Sorrento Therapeutics, Inc.
Form 10-K
March 16, 2015

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, 2014

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

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 30, 2014 (the last trading day of the registrant's second fiscal quarter of 2014), was approximately $163.05 million.

At March 10, 2015, the registrant had 36,205,517 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of our Proxy Statement for the 2015 Annual Meeting of Stockholders, to be filed within 120 days of December 31, 2014, 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.

SORRENTO THERAPEUTICS, INC.

ANNUAL REPORT ON FORM 10-K

FISCAL YEAR ENDED DECEMBER 31, 2014

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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 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," "exp "intend," "may," "ongoing," "opportunity," "plan," "potential," "predicts," "seek," "should," "will," or "would," and similar ex 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 as well as 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) Cynviloq™, our lead oncology drug product candidate, a polymeric, albumin-free nanoparticle paclitaxel formulation, and (ii) resiniferatoxin, or 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 monoclonal antibodies (mAbs), including our fully human anti- PD-L1 and anti-PD-1 checkpoint inhibitors derived from our proprietary G-MAB® library platform, antibody drug conjugates (ADCs), bispecific antibodies (BsAbs), as well as Chimeric Antigen Receptor Tumor-attacking Neukoplast® (CAR.TNK™, pronounced "CARTANK") for adoptive cellular immunotherapies (ACI). Our objective is to develop our antibody drug products and adoptive cellular immunotherapies as: (i) First in Class (FIC), and/or (ii) Best in Class (BIC), which may offer greater efficacy and/or fewer adverse events or side effects as compared to existing drugs.

SORRENTO PIPELINE:

In October 2014, we entered into a product licensing agreement with China Oncology Focus Limited, an Affiliate of Lee's Pharmaceutical Holdings Limited, or Lee's Pharma, a public biopharmaceutical company listed on the Hong Kong Stock Exchange for exclusive rights to develop and commercialize our fully human immune-oncology anti-PD-L1 mAb STI-A1014 for the greater Chinese market, including Mainland China, Hong Kong, Macau and Taiwan. Under the terms of the agreement, we received an up-front payment of $1.0 million recorded as deferred revenue at December 31, 2014, and will receive potential future milestone payments and royalties on future net sales. In total, we have the potential to receive more than $46 million upon the successful attainment of key milestones, excluding royalties, and retain all the rights to use data generated by Lee's Pharma for territories outside of the greater Chinese market. Additionally, Lee's Pharma purchased 400,000 shares of our common stock at a price of $9.00 per share, or an aggregate of $3.6 million, before commissions. We view this transaction as strategic in advancing our immunomodulatory program from pre-clinical to clinical stage. Lee's Pharma will be responsible for most of the pre-clinical and CMC work, including the development of master cell bank for STI-A1014 and cGMP antibody manufacturing in preparation for regulatory filing in China. We may be able to utilize some aspects of the work performed under Lee's Pharma auspices to supplement and accelerate our US IND filing of STI-A1014 in the first half of 2016, potentially saving significant resources and time for us.

In December 2014, we entered into an agreement with NantBioCell, LLC, or NantBioCell, a wholly-owned subsidiary of Nantworks, a private company owned by Dr. Patrick Soon-Shiong. Under the terms of the agreement, we and NantBioCell intend to establish a new joint venture called "The Immunotherapy Antibody JV", or JV, as an independent biotechnology company with $20.0 million initial joint funding expected mid-2015, $12.0 million from NantBioCell and $8.0 from us representing a 60:40 ownership between NantBioCell and us, respectively. NantBioCell will bring a late clinical stage monoclonal antibody as the lead program in the JV while we will contribute several immunomodulatory antibodies, antibody drug conjugates and bispecific antibodies. The JV will be responsible for accelerating the development of our multiple immuno-oncology mAbs for the treatment of cancer, including but not limited to anti-PD-1, anti-PD-L1, anti-CTLA4 mAbs, and other immune-checkpoint antibodies as well as antibody drug conjugates and bispecific antibodies. Through the JV, we believe we can advance several of our core programs into the clinic as expeditiously as possible. In conjunction with the JV, we entered into a securities purchase agreement with Cambridge Equities, LP, or Cambridge, a limited partnership owned by Dr. Soon-Shiong, pursuant to which we issued and sold to Cambridge a 19.9% equity stake or an aggregate of 7,188,062 shares of our common stock at a price of $5.80 per share, which represented the closing share price of the day prior to the transaction, for an aggregate purchase price of $41.7 million. In connection with the purchase agreement, Cambridge also received a warrant to purchase 1,724,138 shares of our common stock. The warrant is exercisable for a period of three years from the date of issuance at an initial exercise price of $5.80 per share and is subject to customary adjustment provisions for stock splits, stock dividends, recapitalizations.

In December 2014, we also entered into a collaboration agreement with Conkwest Incorporated, or Conkwest, a privately-held life sciences company developing and commercializing the proprietary cancer-killing cell line Neukoplast (also known as NK-92) for the treatment of cancers and viral infections. Jointly, we and Conkwest will generate and develop products for adoptive immunocellular therapy utilizing Neukoplast cells and chimeric antigen receptors, or CARs, derived from our G-MAB antibody library. The product candidates, coined chimeric antigen receptor tumor-attacking Neukoplast (CAR.TNK), will be developed for the treatment of hematological malignancies as well as solid tumors. Under the terms of the agreement, Conkwest and us will establish an exclusive global strategic collaboration focused on accelerating the development of CAR.TNKs, including CD19-CAR.TNK™, PD-L1-CAR.TNK™, PSMA-CAR.TNK™, CD123-CAR.TNK™, and other CAR.TNKs for the treatment of hematological malignancies as well as solid tumors. Both companies will jointly own and share development costs and revenues from any developed CAR.TNK products. In connection with this agreement we entered into a subscription and investment agreement with Conkwest, as amended, pursuant to which Conkwest issued and sold to us an aggregate of

3,034,473 shares of Conkwest Class A common stock for an aggregate purchase price of $10.0 million representing an equity stake in Conkwest of approximately 9%.

Although we intend to retain ownership and control of product candidates by advancing their development, we regularly also consider partnerships with pharmaceutical or biopharmaceutical companies in order to balance the risks and costs 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. Moreover, we are looking at strategic collaborations whereby the partner will be responsible for certain product and clinical development costs in exchange for co-promotion rights in the US or outside of the US. Through various joint ventures, we will also be able to advance our pipeline into the clinic without significantly draining our resources and focus since these entities will be operating and funded independently.

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, either directly or with a partner. 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 nanoparticle paclitaxel formulation: 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, albumin-bound paclitaxel (brand name 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 recently announced completion of patient enrollment in the Cynviloq™ registrational TRIBECA™ Study. (TRIal establishing bioequivalence (BE) between Cynviloq™ and Albumin-bound paclitaxel). We expect to file the NDA before the end of 2015.
- 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 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 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 under our own IND.
- G-MAB®, our proprietary platform, provides us with specific therapeutic antibodies for specific cancer cell targeting and killing. Our proprietary G-MAB human antibody library has provided us with fully human therapeutic mAbs against many 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 of 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. Our lead antibody programs include anti-PD-1 and anti-PD-L1 immunomodulatory antibodies. Based on clinical data from competitor programs, such as anti-PD-1 antibodies Opvido® (BMS) and Keytruda® (Merck) and anti-PD-L1 mAbs MPDL3280A (Genentech) and MEDI4736 (AstraZeneca), such immunomodulatory antibodies have demonstrated significant clinical efficacy across a number of different oncology indications
- Antibody drug conjugates (ADC) and Bispecific antibodies (BsAbs) for targeted tumor killing. By leveraging the extensive G-MAB Library with our proprietary conjugation and bispecific antibody chemistries, we are positioned to generate proprietary ADCs and BsAbs with significant clinical activity. As both of our technologies are solely based on chemical modifications of the antibody rather than relying on genetic modifications, fusion proteins, or incorporation of unnatural amino acids, they can be utilized with “off-the-shelf” antibodies. This will further empower our G-MAB-derived antibodies and potentially lower development costs. Our lead BsAb programs currently focus on combinations of our anti-PD-1 or anti-PD-L1 antibodies paired with another immunomodulatory antibody component or an anti-cancer antigen antibody.
- Adoptive Cellular Immunotherapy with CAR.TNKs: The adoptive immunotherapy field has emerged as the one of most promising and innovative anti-cancer strategies. To date, T-cell based therapies like CAR-T have shown the most promise in hematologic cancers, especially B-cell malignancies like acute lymphoblastic leukemia (ALL) and

chronic lymphocytic leukemia (CLL). They have also demonstrated outstanding therapeutic impact, including a high percentage of complete responses (CRs) in Hodgkin lymphoma patients using CD19-CAR T cells. While the clinical results seen have been promising, CAR-T therapies have also caused some concerning side effects, especially cytokine-release syndrome due to the injection of cytokine-releasing T cells. Currently, patient-derived T cells are isolated, propagated, and modified with the CAR in the laboratory and then administered back into the patient. The process, however, solely relies on the ability to obtain sufficient numbers of patient immune cells and to successfully bestow upon them the ability to express the CAR

The CAR.TNK approach will utilize an immortalized NK cell line from Conkwest called Neukoplast (NK-92) as the source for the immune cells. These NK-92 cells will be genetically modified to express surface receptors using our G-MAB library that would allow these cells to recognize antigens on tumor cells. This “off-the-shelf” approach is independent of patient-derived cells as it utilizes CAR.TNKs stably expressing the tumor-targeting receptor. They can be generated and produced in large quantities, thus, circumventing one of the major drawbacks of current CAR-T cell therapies. Natural killer cells also do not trigger the release of cytokines associated with CAR-T therapies.

