Sorrento Therapeutics, Inc.
Form 10-K
March 22, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended: December 31, 2016

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.)
9380 Judicial Drive, 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:

Title of each class	Name of exchange on which registered
Common Stock, par value $0.0001 per share	The NASDAQ Stock Market LLC

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes 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 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. 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). 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.

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

Large accelerated filer Accelerated filer

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes 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, 2016 (the last trading day of the registrant's second fiscal quarter of 2016), as reported on The NASDAQ Capital Market, was approximately $366.5 million.

At March 9, 2017, the registrant had 50,887,102 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of our Proxy Statement for the 2017 Annual Meeting of Stockholders or an amendment to this Annual Report on Form 10-K, to be filed within 120 days of December 31, 2016, are incorporated by reference in Part III.

SORRENTO THERAPEUTICS, INC.

ANNUAL REPORT ON FORM 10-K

FISCAL YEAR ENDED DECEMBER 31, 2016

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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

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

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

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

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

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

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

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

Our Strategy

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

Our core strategic objectives and resources are focused on:

1. Advancing our lead product candidates through the clinic. These include the initiation of Phase I, Phase II and potentially accelerated approval trials for our cellular therapies, oncolytic virus immunotherapy and RTX in oncology and/or hematology indications.
2. Continuing the development of our preclinical programs with the aim of filing several new INDs over the next 5 years. These include moving our checkpoint inhibitors from our core antibody portfolio into the clinic with several of our strategic partners, while internally focusing on advancing our transformational intracellular targeting antibodies ("iTAbs"), with LA Cell.
3. Collaborating with key opinion leaders and leading clinical and research institutes to enhance our preclinical and clinical development plans. We currently have such agreements in place with the Karolinska Institute, The Scripps Research Institute ("TRSI"), the NIH, City of Hope, Tufts Medical School, and Roger Williams Medical Center, among others.
4. Manufacturing our preclinical and clinical materials in-house. We have established a quality control and quality assurance program, which includes a set of standard operating procedures and specifications designed to ensure that our products are manufactured in accordance with current good manufacturing practices ("cGMPs"), and other applicable domestic and foreign regulations.
5. Exploring strategic relationships to share in the risk reward of our core franchises and to derive near term value from our non-core franchise, such as our pain franchise. Our partnering objectives include generating revenue through license fees, milestone-related development fees and royalties as well as profit shares or joint ventures to generate potential returns from our product candidates and technologies.

Segment Information and Financial Information about Geographic Areas

We have determined that we operate in one operating segment. See Note 3 to the notes to our consolidated financial statements accompanying this Form 10-K for further information. All of our revenues from continuing operations are essentially attributed to the United States. All of our long-lived assets are essentially located within the United States.

Pipeline and Product Candidates

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

Near Term Clinical Programs

Cellular Therapies

With our cellular therapy subsidiary, TNK Therapeutics, Inc. ("TNK"), we are focusing on the development of Chimeric Antigen Receptor ("CAR")-based immunotherapies using autologous T-cells.

T-007: CD38 Directed CAR-T Program

Our most advanced cellular therapy is T-007, a proprietary, second generation anti-CD38 CAR-T therapy, which we are developing for the treatment of multiple myeloma and for additional potential indications including amyloidosis and graft-versus-host disease. Our anti-CD38 CAR-T is based on a fully human anti-CD38 mAb derived from our G-MAB™ antibody library.

The membrane glycoprotein CD38 is widely found on the surface of lymphoid and myeloid lineages including B, T and NK cells, but absent from most mature resting lymphocytes with the notable exception of terminally differentiated plasma cells. Because CD38 is highly expressed on multiple myeloma cells, it represents a valuable and validated therapeutic target against myeloma. Multiple myeloma (MM) is a hematologic malignancy in which clonal plasma cells accumulate in the bone marrow or extramedullary sites and give rise to clinical complications such as painful, lytic bone lesions, hypercalcemia, renal impairment, cytopenias, and symptomatic plasmacytomas.

The American Cancer Society estimate 30,280 new cases and 12,590 deaths from multiple myeloma in the U.S. during 2017. The anti-CD38 monoclonal antibody DARZALEX® (daratumumab), marketed by Janssen Oncology, was granted accelerated approval by the FDA for the treatment of multiple myeloma on November 16, 2015. Worldwide net sales of DARZALEX® were $572 million in 2016. We are encouraged by the validation of this important target in the market for multiple myeloma therapeutics and its rapid adoption by clinicians in the myeloma community. We believe our CD38 cellular therapy will provide an additional significant advance in the CD38 blockade for multiple myeloma patients that are resistant or have failed current therapies.

