding under our existing NIH grants, and we may not be successful in securing additional grants from the NIH in the future.

In addition, certain investors, including institutional investors, may be unwilling to invest in our securities since we are traded on the Over-the-Counter Bulletin Board, or OTCBB, and not on a national securities exchange. 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 have a limited operating history and 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. Because we only recently commenced operations, we have a limited operating history upon which you can evaluate our business and prospects. Also, as an early stage company, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. Our future success is substantially dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize such product candidates. Our product candidates are currently in preclinical development or in clinical trials. Our business depends entirely on the successful development and commercialization of our product candidates, which may never occur. We currently generate no revenues from sales of any drugs, and we may never be able to develop or commercialize a marketable drug.

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

- developing our technology platform;
- identifying, developing, manufacturing and commercializing product candidates;
- entering into successful licensing and other arrangements with product development partners;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

Our operations have been limited to organizing our company, acquiring, developing and securing our proprietary technology and identifying and obtaining early preclinical data or clinical data for various product candidates. These operations provide a limited basis for you to assess our ability to continue to develop our technology, identify product candidates, develop and commercialize any product candidates we are able to

Table of Contents

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 United States 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 IG-001, 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 or Tocosol® 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™, 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

Table of Contents

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

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

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

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

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing with partners; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

Table of Contents

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 United States, 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.

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

Table of Contents

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

AfDCs, 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.

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.

Table of Contents

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

Table of Contents

regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

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

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

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

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

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

We currently have no sales and marketing organization. If we are unable to establish a direct sales force in the United States 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

Table of Contents

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 United States, 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.

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.

35

Table of Contents

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 United States 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.

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;

36

Table of Contents

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.

Table of Contents

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 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 United States 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 and NSCLC and approvals are being pursued for Pancreatic and Melanoma cancers. 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.

Table of Contents

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

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

- successfully and rapidly complete clinical trials and submit for and obtain all requisite regulatory approvals in a cost-effective manner;
- maintain a proprietary position for our products and manufacturing processes and other related product technology;
- attract and retain key personnel;
- develop relationships with physicians prescribing these products; and
- build an adequate sales and marketing infrastructure for our product candidates.

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

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

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

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 United States, 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.

Table of Contents

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 United States 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 United States 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 United States. 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 United States or internationally and the amount of reimbursement available from governmental agencies or other third-party payors.

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

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

The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of biopharmaceutical products. We are in the early stages of developing potential product candidates, and any candidates that we develop will require extensive preclinical and clinical testing before they will be approved by the FDA or another regulatory authority in a jurisdiction outside the United States, 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 United States or abroad, or whether such applications would be approved by the

Table of Contents

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

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

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

- funding research, preclinical development, clinical trials and manufacturing;
- seeking and obtaining regulatory approvals; and
- successfully commercializing any future product candidates.

If we are not able to establish further collaboration agreements, we may be required to undertake product development and commercialization at our own expense. Such an undertaking may limit the number of product

Table of Contents

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.

Occasionally, we expect to rely on third parties to gain access to certain antigens.

We expect to gain access to certain antigens through contractual arrangements with leading academic researchers, through companies involved in supplying antigens, by isolating them ourselves, or from publicly available sources. In the event we are unable to access antigens in sufficient quantities, or at all, we may not be able to perform antibody discovery activities for certain antigens, which may have an adverse impact on our business 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 United States. 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

Table of Contents

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 profitably in the future.

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

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

We believe that if any of our product candidates were to be approved as biological products under a BLA, such approved products should qualify for the 12-year period of exclusivity. However, there is a risk that the United States. 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

Table of Contents

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, our Chief Executive Officer and President, Vuong Trieu, who currently serves as the Chief Executive Officer of IgDraSol and is slated to become our Chief Scientific Officer after the potential consummation of the merger, 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.

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

Table of Contents

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 United States, 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.

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;

Table of Contents

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.