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

- Completing the development and analysis on our potentially pivotal registrational trial for our oncolytic drug candidate Cynviloq, and preparing for FDA submission of an NDA filing (H2, 2015), as well as continuing with Cynviloq partnering process for US and ex-US collaborations
- Advancing RTX into phase II clinical human development under an IND; and seeking strategic alternatives for potential veterinary indications
- Prioritizing our preclinical pipeline, and advancing selected drug development candidates (mAbs: PD-1, PD-L1, VEGFR2; BsAbs: PD-L1/c-MET, PD-L1/EGFR; ADCs: VEGFR2-ADC, c-MET-ADC), into clinical trials ourselves or through strategic collaborations with biotech and/or pharmaceutical companies
- Working with our strategic partners, Conkwest (for CAR.TNKs) and NantBioCell (for the Immunotherapy Antibody Joint Venture), to advance several key programs into the clinics
- Exploring possible ‘spin-off’ of CAR.TNK and other assets into separate public entities
- Supporting NantBioCell in preparation for potential IPO of the ‘Immunotherapy Antibody Joint Venture’
- Continuing to explore potential accretive and/or synergistic products and/or platforms that will enhance our pipeline and technologies

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, completing a BE registrational trial for multiple solid tumor indications with plans for topline data availability in April 2015, and an ongoing phase Ib 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 against validated cancer targets. We believe these individual mAb or ADC product candidates have the potential to address major unmet medical needs.

Cynviloq™

Cynviloq was licensed through an exclusive distribution agreement, for North America, 27 countries of the EU, and Australia, from Samyang Biopharmaceutical Corporation, or Samyang, a South Korean corporation. Cynviloq is currently approved and marketed by Samyang in South Korea for Metastatic Breast Cancer (MBC), Non Small Cell Lung Cancer (NSCLC) and Ovarian

Cancer (OC), under the trade name Genexol-PM®[1], and 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, under the trade name Genexol-PM, 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 1,260 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®[2]) clinical data. Samyang has completed 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 260 mg/m^2 every 3 weeks (q3w), as compared to Taxol®[3] (Cremophor-paclitaxel) given at a standard 175 mg/m^2 q3w dose. Final results have shown statistically significant improvement in the objective response rate (ORR) with Cynviloq when compared to Taxol, with results comparable to data generated from the pivotal registrational studies submitted for Abraxane that were the basis for its 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 (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 post-marketing 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 a 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, commenced our BE study in March 2014 (first patient in), and completed recruitment to the phase 3 registrational TRIBECA (TRIal establishing bioequivalence (BE) between Cynviloq™ and Albumin-bound paclitaxel) study in January 2015. Previously, we also announced positive pharmacokinetic (PK) data from the first eight (8) patients enrolled in the TRIBECA study suggesting that Cynviloq was bioequivalent to albumin-bound paclitaxel when both drugs are dosed at 260 mg/m^2 and infused over 30 minutes in patients with metastatic breast cancer.

Cynviloq—Differentiation versus Cremophor Taxol® and nab-paclitaxel Abraxane® formulations of paclitaxel

Paclitaxel is a water insoluble drug that requires a solvent formulation. The first generation paclitaxel formulation, Taxol; developed by Bristol-Myers-Squibb (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.

Nab-paclitaxel (Abraxane®) is a second generation paclitaxel formulation that utilizes the biological polymer, donor-derived human serum albumin (HSA) to encapsulate paclitaxel.

Cynviloq is a next-generation paclitaxel formulation comprised of paclitaxel encapsulated in a non-biological polymeric micelle composed of a polylactide and polyethylene glycol diblock copolymers resulting in an injectable suspension of paclitaxel. Cynviloq is free from human serum albumin (HSA), which poses a hypothetical risk of viral/prion transmission from donor-derived blood. The absence of albumin in the Cynviloq formulation can

potentially lead to easier preparation, handling and storage- an important logistical consideration especially for busy practices and pharmacies.

Basis for bioequivalence

Particle dissociation in vitro studies comparing nab-paclitaxel 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. Pilot PK data from the first 8 patients recruited in the TRIBECA trial suggest that Cynviloq is bio-equivalent to albumin-bound paclitaxel in total paclitaxel when both drugs are given at equivalent dose (260 mg/m2) and administered intravenously over 30 minutes in patients with metastatic breast cancer. Based on our reported positive data, sample size estimates suggest that only 53 patients are needed to establish bioequivalence (BE) based on 90% confidence interval (CI) specified in the End of Phase 2 meeting minutes from the FDA in July of 2013.

[1] Genexol-PM® is a trademark of Samyang Biopharmaceutical Corporation.
[2] Abraxane® is a trademark of Celgene Corporation
[3] Taxol® is a trademark of Bristol Myers Squibb Corporation.

PILOT PK DATA ANALYSIS FROM TRIBECA STUDY:

Clinical Strategy: Differentiation versus albumin-bound paclitaxel

Roche has recently announced three phase 3 trials (GO29436, GO29537, GO29437) combining their anti-PDL1 (in patients with advanced squamous NSCLC comparing the combination of Roche's anti-PD-L1 MPDL3280A with paclitaxel or albumin-bound paclitaxel in various combinations with carboplatin (with or without bevacizumab). Close to 3,000 patients will be recruited in these studies (ClinicalTrials.gov Identifiers: NCT02367781, NCT02367794 and NCT02366143).

BMS and Merck also have phase 1 and phase 2 studies exploring combination of anti-PD-1 with taxane-based therapies in melanoma (CheckMate037; NCT01721746 and NCT01840579), NSCLC (NCT01840579 and NCT01454102), and pancreatic cancer (NCT02309177).

We plan to conduct Cynviloq combination studies with our own anti-PD-1/anti-PD-L1 mAbs in several tumor indications in both metastatic and adjuvant settings.

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) 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 nab-paclitaxel and Taxol® formulations. According to the Section 505(b)(2) guidance, 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 states that measurements of both total and unbound paclitaxel should be made to establish BE. We believe that this is an appropriate method of comparison for marketing approval.

Based on our reported positive data, sample size estimates suggest that only 53 patients are needed to establish bioequivalence (BE) based on 90% confidence interval (CI) specified in the End of Phase 2 meeting minutes from the FDA in July of 2013. A single BE crossover study, TRIBECA, was planned and we enrolled 111 MBC patients by the end of January 2015 (9 in the pilot PK portion of the trial and 102 in the blinded BE portion) MBC patients to: (i) treat patients with nab-paclitaxel or Cynviloq to measure the PK parameters between the two drug formulations in order to establish BE, and (ii) determine the measurements of both total and unbound paclitaxel in both formulations. We filed an amendment to the protocol to continue to treat all patients enrolled in the

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TRIBECA study with additional 4 cycles of Cynviloq after the patients come off the BE portion of the study so we can collect safety data on Cynviloq dosed at 260 mg/m2 and administered over 30 min. We believe that the additional safety data collected in over 100 MBC patients treated with 5 cycles of Cynviloq will strengthen our overall NDA package.

The BE trial enrollment was completed in January 2015, with current plans for NDA submission in the 3rd quarter 2015 and potential approval in 2016. If Cynviloq and nab-paclitaxel are found to be bioequivalent and FDA approval is granted: (i) Cynviloq will receive the same label indications as nab-paclitaxel, including MBC and NSCLC, in addition to recently approved nab-paclitaxel indications, namely advanced pancreatic cancer once marketing exclusivity expires, and (ii) additional life cycle indications, such as bladder or ovarian cancers, could be pursued with additional studies either as monotherapy or in combination with our PD-L1/PD-1 antibodies.

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 countries 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

Taxanes are the most widely used chemotherapic class 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. Recently, with approval of albumin-bound paclitaxel as combination with gemcitabine in advanced pancreatic cancer, albumin-bound paclitaxel is extensively used as first-line treatment of patients with metastatic pancreatic cancer. 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 nab-paclitaxel (Abraxane®), generic paclitaxel (Taxol®) and generic docetaxel (Taxotere®). At the 2015 J.P. Morgan Annual Healthcare Conference, Celgene forecast albumin-bound paclitaxel to achieve sales of US $2.2 billion by 2020.

Metastatic Breast Cancer (MBC)[1]

Breast cancer ranks second as a cause of cancer death in women, after lung cancer. A total of 231,840 new breast cancer cases (29%) and 40,290 cancer deaths (15%) are projected to occur in the US in 2015 (Cancer Statistics, 2015, RL Siegel et al., CA Cancer J Clin. 2015, 65:5-29). 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.

