Sorrento Therapeutics, Inc.
Form 10-K
April 01, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended: December 31, 2013

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission File Number 001-36150

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**
(Address of Principal Executive Offices)	(Zip Code)

(858) 210-3700

(Registrant s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value $0.0001 per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ¨ Yes x No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. ¨ Yes x No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to the filing requirements for at least the past 90 days. x Yes ¨ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (Section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). x Yes ¨ No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). ¨ Yes x No

The aggregate market value of voting stock held by non-affiliates of the registrant is calculated based upon the closing sale price of the common stock on June 28, 2013 (the last trading day of the registrant s second fiscal quarter of 2013), as reported on the Over-the-Counter Bulletin Board, and such aggregate market value was approximately $51,715,293.

At March 21, 2014, the registrant had 23,028,101 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of our Proxy Statement for the 2014 Annual Meeting of Stockholders, to be filed within 120 days of December 31, 2013, are incorporated by reference in Part III. Such Proxy Statement, except for the parts therein which have been specifically incorporated by reference, shall not be deemed filed for the purposes of this Annual Report on Form 10-K.

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SORRENTO THERAPEUTICS, INC.

ANNUAL REPORT ON FORM 10-K

FISCAL YEAR ENDED DECEMBER 31, 2013

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Form 10-K, contains forward-looking statements that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially and adversely from those expressed or implied by such forward-looking statements. The forward-looking statements are contained principally in Item 1 Business, Item 1.A Risk Factors and Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations but appear throughout the Form 10-K. Examples of forward-looking statements include, but are not limited to our expectations, beliefs or intentions regarding our potential product offerings, business, financial condition, results of operations, strategies or prospects and other matters that do not relate strictly to historical facts or statements of assumptions underlying any of the foregoing. These statements are often identified by the use of words such as anticipate, believe, continue, could, estimate, expect, intend, may, ongoing, opportunity, plan, potential, predicts, seek, should, will, or would, and similar expressions and variations or negatives of these words. These forward-looking statements are based on the expectations, estimates, projections, beliefs and assumptions of our management based on information currently available to management, all of which are subject to change. Such forward-looking statements are subject to risks, uncertainties and other factors that are difficult to predict and could cause our actual results and the timing of certain events to differ materially and adversely from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed under Item 1.A Risk Factors in this Form 10-K. Furthermore, such forward-looking statements speak only as of the date of this Form 10-K. We undertake no obligation to update or revise publicly any forward-looking statements to reflect events or circumstances after the date of such statements for any reason, except as otherwise required by law.

PART I

Item 1. Business.

Overview

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

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

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

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

Our Strategy

Our mission is to improve the lives of patients and assist their caretakers by delivering novel therapies that improve outcomes while reducing the undesirable side effects of many current therapies. We intend to pursue this initially through the further development and potential approval, launch and marketing of Cynviloq and resiniferatoxin. We believe we have assembled a strong team with in-depth domain knowledge in targeted therapeutics development and commercialization. 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 described below:

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 next generation injectable nanoparticle paclitaxel, Cynviloq, which is both Cremophor-free and HSA-free, and is approved and marketed for a variety of cancers in South Korea, India, Vietnam and the Philippines. We believe our formulation offers improved administration, the potential for improved dose and duration, and may provide cancer patients and oncology practitioners with a much needed alternative to the current paclitaxel-based chemotherapies with the potential for improved patient outcomes. Through our partnership with Autotelic Inc., or Autotelic (formerly Biomiga Diagnostics), we intend to simultaneously develop a companion pharmacokinetic monitoring device to allow for personalized cancer therapy in combination with Cynviloq.

Resiniferatoxin, or RTX, may permanently eliminate intractable cancer pain and may be applicable to other therapeutic indications in both humans and animals. RTX is a novel, small molecule with a non-opiate mechanism of action that may permanently eliminate targeted intractable cancer pain experienced by end-stage cancer patients. When injected intraspinally or paraspinally, RTX directly interacts with nerve cells expressing TRPV-1 receptors without affecting normal sensation (touch and vibration sense) or muscle function. RTX has been extensively tested in animals and is currently being tested in an investigator-sponsored Phase I/II clinical trial at the National Institute of Health, or NIH under a Cooperative Research and Development Agreement. To date, 10 patients with terminal cancer pain have been treated at NIH. We intend to launch additional trials to rapidly advance clinical development of the drug in patients with intractable cancer pain.

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 validated cancer targets. The individual mAbs discovered from our G-MAB library potentially give us a multitude of therapeutic options to target and attack cancer cells. This could be either directly, such as: (i) recruitment of immune effector functions, including, but not limited to, antibody-dependent cellular cytotoxicity, or ADCC, or (ii) antagonistic suppression of cellular signaling processes required for cancer proliferation and metastasis; or indirectly, via modulation host biology, such as: (a) enhancement of immune activity in the tumor, or (b) normalization of the tumor microenvironment, including anti-angiogenesis for cutting off blood supplies to the tumor. In addition, we intend to utilize our G-MAB library-derived antibodies as the foundation for the development of companion diagnostics.

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Antibody drug conjugates (ADC) for targeted tumor killing. By leveraging the extensive G-MAB Library with our proprietary chemistry, linker and payload technologies, we are uniquely positioned to generate proprietary ADCs with potentially better efficacy and safety profiles than currently available therapies. Several ADCs candidates are being advanced and are expected to enter clinical development in the near future.

In the near term, we expect to focus our resources on:

- executing on our pivotal registration trial for our oncolytic drug candidate **Cynviloq,** and preparing for FDA submission of an NDA filing, based on the 505(b)(2) Bioequivalence (BE) pathway,

- advancing **RTX** into phase II clinical human development; and seeking strategic alternatives for potential veterinary indications, and

- prioritizing our preclinical pipeline, and advancing selected drug development candidates into clinical trials.

See the section entitled Risk Factors in this Form 10-K for a discussion of some of the risks relating to the execution of our business strategy.

Product Candidates

We currently have one late-stage oncology drug candidate, **Cynviloq**, commencing a BE registration trial for multiple solid tumor indications in March 2014, and an ongoing phase I study in progress for intractable cancer pain, **RTX**. Additionally, we have multiple mAb product candidates in preclinical development, including our fully human anti-PD-L1 and anti-PD-1 mAbs and several ADCs. We believe these individual mAb or ADC product candidates have the potential to address major unmet medical needs.

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Cynviloq

Cynviloq was licensed through an exclusive distribution agreement, as amended, for North America, 27 countries of the EU, and Australia, from 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 is approved ex-U.S. for MBC without premedication and for NSCLC and ovarian cancers with premedication in combination with platinum.

Cynviloq has been clinically tested in over 900 patients in the U.S., 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 Taxol (Cremophor-paclitaxel) 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 U.S. and in China for the MBC indication.

On July 29, 2013, we received official meeting minutes from an End-of-Phase II meeting held on July 23, 2013 for Cynviloq (or IG-001) with the U.S. Food and Drug Administration, or FDA. Cynviloq is initially under development for the treatment of MBC and NSCLC, in the U.S. The FDA Division of Oncology Products 1 agreed that the data available from: (i) the postmarketing surveillance studies conducted in ex-U.S. territories for MBC and NSCLC, (ii) Phase I-III studies for MBC, and (iii) Phase I-II studies in NSCLC, Ovarian, Bladder, and Pancreatic cancers are sufficient to support pursuing the 505(b)(2) BE regulatory submission pathway approach using Abraxane and Taxol as the Reference Listed Drugs. Abraxane is an albumin-bound paclitaxel (*nab*-paclitaxel) product approved for MBC, NSCLC and pancreatic cancer indications. Taxol is a Cremophor-based paclitaxel product approved for these indications as well as other cancer indications. We filed our BE protocol in 2013 and commenced our BE study in March 2014.

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. Although often used in clinical practice, patients receiving Abraxane do not require pre-medication to allay any potential toxic side effects associated with Abraxane.

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

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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

Particle dissociation studies comparing Abraxane and Cynviloq have shown that both formulations rapidly disintegrate under physiologically-relevant conditions, suggesting that both formulations 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 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). 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, derived from two separate studies, 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 PK Parameters at 135 mg/m^2 on a 3 hr Infusion Regimen

	Cmax (ng/mL)	AUC_{inf} (ng/mL*h)	$T_{1/2}$ (hr)	CL (L/hr/m^2)
Cynviloq	1357	5473	12.7	25.5
Abraxane	1392	5654	12.9	27.4

4. Overlapping 95% confidence interval (CI) for AUC_{inf}/D, $T_{1/2}$, CL, and V_z. 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 AUC_{inf}/D, $T_{1/2}$ and V_z 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	AUC_{inf}/D (ng/hr/mL/D)	T1/2 (hr)	CL (L/hr/m^2)	Vz (L/m^2)
		Mean (95% confidence interval)			
Abraxane®	30 min	53	17	22	536

(N=14)		(20-86)	(10-24)	(11-33)	(145-928)
Cynviloq		48	14	25	631
(N = 9)	180 min	(11-84)	(8-19)	(9-40)	(252-1010)
Cynviloq*					
(N = 7)	60 min	(26-61)	(6.0-18.6)		(249-1512)

* Lim, et al, 2009, the AUC, $T_{1/2}$, CL or V_z 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

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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 AUC_{0-t} and AUC_{inf} between Cynviloq and Abraxane (Study Camargo1).

Simulated mean PK Parameter Values after Administration of 260 mg/m² Cynviloq in 30 minutes and Summary of Abraxane s PK Parameter Values

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

Cynviloq Regulatory and Development 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 (C_{max} 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.

A single BE crossover study is planned and expected to enroll up to 100 MBC patients to: (i) treat patients with Abraxane or Cynviloq to measure the PK parameters between the two drug formulations to establish BE, and (ii) determine the measurements of both total and unbound paclitaxel in both formulations.

The BE trial is expected to be completed in the first half of 2015, with potential approval in early 2016. If Cynviloq and Abraxane are found to be bioequivalent and FDA approval is granted: (i) Cynviloq will receive the same label indications as Abraxane, including MBC and NSCLC, in addition to potentially recently approved Abraxane indications, namely advanced pancreatic cancer (upon expiration of Abraxane s marketing exclusivity), and (ii) additional life cycle indications, such as bladder or ovarian cancers, could be pursued with additional studies.

Cynviloq Manufacturing

Under the terms of our agreement with Samyang, we purchase from Samyang all of our required supplies of the product. 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.

Market Opportunity

Cynviloq

According to the 2012 IMS NSP, the taxane market in the U.S. is estimated to be one billion dollars in 2012, and is comprised of Abraxane, generic paclitaxel (Taxol) and generic docetaxel (Taxotere®; Sanofi-Aventis).

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Abraxane had approximately 40% market share in the U.S. 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.

Metastatic Breast Cancer (MBC)[1]

It is estimated that over 230,000 new cases of invasive breast cancer will be diagnosed among women in the U.S. 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 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 U.S. 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 U.S. and the top five (5) EU countries (Germany, France, Italy, Spain, United Kingdom). Half of these patients live in the U.S., 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 and 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 and carboplatin and Perjeta® plus Herceptin® and 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 U.S., 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

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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 U.S. 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 U.S. 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 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 survival, or OS.

In 2012 in the U.S. 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 U.S., 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 U.S. 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 U.S. and the top 5 EU countries. In 2013, an estimated 45,000 new cases of pancreatic cancer will be diagnosed in the U.S. 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 U.S. In 2013, an estimated 38,000 people are expected to die from pancreatic cancer in the U.S. 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 U.S. and top 5 EU countries, with the U.S. accounting for 27,000 of these patients. Another 26,000 patients were treated in the second-line setting in the U.S. and top 5 EU countries, with the U.S. 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

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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 U.S.

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) > 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 U.S., 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.

Cynviloq Sales and Marketing

We intend to build the commercial infrastructure in the U.S. 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 U.S., 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.

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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.

Therapeutic Drug Monitoring for personalized dosing using Cynviloq

We intend to further expand the Cynviloq treatment with innovative personalized dosing regimens of Cynviloq, through our partnership with Autotelic. Autotelic is developing 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 could enable the best treatment outcome possible maximum efficacy with lower toxicity. Cynviloq s dose linearity and high MTD (up to 435 mg/m^2 in Phase I studies) makes it the ideal taxane formulation for individualized dosing. TDM has the potential to substantially enhance the value proposition by improving the therapeutic index, the commercial viability and competitiveness of Cynviloq versus other chemotherapy agents.

RTX

On October 9, 2013, we acquired Sherrington Pharmaceuticals, Inc., or Sherrington, a private-held company focused on the development of an intractable pain treatment for end-stage disease, including cancer, HIV, and other conditions.

According to the American Cancer Society, about 1.5 million people are diagnosed annually with cancer. Each year in the U.S., almost 600,000 people die from cancer, of which approximately 80 percent of those patients experience moderate to severe pain lasting over 90 days. The cost of keeping these patients comfortable adds significantly to the overall cost of treatment. Patient s primary options are nonsteroidal anti-inflammatory drugs (NSAIDs) or opiates that have a wide variety of administration routes. NSAID s have marginal efficacy, and while opioids can be efficacious, the doses required to achieve efficacy often are accompanied by considerable side effects that severely impact the patients quality of life such that patients require significant supportive care. In 2005, over 345 million doses of morphine were sold in the U.S. for breakthrough pain alone. High dose opiates are given as a baseline treatment and then patients with breakthrough pain receive additional medication. The cost for treating breakthrough cancer pain using rapidly acting fentanyl preparations (e.g. Actiq® or Fentora®) can reach over $5,000 per patient over a 90 day period. Implantable intrathecal morphine pumps (for 24-hour morphine delivery) can cost over $60,000 to implant, excluding the cost of the medicine and related maintenance. Furthermore, opiates are highly addictive and when misused can result in death from respiratory depression. Risk Evaluation and Mitigation programs are regulatory requirements put in place in an effort to assure safe use of these DEA-scheduled compounds, and are costly not only to the manufacturers but also to the healthcare system. Patients develop tolerance to opioids, requiring higher doses to treat the same amount of pain, which can lead to greater or more frequent side effects and the potential for addiction.

RTX is a novel small molecule with a non-opiate mechanism of action that may permanently eliminate intractable cancer pain experienced by end-stage cancer patients. When injected intraspinally or paraspinally, RTX directly interacts with nerve cells expressing TRPV-1 receptors without affecting normal sensation (touch and vibration sense) or muscle function. RTX has been extensively tested in animals and is currently being tested in an investigator-sponsored Phase I/II clinical trial at the National Institute of Health or NIH under a Cooperative Research and Development Agreement. To date, 10 patients with terminal cancer pain have been treated at NIH. We intend to launch additional trials to rapidly advance clinical development of the drug in patients with intractable cancer pain.

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The mechanism of action for RTX is well understood and has been validated by compelling data in both animals and humans. In chronic pain states, TRPV-1 is upregulated and expressed to a greater degree resulting in central hypersensitivity and pathological pain states. When the drug is delivered via intrathecal injection, through a catheter placed in the cerebrospinal fluid space, it targets and binds to TRPV-1 receptors expressed by specific neurons in the dorsal root ganglion and superficial layers of the dorsal horn of the spinal column. RTX binding to TRPV-1 results in calcium influx, which initiates programmed cell death (apoptosis) of only the targeted neurons and, therefore, results in the permanent reduction of pain transmitted by these TRPV-1 positive neurons. The drug is highly specific and does not bind to the large myelinated nerves that transmit normal pain sensations (touch and vibration or position sense), control muscle function or impact cognition. The RTX injection is performed by an anesthesia pain specialist, neurologist, spine surgeon or interventional radiologist trained in such procedures under fluoroscopic guidance as an outpatient procedure under general anesthesia to prevent patient awareness of the pain related to the procedure or injection. RTX has the potential of reducing pain without the side effects associated with opiates, including impairment of physical and/or mental facilities. Treatment is expected to address significant unmet medical needs by producing long lasting, analgesic coverage of intractable chronic pain syndromes. Other potential indications include intractable phantom limb pain, pain related to spinal cord injury, and intractable interstitial cystitis.

An intrathecal injection approach is designed to target more generalized pain syndromes. For more focal and unilateral pain conditions, we also plan to evaluate targeted injections into or near specific ganglia (e.g., dorsal root ganglia, trigeminal ganglia or sympathetic ganglia). This approach can place RTX in a precise location and avoids the diffuse spread that is possible with RTX injected intrathecally. We intend to start a Phase I/II periganglion injection trial in conjunction with the NIH in the second half of 2014 in patients with cancer-induced bone pain. We intend to identify and pursue other severe pain indications that may be approached by local administration of our existing formulations. We believe that these applications of RTX have high unmet needs that can be addressed with relatively low-cost and short-duration development plans.

We also plan to utilize the existing data on osteosarcoma-associated pain in dogs and file for conditional marketing approval with the Center for Veterinary Medicine (CVM) division of the FDA under the minor use/minor species (MUMS) act, legislation which is similar to an Orphan Product Designation for human medicines. Under a MUMS designation, drugs with a reasonable expectation of efficacy in a minor use, such as osteosarcomas, may be marketed in parallel with the pivotal efficacy trial. The sponsor company then has four years, while it is marketing the product, to complete the registration trial and any additional work required by CVM for full approval. We also plan to study additional indications using RTX delivered by the intrathecal route, and potentially other routes for additional indications. The veterinary market for RTX presents additional low risk opportunities to generate value for our enterprise and to support the human development programs a low cost. We are considering strategic options for the vet opportunity, including out-licensing the vet opportunity to a wholly-owned subsidiary focused on animal therapeutics or to other vet companies specializing in veterinary medicine.

RTX Development Strategy

The initial signals of safety and efficacy observed by the NIH investigators in the Phase I/II trial and the published data in dogs with osteosarcoma and metastatic bone cancers from the University of Pennsylvania are quite promising. We intend to continue enrolling patients in the NIH intrathecal trial in order to identify the MTD for RTX and to characterize any dose limiting toxicities. We intend to sponsor clinical studies in early 2015 to supplement the current data set from the current NIH intrathecal trial and the planned periganglionic trial. Assuming the Phase I/II studies are successfully completed, and assuming confirmation of the activity observed to date, we intend to pursue future development on an accelerated basis. Other potential indications we may consider include the treatment of pain related to spinal cord injury, intractable phantom pain, intractable neuropathic or visceral pain, and other similar conditions.

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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. Our library achieves its high diversity from a large collection of high-quality antibodies. The theoretical diversity of our library has been calculated to be more than one quadrillion unique antibodies, making it, to our knowledge, one of the largest fully human antibody libraries available to pharmaceutical and biotechnology companies for drug discovery and development partnerships. Our objective is to leverage our library to develop both FIC and/or BIC antibody drug candidates that we expect will possess greater efficacy and fewer side effects as compared to existing drugs. In addition, the success we have achieved finding strong fully human antibodies that bind to a diverse array of targets provides an ample menu of antibodies for conjugating various small molecule drugs with our antibodies used as the targeting moieties of ADC s.

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 have 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 drug conjugates, or ADCs, and (ii) create recombinant intravenous globulins, or rIVIG, for the treatment of certain auto-immune diseases as well as immunodeficiencies.