Risks Related to the Proposed Acquisition of IgDraSol

Completion of the proposed acquisition of IgDraSol is subject to various closing conditions, involves significant costs, and will require considerable attention from our management. Failure to complete the acquisition could adversely affect our stock price and our future business and operations.

As more fully described in this prospectus, on March 7, 2013, we entered into the IgDraSol Transactions, including an exclusive option agreement with IgDraSol. Pursuant to the option agreement, IgDraSol granted us an irrevocable option to acquire IgDraSol by means of an agreement and plan of merger.

The completion of the proposed acquisition of IgDraSol is subject to the satisfaction of various closing conditions, and we cannot assure you that such conditions will be satisfied and that the acquisition will be successfully completed. In the event that the acquisition is not consummated, we will have spent considerable time and resources, and incurred substantial costs, including costs related to the acquisition, many of which must be paid even if the acquisition is not completed. If the acquisition is not consummated, our reputation in our industry and in the investment community could be damaged and, as a result, the market price of our common stock could decline.

47

Table of Contents

We may fail to realize the anticipated benefits of the acquisition of IgDraSol and IgDraSol Transactions.

The success of the acquisition of IgDraSol and IgDraSol Transactions will depend on, among other things, our ability to combine our business with IgDraSol 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.

We and IgDraSol have operated and will continue to operate independently until the potential close of the acquisition near the end of the third quarter of 2013. 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 IgDraSol; 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 and the IgDraSol Transactions and integrating the companies into a single business.

During the first half of 2013, we incurred significant legal and professional fees in connection with the proposed IgDraSol acquisition. 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 the two companies and advancement of the Cynviloq 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 United States 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® which expires in 2022 and the examination of its European equivalent is currently in progress. In 2011, several improvement patent applications were filed for our proprietary antibody library technology. However, due to the difficulties of enforcing such antibody library technology, we filed a key patent application in the U.S. only and requested nonpublication. 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

Table of Contents

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 United States. 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.

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

49

Table of Contents

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.

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 United States 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. For example, we are aware of third party patent US 8,338,143 (expected expiry in 2016), which covers production of paclitaxel from cell cultures of a *Taxus* species, and pending third party patent application USSN 13/618,284 (expected expiry 2016), whose current claims cover production of paclitaxel from cell cultures of a *Taxus* species. 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.

Table of Contents

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 United States. 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 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 United States 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

Table of Contents

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.

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

Table of Contents

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;

failure to consummate the contemplated IgDraSol merger transaction;

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.

Table of Contents

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.

Trading of our common stock is limited, and trading restrictions imposed on us by applicable regulations may further reduce our trading, making it difficult for our stockholders to sell their shares.

Trading of our common stock is currently conducted on the OTC QB. The liquidity of our common stock is limited, not only in terms of the number of shares that can be bought and sold at a given price, but also as it may be adversely affected by delays in the timing of transactions and reduction in security analysts and the media s coverage of us, if at all.

The foregoing factors may result in lower prices for our common stock than might otherwise be obtained and could also result in a larger spread between the bid and asked prices for our common stock. In addition, without a large public float, our common stock is less liquid than the stock of companies with broader public ownership, and, as a result, the trading price of our common stock may be more volatile. In the absence of an active public trading market, an investor may be unable to liquidate his investment in our common stock. Trading of a relatively small volume of our common stock may have a greater impact on the trading price of our stock than would be the case if our public float were larger. We cannot predict the price at which our common stock will trade at any given time.

We do not expect to pay cash dividends on our common stock, and investors will be able to receive cash in respect of their shares of our common stock only upon the sale of such shares.

We have no intention in the foreseeable future to pay any cash dividends on our common stock. Therefore, an investor in our common stock may obtain an economic benefit from the common stock only after an increase in its trading price and only then by selling the common stock.

Because our common stock is a penny stock, it may be more difficult for investors to sell shares of our common stock, and the market price of our common stock may be adversely affected.