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 nab-paclitaxel, 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 2012, an estimated 1.8 million people were diagnosed with lung cancer resulting in 1.6 million deaths (GLOBOCAN 2012: Estimated Cancer Incidence, Mortality and Prevalence Worldwide in 2012, World Health Organization). Lung cancer is the leading malignant cause of death in 93 countries accounting for a fifth of the total global burden of disability-adjusted life years from cancer. A total of 105,590 new lung cancer cases (13%) and 71,660 cancer deaths (26%) are projected to occur in the US in 2015 (Cancer Statistics, 2015, RL Siegel et al., CA Cancer J Clin. 2015, 65:5-29).

In the U.S., lung cancers are expected to represent approximately 14% of new cancer diagnoses, or an estimated 223,000 new cases (2013). Lung cancer accounts for more deaths than any other cancer in both men and women. Lung cancer is classified as small cell (15%) or non-small cell (84%) for the purposes of treatment. Based on type and stage of cancer, treatments include surgery, radiation therapy, chemotherapy, and targeted therapies such as bevacizumab (Avastin®/), 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 nab-paclitaxel, 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. The FDA approved Opdivo (nivolumab) for the treatment of patients with metastatic squamous non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy on March 4, 2015, five days after BMS filed the supplemental NDA. Opdivo is the first and only PD-1 therapy to demonstrate overall survival in previously treated metastatic squamous NSCLC. Opdivo demonstrated significantly superior overall survival (OS) vs. docetaxel, with a 41% reduction in the risk of death (hazard ratio: 0.59 [95% CI: 0.44, 0.79; p=0.00025]), in a prespecified interim analysis of a Phase III clinical trial. The median OS was 9.2 months in the Opdivo arm (95% CI: 7.3, 13.3) and 6 months in the docetaxel arm (95% CI: 5.1, 7.3).

Ovarian cancer[1]

In 2014, approximately 48,500 women were diagnosed with ovarian cancer in the U.S. and the top 5 EU countries. A total of 21,290 new ovarian cancer cases (26%) and 14,180 cancer deaths (5%) are projected to occur in the US in 2015 (Cancer Statistics, 2015, RL Siegel et al., CA Cancer J Clin. 2015, 65:5-29). More than 70% of women diagnosed with ovarian cancer will have an 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 approximately 17,000 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 2013, 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. A total of 24,120 new pancreatic cancer cases (36%) and 19,850 cancer deaths (7%) are projected to occur in the US in 2015 (Cancer Statistics, 2015, RL Siegel et al., CA Cancer J Clin. 2015, 65:5-29). 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.

Gemcitabine-and fluoro-pyrimidine based therapies 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.

Competition

Cynviloq will be competing against other taxane formulations in the market. These include generic docetaxel and Cremophor-paclitaxel and albumin-bound paclitaxel, marketed by Celgene as Abraxane®.

RTX

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 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 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.

The mechanism of action for RTX is well understood and has been validated by extensive 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 are testing 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 are evaluating 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 have opened an INAD for osteosarcoma-associated pain in dogs with the Center for Veterinary Medicine ("CVM") division of the FDA. We are requesting recognition of the program 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 are also testing other veterinary indications whose pathology is driven by afferent nerves and delivery of RTX may be beneficial. 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 have formed a wholly owned subsidiary, ARK Animal Health, and are accumulating other products to add to ARK's pipeline.

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 are recruiting additional patients for the NIH intrathecal trial in order to identify the MTD (maximum tolerated dose) for RTX and to characterize any dose limiting toxicities. We plan to file an IND and begin enrolling patients in corporate sponsored study (s) in 2015. 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.

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 vast 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 ADCs or components of BsAbs.

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 2016, including anti-PD-L1, anti-PD-1, and anti-VEGFR2 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, for the treatment of certain auto-immune diseases as well as immunodeficiencies.

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. 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, immune-oncology 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-A1014 (lead candidate), and STI-A1015. In preclinical studies, our mAbs were at least as potent and effective as the anti-PD-1 and anti-PD-L1 mAbs from competitor companies. We have concluded cell line development for our anti-PD-L1 antibody, STI-A1014, which will lay the foundation for Investigational New Drug, or IND, -enabling studies in the U.S. in 2015. We anticipate that a Phase I clinical trial for the lead candidate anti-PD-L1 antibody could be initiated in 2016. Last year, we entered into a licensing agreement with Lee's Pharma granting them exclusive rights to STI-A1014 for the greater Chinese market, where STI-A1014 is progressing in IND-enabling studies. Lee's Pharma will be responsible for most of the pre-clinical and CMC work, including the development of master cell bank for STI-A1014 and cGMP antibody manufacturing in preparation for regulatory filing in China. We may be able to utilize some aspects of the work performed under Lee's Pharma auspices to supplement and accelerate our US IND filing of STI-A1014 in the first half of 2016, potentially saving significant resources and time for us.

Our anti-PD-1 mAb STI-A1110, the anti-VEGFR2 mAb STI-A0168, and anti-PD-L1 mAb STI-A1015s will enter into IND-enabling studies in 2016. We are currently seeking strategic collaborations to advance these programs as quickly as possible into the clinic.

While our checkpoint inhibitors maybe late into the market as compared to other big pharma players like BMS, Roche, Merck and Merck Serrono, we believe that the future with the immunomodulatory antibodies lie with combination therapy. We note that several large clinical trials are currently recruiting combining antibodies with taxanes and other chemotherapy/small molecules such as tyrosine kinase inhibitors in various solid tumor types. We believe we are well positioned to exploit our internal pipeline comprising of small molecules, ACI and immunomodulatory antibodies to become a leader in the oncology space.

Antibody Drug Conjugates (ADC) Technologies

Our ADCs, have cytotoxic payloads as well as C-Lock™ and K-Lock™ conjugation technologies that allow for site-specific toxin conjugation to the antibody. The ADC technology complements our existing development programs, particularly our G-MAB-derived monoclonal antibodies.

Our two most advanced ADC projects utilize G-MAB-derived VEGFR2 and c-MET antibodies.

The G-MAB Library was initially invented by Henry Ji, Ph.D., STI's co-founder, Chief Executive Officer and President. A U.S. patent covering the initial incarnation of the G-MAB Library was issued in July 2008 (US Patent 7,405,062) 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 improvements to the initial G-MAB Library, with the key improvements relating to what we believe is our ability to achieve greater library diversity.

Our mAb Technology Advantages

We believe the G-MAB Library may offer the following advantages over competing antibody libraries:

· The G-MAB Library has been designed to provide a full spectrum of human immunoglobulin gene recombination in fully-human mAb libraries. Unlike chimeric and humanization technologies, the G-MAB Library 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 G-MAB Library represents an in vitro human mAb library technology, it enables faster and cost-effective in vitro screening of a large number of antigens. The G-MAB Library 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 compared to a human-mouse technology, the G-MAB Library 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 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.

Our Adoptive Cellular Immunotherapy Approach

The adoptive immunotherapy field has emerged as the one of most promising and innovative anti-cancer strategies. To date, T-cell based therapies like CAR-T have shown the most promise in hematologic cancers, especially B-cell malignancies like acute lymphoblastic leukemia (ALL) and chronic lymphocytic leukemia (CLL). They have also demonstrated outstanding therapeutic impact, including a high percentage of complete responses (CRs) in Hodgkin lymphoma patients using CD19-CAR T cells. While the clinical results seen have been promising, CAR-T therapies have also caused some concerning side effects, especially cytokine-release syndrome due to the injection of cytokine-releasing T cells. Currently, patient-derived T cells are isolated, propagated, and modified with the CAR in the laboratory and then administered back into the patient. The process, however, solely relies on the ability to obtain sufficient numbers of patient immune cells and to successfully bestow upon them the ability to express the CAR

The CAR.TNK approach will utilize an immortalized NK cell line from Conkwest called Neukoplast (NK-92) as the source for the immune cells. These NK-92 cells will be genetically modified to express surface receptors using our G-MAB library that would allow these cells to recognize antigens on tumor cells. This “off-the-shelf” approach is independent of patient-derived cell as it utilizes CAR.TNKs stably expressing the tumor-targeting receptor. They can be generated and produced in large quantities, thus, circumventing one of the major drawbacks of current CAR-T cell therapies. Natural killer cells also do not trigger the release of cytokines associated with CAR-T therapies.

Our Joint Venture and Collaborations:

The Immunotherapy Antibody Joint Venture:

We entered into an agreement with NantBioCell, to establish a new joint venture called “The Immunotherapy Antibody JV. NantBioCell will bring a late clinical stage monoclonal antibody as the lead program in the JV while we will contribute several immunomodulatory antibodies, antibody drug conjugates and bispecific antibodies. The JV will be responsible for accelerating the development of our multiple immuno-oncology mAbs for the treatment of cancer, including but not limited to anti-PD-1, anti-PD-L1, anti-CTLA4 mAbs, and other immune-checkpoint antibodies as well as antibody drug conjugates and bispecific antibodies. Through the JV, we believe we can advance several of our core programs into the clinic as expeditiously as possible.