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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 or as components of ADCs, 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, immunocology 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 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 U.S. in 2014. We anticipate that a Phase I clinical trial for the lead candidate anti-PD-L1 antibody could be initiated in 2015.

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

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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 antagonistic anti-chemokine receptor mAbs and expression cell line generation for the lead candidate mAb commenced in the first quarter of 2014.

Anti-staphylococcal autoinducing peptide (AIP) antibodies

Overview

Staphylococcus aureus is a Gram-positive bacterium that is commonly found on the skin of humans. 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 ineffective.

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.

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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. Moreover, we are also developing a vaccine-based product for AIP that is also based on the TSRI in-licensed program. Our anti-MRSA program is currently funded by a STTR Fast Track grant from the NIH/National Institute for Allergy and Infectious Diseases (NIAID). If Phase 2 portion of the Fast Track grant is approved by NIH (decision expected in Q3 2014), the 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 2014 with IND-enabling studies commencing in 2015. We anticipate that a Phase I clinical trial for the lead anti-MRSA antibodies could be initiated in 2017.

Antibody Drug Conjugates (ADC) Technologies

On December 19, 2013, we acquired Concortis Biosystems, Corp., or Concortis, a privately-held company with proprietary cytotoxic payloads as well as C-lock® and K-lock® conjugation technologies that allow for site-specific toxin conjugation to the antibody using novel drug delivery systems. These next generation technologies may improve the overall stability and potency of the ADCs. First-generation conjugation technologies lead to inconsistent drug-antibody ratios, which result in a heterogeneous mixture of ADCs. This variability has been a constraining factor in unlocking the full therapeutic potential for current-generation ADCs. The ADC technology complements our existing development programs, particularly our G-MAB antibody library and related monoclonal antibodies. We plan to utilize our ADC technology with our proprietary mAbs as the targeting agents to develop proprietary ADC products. Concortis uses its proprietary technologies to provide drug conjugation services to customers in the pharmaceutical industry.

Our pipeline of mAb-based product candidates can be linked to our proprietary toxins forming novel ADCs. ADCs have proven useful to deliver a highly toxic payload directly to the tumor or cell population while sparing other healthy tissues. Our ADCs utilize proprietary mAbs that rapidly internalize within target cells after binding to a specified cell-surface receptor. Enzymes present inside the cell catalyze the release of the cytotoxic agent from the monoclonal antibody, which then results in the desired activity, specific killing of the target cell. This targeted delivery of the cell-killing agent is intended to maximize delivery of the cytotoxic agent to targeted cells while minimizing toxicity to normal tissues. Our ADCs use proprietary toxins with various mechanisms of action (MOA). In contrast to natural products that are often scarce and very difficult to produce in large quantity, our proprietary payloads are synthetically produced from readily available starting materials. In contrast to conventional drug conjugation strategies, which yield heterogenous conjugates with relatively narrow therapeutic index, our C-lock and K-lock conjugation technologies will enable us to achieve site-specific payload attachment, either on Lys or Cys, without requiring incorporation of unnatural amino acids, utilization of enzymes, or genetic re-engineering of cell lines. By employing our conjugation technologies, the ADCs will be highly homogenous without compromising the stability of antibody, thus potentially improving the therapeutic window. Moreover, the combination of these two conjugation technologies puts us in a unique position to be able to conjugate two distinct classes of payloads to a single antibody at desired conjugation sites with high homogeneity. Our ADC development candidates all utilize our proprietary ADC technologies and form the basis of our corporate / service collaborations. We fully own multiple patents and patent applications covering our ADC technology, which includes payloads, linkers, antibodies, and conjugation methods. We will continue to design and evaluate new linkers, conjugation technologies, antibody formats, and cytotoxic agents for use in our ADC programs. The two most advanced ADC projects targeting VEGFR2 and c-MET, for the treatment of various cancers will enter into IND-enabling activities later this year, while a number of additional in ADCs projects are in discovery stage

Our latest technology development effort focuses on bispecific antibodies, which are able to simultaneously bind two different antigens or two distinct epitopes on the same antigen on the cancer cell. The company is currently developing proprietary bispecific antibody technology that may result in very stable bispecific

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antibodies without common drawbacks, such as domain exchange during the storage and manufacture. We will develop these bispecific antibodies for immunotherapy (combining two therapeutic antibodies) and for the generation of ADCs, which could deliver their cytotoxic payload in a more target-specific manner compared to standard ADCs. These bispecific antibodies may become first-in-class cancer therapies, and bispecific ADCs may further expand the therapeutic window of our ADCs by improving efficacy, overall safety and toxicity profile.

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.

We anticipate obtaining manufacturing as well as in vitro and in vivo proof-of-concept in the second half of 2014. We intend to pursue partnering or strategic options for the further development of rIVIG. Our first family of rIVIG patent applications provide product protection into the latter part of 2032.

About Antibodies

The Function of Antibodies

The human immune system protects the body against a variety of infections and other illnesses. Specialized cells work together with the other components of the immune system to recognize, neutralize and eliminate from the body numerous foreign substances, infectious organisms and malignant cells.

Antibodies are part of the body s principal defense mechanism against disease-causing organisms, other foreign molecules and toxins. Antibodies are protein molecules capable of specifically recognizing substances potentially harmful to the human body, known as antigens, and binding to those antigens to neutralize or block them from interacting with and causing damage to the body. Antibodies are capable of recognizing and distinguishing between the subtlest of molecular differences in antigens. Antibodies that bind tightly to antigens are said to have high affinity.

Antibodies are naturally present in the blood and circulate for extended periods in order to perform their surveillance and defense functions. Antibodies are made in the immune system by human white blood cells, called leukocytes. Human leukocytes produce millions of different types of antibodies, all with varying shapes that allow them to specifically attach to and, as a result, neutralize different disease targets. For example, certain

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antibodies seek out and attach to viruses, bacteria and diseased cells, marking them for destruction by the human immune system. Others attach to specific disease targets and block their interaction with other molecules or can be used to deliver toxic agents to directly kill cancer cells.

As depicted below, the basic structure of an antibody comprises four polypeptides of two different sizes: two identical light chains and two identical heavy chains, named according to their relative size. The heavy and light chains are assembled within the white blood cell to form an antibody molecule. Each chain has a variable region, which contains the binding site for an antigen and gives the antibody its high specificity, and a constant region, which interacts with other parts of the immune system to facilitate the removal of the pathogen or foreign molecule. The genetic code determining the structure of a given variable region is referred to as immunoglobulin variable domain sequence.

The repertoire of antibodies the body uses to defend itself is produced, in part, through random recombination of genes for the variable regions, as well as random pairing of the heavy and light chains. As a result, the immune system is able to adapt and produce antibodies against virtually any antigen. When an antibody encounters an antigen to which it binds, the white blood cell that produces this specific antibody proliferates to generate more antibodies against the target antigen. White blood cells that have differentiated to produce a specific antibody are called B lymphocytes.

Antibodies as Drugs

Recent advances in the technologies for creating and producing antibody products, coupled with a better understanding of how antibodies and the immune system function, have further increased the already significant interest in the commercial development of antibodies as antibodies as drugs to treat a variety of diseases.

We believe antibody drugs have several potential clinical and commercial advantages over traditional therapies, including small molecule drugs and surgery. These advantages may include the following:

- fewer unwanted and uncomfortable side effects as a result of exquisite specificity for the disease target;
- better patient compliance (use) since antibodies are typically injected once every month, or so, versus small molecule oral drugs that may require daily dosing; and
- enhanced ability to deliver various payloads, including drugs, radiation and toxins, to specific disease sites while avoiding surrounding (healthy) tissues.

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Monoclonal and Chimeric / Humanized Antibodies

The therapeutic antibodies marketed today generally belong to a class of molecules known as monoclonal antibodies , or mAbs. This term is used to refer to a homogeneous population of antibody molecules that are identical in their structure and functional characteristics. Historically, the approach to generating monoclonal antibodies has been to immortalize single antibody-producing white blood cells from mice, so that the cells are capable of reproducing over an indefinite period of time. Any of these immortalized, fused cells, known as hybridomas, can be made to produce one specific antibody with desired binding characteristics. The hybridomas can then be selected, cloned and expanded, allowing the large scale production of a murine mAb, or mouse antibody.

However, mouse antibodies are wholly composed of mouse protein sequences and tend to be recognized as foreign by the human immune system. When patients are repeatedly treated with mouse antibodies, they will begin to produce antibodies that effectively neutralize the mouse antibody, a reaction referred to as a Human Anti-Mouse Antibody, or HAMA, response. In many cases, the HAMA response prevents the mouse antibodies from having the desired therapeutic effect and may cause the patient to have an allergic reaction.

Recognizing the limitations of mouse mAbs, researchers have developed a number of approaches to make them appear more human-like to a patient s immune system. For example, improved forms of mouse antibodies, referred to as chimeric and humanized antibodies, are genetically engineered and assembled from portions of mouse and human antibody gene fragments. While these chimeric and humanized antibodies are more human-like, they still retain a varying amount of the mouse antibody protein sequence, and accordingly may continue to trigger a HAMA response. Additionally, the chimeric/humanization process can be expensive and time-consuming, often requiring additional weeks or months of secondary manipulation after the initial generation of the mouse mAbs.

Human Antibodies

The probability of inducing a HAMA response can be eliminated by generating antibody therapeutic products with fully-human protein sequences. Researchers have developed several antibody technologies to produce such fully-human antibodies, including:

- Antibody Display technology, involves cloning and expressing human antibody genes in novel contexts such as on bacteriophages (viruses that infect bacteria), yeast or ribosome/mRNA complexes in order to display libraries of antibody fragments for subsequent *in vitro* selection against antigens. Our proprietary technology, or the STI Technology, and the Winter II Technology discussed below are both antibody display technologies;

- Human Mouse technology, based on genetically-engineered strains of mice capable of producing human antibody responses to antigens; and

- Clonal isolation and expansion of human B-lymphocytes is an approach generally limited to creating antibodies against non-human antigens or antigens to which the lymphocyte donor had previously responded. Accordingly, it may not be suitable for targeting many key diseases, such as cancer and inflammatory and autoimmune disorders, for which appropriate therapy might require antibodies to human antigens.

Proprietary Human Antibody Library Technology

We believe the STI Human Antibody Library Technology is a significant improvement over traditional technologies used to construct large human antibody libraries. STI has the ability to produce fully-human antibody libraries of far greater diversity (that is, the number of different antibody species) and single-class libraries, such as Immunoglobulin G (IgG) for therapeutic antibodies or Immunoglobulin A (IgA) for anti-infective secretory antibodies. It is this dual advantage of diversity and single class libraries that provides STI with what we believe is the premier antibody library asset in the industry.

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The STI Technology was initially invented by Henry Ji, Ph.D., STI s co-founder, Chief Executive Officer and President. A U.S. patent covering the STI Technology was issued in July 2008 and additional patent application families for the generation, display and screening of antibody libraries are pending. We also recently filed a group of patent applications covering significant improvements to the initial STI Technology, with the key improvements relating to what we believe is our ability to achieve greater library diversity and produce single-class libraries.

Our mAb Technology Advantages

We believe the STI Technology may offer the following advantages over competing technologies:

- The STI Technology has been designed to provide the full spectrum of human immunoglobulin gene recombination in fully-human mAb libraries. Unlike chimeric and humanization technologies, the STI Technology has allowed the generation of antibodies with fully-human protein sequences without the challenges and limitations of animal-to-human gene transfer procedures; and

- Because the STI Technology represents an *in vitro* human mAb library technology, it enables fast and cost-effective *in vitro* screening of a large number of antigens. The STI Technology is designed so that any antigen of interest can be investigated, without dependence on the successful induction of a host immune response against the antigen. As opposed to the human-mouse technology, the STI Technology does not require the costly establishment and maintenance of large animal facilities. In addition, a given human antigen may not induce an immune response in mice. In such cases, the human-mouse technology is not suitable for delivering human antibody development candidates.

In addition, since we are an independent, development-stage biotechnology company, we are not a party to agreements that restrict our right to enter into collaborative arrangements with third parties.

mAb, ADC and RTX 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, ADC and RTX 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.

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.

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As of June 14, 2013 we have one issued United States patent relating to G-MAB.

(1) The Cynviloq patent portfolio consists of 1 issued patent and 3 US patent applications all filed and prosecuted by the Cynviloq manufacturer, Samyang. The patent protection provided by the Samyang family of patents expires in 2028.

(2) The RTX product is protected by a small family of patents, one of which has issued in the U.S., that provide product protection until 2021. In addition, there is a family of a formulation for our RTX formulation that provides product protection until 2034 or 2035.

(3) 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 U.S. 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.

(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 derived from our G-MAB library.

(5) There is a family of ADC patents that describe and claim the proprietary conjugation chemistry initially developed by Concortis. These patent application have a term of protection until 2032.

(6) rIVIG is a platform that includes two patent application families.

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.

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Government Regulation

Government authorities in the U.S. (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 U.S., 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 U.S. 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;
- 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 U.S.

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

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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 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.

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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.

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

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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 U.S., 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 U.S. have a similar process that requires the 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 U.S. 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 U.S., there are different types of official

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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 U.S. 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 U.S., or if it affects more than 200,000 individuals in the U.S., 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 U.S. 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 U.S., 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.

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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.

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 (U.S.) 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.

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Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we obtain regulatory approval. In the U.S. and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drugs for a particular indication. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor s decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

In 2003, the U.S. government enacted legislation providing a partial prescription drug benefit for Medicare beneficiaries, which became effective at the beginning of 2006. Government payment for some of the costs of prescription drugs may increase demand for any products for which we receive marketing approval. However, to obtain payments under this program, we would be required to sell products to Medicare recipients through prescription drug plans operating pursuant to this legislation. These plans will likely negotiate discounted prices for our products. Further, the Healthcare Reform Law substantially changes the way healthcare is financed in the U.S. by both government and private insurers. Among other cost containment measures, the Healthcare Reform Law establishes:

- An annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents;
- A new Medicare Part D coverage gap discount program, in which pharmaceutical manufacturers who wish to have their drugs covered under Part D must offer discounts to eligible beneficiaries during their coverage gap period (the donut hole); and
- A new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program.

We expect that federal, state and local governments in the U.S. will continue to consider legislation to limit the growth of healthcare costs, including the cost of prescription drugs. Future legislation could limit payments for pharmaceuticals such as the drug candidates that we are developing.

Different pricing and reimbursement schemes exist in other countries. In the European Community, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, an

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increasing emphasis on managed care in the U.S. has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Other Healthcare Laws and Compliance Requirements

If we obtain regulatory approval for any of our product candidates, we may be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. For example, in the U.S., there are federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services or reward past purchases or recommendations. Violations of these laws can lead to civil and criminal penalties, including fines, imprisonment and exclusion from participation in federal healthcare programs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. The reach of the Anti-Kickback Statute was broadened by the Healthcare Reform Law, which, among other things, amends the intent requirement of the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U.S.C. § 1320a-7b, effective March 23, 2010. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the Healthcare Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute. Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act imposes liability on any person who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The qui tam provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In addition, various states have enacted false claims laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payer and not merely a federal healthcare program. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of $5,500 to $11,000 for each separate false claim.

Also, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, created several new federal crimes, including healthcare fraud, and false statements relating to healthcare matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private third-party payers. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services.

In addition, we may be subject to, or our marketing activities may be limited by, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which established uniform standards for certain covered entities (healthcare providers, health plans and healthcare clearinghouses) and their business associates governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information.

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

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U.S. 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 U.S., 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.

mAb and ADC Clinical Development

We currently focus our efforts primarily in the identification and isolation of human antibody drug candidates and further characterize these antibody candidates in *in vitro* and *in vivo* functional testing. Due to our limited financial resources, we intend to actively seek product development and commercialization partners from the biopharmaceuticals industry to help us advance the clinical development of select product candidates.

mAb, ADC and RTX Marketing and Sales

We currently do not have any clinical or commercial manufacturing or sales capabilities. We may or may not manufacture the products we develop, 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.

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.

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.

Employees

As of December 31, 2013, we had 50 employees and 23 consultants and advisors. A significant number of our management and our other employees and consultants have worked or consulted with pharmaceutical, biotechnology or medical product companies. While we have been successful in attracting skilled and experienced scientific personnel, there can be no assurance that we will be able to attract or retain the necessary qualified employees and/or consultants in the future. None of our employees are covered by collective bargaining agreements and we consider relations with our employees to be good.

Research and Development

Our research and development expenses totaled $9,016,623 and $3,830,404 in the years ended December 31, 2013 and 2012, respectively.

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Corporate Information

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

STI was originally incorporated as San Diego Antibody Company in California in 2006 and was renamed Sorrento Therapeutics, Inc. and reincorporated in Delaware in 2009, prior to the Merger. QuikByte was originally incorporated in Colorado in 1989. Following the Merger, on December 4, 2009, QuikByte reincorporated under the laws of the State of Delaware, or the Reincorporation. Immediately following the Reincorporation, on December 4, 2009, STI merged with and into QuikByte, the separate corporate existence of STI ceased and QuikByte continued as the surviving corporation, or the Roll-Up Merger. Pursuant to the certificate of merger filed in connection with the Roll-Up Merger, QuikByte s name was changed from QuikByte Software, Inc. to Sorrento Therapeutics, Inc. We formed Sorrento Therapeutics, Inc. Hong Kong Limited effective December 4, 2012. Sorrento Hong Kong had no operations in 2012 or 2013. This Annual Report on Form 10-K contains additional trade names, trademarks and service marks of other companies.

Address

Our principal executive offices are located at 6042 Cornerstone Ct. West, Suite B, San Diego, CA 92121, and our telephone number at that address is (858) 210-3700. Our website is www.sorrentotherapeutics.com. The contents of our website are not part of this Form 10-K.

Available Information

We file electronically with the U.S. Securities and Exchange Commission, or SEC, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to reports filed pursuant to Section 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended. We make available on our website at www.sorrentotherapeutics.com, free of charge, copies of these reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Copies of our annual report will also be made available, free of charge, upon written request.

The public may read and copy any materials filed by us with the SEC at the SEC s Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at http://www.sec.gov. The contents of these websites are not incorporated into this filing. Further, our references to the URLs for these websites are intended to be inactive textual references only.

Item 1A. Risk Factors.

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

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involves a substantial degree of risk. There is no assurance that our libraries of fully-human mAbs will be suitable for diagnostic or therapeutic use, or that we will be able to identify and isolate therapeutics product candidates, or develop, market and commercialize these candidates. We do not expect any of our fully-human mAb, ADC, RTX, Cynviloq or related companion diagnostic product candidates to be commercially available for a few years, if at all. Even if we are able to commercialize our product candidates, there is no assurance that these candidates would generate revenues or that any revenues generated would be sufficient for us to become profitable or thereafter maintain profitability.