According to the definition adopted by the SEC, our common stock is a penny stock because, among other things, its price is below $5.00 per share, it is not listed on a national securities exchange and we do not meet certain net tangible asset or average revenue requirements. Broker-dealers that sell penny stock must provide purchasers of such stock with a standardized risk-disclosure document prepared by the SEC. This document provides information about penny stock and the nature and level of risks involved in investing in penny stock. A broker must also give a purchaser, orally or in writing, bid and offer quotations and information regarding broker and salesperson compensation, make a written determination that the penny stock is a suitable investment for the purchaser and obtain the purchaser s written agreement to the purchase. Broker-dealers must also provide customers that hold penny stock in their accounts with such broker-dealer a monthly statement containing price and market information relating to the penny stock. If a penny stock is sold to an investor in violation of the penny stock rules, the investor may be able to cancel its purchase and get its money back.

If applicable, the penny stock rules may make it difficult for investors to sell their shares of our common stock. Because of the rules and restrictions applicable to a penny stock, there is less trading in penny stock, and the market price of our common stock may be adversely affected. Also, many brokers choose not to participate in penny stock transactions. Accordingly, investors may not always be able to publicly resell their shares of our common stock at times and prices that they feel are appropriate.

Table of Contents

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.

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

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

If we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates, potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. If adequate funds are not available, our ability to achieve profitability or to respond to competitive pressures would be significantly limited and we may be required to delay, significantly curtail or eliminate the development of our product candidates.

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

As of May 31, 2013, our directors, executive officers and principal stockholders beneficially owned, in the aggregate, over 62% 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

Table of Contents

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, 2012, we had net operating loss carryforwards aggregating approximately $10.5 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.

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

Table of Contents

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

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

Sarbanes-Oxley specifically requires, among other things, that we maintain effective internal controls for financial reporting and disclosure of controls and procedures. In particular, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of Sarbanes-Oxley. Our testing, or the subsequent testing by our independent registered public accounting firm, if and when required, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Table of Contents

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

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

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

You should read this prospectus and any accompanying prospectus supplement and the documents that we reference herein and therein and have filed as exhibits to the registration statement, of which this prospectus is part, completely and with the understanding that our actual future results may be materially different from what we expect. You should assume that the information appearing in this prospectus and any accompanying prospectus supplement is accurate as of the date on the front cover of this prospectus or such prospectus supplement only. Because the risk factors referred to above, as well as the risk factors referred to on page 25 of this prospectus and incorporated herein by reference, could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. We qualify all of the information presented in this prospectus and any accompanying prospectus supplement, and particularly our forward-looking statements, by these cautionary statements.

Table of Contents

USE OF PROCEEDS

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

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

THE SECURITIES WE MAY OFFER

The descriptions of the securities contained in this prospectus, together with the applicable prospectus supplements, summarize all the material terms and provisions of the various types of securities that we may offer. We will describe in the applicable prospectus supplement relating to any securities the particular terms of the securities offered by that prospectus supplement. If we indicate in the applicable prospectus supplement, the terms of the securities may differ from the terms we have summarized below. We will also include in the prospectus supplement information, where applicable, about material United States federal income tax considerations relating to the securities, and the securities exchange, if any, on which the securities will be listed.

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

- shares of our common stock;
- shares of our preferred stock;
- warrants to purchase any of the securities listed above; and/or
- units consisting of any of the securities listed above.

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

Table of Contents

DESCRIPTION OF CAPITAL STOCK

General

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

As of June 20, 2013, our authorized capital stock consisted of 750,000,000 shares of common stock, $0.0001 par value per share, and 100,000,000 shares of preferred stock, $0.0001 par value per share. Our board of directors may establish the rights and preferences of the preferred stock from time to time. As of June 20, 2013, there are 336,075,440 shares of our common stock issued and outstanding and no shares of preferred stock issued and outstanding.