Pre-clinically, T-007 has demonstrated specific activation through the anti-CD38 CAR resulting in the production of cytokines and CAR-T proliferation. In vitro models have shown that CD38-expressing multiple myeloma tumor cells were killed efficiently, and T-007 completely eradicated tumors in a xenograft mouse model of human myeloma. Importantly, T-007 selectively lysed multiple myeloma target cells expressing high levels of CD38 while avoiding the killing of cells with normal or low levels of CD38. We believe this unique characteristic may result in a more tolerable safety profile in humans and enable a more effective manufacturing process of our anti-CD38 CAR-T cells since we do not anticipate to require a genetic CD38 knock-out or knock-down in our construct.

We believe T-007 benefits from 3 key advantages:

1. Non-Immunogenic: T-007 is based on a fully human mAb generated from our GMAB® library. Fully human mAbs generally do not have the immunogenicity concerns that arise from the mouse antibody sequence found in most current CARs. This may result in a potentially more tolerable CAR-T regimen, and a more durable long term response.
2. Selective Lysing of High Expressing CD38 Positive Cells: Ability to selectively lyse CD38 high expression cells only, may limit on-target / off-tumor toxicity.
3. Has Not Demonstrated Graft versus Host Disease: Our anti-CD38 CAR-T cells did not cause GvHD in vivo. This could have implications on our ability to apply this therapy in an allogeneic setting.

Our intention is to submit an IND for T-007 in 2017, and initiate a Phase I trial shortly thereafter.

T-009: CD123 Directed CAR-T Program

T-009 is a proprietary, second generation anti-CD123 CAR-T therapy which we are developing for the treatment of AML, also known as acute myelogenous leukemia or acute non-lymphocytic leukemia, a cancer of the myeloid line of blood cells, characterized by the rapid growth of abnormal white blood cells that accumulate in the bone marrow and interfere with the production of normal blood cells. AML is the most common acute leukemia affecting adults, and its incidence increases with age. The American Cancer Society estimates 21,380 new cases and 10,590 deaths from acute myeloid leukemia in the U.S. during 2017. Our anti-CD123 CAR-T is based on a fully human anti-CD123 mAb derived from our G-MAB™ antibody library.

CD123 is overexpressed in a variety of hematological neoplasms, including AML, blastic plasmacytoid dendritic cell neoplasm (BPDCN), acute lymphoblastic leukemia (“ALL”), chronic myeloid leukemia (“CML”), Hodgkin’s lymphoma and hairy cell leukemia. The overexpression of CD123 has been clinically correlated with a lower survival rate in AML patients and thus, we believe our T-009 could provide an important therapy in this disease.

To date, T-009 has demonstrated specific activation resulting in the production of cytokines and CAR-T proliferation. T-009 has selectively lysed CD123-expressing AML tumor cells in vitro, and strongly suppressed the growth of established tumors in a xenograft mouse model of human AML. Upon the completion of our preclinical testing of T-009, we will plan to submit an IND for first in human trials in AML.

Technologies and Preclinical Pipeline

G-MAB™: Fully Human Antibody Library Platform

Our G-MAB™ library, which forms the backbone of many of our product candidates, was initially invented by Henry Ji, Ph.D., our co-founder, President and Chief Executive Officer. We believe our proprietary G-MAB™ library is one of the industry’s largest and most diverse fully human antibody libraries, with an estimated one quadrillion unique antibodies available for drug discovery and development. We believe G-MAB™ may offer the following advantages over competing antibody libraries:

- G-MAB™ has been designed to provide a full spectrum of human immunoglobulin gene recombination in fully-human mAbs. Unlike chimeric and humanization technologies, G-MAB™ has allowed the generation of antibodies with fully-human protein sequences without the challenges and limitations of animal-to-human gene transfer procedures.
- Because G-MAB™ represents an in vitro human mAb library technology, research suggests that it enables faster and cost-effective in vitro screening of a large number of antigens. G-MAB™ is designed so that any antigen of interest can be investigated, with no dependence on the successful induction of a host immune response against the antigen.

The following is a depiction of the types of fully human mAbs that we have derived from G-MAB™. 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 ("GPCRs"), a difficult class of antigens to raise therapeutic antibodies against.