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

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

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

As of December 31, 2013 and 2012, we had an accumulated deficit of $32.9 million and $11.0 million, respectively. We 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) conduct our BE registration trial related to Cynviloq and prepare for our New Drug Application filing anticipated in 2015, (ii) advance RTX into clinical trials and potentially pursue other human or veterinary indications, (iii) continue to identify and advance a number of potential mAb and ADC drug candidates into preclinical and clinical development activities, (iv) continue our development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products, and (v) expand our corporate infrastructure, including the costs associated with being a NASDAQ public company. As such, we are subject to all risks incidental to the development of new biopharmaceutical products and related companion diagnostics, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders equity and working capital.

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

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

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.

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

- the progress of the development of our fully-human mAb, ADC, RTX, and Cynviloq or related companion diagnostic product candidates;
- the number of product candidates we pursue;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims;
- our plans to establish sales, marketing and/or manufacturing capabilities;
- the effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- general market conditions for offerings from biopharmaceutical companies;
- our ability to establish, enforce and maintain selected strategic alliances and activities required for product commercialization; and
- our revenues, if any, from successful development and commercialization of our product candidates.

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

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

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

Risks Related to Our Business and Industry

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

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

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

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

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

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

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completion of any clinical trials we initiate, including our planned clinical trials of Cynviloq and RTX, in a way that leads to our obtaining marketing approval for our product candidates in a timely manner, or at all.

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

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

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

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

- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board, or IRB, approval at each site;
- recruiting suitable patients to participate in a trial;
- clinical sites deviating from trial protocol or dropping out of a trial;
- having patients complete a trial or return for post-treatment follow-up;
- developing and validating companion diagnostics on a timely basis, if required;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of product candidate for use in clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians and patients perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we intend to rely on CROs and clinical trial sites to

ensure the proper and timely conduct of our clinical trials and we intend to have agreements governing their committed activities, we will have limited influence over their actual performance.

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

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authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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

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

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

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

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

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the U.S. or elsewhere;

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

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

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

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

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

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

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

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

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

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

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FDA publication Approved Drug Products with Therapeutics Equivalence Evaluations, or the Orange Book, for certain of these referenced products. In the event that one or more patents is listed in the Orange Book for the referenced product after our submission of additional information in support of our NDA for Cynviloq, we may also be required to evaluate the applicability of these patents to Cynviloq and submit additional certifications. A paragraph III certification, stating that a listed patent has not expired, but will expire on a particular date, may delay the approval of Cynviloq until the expiration of the patent. A paragraph IV certification, stating that a listed patent is invalid, unenforceable, or not infringed by Cynviloq may require us to notify the patent owner and the holder of the NDA for the referenced product of the existence of the Cynviloq NDA, and may result in patent litigation against us and the entry of a 30-month stay of FDA ability to issue final approval of the 505(b)(2) NDA for Cynviloq.

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

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

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

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

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

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

- regulatory authorities may withdraw approvals of such products;
- regulatory authorities may require additional warnings on the label;

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- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

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

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with current good clinical practices, or cGCP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the European Medicines Agency, or EMA, or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with cGCP regulations. In addition, our clinical trials must be conducted with product produced under current good manufacturing practices, or cGMP, regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

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

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.

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

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

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

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

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

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

We are dependent on our third party manufacturers to conduct process development and scale-up work necessary to support greater clinical development and commercialization requirements for our product candidates. Carrying out these activities in a timely manner, and on commercially reasonable terms, is critical to the successful development and commercialization of our product candidates. We expect our third-party manufacturers are capable of providing sufficient quantities of our product candidates to meet anticipated clinical and full-scale commercial demands, however if third parties with whom we currently work are unable to meet our supply requirements, we will need to secure alternate suppliers. While we believe that there are other contract manufacturers having the

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technical capabilities to manufacture our product candidates, we cannot be certain that identifying and establishing relationships with such sources would not result in significant delay or material additional costs.

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

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

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

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

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;

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

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

injunctions or the imposition of civil or criminal penalties.

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

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

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

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

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

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

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

- disruption of our business and diversion of our management s time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- higher than expected acquisition and integration costs;
- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- increased amortization expenses;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership;
- inability to motivate key employees of any acquired businesses; and
- assumption of known and unknown liabilities.

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

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

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

- the efficacy and safety as demonstrated in clinical trials;
- the timing of market introduction of such product candidate as well as competitive products;
- the clinical indications for which the drug is approved;
- acceptance by physicians, major operators of cancer clinics and patients of the drug as a safe and effective treatment;

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

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

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

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

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

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

the prevalence and severity of adverse side effects; and

the effectiveness of our sales and marketing efforts.

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

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

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

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

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

- developing product candidates and technologies generally;
- undertaking preclinical testing and clinical trials;
- obtaining FDA and other regulatory approvals of product candidates;
- formulating and manufacturing product candidates; and
- launching, marketing and selling product candidates.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers

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

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

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

- successfully and efficiently 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.

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

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

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

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

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

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

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

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

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

As one of the key elements of our clinical development strategy, we seek to identify patients within a disease category or indication who may derive selective and meaningful benefit from the product candidates we are developing. In collaboration with partners, we plan to develop companion diagnostics to help us to more accurately identify patients within a particular category or indication, both during our clinical trials and in connection with the commercialization of certain of our product candidates. Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate regulatory approval prior to commercialization. We do not develop companion diagnostics internally and thus we are dependent on the sustained cooperation and effort of our third-party collaborators in developing and obtaining approval for these companion diagnostics. We and our collaborators may encounter difficulties in developing and obtaining approval for the companion diagnostics, including issues relating to selectivity/specificity, analytical validation, reproducibility, or clinical validation. Any delay or failure by our collaborators to develop or obtain regulatory approval of the companion diagnostics could delay or prevent approval of our product candidates. In addition, our collaborators may encounter production difficulties that could constrain the supply of the companion diagnostics, and both they and we may have difficulties gaining acceptance of the use of the companion diagnostics in the clinical community. If such companion diagnostics fail to gain market acceptance, it would have an adverse effect on our ability to derive revenues from sales of our products. In addition, the diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

Our product development efforts may not be successful.

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

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

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

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

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

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

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

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

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

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

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patient authorization is subject to the limits set forth in the authorization (i.e., for use in research and in submissions to regulatory authorities for product approvals). As such, we are required to implement policies, procedures and reasonable and appropriate security measures to protect individually identifiable health information we receive from covered entities, and to ensure such information is used only as authorized by the patient. Any violations of these rules by us could subject us to civil and criminal penalties and adverse publicity, and could harm our ability to initiate and complete clinical studies required to support regulatory applications for our proposed products. In addition, HIPAA does not replace federal, state, or other laws that may grant individuals even greater privacy protections. We can provide no assurance that future legislation will not prevent us from generating or maintaining personal data or that patients will consent to the use of their personal information, either of which may prevent us from undertaking or publishing essential research. These burdens or risks may prove too great for us to reasonably bear, and may adversely affect our ability to achieve profitability or maintain 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 U.S. Congress could amend the BPCIA to significantly shorten this exclusivity period as proposed by President Obama, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. In addition, a competitor could decide to forego the biosimilar route and submit a full BLA after completing its own preclinical studies and clinical trials. In such cases, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its product as soon as it is approved.

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

Our research and development activities may involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for using, storing, handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations. We do not currently maintain hazardous materials insurance coverage. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially harm our business.

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

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

We are highly dependent on key members of our management and scientific staff, especially Henry Ji, Ph.D, Chief Executive Officer and President; Vuong Trieu, Chief Scientific Officer; David Miao, Chief Technology Officer; George Uy, Chief Commercial Officer; and Richard Vincent, Chief Financial Officer. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level, and senior managers as well as junior, mid-level, and senior scientific and medical personnel. The loss of any of our executive officers, key employees or key consultants and our inability to find suitable replacements could impede the achievement of our research and development objectives, potentially harm our business, financial condition and prospects. Furthermore, recruiting and retaining qualified scientific personnel to perform research and development work in the future is critical to our success. We may be unable to attract and retain personnel on acceptable terms given the competition among biotechnology, biopharmaceutical and health care companies, universities and non-profit research institutions for experienced scientists. Certain of our current officers, directors, scientific advisors and/or consultants or certain of the officers, directors, scientific advisors and/or consultants hereafter appointed may from time to time serve as officers, directors, scientific advisors and/or consultants of other biopharmaceutical or biotechnology companies. We do not maintain key man insurance policies on any of our officers or employees. All of our employees are employed at will and, therefore, each employee may leave our employment at any time.

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

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,

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

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

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

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

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

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

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

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

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

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

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

injury to our reputation;

withdrawal of clinical trial participants;

initiation of investigations by regulators;

costs to defend the related litigation;

a diversion of management s time and our resources;

substantial monetary awards to trial participants or patients;

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

loss of revenues from product sales; and

the inability to commercialize our product candidates.

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

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

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

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

Our principal executive offices, which house our research and development programs, are located in San Diego, California. Our facilities may be affected by natural or man-made disasters. Earthquakes are of particular significance since our facilities are located in an earthquake-prone area. We are also vulnerable to damage from other types of disasters, including power loss, attacks from extremist organizations, fire, floods and similar events. In the event that our facilities were affected by a natural or man-made disaster, we may be forced to curtail our operations and/or rely on third-parties to perform some or all of our research and development activities. Although we believe we possess adequate insurance for damage to our property and the disruption of

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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 2013 and 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.

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.

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

Effective in March 2014, as amended and restated, we have a $12.5 million loan and security agreement with Oxford Finance LLC, or Oxford, and Silicon Valley Bank, or SVB, that is secured by a lien covering substantially all of our assets, excluding intellectual property. As of December 31, 2013, under our initial $5.0 million loan and security agreement with Oxford and SVB entered into in September 2013, we had an outstanding principal balance of $5.0 million. The amended and restated loan and security agreement contains customary affirmative and negative covenants and events of default. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports and maintain insurance coverage. The negative covenants include, among others, restrictions on transferring collateral, changing our business, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments and creating other liens on our assets, in each case subject to customary exceptions. If we default under the loan agreement, the lenders may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the lender s right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. The lenders could declare a default upon the occurrence of any event that they interpret as a material adverse change as defined under the loan agreement, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by the lenders of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Risks Related to the Acquisitions of IgDraSol, Sherrington and Concortis

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

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

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

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

During 2013, we incurred significant legal and professional fees in connection with such acquisitions. We expect to incur additional costs integrating the companies operations, higher development and regulatory costs, and personnel, which cannot be estimated accurately at this time. If the total costs of the integration of our

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companies and advancement of the Cynviloq, RTX or Concortis assets exceed the anticipated benefits of the acquisition, our financial results could be adversely affected.

Risks Related to Our Intellectual Property

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

Our success, competitive position and future revenues will depend in part on our ability to obtain and maintain patent protection for our product candidates, methods, processes and other technologies, to prevent third parties from infringing on our proprietary rights and to operate without infringing upon the proprietary rights of third parties. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. We attempt to protect our proprietary position by maintaining trade secrets and by filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We have one issued U.S. patent covering our G-MAB® which expires in 2022 and the examination of its European equivalent is currently in progress. In 2011, several improvement patent applications were filed for our proprietary antibody library technology. In 2013, we filed 14 antibody family patents. In 2013, we filed three patent application families for the Concortis conjugation chemistry. However, due to the difficulties of enforcing such antibody library technology, we filed a key patent application in the U.S. only and requested nonpublication. We have commenced generating a patent application portfolio of patents to protect each product candidate in our pipeline. However, the patent position of biopharmaceutical companies involves complex legal and factual questions, and therefore we cannot predict with certainty whether any patent applications that we have filed or that we may file in the future will be approved or any resulting patents will be enforced. In addition, third parties may challenge, seek to invalidate or circumvent any of our patents, once they are issued. Thus, any patents that we own or license from third parties may not provide any protection against competitors. Any patent applications that we have filed or that we may file in the future, or those we may license from third parties, may not result in patents being issued. Also, patent rights may not provide us with adequate proprietary protection or competitive advantages against competitors with similar technologies.

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

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

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

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

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

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

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

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

- obtain licenses, which may not be available on commercially reasonable terms, if at all, and may be non-exclusive, thereby giving our competitors access to the same intellectual property licensed to us;
- redesign our products or processes to avoid infringement;
- stop using the subject matter validly claimed in the patents held by others;
- pay damages; and
- defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our valuable management resources.

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

Our plans to file a NDA under Section 505(b)(2) means we will have to file a subparagraph iv certification for the Orange Book-listed patents for Abraxane.

It is our clear opinion that making, using or selling a ***Cynviloq*** commercial product will not infringe any of the Orange Book listed patents for Abraxane. However, because the Orange Book listed patents require a paclitaxel formulation having human serum albumin coating its particles (and ***Cynviloq*** does not have human serum albumin in its formulation), there can be no assurance that our potential commercial launch of ***Cynviloq*** will not be delayed (up to a maximum of 30 months) in case a frivolous lawsuit is filed by the manufacturer of Abraxane.

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

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

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

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

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,

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we may have to pay substantial damages, including treble damages and attorneys fees for willful infringement, obtain one or more licenses from third parties, limit our uses, pay royalties or redesign our infringing product candidates, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly.

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

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the U.S. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

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

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

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

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

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

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

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

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

Risks Related to Ownership of Our Common Stock

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

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

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

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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 effectively integrate the acquired companies operations;

general political and economic conditions;

effects of natural or man-made catastrophic events; and

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

Further, the equity markets in general have recently experienced extreme price and volume fluctuations. Continued market fluctuations could result in extreme volatility in the price of our common stock, which could

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cause a decline in the value of our common stock. Price volatility of our common stock might worsen if the trading volume of our common stock is low. The realization of any of the above risks or any of a broad range of other risks, including those described in these Risk Factors, could have a dramatic and material adverse impact on the market price of our common stock.

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

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

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

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

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

Our quarterly operating results may fluctuate significantly.

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

- variations in the level of expenses related to our development programs;
- the addition or termination of clinical trials;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting our product candidates;
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements; and
- if Cynviloq receives regulatory approval, the level of underlying demand for that product and wholesalers buying patterns.

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

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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 December 31, 2013, our directors, executive officers and principal stockholders beneficially owned, in the aggregate, over 27.8% of our outstanding voting securities. As a result, if some or all of them acted together, they would have the ability to exert significant influence over the election of our board of directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may also have the effect of delaying or preventing a change in control of our company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

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

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

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

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

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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 within the past three years, subject to certain exceptions as described in the Delaware General Corporation Law.

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

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

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

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

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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.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We currently lease: (i) approximately 12,000 square feet of corporate office and laboratory space in San Diego, California, (ii) approximately 6,350 square feet of laboratory and office space at a second location in San Diego, California, and (iii) approximately 2,400 square feet of office space in Irvine, California. Our initial lease agreement for our corporate office and laboratory space expires in September 2014, but includes an option to extend the term of the lease for one additional four-year period. In June 2012, we entered into a separate lease arrangement for an additional 3,216 square feet of laboratory space adjacent to our corporate office, which expires in April 2017, and contains an option to extend the term for the additional rental space by five years at the then prevailing rate. The lease for our second location in San Diego expires in June 2018. Our Irvine lease, as amended, expires in March 2015. We believe that our current facilities are adequate to meet our needs for the foreseeable future and that, should it be needed, suitable additional space will be available to accommodate expansion of our operations on commercially reasonable terms.

Item 3. Legal Proceedings.

We are not currently a party to any legal proceedings that, individually or in the aggregate, are deemed to be material to our financial condition or results of operations.

Item 4. Mine Safety Disclosures.

None.

PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is traded on The NASDAQ Capital Market under the symbol SRNE and began quotation on The NASDAQ Capital Market in October 2013. Previously, our common stock was traded on the OTCBB under the symbol SRNE and began quotation on the OTCBB on an

unpriced basis in December 2006.

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Our common stock trades only sporadically and has experienced in the past, and is expected to experience in the future, significant price and volume volatility.

The following table sets forth the range of high and low bid quotations for our common stock, as reported by NASDAQ and OTCBB for the fourth quarter ending December 31, 2013 and by the OTCBB, on a quarterly basis for the three quarters ended September 30, 2013 and the fiscal year ended December 31, 2012. Quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions. On July 30, 2013, we completed a 1-for-25 reverse split of its common stock. All common shares and per common share amounts in the table have been adjusted retroactively to reflect the effects of this action.

	2013		2012	
First Quarter	$ 8.75	$ 4.00	$ 14.75	$ 5.00
Second Quarter	12.00	2.50	19.25	3.00
Third Quarter	10.00	5.20	11.25	3.75
Fourth Quarter	10.30	7.80	6.25	1.50

Holders of Record

As of March 14, 2014, there were 235 holders of record of our common stock.

Dividend Policy

We paid no cash dividends in respect of our common stock during our two most recent fiscal years, and we have no plans to pay any dividends or make any other distributions in the foreseeable future. The payment by us of dividends, if any, in the future, rests within the discretion of our board of directors and will depend, among other things, upon our earnings, capital requirements and financial condition.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table sets forth additional information with respect to the shares of common stock that may be issued upon the exercise of options and other rights under our existing equity compensation plans and arrangements in effect as of December 31, 2013. The information includes the number of shares covered by, and the weighted average exercise price of, outstanding options and the number of shares remaining available for future grant, excluding the shares to be issued upon exercise of outstanding options.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders[1]	1,044,100	$ 6.52	293,400[2]
Equity compensation plans not approved by security holders[3]	3,200	$ 1.12	
Total	1,047,300	$ 6.51	293,400

(1) Comprised of our 2009 Stock Incentive Plan, or the 2009 Plan.

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(2) Comprised solely of shares subject to awards available for future issuance under the 2009 Plan. In April 2013, the Company s stockholders approved, among other items, the amendment and restatement of the 2009 Stock Incentive Plan, or the Stock Plan, to increase the number of common stock authorized to be issued pursuant to the Stock Plan to 1,360,000. Such shares of the Company s common stock are reserved for issuance to employees, non-employee directors and consultants of the Company. In addition, this amount will be automatically increased annually on the first day of each fiscal year by the lesser of: (i) 1% of the aggregate number of shares of the Company s common stock outstanding on the last day of the immediately preceding fiscal year, (ii) 200,000 shares, or (iii) an amount approved by the administrator of the Stock Plan. As of December 31, 2013, 1,360,000 shares were authorized under the 2009 Plan, with 293,400 shares remaining available for future issuance under the plan.

(3) Comprised solely of shares issued to non-employee directors prior to our adoption of the 2009 Plan.

Item 6. Selected Financial Data.

As a smaller reporting company, as defined by Item 10(f)(1) of Regulation S-K we are not required to provide the information set forth in this Item.

Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the financial statements and the related notes and other information that are included elsewhere in this Form 10-K. This discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties, such as our plans, objectives, expectations and intentions. Actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of a number of factors, including those set forth under the cautionary note regarding Forward-Looking Statements contained elsewhere in this Form 10-K. Additionally, you should read the Risk Factors section of this Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

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

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

Through December 31, 2013, we identified and further developed a number of potential drug product candidates across various therapeutic areas, and intend to select several lead product candidates to further advance into preclinical development activities in 2014. It is too early to assess which of these candidates, if any, will merit further evaluation in clinical trials. Our libraries were designed to facilitate the rapid identification and isolation of highly specific, antibody therapeutic product candidates that are fully-human and that bind to disease

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targets appropriate for antibody therapy. We built our initial antibody expression and production capabilities to enable us to make sufficient product material to conduct preclinical safety and efficacy testing in animal models.