Common Stock

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

Preferred Stock

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

(a) The distinctive designation of such series and the number of shares which shall constitute such series, which number may be increased (except where otherwise provided by the Board in creating such series) or decreased (but not below the number of shares thereof then outstanding) from time to time by resolution of the Board;

Table of Contents

(b) The rate and manner of payment of dividends payable on shares of such series, including the dividend rate, date of declaration and payment, whether dividends shall be cumulative, and the conditions upon which and the date from which such dividends shall be cumulative;

(c) Whether shares of such series shall be redeemed, the time or times when, and the price or prices at which, shares of such series shall be redeemable, the redemption price, the terms and conditions of redemption, and the sinking fund provisions, if any, for the purchase or redemption of such shares;

(d) The amount payable on shares of such series and the rights of holders of such shares in the event of any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Company;

(e) The rights, if any, of the holders of shares of such series to convert such shares into, or exchange such shares for, shares of common stock, other securities, or shares of any other class or series of preferred stock and the terms and conditions of such conversion or exchange;

(f) The voting rights, if any, and whether full or limited, of the shares of such series, which may include no voting rights, one vote per share, or such higher number of votes per share as may be designated by the Board; and

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

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

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

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

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

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

place limitations on the removal of directors; and

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

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

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

Table of Contents

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

Advance Notice Bylaws. The Bylaws contain an advance notice procedure for stockholder proposals to be brought before any meeting of stockholders, including proposed nominations of persons for election to the Board. Stockholders at any meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the Board or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given the Company s corporate secretary timely written notice, in proper form, of the stockholder s intention to bring that business before the meeting. Although the Bylaws do not give the Board the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, the Bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of the Company.

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

Transfer Agent and Registrar

The Transfer Agent and Registrar for our common stock is Computershare Shareowner Services.

DESCRIPTION OF WARRANTS

The following description, together with the additional information we may include in any applicable prospectus supplements, summarizes the material terms and provisions of the warrants that we may offer under this prospectus and the related warrant agreements and warrant certificates. While the terms summarized below will apply generally to any warrants that we may offer, we will describe the particular terms of any series of warrants in more detail in the applicable prospectus supplement. If we indicate in the prospectus supplement, the terms of any warrants offered under that prospectus supplement may differ from the terms described below. If there are differences between that prospectus supplement and this prospectus, the prospectus supplement will control. Thus, the statements we make in this section may not apply to a particular series of warrants. Specific warrant agreements will contain additional important terms and provisions and will be incorporated by reference as an exhibit to the registration statement which includes this prospectus.

General

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

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

Table of Contents

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

- the offering price and aggregate number of warrants offered;
- the currency for which the warrants may be purchased;
- if applicable, the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each such security or each principal amount of such security;
- if applicable, the date on and after which the warrants and the related securities will be separately transferable;
- in the case of warrants to purchase common stock or preferred stock, the number of shares of common stock or preferred stock, as the case may be, purchasable upon the exercise of one warrant and the price at which these shares may be purchased upon such exercise;
- the warrant agreement under which the warrants will be issued;
- the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreement and the warrants;
- anti-dilution provisions of the warrants, if any;
- the terms of any rights to redeem or call the warrants;
- any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;
- the dates on which the right to exercise the warrants will commence and expire or, if the warrants are not continuously exercisable during that period, the specific date or dates on which the warrants will be exercisable;
- the manner in which the warrant agreement and warrants may be modified;
- the identities of the warrant agent and any calculation or other agent for the warrants;
- federal income tax consequences of holding or exercising the warrants;
- the terms of the securities issuable upon exercise of the warrants;

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

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

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

Exercise of Warrants

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

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

Table of Contents

the reverse side of the warrant certificate, and in the applicable prospectus supplement, the information that the holder of the warrant will be required to deliver to the warrant agent.

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

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

Enforceability of Rights By Holders of Warrants

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

Warrant Agreement Will Not Be Qualified Under Trust Indenture Act

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

Governing Law

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

Calculation Agent

Calculations relating to warrants may be made by a calculation agent, an institution that we appoint as our agent for this purpose. The prospectus supplement for a particular warrant will name the institution that we have appointed to act as the calculation agent for that warrant as of the original issue date for that warrant. We may appoint a different institution to serve as calculation agent from time to time after the original issue date without the consent or notification of the holders.