Mutually Exclusive Collaboration with Conkwest on CAR.TNK:

We also entered into a collaboration agreement with Conkwest. Jointly, we will generate and develop products for adoptive immunocellular therapy utilizing Neukoplast cells and chimeric antigen receptors, or CARs, derived from our G-MAB antibody library. The product candidates, coined chimeric antigen receptor tumor-attacking Neukoplast

(CAR.TNK), will be developed for the treatment of hematological malignancies as well as solid tumors. Under the terms of the agreement, Conkwest and us will establish an exclusive global strategic collaboration focused on accelerating the development of CAR.TNKs. Together with Conkwest, we have identified an initial prospective list of CAR.TNKs for development. The selected candidates will be evenly divided between both companies with each company being the ‘lead’ for certain product candidates. The lead company for an individual CAR.TNK will be responsible for all pre-clinical and clinical development, regulatory filings, and commercialization of that CAR.TNK. Profit sharing on any CAR.TNK revenues, from any business development or commercial activities, will be proportional to contribution made by each company.

PROSPECTIVE CAR.TNKs FOR DEVELOPMENT:

Target	Potential Indication(s)

EGFRviii.TNK	Glioma
EphA3.TNK	Glioma, AML
L1CAM.TNK	Gastric, pancreatic, NSCLC
CSPG4.TNK	H&N, breast, mesothelioma
BCMA.TNK	Myeloma
ROR1.TNK	CLL, ALL, MCL, breast, lung, pancreas
PSMA or PSCA.TNK	Prostate
PDL1.TNK	Myeloma, RCC, NSCLC, TNBC
CS1.TNK	Myeloma
CD123.TNK	AML
CD19.TNK	CLL, ALL
CD22.TNK	CLL, ALL

mAb, CAR.TNK, 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, CAR.TNKs, 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.

We have one issued United States patent relating to G-MAB and one issued US patent for an antibody family obtained from our G-MAB library.

(1)

The Cynviloq patent portfolio consists of 1 issued patent and 5 US patent applications, three filed and prosecuted by the Cynviloq manufacturer, Samyang and two filed by us. The patent protection provided by the Samyang family of patents expires in 2028 and the two patent applications filed by us expire in 2034 and 2035.

(2) The RTX product is protected by a small family of patents, one of which has issued in the US that provides product protection until 2021.

(3) G-MAB has one issued U.S. patent (7,405,062) 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, c-Met, WISP1, CTLA4, CCR2, DLL4, ErbB3, CXCR3, CXCR5, CD147, Oprf, CD47, CD137, TIM3, Jagged-1, and CTLA4 projects.

(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. One patent application from this family has issued as a US patent.

(5) There are two families of ADC patents that describe and claim the conjugation chemistries that we call C-Lock and K-Lock, initially developed by Concortis. These patent application have a term of protection until 2033. Concortis has also developed three families of different toxin derivatives, coupled to the Concortis proprietary conjugation chemistry for proprietary ADCs. The patent applications (three) supporting this effort expire in 2035.

(6) MYC Inhibitors are genus of structurally-related compounds having activity as significant oncology agents to inhibit myc. The initial genus of compounds is the subject of a patent application family exclusively licensed from TSRI (The Scripps Research Institute).

(7) TRAIL Inducers are a genus of structurally-related compounds having activity as significant oncology agents that act as TRAIL inducers and have potential oncology activities. There is a method of treatment patent from Penn State directed to treatment use with a different structure compound that is currently in clinical trials for glioblastoma where it is likely that our patent application for the novel compound structure will dominate any making, using or selling of the Penn State subject matter that has been called “TIC10.” Our claimed lead structure is not TIC10, as described in the Penn State patent. The initial genus of compounds is the subject of a patent application family exclusively licensed from TSRI (The Scripps Research Institute).

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.

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 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. 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 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 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 pharmaco vigilance 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.

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.

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 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 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.

Antibody Clinical Development

We currently focus our research 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.

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, 2014, we had 66 employees and 18 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 $24.0 million and $9.0 million in the years ended December 31, 2014 and 2013, respectively.

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.

We were originally incorporated as San Diego Antibody Company in California in 2006 and were renamed "Sorrento Therapeutics, Inc." and reincorporated in Delaware in 2009, prior to the Merger. QuikByte was originally incorporated in Colorado in 1989. Following the Merger, on December 4, 2009, QuikByte reincorporated under the laws of the State of Delaware, or the Reincorporation. Immediately following the Reincorporation, on December 4, 2009, we merged with and into QuikByte, the separate corporate existence of STI ceased and QuikByte continued as the surviving corporation, 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 from formation through December 31, 2014. 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 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, 2014, 2013 and 2012, we had an accumulated deficit of $67.5 million, $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.

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.

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.

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. For instance, if bioequivalence, or BE, is not established between Abraxane and Cynviloq, then clinical trials to assess the safety and/or efficacy of our formulation may be needed.

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

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

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

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

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

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

In the event we are able to conduct a pivotal clinical trial of a product candidate, the results of such trial may not be adequate to support marketing approval. Because our product candidates are intended for use in life-threatening diseases, in some cases we ultimately intend to seek marketing approval for each product candidate based on the results of a single pivotal clinical trial. As a

result, these trials may receive enhanced scrutiny from the FDA. For any such pivotal trial, if the FDA disagrees with our choice of primary endpoint or the results for the primary endpoint are not robust or significant relative to control, are subject to confounding factors, or are not adequately supported by other study endpoints, including possibly overall survival or complete response rate, the FDA may refuse to approve a BLA based on such pivotal trial. The FDA may require additional clinical trials as a condition for approving our product candidates.

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

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

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

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

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

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence

product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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

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

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

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

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;
- 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.

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.

With respect to Cynviloq (Genexol-PM), we are solely dependent on and are required to purchase from Samyang all of our required supplies of the product, and there can be no assurance that the product we receive is manufactured in accordance with applicable regulatory requirements or that Samyang will provide us with all of the product that we require. Our reliance on Samyang may result in a failure to supply, which would impact our ability to further develop and obtain approval for Cynviloq, or to successfully commercialize the product, even if approved. Any failure of Samyang in supplying Cynviloq to meet our requirements, including cGMP standards, would risk significant delay and potential non-approvability of Cynviloq, which would have a material adverse effect on our business and operations.

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

We rely on our manufacturers to produce or purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our drugs and

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

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

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

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

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

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

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

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

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

Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly

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

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

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

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

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

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

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

and products. Failure of this strategy would impair our ability to grow.

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

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

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

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

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

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

- the efficacy and safety as demonstrated in clinical trials;
- the timing of market introduction of such product candidate as well as competitive products;
- the clinical indications for which the drug is approved;
- acceptance by physicians, major operators of cancer clinics and patients of the drug as a safe and effective treatment;
- the safety of such product candidate seen in a broader patient group, including its use outside the approved indications;
- the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs;
- the availability of adequate reimbursement and pricing by third-party payors and government authorities;
- the relative convenience and ease of administration of Cynviloq for clinical practices;
- the product labeling or product insert required by the FDA or regulatory authority in other countries;
- the approval, availability, market acceptance and reimbursement for a companion diagnostic, if any;
- the prevalence and severity of adverse side effects; and
- the effectiveness of our sales and marketing efforts.

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

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

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

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

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

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

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

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

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

- successfully and 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.

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.

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

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

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

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

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

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

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

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

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

We may have access to very sensitive data regarding patients whose tissue samples are used in our studies. This data will contain information that is personal in nature. The maintenance of this data is subject to certain privacy-related laws, which impose upon us administrative and financial burdens, and litigation risks. For instance, the rules promulgated by the Department of Health and Human Services under the Health Insurance Portability and Accountability Act, or HIPAA, create national standards to protect patients' medical records and other personal information in the U.S. These rules require that healthcare providers and other covered entities obtain written authorizations from patients prior to disclosing protected health care information of the patient to companies. If the patient fails to execute an authorization or the authorization fails to contain all required provisions, then we will not be

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

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

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

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

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

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

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

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

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase

or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;
- HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the

privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.
If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

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

·decreased demand for our product candidates or products that we may develop;
·injury to our reputation;
·withdrawal of clinical trial participants;
·initiation of investigations by regulators;
·costs to defend the related litigation;
·a diversion of management's time and our resources;
·substantial monetary awards to trial participants or patients;
·product recalls, withdrawals or labeling, marketing or promotional restrictions;
·loss of revenues from product sales; and
·the inability to commercialize our product candidates.
Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop.

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

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

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. We are moving to new facilities in San Diego in 2015, which may impact the timing and plans if we fail to

timely and successfully move our research staff. Our facilities may be affected by natural or man-made disasters. Earthquakes are of particular significance since our facilities are located in an earthquake-prone area. We are also vulnerable to damage from other types of disasters, including power loss, attacks from extremist organizations, fire, floods and similar events. In the event that our facilities were affected by a natural or man-made disaster, we may be forced to curtail our operations and/or rely on third-parties to perform some or all of our research and development activities. Although we believe we possess adequate insurance for damage to our property and the disruption of our business from casualties, such insurance may not be sufficient to cover all of our potential losses and may not continue to be available

to us on acceptable terms, or at all. In the future, we may choose to expand our operations in either our existing facilities or in new facilities. If we expand our worldwide manufacturing locations, there can be no assurance that this expansion will occur without implementation difficulties, or at all.

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

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

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

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

·difficulties in identifying and acquiring products, technologies, or businesses that will help our business;
·difficulties in integrating operations, technologies, services, and personnel;
·diversion of financial and managerial resources from existing operations;
·the risk of entering new development activities and markets in which we have little to no experience;
·risks related to the assumption of known and unknown liabilities; and
·risks related to our ability to raise sufficient capital to fund additional operating activities.