Although we intend to retain ownership and control of some product candidates by advancing the 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.

Recent Developments

Loan and Security Agreement. In September 2013, we entered into a $5,000,000 loan and security agreement with two banks pursuant to which the lenders provided us a term loan, which was funded at closing. The interest rate on the term loan is 7.95% per annum. We will make interest only payments on the outstanding amount of the loan on a monthly basis until November 1, 2014, after which equal monthly payments of principal and interest are due. The maturity date of the term loan is April 15, 2017 and is secured by a security interest in all of our assets except intellectual property, which is subject to a negative pledge. In connection with the loan, the lenders received a warrant to purchase an aggregate 31,250 shares of our common stock at an exercise price of $8.00 per share exercisable for seven years from the date of issuance. The value of the warrants, totaling $214,680, was recorded as debt discount and additional paid-in capital in September 2013. In March 2014, we entered into an amended and restated loan and security agreement, increasing the facility to $12,500,000, with the same two banks under substantially the same terms and security interest. See Note 11 of the Notes to the Consolidated Financial Statements.

Agreement and Plan of Merger with IgDraSol. On March 7, 2013, we entered into various agreements with IgDraSol, a private company focused on the development of Cynviloq, as follows: (i) an exclusive option agreement, (ii) an asset purchase agreement pursuant to which we agreed to purchase all documentation, equipment, information and other know-how related to micellar nanoparticle technology encompassing Tocosol® and related technologies, and (iii) an initial services agreement, pursuant to which, IgDraSol provided certain product development and technology services related to our antibody platform. On September 9, 2013, we exercised our option to acquire IgDraSol and IgDraSol became a wholly-owned subsidiary.

On July 29, 2013, we received official meeting minutes from an End-of-Phase II meeting held on July 23, 2013 for Cynviloq (or IG-001) with the U.S. Food and Drug Administration, or FDA. Cynviloq is initially under development for the treatment of MBC and NSCLC, in the U.S. The FDA Division of Oncology Products 1 agreed that the data available from: (i) the postmarketing surveillance studies conducted in ex-U.S. territories for MBC and NSCLC, (ii) Phase I-III studies for MBC, and (iii) Phase I-II studies in NSCLC, Ovarian, Bladder, and Pancreatic cancers are sufficient to support pursuing the 505(b)(2) Bioequivalence (BE) regulatory submission pathway approach using Abraxane® and Taxol® as the Reference Listed Drugs. Abraxane is an albumin-bound paclitaxel (nab-paclitaxel) product approved for MBC, NSCLC and pancreatic cancer indications. Taxol is a cremophor-based paclitaxel product approved for these indications as well as other cancer indications. We filed our BE protocol in 2013 and commenced the BE study in March 2014.

Agreement and Plan of Merger with Sherrington. On October 9, 2013, we acquired Sherrington for an aggregate of 200,000 shares of our common stock. Sherrington s sole asset was the license rights to resiniferatoxin. Upon acquisition, Sherrington became a wholly-owned subsidiary.

Underwritten Public Offering and Nasdaq Uplisting. In October 2013, we closed an underwritten public offering of 4,150,000 shares, at $7.25 per share, and closed the full exercise of the over-allotment option granted to the representative of the underwriters to purchase an additional 622,500 shares of its common stock, with total gross proceeds of $34.6 million, before underwriting discounts and commissions and other offering expenses payable by us. The common stock began trading on The NASDAQ Capital Market on October 25, 2013 under the symbol SRNE .

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Agreement and Plan of Merger with Concortis. On December 19, 2013, we completed our previously announced merger with Concortis, which providing us with a comprehensive technology platform to create a new generation of homogenous ADC s with site-specific toxin conjugation and consistent drug-antibody ratios. We issued 1,331,978 shares of our common stock to Concortis shareholders which were valued at $8.48 per share, the closing price per share of our common stock as of December 18, 2013.

License Agreement with OPKO Health, Inc. In June 2009, we entered into a limited license agreement, or the OPKO License, with OPKO pursuant to which we granted OPKO an exclusive, royalty-free, worldwide license under all U.S. and foreign patents and patent applications owned or controlled by us or any of our affiliates, or the STI Patents, to (i) develop, manufacture, use, market, sell, offer to sell, import and export certain products related to the development, manufacture, marketing and sale of drugs for ophthalmological indications, or the OPKO Field, and (ii) use and screen any population of distinct molecules covered by any claim of the STI Patents or which is derived by use of any process or method covered by any claim of the STI Patents to identify, select and commercialize certain products within the OPKO Field. In December 2013, we entered into a termination and release agreement with OPKO whereby we terminated the OPKO License in its entirety for a cash payment of $2,680,000.

Results of Operations

The following discussion of our operating results explains material changes in our results of operations for the years ended December 31, 2013 and 2012. The discussion should be read in conjunction with the consolidated financial statements and related notes included elsewhere in this Form 10-K.

Comparison of the Years Ended December 31, 2013 and 2012

Revenues. Revenues were $460,148 for the year ended December 31, 2013, as compared to $583,774 for the year ended December 31, 2012. The net decrease of $123,626 is due to decreased activities under two active grants received from the National Institute of Allergy and Infectious Diseases, a division of the National Institutes of Health, or NIH, in the year ended December 31, 2013 as compared to three active grants for the year ended December 31, 2012.

In May 2010, we were awarded an Advanced Technology Small Business Technology Transfer Research grant to support our program to generate and develop novel antibody therapeutics and vaccines to combat Staph infections, including Methicillin-resistant Staph, or the Staph Grant award. The project period for the Phase 1 Staph Grant award covered a two-year period which commenced in June 2010 and ended in May 2012, with a total grant award of $600,000. We recorded revenue associated with the grant as the related costs and expenses were incurred. During the year ended December 31, 2013 and for the period from Inception through December 31, 2013, we recorded $0 and $600,000 of revenue associated with the Staph Grant award, respectively.

In July 2011, we were awarded a second Advanced Technology Small Business Technology Transfer Research grant to support our program to generate and develop antibody therapeutics and vaccines to combat C. difficile infections, or the C. difficile Grant award. The project period for the C. difficile Grant award covers a two-year period which commenced in June 2011 and ended in June 2013, with a total grant award of $600,000. The C. difficile Grant award revenues for the years ended December 31, 2013 and 2012 and for the period from Inception through December 31, 2013 were $143,940, $335,579 and $592,717, respectively.

In June 2012, we were awarded a third Advanced Technology Small Business Technology Transfer Research grant, with an initial award of $300,000, to support our program to generate and develop novel human antibody therapeutics to combat Staph infections, including Methicillin-resistant Staph, or the Staph Grant II award. The project period for the phase I grant covers a two-year period which commenced in June 2012, with a total grant award of $600,000. The Staph Grant II award revenues for the years ended December 31, 2013 and 2012, and for the period from Inception through December 31, 2013, were $307,833, $128,816 and $436,649, respectively.

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Sales and service revenues of $8,375 were derived from our Concortis subsidiary that was acquired in December 2013. We had no other revenue during the years ended December 31, 2013 and 2012 as we have not yet developed any product candidates for commercialization or earned any licensing or royalty payments.

We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the unpredictability of the demand for products and services offered as well as the timing and amount of grant awards, research and development reimbursements and other payments received under any strategic collaborations.

Cost of revenues. Cost of revenues relate to sales and services costs totaling $4,440. The costs generally include employee-related expenses including salary and benefits, direct materials and overhead costs including rent, depreciation, utilities, facility maintenance and insurance.

Research and Development Expenses. Research and development expenses for the years ended December 31, 2013 and 2012 were $9,016,623 and $3,830,404, respectively. Research and development expenses include the costs to identify, isolate and advance human antibody drug candidates derived from our libraries, costs to initiate and/or conduct our bioequivalence, or BE, registration trial related to Cynviloq and prepare for our New Drug Application filing anticipated in 2015, preclinical testing expenses and the expenses associated with fulfilling our development obligations related to the NIH grant awards, collectively the NIH Grants. Such expenses consist primarily of salaries and personnel related expenses, stock-based compensation expense, preclinical testing, clinical development expenses, laboratory supplies, consulting costs, depreciation and other expenses. The increase of $5,186,219 is primarily attributable to salaries and compensation related expense, preclinical testing, depreciation, consulting and lab supply costs incurred in connection with our expanded research and development activities, our BE registration trial and receipt of the two NIH Grant awards in July 2011 and June 2012, respectively. We expect research and development expenses to increase in absolute dollars as we: (i) advance our Cynviloq BE registration trial (a single bioequivalence study) and pursue other potential indications, including expenses incurred under agreements with CROs and investigative sites that conduct their clinical trials, the cost of acquiring, developing and manufacturing clinical trial materials, and other regulatory operating activities, (ii) incur incremental expenses associated with our efforts to advance a number of potential drug candidates into preclinical development activities, (iii) continue to identify and advance a number of fully human therapeutic antibody and ADC preclinical drug candidates, (iv) incur higher salary, lab supply and infrastructure costs incurred in connection with supporting all of the Company s programs

Acquired In-process Research and Development Expenses. Acquired in-process research and development expenses for the years ended December 31, 2013 and 2012 were $5,985,542 and $0, respectively. Acquired in-process research and development expenses include: (i) the costs associated with entering into a termination and release agreement with OPKO whereby we terminated the OPKO License in its entirety, (ii) the purchase price of Tocosol, and (iii) the purchase price of the license rights to RTX.

General and Administrative Expenses. General and administrative expenses for the years ended December 31, 2013 and 2012 were $6,317,157 and $1,605,978, respectively. General and administrative expenses consist primarily of salaries and personnel related expenses for executive, finance and administrative personnel, stock-based compensation expense, professional fees, infrastructure expenses, legal and accounting expenses and other general corporate expenses. The increase of $4,711,179 is primarily attributable to higher salaries and related compensation expenses, stock-based compensation, legal costs related general corporate and IP matters, consulting and business development expenses and higher compliance costs associated with our public reporting obligations. We expect general and administrative expenses to increase in absolute dollars as we: (i) incur incremental expenses associated with expanded operations and development efforts, compliance with our public reporting obligations, (ii) assume all of the ongoing operating costs associated with the mergers of IgDraSol, Sherrington and Concortis, and integrate their operations.

Intangible Amortization. Intangible amortization for the years ended December 31, 2013 and 2012 was $804,070 and $0, respectively. The increase resulted primarily from the acquisition and amortization of

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intangible license rights from IgDraSol, from the amortization of our exclusive irrevocable option agreement to acquire IgDraSol, and from acquired technology and customer relationships from Concortis.

Interest Expense. Interest expense for the years ended December 31, 2013 and 2012 was $253,194 and $0, respectively. The increase in interest expense resulted from borrowings under the equipment loan entered into in February 2013 and from borrowings under the loan and security agreement entered into in September 2013.

Interest Income. Interest income for the years ended December 31, 2013 and 2012 was $9,615 and $7,300, respectively. The increase in interest income resulted from higher average cash balances in 2013 as compared to 2012. We expect that continued low interest rates will significantly limit our interest income in the near term.

Net Loss. Net loss for the years ended December 31, 2013 and 2012 was $21,911,263 and $4,845,308, respectively. The increase in net loss is mainly attributable to the expanded research and development, in-process research and development, and general and administrative activities.

Liquidity and Capital Resources

As of December 31, 2013 and 2012, we had $31,666,732 and $5,091,312 in cash and cash equivalents, respectively. The increase in cash is primarily attributable to: (i) the closing of our underwritten public offering in October 2013 and the closing of a private placement in March 2013 with aggregate gross proceeds of $41,000,000, (ii) net borrowings under our $5,000,000 loan and security agreement, and (iii) the issuance of $1,850,000 of convertible promissory notes, which automatically converted into 256,119 shares of our common stock upon the closing of the underwritten public offering.

Cash Flows from Operating Activities. Net cash used for operating activities was $16,489,614 for 2013 and is primarily attributable to our net loss of $21,908,863, which was partially offset by $4,951,264 in non-cash activities relating to stock-based compensation, acquired in-process research and development, depreciation and amortization expense. Net cash used for operating activities was $3,797,476 for 2012 and primarily reflects a net loss of $4,845,308, which was partially offset by $1,156,429 in non-cash activities relating primarily to stock-based compensation and depreciation expense.

We expect to continue to incur substantial and increasing losses and have negative net cash flows from operating activities as we seek to expand and support our clinical and preclinical development and research activities.

Cash Flows from Investing Activities. Net cash used for investing activities was $503,480 for 2013 as compared to $547,884 for 2012. The net cash used related primarily to equipment acquired for research and development activities and the purchase of intangible assets partially offset by cash acquired in connection with the mergers of IgDraSol and Concortis.

We expect to increase our investment in equipment as we seek to expand and progress our research and development capabilities.

Cash Flows from Financing Activities. Net cash provided by financing activities for 2013 and 2012 was $43,568,514 and $5,970,123, respectively, which were primarily derived from the sale of our common stock in an underwritten public offering and private placement transactions. In addition, cash was provided by increases in net borrowings under our $5,000,000 loan and security agreement and the issuance of $1,850,000 of convertible promissory notes.

Future Liquidity Needs. From inception through December 31, 2013, we have principally financed our operations through an underwritten public offering and private equity financings with aggregate net proceeds of $53,152,820, as we have not generated any product related revenue from operations to date, and do not expect to

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generate significant revenue for several years, if ever. We will need to raise additional capital before we exhaust our current cash resources in order to continue to fund our research and development, including our plans for clinical and preclinical trials and new product development, as well as to fund operations generally. As and if necessary, we will seek to raise additional funds through various potential sources, such as equity and debt financings, or through corporate collaboration and license agreements. We can give no assurances that we will be able to secure such additional sources of funds to support our operations, or, if such funds are available to us, that such additional financing will be sufficient to meet our needs.

In March 2014, we entered into an amended and restated loan and security agreement, increasing the September 2013 facility from $5,000,000 to $12,500,000, with two banks. The amended and restated loan was funded in March 2014, and bears interest at 7.95% per annum. We will make interest only payments on the outstanding amount of the loan on a monthly basis until October 1, 2014, after which equal monthly payments of principal and interest are due until the loan maturity date of September 30, 2017. In the event we raise $30 million of net equity or proceeds from a collaboration, if any, the interest only period will be extended by six months. Such loan is secured by a security interest in substantially all of our assets, excluding intellectual property, which is subject to a negative pledge. In connection with the amended and restated loan and security agreement, the Lenders received a warrant to purchase an aggregate 34,642 shares of our common stock at an exercise price of $12.99 per share, which is exercisable for seven years from the date of issuance. (See Note 11 of the Notes to the Consolidated Financial Statements).

We anticipate that we will continue to incur net losses into the foreseeable future as we: (i) conduct our BE registration trial related to Cynviloq and prepare for our New Drug Application filing anticipated in 2015, (ii) advance RTX into clinical trials and potentially pursue other human or veterinary indications, (iii) continue to identify and advance a number of potential mAb and ADC drug candidates into preclinical and clinical development activities, (iv) continue our development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products, and (v) expand our corporate infrastructure, including the costs associated with being a NASDAQ public company. We believe we have the ability to meet all obligations due over the course of the next twelve months.

We plan to continue to fund our losses from operations and capital funding needs through public or private equity or debt financings, strategic collaborations, licensing arrangements, asset sales, government grants or other arrangements. We filed a universal shelf registration statement on Form S-3 with the Securities and Exchange Commission (SEC), which was declared effective by the SEC in July 2013. The Shelf Registration Statement provides us with the ability to offer up to $100 million of securities, including equity and other securities as described in the registration statement. After the October 2013 underwritten offering, we now have the ability to offer up to $65.4 million of additional securities. Pursuant to the Shelf Registration Statement, we may offer such securities from time to time and through one or more methods of distribution, subject to market conditions and our capital needs. Specific terms and prices will be determined at the time of each offering under a separate prospectus supplement, which will be filed with the SEC at the time of any offering. However, we cannot be sure that such additional funds will be available on reasonable terms, or at all. If we are unable to secure adequate additional funding, we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. In addition, if we do not meet our payment obligations to third parties as they come due, we may be subject to litigation claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. Any of these actions could materially harm our business, results of operations, and future prospects.

If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

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Related Party Transactions. In May 2012, pursuant to the December 2011 Stock Purchase Agreement, as amended and restated, we issued 1,500,000 shares of common stock, in a private placement transaction, at $4.00 per share for aggregate gross proceeds of $6,000,000. 250,000 of the shares were purchased by an investor, Hongye SD Group, LLC, of which Dr. Henry Ji, our Chief Executive Officer and President, is a managing director.

Critical Accounting Policies

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. We evaluate our estimates and assumptions on an ongoing basis. Our estimates are based on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Our actual results could differ from these estimates.

We believe the following accounting policies and estimates are most critical to aid in understanding and evaluating our reported financial results.

Cash and Cash Equivalents. We consider all highly liquid investments purchased with original maturities of three months or less to be cash equivalents. We minimize our credit risk associated with cash and cash equivalents by periodically evaluating the credit quality of our primary financial institution. The balance at times may exceed federally insured limits. As of December 31, 2013, we have not experienced any losses on such accounts.

Stock-Based Compensation. We account for stock-based compensation in accordance with authoritative guidance for stock-based compensation, which requires us to measure the cost of employee services received in exchange for equity incentive awards, including stock options, based on the grant date fair value of the award. The fair value is estimated using the Black-Scholes option pricing model. The resulting cost is recognized over the period during which the employee is required to provide services in exchange for the award, which is usually the vesting period. We recognize compensation expense over the vesting period using the straight-line method and classify these amounts in the consolidated statements of operations based on the department to which the related employee reports. To the extent that we issue future stock incentive awards to employees, our stock-based compensation expense will be increased by the additional unearned compensation resulting from such additional issuances.

We account for equity instruments, including restricted stock or stock options, issued to non-employees in accordance with authoritative guidance for equity based payments to non-employees. Stock options issued to non-employees are accounted for at their estimated fair value determined using the Black-Scholes option-pricing model. The fair value of options granted to non-employees is re-measured as they vest, and the resulting increase in value, if any, is recognized as expense during the period the related services are rendered. Restricted stock issued to non-employees is accounted for at its estimated fair value upon vesting. We evaluate the assumptions used to value stock awards to non-employees on a periodic basis. If factors change and we employ different assumptions, including any significant change in the estimated fair value of common stock, stock-based compensation expense may differ significantly from what we have recorded historically. In addition, to the extent that we issue future stock incentive awards to non-employees, our stock-based compensation expense will be increased by the additional unearned compensation resulting from such additional issuances.