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

Table of Contents

DESCRIPTION OF UNITS

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

The applicable prospectus supplement will describe:

- the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;
- any unit agreement under which the units will be issued;
- any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units; and
- whether the units will be issued in fully registered or global form.

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

Table of Contents

PLAN OF DISTRIBUTION

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

- the name or names of any underwriters, if any, and if required, any dealers or agents;
- the purchase price of the securities and the proceeds we will receive from the sale;
- any underwriting discounts and other items constituting underwriters compensation;
- any discounts or concessions allowed or reallowed or paid to dealers; and
- any securities exchange or market on which the securities may be listed.

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

- a fixed price or prices, which may be changed;
- market prices prevailing at the time of sale;
- prices related to such prevailing market prices; or
- negotiated prices.

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

If underwriters are used in an offering, we will execute an underwriting agreement with such underwriters and will specify the name of each underwriter and the terms of the transaction (including any underwriting discounts and other terms constituting compensation of the underwriters and any dealers) in a prospectus supplement. The securities may be offered to the public either through underwriting syndicates represented by managing underwriters or directly by one or more investment banking firms or others, as designated. If an underwriting syndicate is used, the managing underwriter(s) will be specified on the cover of the prospectus supplement. If underwriters are used in the sale, the offered securities will be acquired by the underwriters for their own accounts and may be resold from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. Any public offering price and any discounts or concessions allowed or reallowed or paid to dealers may be changed from time to time. Unless otherwise set forth in the prospectus supplement, the obligations of the underwriters to purchase the offered securities will be subject to conditions precedent and the underwriters will be obligated to purchase all of the offered securities if any are purchased.

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

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

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

Table of Contents

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

In connection with the sale of the securities, underwriters, dealers or agents may receive compensation from us or from purchasers of the common stock for whom they act as agents in the form of discounts, concessions or commissions. Underwriters may sell the securities to or through dealers, and those dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters or commissions from the purchasers for whom they may act as agents. Underwriters, dealers and agents that participate in the distribution of the securities, and any institutional investors or others that purchase common stock directly and then resell the securities, may be deemed to be underwriters, and any discounts or commissions received by them from us and any profit on the resale of the common stock by them may be deemed to be underwriting discounts and commissions under the Securities Act.

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

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

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

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

In order to comply with the securities laws of some states, if applicable, the securities offered pursuant to this prospectus will be sold in those states only through registered or licensed brokers or dealers. In addition, in

Table of Contents

some states securities may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and complied with.

In compliance with guidelines of the Financial Industry Regulatory Authority, or FINRA, the maximum consideration or discount to be received by any FINRA member or independent broker dealer may not exceed 8% of the aggregate amount of the securities offered pursuant to this prospectus and any applicable prospectus supplement.

LEGAL MATTERS

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

Table of Contents

EXPERTS

The consolidated balance sheets as of December 31, 2012 and 2011, 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, 2012 have been incorporated in reliance on the report of Mayer Hoffman McCann P.C., an independent registered public accounting firm, incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

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

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

INCORPORATION OF DOCUMENTS BY REFERENCE

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

- Annual Report on Form 10-K for the year ended December 31, 2012 filed with the SEC on March 25, 2013, as amended by Amendment No. 1 filed with the SEC on March 27, 2013;
- Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2013 filed with the SEC on May 15, 2013;
- Proxy Statement on Schedule 14A filed with the SEC 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 January 11, 2013, February 26, 2013, March 13, 2013, March 14, 2013, April 26, 2013, May 14, 2013, and June 6, 2013; and
- The description of our common stock contained in our Form 8-A/A filed with the SEC on December 7, 2009.

Table of Contents

We also incorporate by reference all additional documents that we file with the Securities and Exchange Commission under the terms of Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act that are made after the initial filing date of the registration statement of which this prospectus is a part until the offering of the particular securities covered by a prospectus supplement or term sheet has been completed. We are not, however, incorporating, in each case, any documents or information that we are deemed to furnish and not file in accordance with Securities and Exchange Commission rules.