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

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

Effective in March 2014, as amended and restated, we entered into a $12.5 million loan and security agreement with Oxford Finance and Silicon Valley Bank that is secured by a lien covering substantially all of our assets, excluding intellectual property. As of December 31, 2014, we had an outstanding principal balance of $12.5 million. The amended and restated loan and security agreement contains customary affirmative and negative covenants and events of default. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports and maintain insurance coverage. The negative covenants include, among others, restrictions on transferring collateral, changing our business, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments and creating other liens on our assets, in each case subject to customary exceptions. If we default under the loan agreement, the lenders may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations.

Further, if we are liquidated, the lender's right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. The lenders could declare a default upon the occurrence of any event that they interpret as a material adverse change as defined under the loan agreement, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by the lenders of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Risks Related to Acquisitions

We have and plan to continue to acquire businesses and technologies and may fail to realize the anticipated benefits of the acquisitions, and acquisitions can be costly and dilutive.

In the past 18 months, we acquired three companies. The success of any acquisitions 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.

During 2013, for example, we incurred significant legal and professional fees in connection with such acquisitions. We expect to incur additional costs integrating the companies' operations, higher development and regulatory costs, and personnel, which cannot be estimated accurately at this time. If the total costs of the integration of our companies and advancement of acquired product candidates and technologies such as Cynviloq, RTX and 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. However, due to the difficulties of enforcing such antibody library technology, we filed a key patent application in the U.S. only and requested nonpublication. In 2013 and 2014, we filed 18 antibody family patents. The first of the antibody family patents applications issued on October 14, 2014 as U.S. Patent 8,859,740. In 2013 and 2014, we filed five patent application families for the Concortis conjugation chemistry associated with ADC's.

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

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

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 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.

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

We plan to file an NDA for Cynviloq under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act and as a result we will be required to file a subparagraph (iv) certification for the Orange Book-listed patents for Abraxane. The Orange Book listed patents for Abraxane require a paclitaxel formulation having human serum albumin coating its particles (Cynviloq does not have human serum albumin in its formulation). The commercial manufacturer of Abraxane may file a lawsuit against us for which we

believe there is not merit. In the event a lawsuit is filed against us the potential commercial launch of Cynviloq could be delayed up to a maximum of 30 months which would have a material adverse effect on our business.

Our 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.

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

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

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

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

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

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

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

candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly.

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

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

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

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

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

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

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

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

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

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

- Others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- We or our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- We or our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions;

- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- It is possible that our pending patent applications will not lead to issued patents;
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- We may not develop additional proprietary technologies that are patentable; 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;
- 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;

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- 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 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.

Our strategic investments may result in losses.

We periodically make strategic investments in various public and private companies with businesses or technologies that may complement our business. The market values of these strategic investments may fluctuate due to market conditions and other conditions over which we have no control. Other-than-temporary declines in the market price and valuations of the securities that we hold in other companies would require us to record losses related to our investment. This could result in future charges to our earnings. It is uncertain whether or not we will realize any long-term benefits associated with these strategic investments.

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

If our stockholders sell, or the market perceives that our stockholders intend to sell for various reasons, substantial amounts of our common stock in the public market, including shares issued in connection with the exercise of

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

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

Our quarterly operating results may fluctuate significantly.

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

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

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

Existing stockholders' interest in us may be diluted by additional issuances of equity securities and raising funds through acquisitions, 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, 2014, our directors, executive officers and principal stockholders beneficially owned, in the aggregate, over 41.3% 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, 2014, we had net operating loss carryforwards aggregating approximately $58.8 million.

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

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

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

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

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

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 in San Diego, California approximately 18,500 square feet of corporate office and laboratory space, approximately 6,350 square feet of laboratory and office space at a second location and approximately 6,400 square feet of office space at a third location adjacent to our corporate offices. We also lease 2,400 square feet of office space in Irvine, California and approximately 1,800 square feet of office space in Cary, North Carolina. Our lease agreements in San Diego, as amended, for our corporate office and laboratory space, our second laboratory and office space and our third office space, expire in March 2016, June 2018 and January 2016, respectively. Our Irvine lease, as amended, expires in March 2015 and will not be renewed and the lease on office space in North Carolina expires March 2016.

In February 2015, we entered into a new lease for 43,022 square feet of corporate office and laboratory space in San Diego, California. This lease expires in 2025. We intend to sublease our existing corporate office and laboratory space until the leases expire. We believe that this new leased facility will be adequate to meet our needs for the foreseeable future and that, should it be needed, suitable additional space will be available to accommodate expansions 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.

The following table sets forth the range of high and low sale prices for our common stock for the periods indicated in 2014 as reported by NASDAQ, and for the fourth quarter ending December 31, 2013 as reported by NASDAQ and the high and low bid quotations for our common stock, as reported by the OTCBB on a quarterly basis for the three quarters ended September 30, 2013. 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 our common stock. All common shares and per common share amounts in the table have been adjusted retroactively to reflect the effects of this action.

	2014		2013	
First Quarter	$16.40	$7.92	$8.75	$4.00
Second Quarter	13.30	4.75	12.00	2.50
Third Quarter	6.87	4.20	10.00	5.20
Fourth Quarter	10.80	3.10	10.30	7.80

Holders of Record

As of March 10, 2015, there were 221 holders of record of our common stock.

Dividend Policy

We have never declared or paid any cash dividends on our common stock and we do not anticipate paying any dividends or making 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, 2014. 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	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))

	(a)	(b)	(c)
Equity compensation plans approved by security holders (1)	2,252,434	$ 6.38	1,417,866 (2)
Equity compensation plans not approved by security holders (3)	3,200	1.12	—
Total	2,255,634		1,417,866

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

(2) Comprised solely of shares subject to awards available for future issuance under the 2009 Plan. In June 2014, our 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 3,760,000. Such shares of common stock are reserved for issuance to our employees, non-employee directors and consultants. As of December 31, 2014, 3,760,000 shares were authorized under the 2009 Plan, with 1,417,866 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.

Performance Graph

The following graph compares the cumulative total stockholder return on our common stock from December 31, 2009 to December 31, 2014 with the cumulative total return of (i) the NASDAQ Market Index and (ii) the NASDAQ Biotechnology Index. This graph assumes the investment of $100.00 after the market closed on December 31, 2009 in our common stock, and in the NASDAQ Market Index and the NASDAQ Biotechnology Index, and it assumes any dividends are reinvested. The stock price performance included in this graph is not necessarily indicative of future stock price performance.

Item 6. Selected Financial Data.

You should read the selected consolidated financial data presented below in conjunction with the audited consolidated financial statements appearing elsewhere in this report and the notes to those statements and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The selected consolidated financial data as of December 31, 2014 and 2013, and for each of the years in the three-year period ended December 31, 2014, have been derived from our audited consolidated financial statements which appear elsewhere in this report. The selected consolidated financial data as of December 31, 2012, 2011 and 2010 and for the years ended December 31, 2011 and 2010 have been derived from our audited consolidated financial statements which are not included in this report. The historical results are not necessarily indicative of the operating results to be expected in the future. All financial information presented has been prepared in United States dollars and in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP).

Year Ended December 31,

(In thousands, except per share data)

Income Statement Data:	2014	2013	2012	2011	2010
Revenues:					
Grant	$488	$452	$584	$329	$659
Sales and services	3,337	8	—	—	—
Collaboration and reimbursable research and development costs	—	—	—	200	23
Total revenues	3,825	460	584	529	682
Loss from operations	(34,742)	(21,668)	(4,852)	(3,242)	(1,812)
Net loss	$(34,657)	$(21,911)	$(4,845)	$(3,236)	$(1,808)
Net loss per share - basic and diluted	$(1.30)	$(1.46)	$(0.42)	$(0.33)	$(0.20)
Weighted average number of shares during the period - basic and diluted	26,679	15,046	11,405	9,922	8,834

As of December 31,

(In thousands)

Balance Sheet Data:	2014	2013	2012	2011	2010
Cash and cash equivalents	$71,902	$31,667	$5,091	$3,467	$5,278
Intangibles, net	30,976	33,321	—	—	—
Goodwill	24,041	24,041	—	—	—
Total assets	141,541	92,582	6,781	4,569	5,688
Total liabilities	32,828	25,773	584	359	604
Stockholders' equity	108,713	66,809	6,197	4,210	5,084

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 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 as well as 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) Cynviloq™, our lead oncology drug product candidate, a polymeric, albumin-free nanoparticle paclitaxel formulation, and (ii) resiniferatoxin, or 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 monoclonal antibodies (mAbs), including our fully human anti- PD-L1 and anti-PD-1 checkpoint inhibitors derived from our proprietary G-MAB® library platform, antibody drug conjugates (ADCs), bispecific antibodies (BsAbs), as well as Chimeric Antigen Receptor Tumor-attacking Neukoplast® (CAR.TNK™, pronounced “CARTANK”) for adoptive cellular immunotherapies (ACI). Our objective is to develop our antibody drug products and adoptive cellular immunotherapies as: (i) First in Class (FIC), and/or (ii) Best in Class (BIC), which may offer greater efficacy and/or fewer adverse events or side effects as compared to existing drugs.