Revenue Recognition. Our revenues are generated from grant awards and a Collaboration Agreement. The revenue from grant awards is based upon subcontractor costs and internal costs incurred that are specifically covered by each grant, and where applicable, plus a facilities and administrative rate that provides funding for overhead expenses. These revenues are recognized when expenses have been incurred by subcontractors or when we incur internal expenses that are related to the grant. The revenue from the Collaboration Agreement is derived

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from the completion of certain development services and the reimbursement of certain development costs incurred to provide such development services as provided for in the Collaboration Agreement. Revenue from upfront, nonrefundable service fees are recognized when earned, as evidenced by written acknowledgement from the collaborator, or other persuasive evidence that all service deliverables have been achieved, provided that the service deliverables are substantive and their achievability was not reasonably assured at the inception of the Collaboration Agreement. Any amounts received prior to satisfying our revenue recognition criteria are recorded as deferred revenue.

Revenues from sales and services are generated from the sale of customized reagents and providing professional services. Reagents are used for preparing ADCs, these reagents include industrial standard cytotoxins, linkers, and linker-toxins. The professional services include providing synthetic expertise to customer s synthesis by delivering them proprietary cytotoxins, linkers and linker-toxins and ADC service using industry standard toxin and antibodies provided by customers. Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) the product has been shipped or the services have been rendered, (iii) the price is fixed or determinable, and (iv) collectability is reasonably assured.

Off-Balance Sheet Arrangements

From our inception through December 31, 2013, we did not engage in any off-balance sheet arrangements, as defined in Item 303(a)(4) of Regulation S-K.

Recent Accounting Pronouncements

Refer to Note 2, Nature of Operations and Summary of Significant Accounting Polices, in the accompanying notes to the consolidated financial statements for a discussion of recent accounting pronouncements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

As a smaller reporting company, as defined by Item 10(f)(1) of Regulation S-K, we are not required to provide the information set forth in this Item.

Item 8. Financial Statements and Supplementary Data.

Our consolidated financial statements and supplementary data required by this item are set forth at the pages indicated in Item 15(a)(1) and (a)(2), respectively, of this Form 10-K.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC s regulations, rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow for timely decisions regarding required disclosure.

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of

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achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. As required by Rule 13a-15(b) promulgated by the SEC under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Form 10-K. Based on the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Form 10-K.

Management s Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) promulgated by the SEC under the Exchange Act. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2013.

This Form 10-K does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management s report was not subject to attestation by our registered public accounting firm pursuant to rules of the SEC that permit us to provide only management s report in this Form 10-K.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended December 31, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

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

On March 30, 2014, Dr. Daniel Levitt resigned as a member of our board of directors. On March 31, 2014, Richard Vincent, Executive Vice President and Chief Financial Officer resigned as a member of our board of directors so that we would remain in compliance with Nasdaq rules with respect to number of independent directors.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information regarding our directors, including the audit committee and audit committee financial experts, and executive officers and compliance with Section 16(a) of the Exchange Act will be included in our 2014 Proxy Statement and is incorporated herein by reference.

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We have adopted a Code of Business Conduct and Ethics for all of our directors, officers and employees as required by NASDAQ governance rules and as defined by applicable SEC rules. Stockholders may locate a copy of our Code of Business Conduct and Ethics on our website at *www.sorrentotherapeutics.com* or request a copy without charge from:

Sorrento Therapeutics, Inc.

Attention: Investor Relations

6042 Cornerstone Court West, Suite B

San Diego, CA 92121

We will post to our website any amendments to the Code of Business Conduct and Ethics, and any waivers that are required to be disclosed by the rules of either the SEC or NASDAQ.

Item 11. Executive Compensation.

The information required by this item regarding executive compensation will be included in our 2014 Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item regarding security ownership of certain beneficial owners and management will be included in the 2014 Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships, Related Transactions and Director Independence.

The information required by this item regarding certain relationships and related transactions and director independence will be included in the 2014 Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this item regarding principal accounting fees and services will be included in the 2014 Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a)(1) Financial Statements

Reference is made to the Index to Consolidated Financial Statements of Sorrento Therapeutics, Inc. appearing on page F-1 of this report.

(a)(2) Financial Statement Schedules

The schedules required to be filed by this item have been omitted because of the absence of conditions under which they are required, or because the required information is included in the consolidated financial statements or the notes thereto.

(a)(3) Exhibits

Exhibit

No.	Description
2.1+	Option Agreement, dated March 7, 2013, by and between IgDraSol, Inc. and Sorrento Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to the Registrant s Quarterly Report on Form 10-Q/A filed with the SEC on July 12, 2013).

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Exhibit

No.	Description
2.2*	Agreement and Plan of Merger between Sorrento Therapeutics, Inc. and IgDraSol, Inc. dated September 9, 2013 (incorporated by reference to Exhibit 2.1 to the Registrant s Current Report on Form 8-K filed with the SEC on September 11, 2013).
2.3*	Agreement of Merger by and among Sorrento Therapeutics, Inc., Catalyst Merger Sub, Inc., Concortis Biosystems, Corp., Zhenwei Miao and Gang Chen dated as of November 11, 2013 (incorporated by reference to Exhibit 2.1 to the Registrant s Current Report on Form 8-K filed with the SEC on November 14, 2013).
3.1	Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant s Quarterly Report on Form 10-Q filed with the SEC on May 15, 2013).
3.2	Certificate of Amendment of the Restated Certificate of Incorporation of Sorrento Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K filed with the SEC on August 1, 2013).
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).
3.4	Certificate of Designation of Rights, Preferences and Privileges of Series A Junior Participating Preferred Stock of Sorrento Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K filed with the SEC on November 12, 2013).
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	Form of Convertible Promissory Note (incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed with the SEC on October 21, 2013).
4.3	Rights Agreement, dated as of November 7, 2013 by and between Sorrento Therapeutics, Inc. and Computershare Trust Company, N.A., as rights agent (incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed with the SEC on November 12, 2013).
10.1	Amended and Restated Stock Purchase Agreement dated May 14, 2012 by and between the Sorrento Therapeutics, Inc. and the investors whose names appear on the signature pages thereof (incorporated by reference to Exhibit 10.1 to Registrant s Current Report on form 8-K filed with the SEC on May 14, 2012).
10.2	Standard Multi-Tenant Office Lease-Net, dated July 28, 2008, by and between Sorrento Therapeutics, Inc. and Suntree Garden, LLC (incorporated by reference to Exhibit 10.6 to the Registrant s Current Report on Form 8-K filed with the SEC on September 21, 2009).
10.3	First Amendment to Office Lease, dated August 18, 2009, by and between Sorrento Therapeutics, Inc. and Suntree Garden, LLC (incorporated by reference to Exhibit 10.7 to the Registrant s Current Report on Form 8-K filed with the SEC on September 21, 2009).
10.4	Second Amendment to Office Lease, dated October 1, 2009, by and between Sorrento Therapeutics, Inc. and Suntree Garden, LLC (incorporated by reference to Exhibit 10.10 to the Registrant s Annual Report on Form 10-K filed with the SEC on March 25, 2010).
10.5	Third Amendment to Office Lease, dated November 11, 2010, by and between Sorrento Therapeutics, Inc. and Suntree Garden, LLC (incorporated by reference to Exhibit 10.12 to the Registrant s Annual Report on Form 10-K filed with the SEC on March 30, 2012).
10.6	Fourth Amendment to Office Lease, dated January 17, 2011, by and between Sorrento Therapeutics, Inc. and Suntree Garden, LLC (incorporated by reference to Exhibit 10.13 to the Registrant s Annual Report on Form 10-K filed with the SEC on March 30, 2012).

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Exhibit No.	Description
10.7	Fifth Amendment to Office Lease, dated February 9, 2012, by and between Sorrento Therapeutics, Inc. and Suntree Garden, LLC (incorporated by reference to Exhibit 10.14 to the Registrant s Annual Report on Form 10-K filed with the SEC on March 30, 2012).
10.8	Sixth Amendment to Office Lease, dated June 20 2012, by and between Sorrento Therapeutics, Inc. and Suntree Garden, LLC (incorporated by reference to Exhibit 10.15 to the Registrant s Quarterly Report on Form 10-Q filed with the SEC on August 14, 2012).
10.9+	Patent Assignment Agreement, dated June 10, 2009, by and between Henry H. Ji and Sorrento Therapeutics, Inc. (incorporated by reference to Exhibit 10.10 to the Registrant s Current Report on Form 8-K filed with the SEC on September 21, 2009).
10.10+	License Agreement, dated January 8, 2010, by and between The Scripps Research Institute and the Company (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q filed with the SEC on May 14, 2010).
10.11±	Form of Stock Option Agreement (incorporated by reference to Exhibit 10.11 to the Registrant s Current Report on Form 8-K/A filed with the SEC on September 22, 2009).
10.12±	Form of Indemnity Agreement (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed with the SEC on October 23, 2009).
10.13±	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed with the SEC on August 7, 2012).
10.14±	2009 Amended and Restated Stock Incentive Plan, and forms of agreements related thereto (incorporated by reference to Appendix A to the definitive proxy statement filed by Sorrento Therapeutics, Inc. with the Securities and Exchange Commission on April 16, 2013).
10.15±	2009 Equity Incentive Plan, and forms of agreement related thereto (incorporated by reference to Exhibit 10.17 to the Registrant s Annual Report on Form 10-K filed with the SEC on March 25, 2010).
10.16±	Employment Agreement, dated September 21, 2012, by and between Sorrento Therapeutics, Inc. and Henry Ji, Ph.D. (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q filed with the SEC on November 8, 2012).
10.17±	First Amendment to Employment Agreement dated October 18, 2012, by and between Sorrento Therapeutics, Inc. and Henry Ji, Ph.D. (incorporated by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q filed with the SEC on November 8, 2012).
10.18±	Employment Agreement, dated September 21, 2012, by and between Sorrento Therapeutics, Inc. and Richard G. Vincent (incorporated by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q filed with the SEC on November 8, 2012).
10.19±	First Amendment to Employment Agreement, dated October 18, 2012, by and between Sorrento Therapeutics, Inc. and Richard G. Vincent (incorporated by reference to Exhibit 10.4 to the Registrant s Quarterly Report on Form 10-Q filed with the SEC on November 8, 2012).
10.20±	Independent Director Compensation Policy (incorporated by reference to Exhibit 10.28 to the Registrant s Annual Report on Form 10-K filed with the SEC on March 25, 2013).
10.21±	Stock Option Cancellation Agreement and Option Amendment, dated September 30, 2012, by and between Sorrento Therapeutics, Inc. and Richard G. Vincent (incorporated by reference to Exhibit 10.29 to the Registrant s Annual Report on Form 10-K filed with the SEC on March 25, 2013).
10.22±	Stock Option Cancellation Agreement, dated October 17, 2012, by and between Sorrento Therapeutics, Inc. and David Webb, Ph.D (incorporated by reference to Exhibit 10.30 to the Registrant s Annual Report on Form 10-K filed with the SEC on March 25, 2013).

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Exhibit

No.	Description
10.23	Assignment Agreement dated January 7, 2013 by and between Sorrento Therapeutics, Inc., Tien-Li Lee, M.D. and Jane Wu Lee, M.D. (incorporated by reference to Exhibit 10.01 to the Registrant s Quarterly Report on Form 10-Q filed with the SEC on May 15, 2013).
10.24	Loan and Security Agreement between Sorrento Therapeutics, Inc. and Silicon Valley Bank, dated as of February 22, 2013 (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed with the SEC on February 26, 2013).
10.25	Amended and Restated Stock Purchase Agreement dated March 13, 2013 by and between the Sorrento Therapeutics, Inc. and the investors whose names appear on the signature page thereof (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed with the SEC on March 14, 2014).
10.26+	Asset Purchase Agreement, dated March 7, 2013, by and between IgDraSol, Inc. and Sorrento Therapeutics, Inc. (incorporated by reference to Exhibit 10.03 to the Registrant s Quarterly Report on Form 10-Q/A filed with the SEC on July 12, 2013).
10.27+	Initial Services Agreement, dated March 7, 2013, by and between IgDraSol, Inc. and Sorrento Therapeutics, Inc. (incorporated by reference to Exhibit 10.04 to the Registrant s Quarterly Report on Form 10-Q/A filed with the SEC on July 12, 2013).
10.28	Voting Agreement, dated March 7, 2013, by and among Sorrento Therapeutics, Inc., IgDraSol, Inc., and the stockholders signatories thereto (incorporated by reference to Exhibit 10.05 to the Registrant s Quarterly Report on Form 10-Q filed with the SEC on May 15, 2013).
10.29	Option Agreement between Sorrento Therapeutics, Inc. and B.G, Negev Technologies and Applications Ltd. (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q filed with the SEC on August 13, 2013).
10.30*	Loan and Security Agreement dated as of September 27, 2013 among Oxford Finance LLC, Silicon Valley Bank, Sorrento Therapeutics, Inc. and IgDraSol, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed with the SEC on October 15, 2013).
10.31*	Registration Rights Agreement by and among Sorrento Therapeutics, Inc. and the stockholders of Sherrington Pharmaceuticals, Inc. dated as of October 9, 2013 (incorporated by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K filed with the SEC on October 15, 2013).
10.32*	Amended and Restated Loan and Security Agreement dated as of March 31, 2014 among Oxford Finance LLC, Silicon Valley Bank, Sorrento Therapeutics, Inc., IgDraSol, Inc., Sherrington Pharmaceuticals, Inc., Concortis Biosystems, Corp. and Ark Animal Therapeutics, Inc.
10.33±	Employment Agreement, dated December 19, 2013, by and between Sorrento Therapeutics, Inc. and Zhenwei Miao.
21.1	List of Subsidiaries
23.1	Consent of Mayer Hoffman McCann P.C.
31.1	Certification of Henry Ji, Ph.D., Principal Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.
31.2	Certification of Richard Glenn Vincent, Principal Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.
32.1	Certification of Henry Ji, Ph.D., Principal Executive Officer, and Richard Glenn Vincent, Principal Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, as amended.

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Exhibit No.	Description
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Non-material schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Registrant hereby undertakes to furnish supplementally copies of any of the omitted schedules and exhibits upon request by the SEC.

\+ The SEC has granted confidential treatment with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

± Management contract or compensatory plan.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: April 1, 2014

SORRENTO THERAPEUTICS, INC.

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title(s)	Date
/s/ Henry Ji **Henry Ji, Ph.D.**	Director, Chief Executive Officer & President *(Principal Executive Officer)*	April 1, 2014
/s/ Richard G. Vincent **Richard G. Vincent**	Chief Financial Officer *(Principal Financial and Accounting Officer)*	April 1, 2014
/s/ William S. Marth **William S. Marth, Ph.D.**	Director	April 1, 2014
/s/ Cam Gallagher **Cam Gallagher**	Director	April 1, 2014
/s/ Kim D. Janda **Kim D. Janda, Ph.D.**	Director	April 1, 2014
/s/ Vuong Trieu **Vuong Trieu**	Director	April 1, 2014
/s/ Mark Durand **Mark Durand**	Director	April 1, 2014
/s/ Jaisim Shah **Jaisim Shah**	Director	April 1, 2014

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Sorrento Therapeutics, Inc.

(a Development Stage Company)

Index to Consolidated Financial Statements

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of

Sorrento Therapeutics, Inc. and Subsidiaries

San Diego, California

We have audited the accompanying consolidated balance sheets of Sorrento Therapeutics, Inc. and Subsidiaries (the Company) as of December 31, 2013 and 2012, and the related consolidated statements of operations, stockholders equity, and cash flows for the years then ended and for the period from January 25, 2006 (Inception) through December 31, 2013. These consolidated financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (U.S.). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Sorrento Therapeutics, Inc. and Subsidiaries as of December 31, 2013 and 2012, and the consolidated results of their operations and their cash flows for the years then ended and for the period from January 25, 2006 (Inception) through December 31, 2013, in conformity with accounting principles generally accepted in the United States of America.

/s/ Mayer Hoffman McCann P.C.

San Diego, CA

April 1, 2014

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SORRENTO THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED BALANCE SHEETS

	December 31, 2013	2012
Assets		
Current assets:		
Cash and cash equivalents	$ 31,666,732	$ 5,091,312
Grants and accounts receivable, net	394,246	79,760
Prepaid expenses and other	570,956	80,918
Total current assets	32,631,934	5,251,990
Property and equipment, net .	2,439,853	1,480,989
Intangibles, net	33,321,192	
Goodwill	24,040,966	
Other	148,058	48,625
Total assets	$ 92,582,003	$ 6,781,604
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 2,153,880	$ 439,533
Accrued payroll and related	1,663,518	77,744
Current portion of deferred compensation	903,763	
Accrued expenses	384,640	66,896
Current portion of debt	373,930	
Total current liabilities	5,479,731	584,173
Long-term liabilities:		
Long-term debt	4,430,864	
Deferred compensation	1,497,004	
Deferred rent	81,242	
Deferred tax liabilities	14,248,000	
Accrued other	36,031	
Commitments and contingencies (Note 8)		
Stockholders equity:		
Preferred stock, $0.0001 par value; 100,000,000 shares authorized and no shares issued or outstanding		
Common stock, $0.0001 par value; 750,000,000 shares authorized and 23,028,100 and 12,004,687 shares issued and outstanding at December 31, 2013 and 2012, respectively	2,303	1,200
Additional paid-in capital	99,668,390	17,146,530
Deficit accumulated during the development stage	(32,861,562)	(10,950,299)
Total stockholders equity	66,809,131	6,197,431
Total liabilities and stockholders equity	$ 92,582,003	$ 6,781,604

See accompanying notes

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SORRENTO THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		Period from January 25, 2006 (Inception) through December 31,
	2013	2012	2013
Revenues:			
Grant	$ 451,773	$ 583,774	$ 2,023,846
Sales and services	8,375		8,375
Collaboration and reimbursable research and development costs			223,453
Total revenues	460,148	583,774	2,255,674
Operating costs and expenses:			
Cost of sales and services revenues	4,440		4,440
Research and development	9,016,623	3,830,404	17,219,949
Acquired in-process research and development	5,985,542		5,985,542
General and administrative	6,317,157	1,605,978	10,888,550
Intangible amortization	804,070		804,070
Total operating costs and expenses	22,127,832	5,436,382	34,902,551
Loss from operations	(21,667,684)	(4,852,608)	(32,646,877)
Interest expense	(253,194)		(253,194)
Interest income	9,615	7,300	38,509
Net loss	$ (21,911,263)	$ (4,845,308)	$ (32,861,562)
Net loss per share basic and diluted	$ (1.46)	$ (0.42)	
Weighted average number of shares during the period basic and diluted	15,045,711	11,405,042	

See accompanying notes

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SORRENTO THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