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

Sorrento Therapeutics, Inc.

6042 Cornerstone Ct. West, Suite B

San Diego, California 92121

Attn.: Corporate Secretary

Table of Contents

PART II INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The following table sets forth an estimate of the fees and expenses relating to the issuance and distribution of the securities being registered hereby, other than underwriting discounts and commissions, all of which shall be borne by the Registrant. All of such fees and expenses, except for the SEC Registration Fee and the FINRA filing fee, are estimated:

SEC registration fee	$ 13,640
FINRA filing fee	$ 15,500
Transfer agent s fees and expenses	$ 2,500
Legal fees and expenses	$ 25,000
Printing fees and expenses	$ 10,000
Accounting fees and expenses	$ 15,000
Miscellaneous fees and expenses	$ 3,360
Total	$ 85,000

Item 15. Indemnification of Officers and Directors.

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.

Item 16. Exhibits.

a) Exhibits.

Exhibit Number	Description of Document
1.1*	Form of Underwriting Agreement
3.1	Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K filed with the SEC on October 23, 2009)
3.2	Restated Certificate of Incorporation
3.3	Bylaws (incorporated by reference to Exhibit 3.2 to the Registrant s Current Report on Form 8-K filed with the SEC on October 23, 2009)

Table of Contents

Exhibit Number	Description of Document
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed with the SEC on October 23, 2009).
4.2*	Specimen Preferred Stock Certificate and Form of Certificate of Designation of Preferred Stock
4.3*	Form of Warrant Agreement (including Warrant Certificate)
4.4*	Form of Unit Agreement (including Unit Certificate)
5.1**	Opinion of Sichenzia Ross Friedman Ference LLP
23.1**	Consent of Sichenzia Ross Friedman Ference LLP (included in Exhibit 5.1).
23.2	Consent of Mayer Hoffman McCann P.C.
24.1	Power of Attorney (included on signature pages to the registration statement)

* To the extent applicable, to be filed by an amendment or as an exhibit to a document filed under the Securities Exchange Act of 1934, as amended, and incorporated by reference herein.

** To be filed by amendment.

Item 17. 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 this 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 this registration statement. Notwithstanding the foregoing, any increase or decrease in the volume of securities offered (if the total dollar value of the 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; and

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

provided, however, that the undertakings set forth in paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) above 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 Securities Exchange Act of 1934, as amended (the Exchange Act) that are incorporated by reference in this registration statement or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of this 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 therein, 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.

Table of Contents

(4) That, for the purpose of determining liability under the Securities Act to any purchaser:

If the registrant is relying on Rule 430B;

(i) Each prospectus filed by the registrant pursuant to Rule 424 (b)(3) shall be deemed to be part of this registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424 (b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date of the Securities Act prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date; or

(iii) If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(5) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

Table of Contents

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant s annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan s annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(h) 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 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.

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-3 and has duly caused this Form S-3 to be signed on its behalf by the undersigned, thereunto duly authorized, in New York, New York, on the 21st day of June 2013.

SORRENTO THERAPEUTICS INC.

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

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Henry Ji, 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.

Signature	Title	Date
/s/ HENRY JI	Director, Chief Executive Officer and President	June 21, 2013
Henry Ji	*(Principal Executive Officer)*	
/s/ RICHARD G. VINCENT	Director, Chief Financial Officer	June 21, 2013
Richard G. Vincent	*(Principal Financial and Accounting Officer)*	
/s/ DAVID WEBB	Director	June 21, 2013
David Webb		
/s/ ERNST-GUNTER AFTING	Director	June 21, 2013
Ernst-Gunter Afting		
/s/ CAM GALLAGHER	Director	June 21, 2013
Cam Gallagher		
/s/ KIM D. JANDA	Director	June 21, 2013
Kim D. Janda		

/s/ M. SCOTT SALKA	Director	June 21, 2013

M. Scott Salka