Through December 31, 2014, 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 2015. 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 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 product candidates by advancing the development, we regularly also consider partnerships with pharmaceutical or biopharmaceutical companies in order to balance the risks and costs 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.

Significant 2014 Developments

Bank Loan and Security Agreement. In March 2014, we entered into an amended and restated loan and security agreement, increasing the September 2013 facility to $12.5 million from $5.0 million, with the same two banks, which was funded at closing. The interest rate on the amended and restated loan is 7.95% per annum. In October 2014, we entered into a second amendment to the amended and restated loan and security agreement which extended the interest only period from October 1, 2014 to May 1, 2015, after which equal monthly payments of principal and interest are due until the loan maturity date of September 30, 2017.

Underwritten Public Offering. In May 2014, we closed an underwritten public offering of 4,765,000 shares of common stock, at $5.25 per share, and in June 2014, closed the full exercise of the over-allotment option granted to the representative of the underwriters to purchase an additional 714,750 shares of its common stock, with total gross proceeds of $28.8 million, before underwriting discounts and commissions and other offering expenses payable by us.

Agreement with Morphotek. In June 2014, we entered into a collaboration agreement with Morphotek, Inc., or Morphotek, to generate novel ADCs based on a Morphotek antibody linked to chemotherapeutic agents using proprietary ADC Technology. Under the terms of the agreement, we received $200,000 during 2014 upon the completion and delivery of the agreed upon initial quantity of ADC's and we will receive future research fees, milestone payments and royalties on future net sales. Additionally, we have the potential to receive up to $50 million upon the successful attainment of key milestones.

Agreement with Lee's Pharmaceutical. In October 2014, we entered into a license agreement with China Oncology Focus Limited, an affiliate of Lee's Pharmaceutical Holdings Limited, or Lee's Pharma, pursuant to which Lee's Pharma licensed our fully human immune-oncology anti-PD-L1 monoclonal antibody STI-A1014. Under the terms of the agreement, Lee's Pharma received exclusive rights to develop and commercialize the STI-A1014 for the greater Chinese market, including Mainland China, Hong Kong, Macau, and Taiwan. In turn, we received an up-front payment of $1.0 million recorded as deferred revenue at December 31, 2014, and will receive potential future milestone payments and royalties on future net sales. In total, we have the potential to receive more than $46 million upon the successful attainment of key milestones, excluding royalties, and retain all the rights to use data generated by Lee's Pharma for territories outside of the greater Chinese market. Additionally, Lee's Pharma purchased 400,000 shares of our common stock at a price of $9.00 per share, or an aggregate of $3.6 million, before commissions.

Joint Venture Agreement. In December, 2014, we entered into an agreement with NantBioCell, LLC, or NantBioCell, a wholly owned subsidiary of Nantworks, a private company owned by Dr. Patrick Soon-Shiong. Under the terms of the agreement, we and NantBioCell intend to establish a new joint venture called The Immunotherapy Antibody JV,

or JV, as an independent biotechnology company with $20.0 million initial joint funding expected mid-2015, $12.0 million from NantBioCell and $8.0 from us representing a at 60:40 ownership between NantBioCell and us, respectively. The JV will focus on accelerating the development of multiple immuno-oncology monoclonal antibodies (mAbs) for the treatment of cancer, including but not limited to anti-PD-1, anti-PD-L1, anti-CTLA4 mAbs, and other immune-check point antibodies as well as antibody drug conjugates (ADCs) and bispecific antibodies. In connection with this agreement we entered into a securities purchase agreement with Cambridge Equities, LP, or Cambridge, a limited partnership owned by Dr. Soon-Shiong, pursuant to which we agreed to issue and sell to Cambridge a 19.9% equity stake or an aggregate of 7,188,062 shares of our common stock at a price of $5.80 per share for an aggregate purchase price of $41.7 million. In connection with the purchase agreement, Cambridge received a warrant to purchase 1,724,138 shares of our common stock. The warrant is exercisable for a period of three years from the date of issuance at an initial exercise price of $5.80 per share and is subject to customary adjustments provisions for stock splits, stock dividends, recapitalizations and the like.

Agreement with Conkwest Incorporated. In December 2014, we also entered into a collaboration agreement with Conkwest Incorporated, or Conkwest, a privately-held life sciences company developing and commercializing the proprietary cancer-killing cell line Neukoplast (also known as NK-92) for the treatment of cancers and viral infections. Jointly, we and Conkwest will generate and

develop products for adoptive immunocellular therapy utilizing Neukoplast cells and chimeric antigen receptors, or CARs, derived from our G-MAB antibody library. The product candidates, coined chimeric antigen receptor tumor-attacking Neukoplast (CAR.TNK), will be developed for the treatment of hematological malignancies as well as solid tumors. Under the terms of the agreement, we and Conkwest will establish an exclusive global strategic collaboration focused on accelerating the development of CAR.TNKs, including CD19-CAR.TNK™, PD-L1-CAR.TNK™, PSMA-CAR.TNK™, CD123-CAR.TNK™, and other CAR.TNKs for the treatment of hematological malignancies as well as solid tumors. Both companies will jointly own and share development costs and revenues from any developed CAR.TNK products. In connection with this agreement we entered into a subscription and investment agreement with Conkwest, as amended, pursuant to which Conkwest issued and sold to us an aggregate of 3,034,473 shares of Conkwest Class A common stock for an aggregate purchase price of $10.0 million representing an equity stake in Conkwest of approximately 9%.

Related Party Agreements with Wholly-Owned Subsidiary Ark Animal Health, Inc.

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

Transition Services Agreement. On June 18, 2014, we entered into a Transition Services Agreement (TSA) with Ark which became effective retroactively to April 1, 2014. Under the TSA, we have provided and/or have made available to Ark various administrative, financial, legal, insurance, facility, information technology, laboratory, real estate and other services to be provided by, or on our behalf, together with such other services as reasonably requested by Ark. In consideration for such services, Ark will pay fees to us for the services provided, and those fees will generally be in amounts intended to allow us to recover all of our direct and indirect costs incurred in providing such services. The personnel performing services under the TSA are employees and/or independent contractors of ours and are not under the direction or control of Ark. These personnel costs are based upon the actual percentages of time spent by our personnel performing services for Ark under the TSA. In addition, Ark will reimburse us for direct out-of-pocket costs incurred by us for third party services provided to Ark. As of December 31, 2014, we have recorded $991,000 of costs associated with activities contemplated under the TSA. Such intercompany transactions have been eliminated in consolidation. In order for us to be reimbursed by Ark for activities provided under the TSA, Ark must be successful in raising financing on a stand-alone basis. There can be no assurance that Ark will be successful in securing third party financing.

Loan and Security Agreement. On June 18, 2014, we entered into a Loan and Security Agreement (Loan Agreement) with Ark pursuant to which we agreed to lend Ark, as amended in August 2014, up to $1.0 million for working capital purposes. Advances under the Loan Agreement bear interest at six percent (6%) per annum. Outstanding advances mature on the earlier of: (i) following the consummation of any public or private offering of securities in which Ark receives gross proceeds of at least $5.0 million, (ii) an event of default under the Loan Agreement, or (iii) June 18, 2015. In connection with the Loan Agreement, we have a security interest in all of Ark’s assets, including Ark’s intellectual property, until the loan is repaid in full. During the period from Ark’s inception in February 2014 through December 31, 2014, we paid for certain general, administrative and research and development expenses totaling $991,000. The intercompany balances associated with these transactions have been eliminated in consolidation.

Results of Operations

The following discussion of our operating results explains material changes in our results of operations for the years ended December 31, 2014, 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, 2014 and 2013

(figures in 000's unless otherwise specified)

Revenues. Revenues were $3,825 for the year ended December 31, 2014, as compared to $460 for the year ended December 31, 2013. The net increase of $3,365 is primarily due to sales and service revenues of $3,337 generated from the sale of customized reagents and providing contract development services from the Concortis operations that was acquired in December 2013. Activities under our active grants for the year ended December 31, 2014 were higher than in the corresponding period of 2013 due primarily to an increase in active grants in the year ending December 31, 2014 as compared to the active grants in the same period of 2013.

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, 2014, 2013 and 2012, were $150, $308 and $129, respectively

In June 2014, the NIAID awarded us a Phase II STTR grant to support the advanced preclinical development of human bispecific antibody therapeutics to prevent and treat Staphylococcus aureus (S. aureus or Staph) infections, including methicillin-resistant S. aureus (MRSA), or the Staph Grant III award. The project period for this Phase II grant covers a two-year period which commenced in June 2014, with total funds available of approximately $1 million per year for up to 2 years. During the year ended December 31, 2014, we recorded $220 of revenue associated with the Staph Grant III award.

In June 2014, we were awarded a Phase I STTR grant entitled “Anti-Pseudomonas Immunotherapy and Targeted Drug Delivery” from the NIAID. This grant will support the preclinical development of novel anti-Pseudomonas aeruginosa mAb immunotherapy or an antibody-mediated targeted antibiotic delivery vehicle. Each modality may be an effective and safe stand-alone therapy and/or a component of a “cocktail” therapeutic option for prevention and treatment of P. aeruginosa infections. The project period for this Phase I grant covers a two-year period which commenced in July 2014, with total funds available of approximately $300 per year for up to 2 years. During the year ended December 31, 2014, we recorded $28 of revenue associated with the Phase I STTR grant award.