	Common Stock					
	Shares	Amount	Additional Paid-in Capital	Stockholder Note Receivable	Deficit Accumulated During the Development Stage	Total
Balance, January 25, 2006 (Inception)		$	$	$	$	$
Issuance of common stock for $400 cash to founders	4,077,493	408	(8)			400
Net loss					(75,801)	(75,801)
Balance, December 31, 2006	4,077,493	408	(8)		(75,801)	(75,401)
Net loss					(16,302)	(16,302)
Balance, December 31, 2007	4,077,493	408	(8)		(92,103)	(91,703)
Net loss					(25,745)	(25,745)
Balance, December 31, 2008	4,077,493	408	(8)		(117,848)	(117,448)
Issuance of restricted common stock for $291 cash to consultants in March	296,155	30	261			291
Issuance of common stock for $10 cash and a $30 note to consultants in March	40,775	4	36	(30)		10
Issuance of common stock for cash at $0.98 per share in June, net of issuance costs of $25,999	2,360,611	236	2,273,765			2,274,001
Issuance of common stock for cash at $1.12 per share in September	1,785,375	179	1,999,821			2,000,000
Issuance of common stock to former QuikByte stockholders in connection with the Merger	442,958	44	100,342			100,386
Costs associated with the Merger			(168,767)			(168,767)
Stock-based compensation			54,524			54,524
Net loss					(942,266)	(942,266)
Balance, December 31, 2009	9,003,367	901	4,259,974	(30)	(1,060,114)	3,200,731
Collection of note receivable				30		30
Issuance of common stock for cash at $3.50 per share in December, net of issuance costs of $159,905	1,028,686	102	3,440,393			3,440,495
Stock-based compensation			250,954			250,954
Net loss					(1,808,386)	(1,808,386)
Balance, December 31, 2010	10,032,053	1,003	7,951,321		(2,868,500)	5,083,824
Repurchase of common stock	(44,166)	(5)	(38)			(43)
Issuance of common stock in connection with the exercise of stock options	6,000	1	13,124			13,125
Issuance of common stock for cash at $4.00 per share in December, net of issuance costs of $28,999	500,000	50	1,970,951			1,971,001
			80,039			80,039

Reduction of stock issuance costs accrued in December 2010					
Stock-based compensation			298,034		298,034
Net loss				(3,236,491)	(3,236,491)
Balance, December 31, 2011	10,493,887	1,049	10,313,431	(6,104,991)	4,209,489
Issuance of common stock in connection with the exercise of stock options	10,800	1	36,091		36,092
Issuance of common stock for cash at $4.00 per share in May, net of issuance costs of $65,969	1,500,000	150	5,933,881		5,934,031
Stock-based compensation			863,127		863,127
Net loss				(4,845,308)	(4,845,308)
Balance, December 31, 2012	12,004,687	1,200	17,146,530	(10,950,299)	6,197,431

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SORRENTO THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (Continued)

	Common Stock					
	Shares	Amount	Additional Paid-in Capital	Stockholder Note Receivable	Deficit Accumulated During the Development Stage	Total
Issuance of common stock in connection with the exercise of stock options	7,300	1	17,144			17,145
Issuance of common stock for cash at $4.50 per share in March, net of issuance costs of $64,086	1,426,406	143	6,354,266			6,354,409
Issuance of common stock with assignment agreement	10,000	1	39,999			40,000
Issuance of common stock in connection with IgDraSol merger at $9.25 per share	3,006,641	301	27,811,128			27,811,429
Issuance of common stock in connection with Sherrington acquisition at $8.48 per share	200,000	20	1,697,580			1,697,600
Issuance of common stock warrants in connection with loan and security agreement			214,680			214,680
Issuance of common stock in connection with Concortis merger at $8.48 per share	1,331,978	133	11,295,040			11,295,173
Issuance of common stock for convertible note holders at $7.25 per share	256,119	26	1,856,806			1,856,832
Issuance of common stock for cash at $7.25 per share in October, net of issuance costs of $3,253,770	4,772,500	477	31,346,483			31,346,960
Issuance of common stock in lieu of cash legal fees	12,469	1	100,000			100,001
Stock-based compensation			1,788,734			1,788,734
Net loss					(21,911,263)	(21,911,263)
Balance, December 31, 2013	23,028,100	$ 2,303	$ 99,668,390	$	$ (32,861,562)	$ 66,809,131

See accompanying notes

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SORRENTO THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,		Period from January 25, 2006 (Inception) through December 31,
	2013	2012	2013
Operating activities			
Net loss	$ (21,911,263)	$ (4,845,308)	$ (32,861,562)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	1,290,407	293,302	1,769,096
Stock-based compensation	1,788,734	863,127	3,255,373
Acquired in-process research and development	1,904,542		1,904,542
Increase (decrease) in cash resulting from changes in, net of acquisitions:			
Grants and accounts receivable	116,755	(18,522)	36,995
Prepaid expenses and other	(441,179)	(76,947)	(550,572)
Accounts payable	878,641	(23,171)	1,055,587
Accrued expenses and other liabilities	(116,251)	10,043	108,428
Net cash used for operating activities	(16,489,614)	(3,797,476)	(25,282,113)
Investing activities			
Purchases of property and equipment	(420,233)	(547,884)	(2,141,950)
Purchase of intangible assets	(511,065)		(511,065)
Cash acquired in connection with Mergers	427,818		532,678
Net cash used for investing activities	(503,480)	(547,884)	(2,120,337)
Financing activities			
Proceeds from issuance of common stock, net of issuance costs and repurchases	37,701,369	5,934,031	53,152,820
Proceeds from exercise of stock options	17,145	36,092	66,362
Net payments of deferred compensation	(1,000,000)		(1,000,000)
Net borrowings under debt agreements	6,850,000		6,850,000
Net cash provided by financing activities	43,568,514	5,970,123	59,069,182
Net change in cash and cash equivalents	26,575,420	1,624,763	31,666,732
Cash and cash equivalents at beginning of period	5,091,312	3,466,549	
Cash and cash equivalents at end of period	$ 31,666,732	$ 5,091,312	$ 31,666,732
Supplemental disclosures:			
Cash paid during the period for:			
Income taxes	$ 800	$ 800	$ 5,600

Non-cash financing activities:

In December 2012 and 2013, the Company purchased equipment with an aggregate cost of $237,960 and $385,958, which has been included in accounts payable as of December 31, 2012 and 2013, respectively.

In January 2013, $40,000 of purchased patent rights were paid from the issuance of 10,000 shares of common stock.

In September 2013, October 2013, and December 2013, the Company issued 3,006,641, 200,000, and 1,331,978 shares of common stock valued at $27,811,429, $1,697,600, and $11,295,173 to effect the IgDraSol, Inc., Sherrington Pharmaceuticals, Inc., and Concortis Biosystems Corp. mergers, respectively. See Note 5.

See accompanying notes

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SORRENTO THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Operations and Business Activities

Nature of Operations and Basis of Presentation

Sorrento Therapeutics, Inc. (NASDAQ: SRNE), together with its wholly-owned subsidiaries (collectively, the Company) is a biopharmaceutical company focused on the discovery, acquisition, development and commercialization of proprietary drug therapeutics for addressing significant unmet medical needs in the U.S., Europe and additional international markets. The Company s primary therapeutic focus is oncology, including the treatment of chronic cancer pain, but is also developing therapeutic products for other indications, including immunology and infectious diseases. The Company s pipeline consists of its lead oncology product candidate Cynviloq , a micellar paclitaxel formulation, resiniferatoxin (or RTX), a non-opiate, ultra potent and selective agonist of the TRPV-1 receptor for intractable pain in end-stage disease, as well as fully human therapeutic antibodies derived from our proprietary G-MAB® library platform and antibody drug conjugates, or ADCs, and recombinant intravenous immunoglobulin, or rIVIG.

Through December 31, 2013, the Company had devoted substantially all of its efforts to product development, acquiring companies and in-licensing assets, raising capital and building infrastructure, and had not realized revenues from its planned principal operations. Accordingly, the Company is considered to be in the development stage.

The accompanying consolidated financial statements include the accounts of the Company s wholly-owned subsidiaries, IgDraSol, Inc., or IgDraSol, Sherrington Pharmaceuticals, Inc., or Sherrington, Concortis Biosystems, Corp., or Concortis, and Sorrento Therapeutics, Inc. Hong Kong Limited, or Sorrento Hong Kong, which was registered effective December 4, 2012. Sorrento Hong Kong had no operating activity in 2012 and 2013. All intercompany balances and transactions have been eliminated in consolidation.

Reverse Stock Split

On July 30, 2013, the Company completed a 1-for-25 reverse split of its common stock. All common shares and per common share amounts in the financial statements and footnotes have been adjusted retroactively to reflect the effects of this action.

Liquidity and Going Concern

The Company anticipates that it will continue to incur net losses into the foreseeable future as it: (i) conducts its bioequivalence, or BE, registration trial related to Cynviloq and prepares for its New Drug Application filing anticipated in 2015, (ii) advance RTX into clinical trials and potentially pursue other human or veterinary indications, (iii) continues to identify and advance a number of potential mAb and ADC drug candidates into preclinical and clinical development activities, (iv) continues development of, and seeks regulatory approvals for, its product candidates, and begin to commercialize any approved products, and (v) expand corporate infrastructure, including the costs associated with being a NASDAQ public company.

In September 2013, the Company entered into a $5,000,000 loan and security agreement with two banks pursuant to which the lenders provided the Company a term loan, which was funded at closing. Contemporaneously with such closing, the Company repaid its then outstanding equipment loan balance of $762,361. In October 2013, the Company: (i) closed an underwritten public offering of 4,772,500 shares of its common stock, including the Underwriters exercise of an over-allotment of 622,500 shares of common stock, at $7.25 per share and total gross proceeds of $34.6 million, and (ii) issued an aggregate $1,850,000 principal amount of Convertible Promissory Notes (the Notes) with an interest rate of 7% per annum. Such Notes and

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SORRENTO THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

related accrued interest automatically converted into 256,119 shares of common stock at $7.25 per share, effective in October 2013. In March 2014, the Company entered into an amended and restated loan and security agreement, increasing the September 2013 facility to $12,500,000 from $5,000,000, with the same two banks, which was funded at closing. This new loan will be used to pay off the Company s existing $5,000,000 term loan. The interest rate on the amended and restated loan is 7.95% per annum. The Company will make interest only payments on the outstanding amount of the loan on a monthly basis until October 1, 2014, after which equal monthly payments of principal and interest are due until the Term Loan maturity date of September 30, 2017. In the event the Company raises $30 million of net equity or proceeds from a collaboration, if any, the interest only period will be extended by six months. See Note 11. Management believes the Company has the ability to meet all obligations due over the course of the next twelve months.

The Company plans to continue to fund its losses from operations and capital funding needs through public or private equity or debt financings, strategic collaborations, licensing arrangements, asset sales, government grants or other arrangements. The Company filed a universal shelf registration statement on Form S-3 with the Securities and Exchange Commission (SEC), which was declared effective by the SEC in July 2013. The Shelf Registration Statement provides the Company the ability to offer up to $100 million of securities, including equity and other securities as described in the registration statement. After the October 2013 underwritten offering, the Company has the ability to offer up to $65.4 million of additional securities. Pursuant to the Shelf Registration Statement, the Company may offer such securities from time to time and through one or more methods of distribution, subject to market conditions and the Company s capital needs. Specific terms and prices will be determined at the time of each offering under a separate prospectus supplement, which will be filed with the SEC at the time of any offering. However, the Company cannot be sure that such additional funds will be available on reasonable terms, or at all. If the Company is unable to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. In addition, if the Company does not meet its payment obligations to third parties as they come due, it may be subject to litigation claims. Even if the Company is successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. Any of these actions could materially harm the Company s business, results of operations, and future prospects.

If the Company raises additional funds by issuing equity securities, substantial dilution to existing stockholders would result. If the Company raises additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict the Company s ability to operate its business.

Business Activities

Reverse Merger Transaction and Accounting

On September 21, 2009, QuikByte Software, Inc., a shell company (QuikByte) acquired Sorrento Therapeutics, Inc., a privately held Delaware corporation (STI), in a reverse merger (the Reverse Merger). Pursuant to the Reverse Merger, all of the issued and outstanding shares of STI common stock were exchanged into an aggregate of 6,775,032 shares of QuikByte common stock and STI became a wholly owned subsidiary of QuikByte. The holders of QuikByte s common stock as of immediately prior to the Reverse Merger held an aggregate of 2,228,332 shares of QuikByte s common stock. STI and QuikByte reincorporated in Delaware in December 2009, and on December 4, 2009, STI merged with and into QuikByte, the separate corporate existence of STI ceased and QuikByte continued as the surviving corporation. Contemporaneously, QuikByte Software,

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SORRENTO THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Inc. changed its name to Sorrento Therapeutics, Inc. In connection with the Reverse Merger, the Company received cash of $104,860.

Agreement and Plan of Merger with IgDraSol

On March 7, 2013, the Company entered into various agreements with IgDraSol, Inc. (IgDraSol) a private company focused on the development of Cynviloq, an oncologic agent for the treatment of metastatic breast cancer, or MBC, non-small cell lung cancer, or NSCLC, and other cancers, as follows: (i) an exclusive option agreement, (ii) an asset purchase agreement pursuant to which the Company agreed to purchase all documentation, equipment, information and other know-how related to micellar nanoparticle technology encompassing Tocosol® and related technologies, and (iii) an initial services agreement, pursuant to which, IgDraSol is to provide certain product development and technology services related to the Company s antibody platform. On September 9, 2013, the Company exercised its option to acquire IgDraSol. See Note 5.

Loan and Security Agreement

In September 2013, the Company entered into a $5,000,000 loan and security agreement with two banks pursuant to which the lenders provided the Company a term loan, which was funded at closing. In connection with such closing, the Company repaid its then outstanding equipment loan balance of $762,361. The interest rate on the term loan is 7.95% per annum. The Company will make interest only payments on the outstanding amount of the loan on a monthly basis until November 1, 2014, after which equal monthly payments of principal and interest are due. The maturity date of the term loan is April 15, 2017 and is secured by a security interest in all of the Company s assets except intellectual property. The Company s intellectual property is subject to a negative pledge. In connection with the term loan, the lenders received a warrant to purchase an aggregate 31,250 shares of the Company s common stock at an exercise price of $8.00 per share exercisable for seven years from the date of issuance. The value of the warrants, totaling $214,680, was recorded as debt discount and additional paid-in capital in the consolidated balance sheet as of December 31, 2013. See Note 6 and 11.

Agreement and Plan of Merger with Sherrington Pharmaceuticals

On October 9, 2013, the Company acquired Sherrington Pharmaceuticals, Inc. (Sherrington) a privately-held company focused on the development of a chronic pain treatment for end-stage cancer patients and other severe pain indications. The Company issued an aggregate of 200,000 shares of its common stock to the Sherrington shareholders. See Note 5.

Underwritten Public Offering and Nasdaq Uplisting

In October 2013, the Company closed an underwritten public offering of 4,150,000 shares, at $7.25 per share, and closed the full exercise of the over-allotment option granted to the representative of the underwriters to purchase an additional 622,500 shares of its common stock, with total gross proceeds of $34.6 million, before underwriting discounts and commissions and other offering expenses payable by the Company. The common stock began trading on The NASDAQ Capital Market on October 25, 2013 under the symbol SRNE .

Agreement and Plan of Merger with Concortis

On December 19, 2013, the Company completed its previously announced merger with Concortis Biosystems, Corp., (Concortis) providing the Company with a comprehensive technology platform to create a

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SORRENTO THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

new generation of homogenous antibody drug conjugates (ADC s) with site-specific toxin conjugation and consistent drug-antibody ratios. The Company issued 1,331,978 shares of its common stock to Concortis shareholders. See Note 5.

2. Significant Accounting Policies

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Management believes that these estimates are reasonable; however, actual results may differ from these estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of three months or less to be cash equivalents. The Company minimizes its credit risk associated with cash and cash equivalents by periodically evaluating the credit quality of its primary financial institution. The balance at times may exceed federally insured limits. The Company has not experienced any losses on such accounts.

Fair Value of Financial Instruments

The Company s financial instruments consist of cash and cash equivalents, grants and accounts receivable, prepaid expenses and other assets, accounts payable and accrued expenses. Fair value estimates of these instruments are made at a specific point in time, based on relevant market information. These estimates may be subjective in nature and involve uncertainties and matters of significant judgment and therefore cannot be determined with precision. As of December 31, 2013 and 2012, the carrying amount of cash and cash equivalents, grants and accounts receivable, prepaid expenses and other assets, accounts payable and accrued liabilities are generally considered to be representative of their respective fair values because of the short-term nature of those instruments.

Grants and Accounts Receivable

Grants receivable at December 31, 2013 and 2012 represent amounts due under several federal contracts with the National Institute of Allergy and Infectious Diseases, or NIAID, a division of the National Institutes of Health, or NIH, collectively, the NIH Grants. The Company considers the grants receivable to be fully collectible; accordingly, no allowance for doubtful amounts has been established. If amounts become uncollectible, they are charged to operations.

Accounts receivable at December 31, 2013 consists of trade receivables from sales and services provided to Concortis customers, which are generally unsecured and due within 30 days. Estimated credit losses related to trade accounts receivable are recorded as general and administrative expenses and as an allowance for doubtful accounts within grants and accounts receivable, net. The Company reviews reserves and makes adjustments based on historical experience and known collectability issues and disputes. When internal collection efforts on accounts have been exhausted, the accounts are written off by reducing the allowance for doubtful accounts.

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SORRENTO THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Property and Equipment

Property and equipment are carried at cost less accumulated depreciation. Depreciation of property and equipment is computed using the straight-line method over the estimated useful lives of the assets, which are generally three to five years. Leasehold improvements are amortized over the lesser of the life of the lease or the life of the asset. Repairs and maintenance are charged to expense as incurred.

Acquisitions and Intangibles

The Company has engaged in business combination activity. The accounting for business combinations requires management to make judgments and estimates of the fair value of assets acquired, including the identification and valuation of intangible assets, as well as liabilities assumed. Such judgments and estimates directly impact the amount of goodwill recognized in connection with each acquisition, as goodwill presents the excess of the purchase price of an acquired business over the fair value of its net tangible and identifiable intangible assets.

Patent rights are stated at cost and depreciated on a straight-line basis over the estimated useful lives of the assets, determined to be approximately nineteen years from the date of transfer of the rights to the Company in April 2013. The Company had no patent rights as of December 31, 2012. Amortization expense for the year ended December 31, 2013 and for the period from inception (January 25, 2006) (Inception) through December 31, 2013 was $3,750, which has been included in intangibles amortization.

License rights are stated at cost and depreciated on a straight-line basis over the estimated useful lives of the assets, determined to be approximately fifteen years from the date of acquisition of the rights in September 2013. The Company had no licenses rights as of December 31, 2012. Amortization expense for the year ended December 31, 2013 and for the period from Inception through December 31, 2013 was $585,862, which has been included in intangibles amortization.

Acquired technology is stated at cost and depreciated on a straight-line basis over the estimated useful lives of the assets, determined to be approximately nineteen years from the date of acquisition of the technology in December 2013. The Company had no acquired technology as of December 31, 2012. Amortization expense for the year ended December 31, 2013 and for the period from Inception through December 31, 2013 was $5,779, which has been included in intangibles amortization.

Customer relationships are stated at cost and depreciated on a straight-line basis over the estimated useful lives of the assets, determined to be approximately five years from the date of acquisition. The Company had no customer relationships as of December 31, 2012. Amortization expense for the year ended December 31, 2013 and for the period from Inception through December 31, 2013 was $8,679, which has been included in intangibles amortization.

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets with definite lives, such as property and equipment, acquired technology, customer relationships, patent and license rights, for impairment by considering competition by products prescribed for the same indication, the likelihood and estimated future entry of non-generic and generic competition with the same or similar indication and other related factors. The factors that drive the estimate of the life are often uncertain and are reviewed on a periodic basis or when events occur that warrant review. Recoverability is measured by comparison of the assets book value to future net undiscounted cash flows that

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SORRENTO THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

the assets are expected to generate. There have not been any impairment losses of long-lived assets through December 31, 2013.

Research and Development Costs

All research and development costs are charged to expense as incurred. Such costs primarily consist of lab supplies, contract services, stock-based compensation expense, salaries and related benefits.

Acquired In-Process Research and Development Expense

The Company has acquired and may continue to acquire the rights to develop and commercialize new drug candidates. The up-front payments to acquire a new drug compound, as well as future milestone payments, are immediately expensed as acquired in-process research and development provided that the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, have no alternative future use.

Income Taxes

The provisions of the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 740-10, Uncertainty in Income Taxes, address the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under ASC 740-10, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by taxing authorities, based on the technical merits of the position. The Company has determined that it has no uncertain tax positions.

The Company accounts for income taxes using the asset and liability method to compute the differences between the tax basis of assets and liabilities and the related financial amounts, using currently enacted tax rates.

The Company has deferred tax assets, which are subject to periodic recoverability assessments. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount that more likely than not will be realized. The Company evaluates the recoverability of the deferred tax assets annually.

Revenue Recognition

The Company s inception to date revenues are generated primarily from three NIH and two U.S. Department of Treasury (or U.S. Treasury) grant awards and a feasibility study agreement, or the Collaboration Agreement, that the Company entered into with a third party in July 2010, and from revenues generated from Concortis. The revenue from the NIH and U.S. Treasury grant awards are based upon subcontractor and internal costs incurred that are specifically covered by the grant, and where applicable, a facilities and administrative rate that provides funding for overhead expenses. These revenues are recognized when expenses have been incurred by subcontractors or when the Company incurs internal expenses that are related to the grant.

The revenue from the Collaboration Agreement is derived from the completion of certain development services and the reimbursement of certain development costs incurred to provide such development services. Revenue from upfront, nonrefundable service fees are recognized when earned, as evidenced by written acknowledgement from the collaborator, or other persuasive evidence that all service deliverables have been achieved, provided that the service deliverables are substantive and their achievability was not reasonably assured at the inception of the Collaboration Agreement. Any amounts received prior to satisfying the Company s revenue recognition criteria are recorded as deferred revenue.

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SORRENTO THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Revenues from sales and services are generated from the sale of customized reagents and providing professional services. Reagents are used for preparing ADCs, these reagents include industrial standard cytotoxins, linkers, and linker-toxins. The professional services include providing synthetic expertise to customer s synthesis by delivering them proprietary cytotoxins, linkers and linker-toxins and ADC service using industry standard toxin and antibodies provided by customers. Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) the product has been shipped or the services have been rendered, (iii) the price is fixed or determinable, and (iv) collectability is reasonably assured.

The Company is obligated to accept from customers the return of products sold that are damaged or don t meet certain specifications. The Company may authorize the return of products sold in accordance with the terms of its sales contracts, and estimates allowances for such amounts at the time of sale. The Company has not experienced any sales returns.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with FASB ASC Topic 718, which establishes accounting for equity instruments exchanged for employee services. Under such provisions, stock-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense, under the straight-line method, over the employee s requisite service period (generally the vesting period of the equity grant).

The Company accounts for equity instruments, including restricted stock or stock options, issued to non-employees in accordance with authoritative guidance for equity based payments to non-employees. Stock options issued to non-employees are accounted for at their estimated fair value determined using the Black-Scholes option-pricing model. The fair value of options granted to non-employees is re-measured as they vest, and the resulting increase in value, if any, is recognized as expense during the period the related services are rendered. Restricted stock issued to non-employees is accounted for at their estimated fair value as they vest.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company is required to record all components of comprehensive income (loss) in the consolidated financial statements in the period in which they are recognized. Net income (loss) and other comprehensive income (loss), including foreign currency translation adjustments and unrealized gains and losses on investments, are reported, net of their related tax effect, to arrive at comprehensive income (loss). For the years ended December 31, 2013 and 2012, the comprehensive loss was equal to the net loss.

Net Loss per Share

Net loss per share is presented as both basic and diluted net loss per share. Basic net loss per share excludes any dilutive effects of options, shares subject to repurchase and warrants. Diluted net loss per share includes the impact of potentially dilutive securities. During 2013 and 2012, the Company had securities outstanding which could potentially dilute basic earnings per share in the future, but were excluded from the computation of diluted net loss per share, as their effect would have been anti-dilutive.

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These outstanding securities consist of the following:

	Years Ended December 31,	
	2013	2012
Unvested Restricted Common stock subject to repurchase		13,458
Outstanding options	1,047,300	419,600
Outstanding warrants	221,850	8,000
Weighted average exercise price of options	$ 6.51	$ 3.50

Recent Accounting Pronouncements

In February 2013, a new accounting standard was issued that amended existing guidance to improve the reporting of reclassifications out of accumulated other comprehensive income. The new standard requires the disclosure of significant amounts reclassified from each component of accumulated other comprehensive income and the income statement line items affected by the reclassification. The standard is effective prospectively for interim and annual periods beginning after December 15, 2012. We adopted this guidance as of January 1, 2013 and its adoption did not have an effect on our financial statements.

3. Property and Equipment

Property and equipment consisted of the following as of December 31, 2013 and 2012:

	December 31,	
	2013	2012
Furniture and fixtures	$ 39,281	$ 15,739
Office equipment	80,764	23,039
Lab equipment	3,186,735	1,855,220
Leasehold improvements	65,679	65,679
	3,372,459	1,959,677
Less accumulated depreciation and amortization	(932,606)	(478,688)
	$ 2,439,853	$ 1,480,989

Depreciation expense for the years ended December 31, 2013 and 2012 and for the period from Inception through December 31, 2013 was $453,918, $293,302 and $932,607, respectively.

4. Significant Agreements and Contracts

License Agreement with OPKO Health, Inc.

In June 2009, the Company entered into a limited license agreement, or the OPKO License, with OPKO pursuant to which the Company granted OPKO an exclusive, royalty-free, worldwide license under all U.S. and foreign patents and patent applications owned or controlled by the Company or any of its affiliates, or the STI Patents, to (i) develop, manufacture, use, market, sell, offer to sell, import and export certain products related to the development, manufacture, marketing and sale of drugs for ophthalmological indications, or the OPKO Field, and (ii) use

and screen any population of distinct molecules covered by any claim of the STI Patents or which is derived by use of any process or method covered by any claim of the STI Patents to identify, select and commercialize certain products within the OPKO Field. In December 2013, the Company entered into a

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termination and release agreement with OPKO whereby the Company terminated the OPKO License in its entirety for a cash payment of $2,680,000 which was recorded as in-process research and development expense.

License Agreement with The Scripps Research Institute

In January 2010, the Company entered into a license agreement, or the TSRI License, with The Scripps Research Institute, or TSRI. Under the TSRI License, TSRI granted the Company an exclusive, worldwide license to certain TSRI patent rights and materials based on quorum sensing for the prevention and treatment of Staphylococcus aureus (Staph) infections, including Methicillin-resistant Staph. In consideration for the license, the Company: (i) issued TSRI a warrant for the purchase of common stock, (ii) agreed to pay TSRI a certain annual royalty commencing in the first year after certain patent filing milestones are achieved, and (iii) agreed to pay a royalty on any sales of licensed products by the Company or its affiliates and a royalty for any revenues generated by the Company through its sublicense of patent rights and materials licensed from TSRI under the TSRI License. The TSRI License requires the Company to indemnify TSRI for certain breaches of the agreement and other matters customary for license agreements. The parties may terminate the TSRI License at any time by mutual agreement. In addition, the Company may terminate the TSRI License by giving 60 days notice to TSRI and TSRI may terminate the TSRI License immediately in the event of certain breaches of the agreement by the Company or upon the Company s failure to undertake certain activities in furtherance of commercial development goals. Unless terminated earlier by either or both parties, the term of the TSRI License will continue until the final expiration of all claims covered by the patent rights licensed under the agreement. For the years ended December 31, 2013 and 2012 and for the period from Inception through December 31, 2013, the Company recorded $65,574, $41,835 and $192,919 in patent prosecution and maintenance costs associated with the TSRI License, respectively, which have been included in general and administrative expenses.

The fair value of the warrants to purchase Company common stock, issued in connection with the TSRI License in 2010, of $17,989 was determined using the Black-Scholes valuation model with the following weighted-average assumptions: risk-free interest rate of 2.48%, no dividend yield, expected term of 10 years, and volatility of 102%. Such fair value has been included in general and administrative expenses for the period from Inception through December 31, 2013.

License Agreement with B.G. Negev Technologies and Applications Ltd.

In June 2013, the Company entered into an exclusive option agreement with B.G. Negev Technologies and Applications Ltd. (BGN). Pursuant to the terms of the option agreement, BGN granted the Company an option to receive an exclusive sub-licensable worldwide license in and to certain licensed patent rights to develop and commercialize the licensed products. Licensed patent rights refers to any rights arising out of or resulting from any patent application filed by the Company for certain BGN technology relating to a group of defined fully human antibodies that bind to a Hep. C protease enzyme. In exchange the Company agreed to file one provisional patent application and fund the research of the BGN technology. The option terminates on the latest of (i) twelve months from the effective date (June 30, 2013) or (ii) ten months from the date of filing of a first priority patent application as defined in the agreement.

NIH Grants

In May 2010, the NIAID awarded the Company an Advanced Technology Small Business Technology Transfer Research grant to support the Company s program to generate and develop novel antibody therapeutics and vaccines to combat Staph infections, including Methicillin-resistant Staph, or the Staph Grant award. The project period for the Phase I Staph Grant award covered a two-year period which commenced in June 2010 and

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ended in May 2012, with a total grant award of $600,000. The Company recorded revenue associated with the grant as the related costs and expenses were incurred. During the year ended December 31, 2013 and 2012 and for the period from Inception through December 31, 2013, the Company recorded $0, $119,379 and $600,000 of revenue associated with the Staph Grant award, respectively.

In July 2011, the NIAID awarded the Company a second Advanced Technology Small Business Technology Transfer Research grant to support the Company s program to generate and develop antibody therapeutics and vaccines to combat C. difficile infections, or the C. difficile Grant award. The project period for the Phase I C. difficile Grant award covered a two-year period which commenced in June 2011 and ended in June 2013, with a total grant award of $600,000. During the years ended December 31, 2013 and 2012, and for the period from Inception through December 31, 2013, the Company recorded $143,940, $335,579 and $592,717 of revenue associated with the C. difficile Grant award, respectively.

In June 2012, the NIAID awarded the Company a third Advanced Technology Small Business Technology Transfer Research grant to support the Company s program to generate and develop novel human antibody therapeutics to combat Staph infections, including Methicillin-resistant Staph, or the Staph Grant II award. The project period for the phase I grant covers a two-year period which commenced in June 2012, with a total grant award of $600,000. During the years ended December 31, 2013 and 2012, and for the period from Inception through December 31, 2013, the Company recorded $307,833, $128,816 and $436,649 of revenue associated with the Staph Grant II award, respectively.

Collaboration Agreement

In July 2010, the Company entered into the Collaboration Agreement, with a third party. Under the terms of the Collaboration Agreement, the Company provided certain antibody screening services for an upfront cash fee of $200,000 and was reimbursed for certain costs and expenses associated with providing the services, or the Development Costs. The upfront fee and reimbursable Development Costs were accounted for as separate units of accounting. The Company recorded the gross amount of the reimbursable Development Costs as revenue and the costs associated with these reimbursements are reflected as a component of research and development expense.

Any amounts received by the Company pursuant to the Collaboration Agreement prior to satisfying the Company s revenue recognition criteria are recorded as deferred revenue. All agreed upon services under the Collaboration Agreement were delivered in March 2011. For the period from Inception through December 31, 2013, the Company recognized $223,453 in revenue.

U.S. Treasury Grants

During 2010, the U.S. Treasury awarded the Company two one-time grants totaling $394,480 for investments in qualifying therapeutic discovery projects under section 48D of the Internal Revenue Code. The grants cover reimbursement for qualifying expenses incurred by the Company in 2010 and 2009. For the period from Inception through December 31, 2013, the Company recognized $394,480 in grant revenue.

5. Mergers and Acquisitions

IgDraSol Acquisition Transactions

On March 7, 2013, the Company entered into various agreements with IgDraSol as follows: (i) an exclusive option agreement whereby IgDraSol granted the Company an irrevocable option to acquire IgDraSol by means of

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an agreement and plan of merger, and was paid a non-refundable lump sum payment of $200,000 in April 2013, (ii) an asset purchase agreement pursuant to which the Company purchased 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, and (iii) an initial services agreement, pursuant to which IgDraSol provided the Company with certain product development and technology services related to our antibody platform for $1,000,000. All such services were completed prior to May 31, 2013. In April 2013, the Company entered into a development services agreement with IgDraSol related to the development of Tocosol and related technologies for a total of $1,721,193. Such services were completed in August 2013. The payment for the exclusive option agreement was capitalized and fully amortized as intangible amortization expense as of December 31, 2013.

On September 9, 2013, the Company exercised its option to acquire IgDraSol whereby IgDraSol became a wholly-owned subsidiary and the Company acquired all rights to Cynviloq. Pursuant to the merger agreement, the Company issued 3,006,641 shares of common stock to IgDraSol stockholders and paid $382,275 in cash. Upon the later achievement of a specified regulatory milestone, the Company will issue an additional 1,306,272 shares of common stock to former IgDraSol stockholders.

The Company s lead compound is Cynviloq, a micellar 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®. The Company licensed exclusive distribution rights for Cynviloq in North America, the 27 countries of the European Union, and Australia, from Samyang Biopharmaceuticals Corporation, a South Korean corporation.

The following table summarizes the purchase price of the IgDraSol acquisition, the identified assets acquired and liabilities assumed at the acquisition date ($ in thousands):

Assets acquired:	
Cash	$ 126
Prepaid expenses & other	45
PP&E	121
Intangible license rights	29,105
Goodwill	11,571
Total assets	40,968
Liabilities assumed:	
Accounts payable	168
Accrued expenses	124
Net deferred tax liability	11,571
Total liabilities	11,863
Total purchase price	$ 29,105

The intangible license rights will be amortized using the straight-line method through fiscal 2028 at an annual rate of $1,900,093.

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Sherrington Acquisition

On October 9, 2013, the Company entered into an Agreement and Plan of Merger and Reorganization and acquired privately-held Sherrington in exchange for 200,000 shares of its common stock, for an aggregate purchase price of $1,697,600. Sherrington is focused on the development of a treatment for intractable pain in end-stage disease. RTX is a novel, non-opiate, small molecule that permanently eliminates pain experienced by end-stage cancer patients when directly interacting with the nerve cells. RTX is currently being tested in an investigator-sponsored Phase I/II clinical trial under a Cooperative Research and Development Agreement. To date, 10 patients with terminal cancer pain have been treated at the NIH. The Company intends to launch additional trials to rapidly advance clinical development of the drug in patients with terminal cancer pain. The purchase price was recognized as acquired in-process research and development expense.

Concortis Acquisition

On December 19, 2013, the Company completed its Agreement and Plan of Merger and acquired privately-held Concortis. Upon closing, the Company issued an aggregate of 1,331,978 shares of its common stock to the Concortis shareholders. Certain Concortis employees and consultants are to receive annual deferred compensation payments totaling $1,000,000 on December 31 of each of the years ending 2013, 2014, 2015, and 2016. The net present value of the deferred compensation payments was calculated using the effective interest method, and is included in the purchase price. The total transaction is valued at $14.7 million. Concortis, now a wholly-owned subsidiary, has proprietary cytotoxic payloads as well as C-lock® and K-lock® conjugation technologies that allow for site-specific toxin conjugation to the antibody. These next generation technologies may improve the overall stability and potency of the ADCs. First-generation conjugation technologies lead to inconsistent drug-antibody ratios, which result in a heterogeneous mixture of ADCs. This variability has been a constraining factor in unlocking the full therapeutic potential for current-generation ADCs. The ADC technology complements the Company s existing development programs, particularly its G-MAB® antibody library and related monoclonal antibodies. Concortis uses its proprietary technologies to provide various customized reagents as well as drug conjugation services to customers in the pharmaceutical industry.

The following table summarizes the purchase price of the Concortis acquisition, the identified assets acquired and liabilities assumed at the acquisition date ($ in thousands):

Assets acquired:	
Cash	$ 302
A/R, prepaid expenses & other	535
PP&E	441
Customer relationships	1,320
Technologies	3,410
Goodwill	11,798
Total assets	17,806
Liabilities assumed:	
Accounts payable and accrued expenses	1,118
Net deferred tax liability	2,005
Total liabilities	3,123
Total estimated purchase price	$ 14,683

The intangible customer relationships and acquired technology will be amortized using the straight-line method through fiscal 2018 and 2033, at an annual rate of $264,000 and $175,773, respectively.

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The IgDraSol, Sherrington and Concortis acquisitions are being accounted for in accordance with the acquisition method of accounting under FASB ASC Topic 805, *Business Combinations* (Topic 805). Topic 805 requires, among other things, that identifiable assets acquired and liabilities assumed be recognized at their fair values as of the Acquisition Date. Under the acquisition method of accounting, the purchase consideration is allocated to the assets acquired, including tangible assets and other identifiable intangible assets and liabilities assumed, based on their estimated fair market values on the date of acquisition. Any excess purchase price after the initial allocation to identifiable net tangible and identifiable intangible assets is assigned to goodwill. The fair values set forth above are based in part on third party appraisals in accordance with Topic 805.

Each of these acquisitions are being treated for tax purposes as nontaxable transactions and as such, the historical tax bases of the acquired assets and assumed liabilities, net operating losses, and other tax attributes of IgDraSol, Sherrington and Concortis will carryover. As a result, no new tax goodwill will be created in connection with these acquisitions as there is no step-up to fair value of the underlying tax bases of the acquired net assets. Acquisition accounting includes the establishment of a net deferred tax asset or liability resulting from book tax basis differences related to assets acquired and liabilities assumed on the date of acquisition. Acquisition date deferred tax liabilities relate to specifically identified non-goodwill intangibles acquired. The estimated net deferred tax liability was determined as follows ($ in thousands):

	IgDraSol	Sherrington	Concortis	Total
Intangible license rights acquired	$ 29,105	$	$	$ 29,105
Acquired in-process research and development		1,904		1,904
Intangible customer relationships acquired			1,320	1,320
Intangible technologies acquired			3,410	3,410
Book basis	29,105	1,904	4,730	35,739
Tax basis	55	218	(303)	(30)
Difference	(29,050)	(1,686)	(5,033)	(35,769)
Estimated tax rate	39.83%	39.83%	39.83%	39.83%
Estimated net deferred tax liability	$ (11,571)	$ (672)	$ (2,005)	$ (14,248)

Unaudited Pro Forma Financial Information

The unaudited pro forma financial information in the table below summarizes the combined results of operations for the Company as though the IgDraSol, Sherrington and Concortis acquisitions occurred as of January 1, 2013. The unaudited pro forma financial information for all periods presented also includes the business combination accounting effects resulting from these acquisitions including amortization charges from acquired intangible assets. The unaudited pro forma financial information as presented below is for informational purposes only and does not purport to be indicative of the results of operations for future periods or the results what actually would have been realized had the entities been a single entity during these periods. The unaudited pro forma combined results are presented in thousands, except share and per share information.