In July 2014, we were awarded a Phase I STTR grant from the National Cancer Institute (NCI), a division of the NIH, entitled “Targeting of Myc-Max Dimerization for the Treatment of Cancer”. This grant will support the preclinical development of the Myc inhibitor, which interferes with the protein-protein interaction (PPI) between Myc and its obligatory dimerization partner, Max, preventing sequence-specific binding to DNA and subsequent initiation of oncogenic transformation. The project period for this Phase I grant covers a one-year period which commenced in August 2014, with total funds available of approximately $225. During the year ended December 31, 2014, we recorded $86 of revenue associated with the Phase I Myc grant award.

In August 2014, the National Heart, Lung, and Blood Institute (NHBLI), a division of the NIH awarded the Company a Phase I Small Business Technology Transfer (SBIR) grant entitled “Human Anti-WISP-1 Antibodies for Treatment of Idiopathic Pulmonary Fbrosis”. This grant will advance our immunotherapy targeting WNT-1 Inducible Signaling Protein-1(WISP1) for the treatment of Idiopathic Pulmonary Fibrosis (IPF). WISP1 is a protein that has been shown to be upregulated in IPF, linked to key growth factors, cellular proliferation, hyperplasia and is correlated with late stage cancers. IPF is a fatal disease which results in progressive loss of lung function due to fibrosis of the lungs. The project period for this Phase I grant covers a one-year period which commenced in August 2014, with total funds available of approximately $225. During the year ended December 31, 2014, we recorded $5 of revenue associated with the Phase I WISP1 grant award.

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 for the year ended December 31, 2014 and 2013 were $2,043 and $4, respectively. The increase is due primarily to 2014 reflecting a full year of the sale of customized reagents and providing contract development services compared to the costs from our mid December 2013 acquisition of Concortis through the prior year-end. The costs generally include employee salaries and benefits, direct materials and overhead costs including rent, depreciation, utilities, facility maintenance and insurance. We expect cost of revenues to fluctuate with related revenues.

Research and Development Expenses. Research and development expenses for the years ended December 31, 2014 and 2013 were $23,983 and $9,017, respectively. Research and development expenses include the costs to conduct our

BE registration trial related to Cynviloq and prepare for our New Drug Application filing anticipated in 2015, costs to advance our RTX program activities towards entering into future clinical trials, costs to identify, isolate and advance human antibody drug candidates derived from our libraries as well as advancing our ADC preclinical drug candidates, 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, clinical development expenses, preclinical testing, lab supplies, consulting costs, depreciation and other expenses. The increase of $14,966 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 and our BE registration trial and activities to advance RTX into clinical trials and potentially pursue other human indications, and to fund Ark activities in advance of Ark securing stand-alone financing. We expect research and development expenses to increase in absolute dollars as we: (i) advance our Cynviloq BE registration trial and pursue other potential indications, including expenses incurred under agreements with CROs and investigative sites that conduct our 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 further 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 our programs, and (v) invest in our JV's or other third party agreements.

Acquired In-process Research and Development Expenses. Acquired in-process research and development expenses for the years ended December 31, 2014 and 2013 were $209 and $5,986, respectively. Acquired in-process research and development expenses for the year ended December 31, 2014 include the costs associated with a research agreement. Acquired in-process research and development expenses for the year ended December 31, 2013 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, 2014 and 2013 were $9,987 and $6,317, 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 $3,670 is primarily attributable to higher salaries and related compensation expenses, stock-based compensation, legal costs related to general corporate and IP matters, consulting and business development expenses and higher compliance costs associated with our public reporting obligations, and to fund Ark activities in anticipation of Ark securing stand-alone financing. 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) and increased infrastructure costs, and (iii) invest in our JV's or other third party agreements.

Intangible Amortization. Intangible amortization for the years ended December 31, 2014 and 2013 was $2,345 and $804, respectively. The increase resulted primarily from the acquisition and amortization of intangible license rights from IgDraSol and from acquired technology and customer relationships from Concortis, all acquired in the latter part of 2013.

Interest Expense. Interest expense for the years ended December 31, 2014 and 2013 was $1,629 and $253, respectively. The increase in interest expense resulted primarily from higher average borrowings under the amended loan and security agreement entered into in March 2014.

Interest Income. Interest income for the years ended December 31, 2014 and 2013 was $12 and $10, respectively. The increase in interest income resulted from higher average cash balances in 2014 as compared to the same period in 2013. We expect that continued low interest rates will significantly limit our interest income in the near term.

Income tax benefit. Income tax benefit for the years ended December 31, 2014 and 2013 was $1,702 and $0, respectively. The increase in income tax benefit resulted mainly from the amortization and decrease of deferred tax liabilities, return to provision true-ups.

Net Loss. Net loss for the years ended December 31, 2014 and 2013 was $34,657 and $21,911, respectively. The increase in net loss is mainly attributable to the expanded research and development, intangible amortization and general and administrative activities.

Comparison of the Years Ended December 31, 2013 and 2012

Revenues. Revenues were $460 for the year ended December 31, 2013, as compared to $584 for the year ended December 31, 2012. The net decrease of $124 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. We recorded revenue associated with the grant as the related costs and expenses were incurred. During the year ended December 31, 2013 and 2012, we recorded $0 and $119 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. The C. difficile Grant award revenues for the years ended December 31, 2013 and 2012 were $144 and $336, respectively.

In June 2012, we were awarded a third Advanced Technology Small Business Technology Transfer Research grant, with an initial award of $300, 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. The Staph Grant II award revenues for the years ended December 31, 2013 and 2012 were $308 and $129, respectively.

Sales and service revenues of $8 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.

Cost of revenues. Cost of revenues relate to sales and services costs totaling $4. 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 $9,017 and $3,830, 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 $5,187 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.

Acquired In-process Research and Development Expenses. Acquired in-process research and development expenses for the years ended December 31, 2013 and 2012 were $5,986 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 and $1,606, 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 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.

Intangible Amortization. Intangible amortization for the years ended December 31, 2013 and 2012 was $804 and $0, respectively. The increase resulted primarily from the acquisition and amortization of 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 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 $10 and $7, 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 and $4,845, 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, 2014, we had $71,902 in cash and cash equivalents primarily attributable to: (i) issuance of 7.2 million shares of our common stock for cash to Cambridge Equities in a private equity financing totaling $41,723, (ii) issuance of 400,000 shares of our common stock for cash to Lee's Pharmaceuticals in a private equity financing totaling $3,420, (iii) the closing of our underwritten public offerings in October 2013 and May 2014 and conversion of outstanding promissory notes into our common stock for aggregate net proceeds of $59,847, and (iv) net borrowings under our $12.5 million amended and restated loan and security agreement in March 2014. Our working capital as of December 31, 2014 was $64.4 million.

Cash Flows from Operating Activities. Net cash used for operating activities was $28,764 for 2014 and is primarily attributable to our net loss of $34,657 and our net reduction in working capital balances of $222, which were offset by $6,115 in non-cash activities relating to stock-based compensation, acquired in-process research and development, depreciation and amortization expense and other non-cash activities. Net cash used for operating activities was $16,489 for 2013 and primarily reflects a net loss of $21,911, which was partially offset by $4,984 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 $10,591 for 2014 as compared to $503 for 2013. The net cash used related primarily to an investment in Conkwest Incorporated Class A common stock and equipment acquired for research and development activities.

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 2014 and 2013 was $79,590 and $43,568, respectively, which were primarily derived from the issuance of common stock for cash, the closing of our underwritten public offerings and cash provided by increases in net borrowings under our amended and restated loan and security agreement.

Future Liquidity Needs. From inception through December 31, 2014, we have principally financed our operations through underwritten public offerings of our common stock and private equity financings with aggregate net proceeds of $124,938, as we have not generated any product related revenue from our planned principal operations to date, and do not expect to 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 our operations and fund our portion of the JV activities. 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.

We anticipate that we will continue to incur net losses into the foreseeable future as we: (i) complete 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 indications, (iii) continue to identify and advance a number of potential mAb and ADC drug candidates into preclinical development activities, (iv) continue our

development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products, (v) expand our corporate infrastructure, including the costs associated with being a NASDAQ listed public company, and (vi) ownership of our share of JV and collaboration costs for our products and technologies. 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 operating losses 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 the ability to offer up to $100 million of securities, including equity and other securities as described in the registration statement. After the May 2014 underwritten offering (see Note 9), we have the ability to offer up to $36.6 million of additional securities. In November 2014, we filed an additional universal shelf registration statement on Form S-3 with the SEC, which was declared effective by the SEC in December 2014. This Shelf Registration Statement provides us with the ability to offer up to $250 million of securities, including equity and other securities as described in the registration statement. Included in the November 2014 shelf registration is a sales agreement prospectus covering the offering, issuance and sale by us of up to a maximum aggregate offering price of $50.0 million of our common stock that may be issued and sold under a sales agreement with MLV & Co. LLC. Pursuant to these Shelf Registration Statements, 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.