	Years Ended December 31,	
	2013	2012
Total Revenues	$ 3,850	$ 584

Loss from operations	$ (23,589)	$ (4,853)
Net loss	$ (24,084)	$ (4,845)
Net loss per share basic and diluted	$ (1.60)	$ (0.42)

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6. Debt

Equipment Loan and Security Agreement

In February 2013, the Company entered into an equipment loan and security agreement with a bank pursuant to which the lender provided the Company a loan in the principal amount of $875,888 to finance certain equipment. Interest accrues on the outstanding advance at the fixed rate of 5.15%. The Company granted the lender a security interest in any equipment financed under the equipment loan agreement. In September 2013, the equipment loan was paid in full, the Company had no further obligations thereunder, and the bank released its security interest in such assets.

Loan and Security Agreement

In September 2013, the Company entered into a $5,000,000 loan and security agreement with two banks pursuant to which the lenders provided the Company a term loan, which was funded at closing. The interest rate on such loan is 7.95% per annum. The Company will make interest only payments on the outstanding amount of the loan on a monthly basis until November 1, 2014, after which equal monthly payments of principal and interest are due until the loan maturity date of April 15, 2017. The loan is secured by a security interest in all of the Company s assets except intellectual property, which is subject to a negative pledge. In connection with the loan, the Lenders received a warrant to purchase an aggregate 31,250 shares of the Company s common stock at an exercise price of $8.00 per share exercisable for seven years from the date of issuance. The original value of the warrants, totaling $214,680, was recorded as debt discount and additional paid-in capital. See Note 11.

At the Company s option, it may prepay all of the outstanding principal balance, subject to certain pre-payment fees ranging from 1% to 3% of the prepayment amount. In the event of a final payment of the loans under the loan agreement, either in the event of repayment of the loan at maturity or upon any prepayment, the Company is obligated to pay the amortized portion of the final fee of $200,000.

The Company is also subject to certain affirmative and negative covenants under the loan agreement, including limitations on its ability to: undergo certain change of control events; convey, sell, lease, license, transfer or otherwise dispose of any equipment financed by loans under the loan agreement; create, incur, assume, guarantee or be liable with respect to indebtedness, subject to certain exceptions; grant liens on any equipment financed under the loan agreement; and make or permit any payment on specified subordinated debt. In addition, under the loan agreement, subject to certain exceptions, the Company is required to maintain with the lender its primary operating, other deposit and securities accounts.

Long-term debt and unamortized discount balances are as follows:

Balance at December 31, 2012	$
Face value of term loan	5,000,000
Fair value of warrants	(214,680)
Accretion of debt discount	19,474
Balance at December 31, 2013	$ 4,804,794

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Future minimum payments under the loan and security agreement are as follows:

Year Ending December 31,	
2014	$ 851,106
2015	2,211,925
2016	2,211,925
2017	734,841
Total future minimum payments	6,009,797
Unamortized interest	(1,009,797)
Debt discount	(195,206)
Total minimum payment	4,804,794
Current portion	(373,930)
Long-term debt	$ 4,430,864

7. Stockholders Equity

Common Stock and Related Party Transaction

In February 2006, in conjunction with the founding of the Company, 4,077,493 shares of common stock were issued to founders, at the pre-Merger par value, for total consideration of $400 in cash.

In March 2009, the Company: (i) issued 296,155 shares of restricted common stock to certain consultants, at the pre-Merger par value, for aggregate gross proceeds of $291, and (ii) issued 40,775 shares of unrestricted common stock to certain consultants for aggregate cash gross proceeds of $10 and issued a note receivable for $30. The note was paid in full in 2010.

In June 2009, the Company issued 2,360,611 shares of common stock at $0.98 per share for aggregate gross proceeds of $2,300,000 in a private placement transaction. Related stock issuance costs totaled $25,999.

In September 2009, and in connection with the Merger, the Company: (i) issued 1,785,375 shares of common stock, in a private placement transaction, at $1.12 per share for aggregate gross proceeds of $1,999,620, (ii) issued 442,958 shares of common stock to the former stockholders of QuikByte, and (iii) incurred costs associated with the Merger totaling $168,767.

In December 2010, the Company issued 1,028,686 shares of common stock, in a private placement transaction, at $3.50 per share for aggregate gross proceeds of $3.6 million. Related stock issuance costs were estimated at $159,905. In 2011, the Company reduced its stock issuance costs accrued in 2010 by $80,039.

In December 2011, the Company entered into a Stock Purchase Agreement and issued 500,000 shares of common stock, in a private placement transaction, at $4.00 per share for aggregate gross proceeds of $2,000,000. In May 2012, pursuant to the Stock Purchase Agreement, as amended and restated, the Company issued 1,500,000 shares of common stock, in a private placement transaction, at $4.00 per share for aggregate gross proceeds of $6,000,000. Two hundred and fifty thousand of the shares were purchased by an investor, Hongye SD Group, LLC, of which Dr. Henry Ji, the Company s Chief Executive Officer and President, is a managing director.

In January 2013, the Company entered into the assignment agreement and issued 10,000 shares of common stock valued at $40,000.

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In March 2013, the Company entered into a Stock Purchase Agreement and issued 1,426,406 shares of common stock, in a private placement transaction, at $4.50 per share for aggregate gross proceeds of $6,418,495.

On October 30, 2013, the Company closed an underwritten public offering of 4,150,000 shares of common stock, at $7.25 per share, and closed the full exercise of the over-allotment option granted to the representative of the underwriters to purchase an additional 622,500 shares of its common stock, with total gross proceeds of $34.6 million, before underwriting discounts and commissions and other offering expenses payable by the Company. The common stock began trading on The NASDAQ Capital Market on October 25, 2013 under the symbol SRNE .

Purchase Warrants

Concurrent with the offering, the Company agreed to issue and sell to the underwriters a warrant (Underwriters Warrant) for the purchase of an aggregate of 182,600 shares of common stock, for $100. The Underwriters Warrant agreement is exercisable, in whole or in part, commencing on a date which is one (1) year after the effective date of the Registration Statement and expiring on the five-year anniversary of the effective date of the Registration Statement at an initial exercise price per share of common stock of $9.0625, which is equal to 125% of the initial public offering price of $7.25 per share.

Convertible Promissory Notes

In October 2013, the Company issued an aggregate $1,850,000 principal amount of Notes that bear interest at 7% per annum. Concurrently with the closing of the public offering, such Notes and related accrued interest totaling $6,832 automatically converted into 256,119 shares of common stock.

Stock Incentive Plans

2009 Equity Incentive Plan

In February 2009, prior to the Merger, the Company s Board of Directors approved the 2009 Equity Incentive Plan, or the EIP, under which 400,000 shares of common stock were reserved for issuance to employees, non-employee directors and consultants of the Company. In March 2009, the Company issued 296,154 restricted common stock awards to certain consultants for aggregate gross proceeds of $291, of which the Company repurchased 44,166 unvested shares of restricted common stock for $43 in January 2011. The restricted shares vest monthly over four years and all remaining shares were fully vested as of December 31, 2013. No further shares are available for grant under the EIP.

2009 Non-Employee Director Grants

In September 2009, prior to the adoption of the 2009 Stock Incentive Plan, the Company s Board of Directors approved the reservation and issuance of 8,000 nonstatutory stock options to the Company s non-employee directors. The outstanding options vested on the one year anniversary of the vesting commencement date in October 2010. Such options are exercisable on the two year anniversary of the grant date and are generally exercisable for up to 10 years from the grant date. No further shares may be granted under this plan and, as of December 31, 2013, 3,200 options were outstanding.

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The following table summarizes stock option activity as of December 31, 2012 and 2013, and the changes for the years then ended:

	Options Outstanding	Weighted-Average Exercise Price
Outstanding at December 31, 2011	4,800	$ 1.12
Options Granted		
Options Canceled		
Options Exercised	(1,600)	$ 1.12
Outstanding at December 31, 2012	3,200	$ 1.12
Options Granted		
Options Canceled		
Options Exercised		
Outstanding, Vested and Exercisable at December 31, 2013	3,200	$ 1.12

2009 Stock Incentive Plan

In October 2009, the Company s stockholders approved the 2009 Stock Incentive Plan. In April 2013, the Company s stockholders approved, among other items, the amendment and restatement of the 2009 Stock Incentive Plan, or the Stock Plan, to increase the number of common stock authorized to be issued pursuant to the Stock Plan to 1,360,000. Such shares of the Company s common stock are reserved for issuance to employees, non-employee directors and consultants of the Company. In addition, this amount will be automatically increased annually on the first day of each fiscal year by the lesser of: (i) 1% of the aggregate number of shares of the Company s common stock outstanding on the last day of the immediately preceding fiscal year, (ii) 200,000 shares, or (iii) an amount approved by the administrator of the Stock Plan. The Stock Plan provides for the grant of incentive stock options, non-incentive stock options, stock appreciation rights, restricted stock awards, unrestricted stock awards, restricted stock unit awards and performance awards to eligible recipients. Recipients of stock options shall be eligible to purchase shares of the Company s common stock at an exercise price equal to no less than the estimated fair market value of such stock on the date of grant. The maximum term of options granted under the Stock Plan is ten years. Employee option grants will generally vest 25% on each anniversary of the original vesting date over four years. The vesting schedules for grants to non-employee directors and consultants will be determined by the Company s Compensation Committee. Stock options are generally not exercisable prior to the applicable vesting date, unless otherwise accelerated under the terms of the applicable stock plan agreement. Unvested shares of the Company s common stock issued in connection with an early exercise however, may be repurchased by the Company upon termination of the optionee s service with the Company.

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The following table summarizes stock option activity as of December 31, 2012 and 2013, and the changes for the years then ended:

	Options Outstanding	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2011	113,100	$ 3.00	
Options Granted	341,400	$ 4.00	
Options Canceled	(28,900)	$ 3.75	
Options Exercised	(9,200)	$ 3.25	
Outstanding at December 31, 2012	416,400	$ 3.75	$ 54,750
Options Granted	650,200	$ 8.19	
Options Canceled	(15,200)	$ 3.92	
Options Exercised	(7,300)	$ 2.35	
Outstanding at December 31, 2013	1,044,100	$ 6.52	$ 1,859,880
Vested and Exercisable at December 31, 2013	319,325	$ 5.80	$ 777,462

The Company uses the Black-Scholes valuation model to calculate the fair value of stock options. The fair value of employee stock options was estimated at the grant date using the following assumptions:

	Years Ended December 31, 2013	2012
Weighted-average grant date fair value	$ 8.19	$ 7.25
Dividend yield		
Volatility	87%	103%
Risk-free interest rate	1.68%	0.88%
Expected life of options	6.1 years	5.5 years

The assumed dividend yield was based on the Company s expectation of not paying dividends in the foreseeable future. Due to the Company s limited historical data, the estimated volatility incorporates the historical and implied volatility of comparable companies whose share prices are publicly available. The risk-free interest rate assumption was based on the U.S. Treasury s rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The weighted average expected life of options was estimated using the average of the contractual term and the weighted average vesting term of the options.

The total employee stock-based compensation recorded as operating expenses was $1,545,038, $324,958, and $1,963,854 for the years ended December 31, 2013 and 2012 and for the period from Inception through December 31, 2013, respectively.

The total unrecognized compensation cost related to unvested stock option grants as of December 31, 2013 was $3,752,673 and the weighted average period over which these grants are expected to vest is 3.3 years.

The Company records equity instruments issued to non-employees as expense at their fair value over the related service period as determined in accordance with the authoritative guidance and periodically revalues the equity instruments as they vest. Stock-based compensation expense

related to non-employee consultants recorded as operating expenses was $243,696, $538,169, and $1,291,519 for the years ended December 31, 2013 and 2012 and for the period from Inception through December 31, 2013, respectively.

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SORRENTO THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following at December 31, 2013:

Common stock warrants outstanding under the TSRI License	8,000
Common stock warrants outstanding under the Underwriters Agreement	182,600
Common stock warrants outstanding under the loan and security agreement	31,250
Common stock options outstanding under the EIP	3,200
Authorized for future grant or issuance under the Stock Plan	293,400
Issuable to former IgDraSol stockholders upon achievement of specified regulatory milestone	1,306,272
Issuable under assignment agreement based upon achievement of certain milestones	80,000
	1,904,722

8. Commitments and Contingencies

Litigation

In the normal course of business, the Company may be named as a defendant in one or more lawsuits. Management is currently not aware of any pending lawsuits.

Operating Leases

The Company currently leases: (i) approximately 12,000 square feet of corporate office and laboratory space in San Diego, California, (ii) approximately 6,350 square feet of laboratory and office space at a second location in San Diego, California, and (iii) approximately 2,400 square feet of office space in Irvine, California. Our initial lease agreement for our corporate office and laboratory space expires in September 2014, but includes an option to extend the term of the lease for one additional four-year period. In June 2012, we entered into a separate lease arrangement for an additional 3,216 square feet of laboratory space adjacent to our corporate office, which expires in April 2017, and contains an option to extend the term for the additional rental space by five years at the then prevailing rate. The lease for our second location in San Diego expires in June 2018. Our Irvine lease, as amended, expires in March 2015. We believe that our current facilities are adequate to meet our needs for the foreseeable future and that, should it be needed, suitable additional space will be available to accommodate expansion of our operations on commercially reasonable terms.

For all leased properties the Company has provided a total security deposit of $50,479 to secure its obligations under the various leases, which has been included in prepaid and other assets.

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SORRENTO THERAPEUTICS, INC.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Minimum future non-cancelable annual operating lease obligations are as follows for the years ending December 31:

2014	$ 341,325
2015	214,427
2016	202,272
2017	186,786
2018	89,520
	$ 1,034,330

Rental expense paid for the years ended December 31, 2013 and 2012 and for the period from Inception through December 31, 2013 under the above leases totaled $198,259, $128,300 and $533,443, respectively.

9. Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company s net deferred tax assets are as follows as of December 31, 2013 and 2012:

	2013	2012
Deferred tax assets:		
Net operating loss carryforwards and credits	$ 11,995,000	$ 5,047,000
Stock based compensation	506,000	97,000
Accrued expenses and other	(202,000)	(99,000)
Total deferred tax assets	12,299,000	5,045,000
Less valuation allowance	(13,930,000)	(5,045,000)
Net deferred tax assets	(1,631,000)	
Deferred tax liabilities:		
Amortization of intangibles	(12,617,000)	
Net deferred tax liabilities	$ (14,248,000)	$

The Company has evaluated the available evidence supporting the realization of its gross deferred tax assets, including the amount and timing of future taxable income, and has determined that it is more likely than not that the deferred tax assets will not be realized. Due to such uncertainties surrounding the realization of the domestic deferred tax assets, the Company maintains a valuation allowance of $13,930,000 against its deferred tax assets as of December 31, 2013. Realization of the deferred tax assets will be primarily dependent upon the Company s ability to generate sufficient taxable income prior to the expiration of its net operating losses.

As of December 31 2013, the Company had net operating loss carryforwards of approximately $28,138,000 and $25,732,000 for federal and state income tax purposes, respectively. These may be used to offset future taxable income and will begin to expire in varying amounts in 2027

to 2033. The Company also has research and development credits of approximately $541,000 and $586,000 for federal and state income tax purposes, respectively. The federal credits may be used to offset future taxable income and will begin to expire in varying amounts in 2029 to 2033. The state credits may be used to offset future taxable income, such credits carryforward indefinitely.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company is subject to taxation in the U.S. and California jurisdictions. Currently, no historical years are under examination. The Company s tax years ending December 31, 2013 and 2012 are subject to examination by the U.S. and state taxing authorities due to the carryforward of unutilized net operating losses and research and development credits.

Utilization of the Company s net operating loss carryforwards and research and development credit carryforwards may be subject to a substantial annual limitation due to an ownership change that may have occurred, or that could occur in the future, as defined and required by Section 382 of the Internal Revenue Code of 1986, as amended (the Code), as well as similar state provisions. These ownership changes may limit the amount of net operating loss carryforwards and research and development credit carryforwards, and other tax attributes that can be utilized annually to offset future taxable income and tax, respectively. Any limitation may result in the expiration of a portion of the net operating loss carryforwards or research and development credit carryforwards before utilization.

In general, an ownership change results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50% of the outstanding stock of a company by certain stockholders or public groups. The Company intends to complete a study in the future to assess whether an ownership change has occurred or whether there have been multiple ownership changes since the Company s formation, and will complete such study before the use of any of the aforementioned attributes.

10. 401(k) Plans

The Company maintains a defined contribution 401(k) plan available to eligible employees. Employee contributions are voluntary and are determined on an individual basis, limited to the maximum amount allowable under federal tax regulations. The Company, at its discretion, may make certain contributions to the 401(k) plan. Through December 31, 2013, no such contributions were made. In addition, Concortis maintains a defined contribution 401(k) plan available to its eligible employees. Employee contributions are voluntary and are determined on an individual basis, limited to the maximum amount allowable under federal tax regulations. The Company may make matching contributions to the Concortis 401(k) plan, in its sole discretion.

11. Subsequent Events

On March 25, 2014, the Company announced the formation of a wholly-owned subsidiary, Ark Animal Therapeutics, Inc., or Ark, which will initially focus on developing animal health applications for RTX. RTX targets TRPV-1, a receptor expressed on afferent nerves that has been shown to become hyper-activated in diseases associated with chronic inflammation and the resulting severe pain. The Company intends to assemble a seasoned management team to operate and secure external financing for Ark s planned development activities.

In March 2014, the Company entered into an amended and restated loan and security agreement, increasing the September 2013 facility to $12,500,000 from $5,000,000, with the same two banks. Such loan was funded at closing and is secured by a lien covering substantially all of the Company s assets, excluding intellectual property, which is subject to a negative pledge. As amended and restated, the loan interest rate is 7.95% per annum. The Company will make interest only payments on the outstanding amount of the loan on a monthly basis until October 1, 2014, after which equal monthly payments of principal and interest are due until the loan maturity date of September 30, 2017. In the event the Company raises $30 million of net equity or proceeds from a collaboration, if any, the interest only period will be extended by six months. The amended and restated loan: (i) interest rate is 7.95% per annum, and (ii) provided the Lenders warrants to purchase an aggregate of 34,642 shares of the Company s common stock at an exercise price of $12.99 per share exercisable for seven years from the date of issuance.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

On March 30, 2014, Dr. Daniel Levitt resigned as a member of our board of directors. On March 31, 2014, Richard Vincent, Executive Vice President and Chief Financial Officer resigned as a member of our board of directors so that we would remain in compliance with Nasdaq rules with respect to number of independent directors.