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, 2014, 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. 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. 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 contract development services. Reagents are used for preparing ADCs, these reagents include industrial standard cytotoxins, linkers, and linker-toxins. The contract development 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, 2014, 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.

Interest Rate Risk. Our exposure to market risk is confined to our cash and cash equivalents. We have cash and cash equivalents and invest primarily in high-quality money market funds, which we believe are subject to limited credit risk. Due to the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. Our amended and restated loan and security agreement has a fixed interest rate of 7.95% per annum through the loan maturity. We do not believe that we have any material exposure to interest rate risk arising from our investments.

Capital Market Risk. We currently do not have significant revenues from grants or sales and services and we have no product revenues from our planned principal operations and therefore depend on funds raised through other sources. One source of funding is through future debt or equity offerings. Our ability to raise funds in this manner depends upon, among other things, capital market forces affecting our stock price.

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.

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 principal financial and accounting 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 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 principal financial and accounting 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 principal financial and accounting officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by 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, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for our company. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) promulgated under the Exchange Act, as a process designed by, or under the supervision of, a company's principal executive and principal financial officer and effected by the Company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

(1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made in accordance with authorizations of management and directors of the company; and

(3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible enhancements to controls and procedures.

We conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our principal executive officer and principal financial officer conclude that, at December 31, 2014, our internal control over financial reporting was effective.

The effectiveness of our internal control over financial reporting at December 31, 2014 has been audited by Mayer Hoffman McCann P.C., an independent registered public accounting firm, as stated in their report which appears

herein.

Item 9B. Other Information.
None

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 2015 Proxy Statement and is incorporated herein by reference.

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 2015 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 2015 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 2015 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 2015 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*	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).
2.2*	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).

Exhibit No.	Description
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	Amended and Restated Rights Agreement, dated as of December 22, 2014 by and between Sorrento Therapeutics, Inc. and Philadelphia Stock Transfer, Inc.., 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 December 23, 2014).
4.4	Common Stock Purchase Warrant issued to Cambridge Equities, LP.
10.1+	Exclusive License and Development Agreement between Sorrento Therapeutics, Inc. and China Oncology Focus Limited dated October 3, 2014 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q/A filed with the SEC on November 25, 2014).
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).
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+	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).
10.10±	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).
10.11±	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 September 7, 2012).	

Exhibit No.	Description
10.12±	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).
10.13±	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).
10.14±	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).
10.15±	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).
10.16±	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).
10.17±	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).
10.18	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).
10.19*	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).

10.20*	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).
10.21*	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. (incorporated by reference to Exhibit 10.32 to the Registrant's Annual Report on Form 10-K filed with the

	SEC on April 1, 2014).
10.22	Second Amendment to Amended and Restated Loan and Security Agreement between Sorrento Therapeutics, Inc., Oxford Finance LLC and Silicon Valley Bank dated October 30, 2014 (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 4, 2014).
10.23±	Employment Agreement, dated December 19, 2013, by and between Sorrento Therapeutics, Inc. and Zhenwei Miao. (incorporated by reference to Exhibit 10.33 to the Registrant's Annual Report on Form 10-K filed with the SEC on April 1, 2014)
10.24	Securities Purchase Agreement dated December 14, 2014 by and between Sorrento

	Therapeutics, Inc. and Cambridge Equities, LP.
10.25	First Amendment to Securities Purchase Agreement dated December 22, 2014 by and between Sorrento Therapeutics, Inc. and Cambridge Equities, LP.
10.26	Form of Subscription and Investment Agreement, dated as of December 18, 2014, by and between Conkwest, Inc. and Sorrento Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on December 19, 2014).
10.27	Form of Registration Rights Agreement, dated as of December 18, 2014, by and between Conkwest, Inc. and Sorrento Therapeutics,

	Inc. (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on December 19, 2014).
10.28	Form of First Amendment to Subscription and Investment Agreement, dated as of December 23, 2014, by and between Conkwest, Inc. and Sorrento Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on December 29, 2014).

Exhibit No.	Description
10.29	Form of Stockholders' Agreement, dated as of December 23, 2014, by and among Conkwest, Inc., Sorrento Therapeutics, Inc., Cambridge Equities, LP and the persons listed on Schedule A thereto (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on December 29, 2014).
10.30*	Lease dated as of February 3, 2015 by and between HCP University Center West LLC and Sorrento Therapeutics, Inc.
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 Douglas Langston, Principal Financial and Accounting 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 Douglas Langston, Principal Financial and Accounting Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, as amended.
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.

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: March 13, 2015 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)	March 13, 2015
/s/ Douglas Langston Douglas Langston	Vice President, Finance (Principal Financial and Accounting Officer)	March 13, 2015
/s/ WILLIAM S. MARTH William S. Marth, Ph.D.	Director	March 13, 2015
/s/ Douglas Ebersole Douglas Ebersole	Director	March 13, 2015
/s/ KIM D. JANDA Kim D. Janda, Ph.D.	Director	March 13, 2015
/s/ MARK DURAND Mark Durand	Director	March 13, 2015
/s/ JAISIM SHAH	Director	March 13, 2015

Jaisim Shah

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Sorrento Therapeutics, Inc.

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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, 2014 and 2013, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three year period ended December 31, 2014. 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 (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes 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 financial position of Sorrento Therapeutics, Inc. and Subsidiaries as of December 31, 2014 and 2013, and the results of their operations and their cash flows for each of the years in the three year period ended December 31, 2014, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Sorrento Therapeutics, Inc. and Subsidiaries internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 13, 2015 expressed an unqualified opinion.

/s/ Mayer Hoffman McCann P.C.

San Diego, CA

March 13, 2015

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 Sorrento Therapeutics, Inc. and Subsidiaries (the "Company") internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that

controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Sorrento Therapeutics, Inc. and Subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets and the related statements of operations, stockholders' equity, and cash flows of Sorrento Therapeutics, Inc. and Subsidiaries, and our report dated March 13, 2015, expressed an unqualified opinion.

/s/ Mayer Hoffman McCann P.C.

San Diego, California

March 13, 2015

SORRENTO THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except for share amounts)

	December 31,	
	2014	2013
ASSETS		
Current assets:		
Cash and cash equivalents	$71,902	$31,667
Grants and accounts receivables, net	732	394
Prepaid expenses and other, net	1,281	571
Total current assets	73,915	32,632
Property and equipment, net	2,277	2,440
Intangibles, net	30,976	33,321
Goodwill	24,041	24,041
Investment in common stock	10,000	—
Other, net	332	148
Total assets	$141,541	$92,582
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$1,656	$2,153
Accrued payroll and related	1,825	1,664
Current portion of deferred compensation	1,893	904
Accrued expenses	867	385
Current portion of debt	3,316	374
Total current liabilities	9,557	5,480
Long-term debt	8,830	4,431
Deferred compensation	796	1,497
Deferred tax liabilities	12,546	14,248
Deferred revenue, rent and other	1,099	117
Commitments and contingencies		
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 36,184,912 and 23,028,100 shares issued and outstanding at December 31, 2014 and 2013, respectively	4	2
Additional paid-in capital	176,227	99,668
Accumulated deficit	(67,518)	(32,861)
Total stockholders' equity	108,713	66,809
Total liabilities and stockholders' equity	$141,541	$92,582

See accompanying notes

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SORRENTO THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

For the Years Ended December 31, 2014, 2013 and 2012

(In thousands, except for share amounts)

	2014	2013	2012
Revenues:			
Grant	$488	$452	$584
Sales and services	3,337	8	—
Total revenues	3,825	460	584
Operating costs and expenses:			
Costs of revenues	2,043	4	—
Research and development	23,983	9,017	3,830
Acquired in-process research and development	209	5,986	—
General and administrative	9,987	6,317	1,606
Intangible amortization	2,345	804	—
Total costs and operating expenses	38,567	22,128	5,436
Loss from operations	(34,742)	(21,668)	(4,852)
Interest expense	(1,629)	(253)	—
Interest income	12	10	7
Loss from operations before income tax	(36,359)	(21,911)	(4,845)
Income tax benefit	(1,702)	—	—
Net loss	$(34,657)	$(21,911)	$(4,845)
Net loss per share - basic and diluted	$(1.30)	$(1.46)	$(0.42)
Weighted average number of shares during the period - basic and diluted	26,679	15,046	11,405

See accompanying notes

SORRENTO THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

For the Years Ended December 31, 2014, 2013 and 2012

(In thousands, except for share amounts)

	Common Stock Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total
Balance, December 31, 2011	10,493,887	$ 1	$ 10,313	$ (6,105)	$4,209
Issuance of common stock in connection with the exercise of stock options	10,800	—	36	—	36
Issuance of common stock for cash at $4.00 per share, net of issuance costs of $66	1,500,000	—	5,934	—	5,934
Stock-based compensation	—	—	863	—	863
Net loss	—	—	—	(4,845)	(4,845)
Balance, December 31, 2012	12,004,687	$ 1	$ 17,146	$ (10,950)	$6,197
Issuance of common stock in connection with the exercise of stock options	7,300	—	17	—	17
Issuance of common stock for cash at $4.50 per share, net of issuance costs of $64	1,426,406	—	6,354	—	6,354
Issuance of common stock with assignment agreement	10,000				