Our objective is to leverage G-MAB™ to develop first in class or best in class antibody drug candidates that will possess greater efficacy and fewer side effects as compared to existing drugs and develop them as novel monotherapies, ADCs (such as c-MET), components of bispecific antibodies, and as part of our adoptive immunotherapy (CD38, CD123) and intracellular targeting programs (STAT3, mutant KRAS).

To date, we have screened over 100 validated targets and generated a number of fully human antibodies against these targets which are at various stages of development. These include PD-1, PD-L1, CD38, CD123, CD47, c-MET, VEGFR2, CCR2, OX40, TIGIT and CD137 among others. Upon the completion of preclinical studies, our objective is to, independently or in tandem with our strategic collaborators, file INDs for these product candidates.

The following diagrams highlight our key antibody-related strategic partnerships and programs:

LA Cell: Intracellular Targeting Antibodies (iTAbs)

With LA Cell, our exclusive joint venture with City of Hope, our objective is to become the global leader in the development of modified antibodies and other macromolecules against intracellular targets. Our internal research suggests that LA Cell's platform is highly disruptive in that it uniquely enables the penetration of large molecules such as antibodies, peptides and modified DNA into disease cells.

We are looking to apply this technology to specifically modulate formerly "undruggable" targets known in the evolution of cancer, inflammation, autoimmune diseases, diabetes, central nervous system diseases, cardiovascular diseases and viral infections.

Antibodies and other protein based therapeutics, compared to other drug modalities, have the advantage of specificity, ease of creation and long-lasting effects in vivo. Although these therapies have benefited many patients across many solid and hematological malignancies, they are currently constrained in their ability to target solely extracellular proteins, either secreted or membrane bound. Separately, small molecule drugs are less specific, depend on defined hydrophobic binding pockets and have proven difficult to administer long term given their many off-target toxicities.

In contrast, LA Cell's proprietary technology and iTAbs enable the ability to modulate intracellular targets with modified antibodies derived from our G-MAB™ library. Our lead product candidates focus on key "undruggable" disease targets, such as STAT3, mutant KRAS, MYC and FOXP3 and we have designed constructs which are at various stages of in vitro and in vivo testing.

STAT3 iTAb

Our lead iTAb is targeted against STAT3 and has demonstrated the inhibition of STAT3 through phosphorylation and downstream gene modulation as well as cytotoxic/cytostatic activity in multiple human cancer cells in vitro. STAT3 is a master regulator of genes controlling cell proliferation, survival, migration and immune suppression which is highly upregulated in human cancers. Persistent STAT3 activation has been shown to lead to abnormal survival and tumorigenesis with constitutive STAT3 activation reported in 50-90% of human cancers. This prevalence can be attributed to STAT3's position as the convergence point of several major oncogenic signaling including EGFR, HER2/Neu, platelet-PDGFR, IL-6R/gp130, c-MET, ABL and Src tyrosine kinases. We believe our STAT3 iTAb will be useful in the treatment of severely undertreated cancers such as glioblastoma. STAT3 has emerged as a key initiator and master regulator of mesenchymal transformation in malignant gliomas. We have completed in vitro and pharmacokinetic work and are currently conducting in vivo validation of this iTAb.

Mutant KRAS iTAb

Our second most advanced iTAb is targeted against mutant KRAS. 30% of human cancers possess activating RAS mutations, 85% of which are KRAS mutations which are most frequently present in colorectal, pancreatic and lung cancers. In vitro, our $KRAS^{G12D}$ iTAb has demonstrated specific cytotoxic activity only in $KRAS^{G12D}$-expressing cancer cells but not in wild-type KRAS cells.

Biosimilar Antibody Portfolio

In August 2015, we entered into an exclusive licensing agreement with Mabtech Limited to develop and commercialize four, late-stage clinical biosimilar or biobetter antibodies based on Erbitux®, Remicade®, Xolair® and Simulect® for the North American, European and Japanese markets. Each of these four antibody programs has completed Phase 3 clinical trials in China. We are assessing the regulatory and strategic path forward for this portfolio due to the fact that, if we are to follow the biosimilar route, we will be required to perform comparative studies versus the reference products in the U.S. and EU.

Pain Franchise

Our pain franchise consists of Scilex Pharmaceuticals Inc. (“Scilex”), a private company which we acquired a majority interest in November 2016, and our subsidiary, Scintilla Pharmaceuticals, Inc. (“Scintilla”), which houses our RTX program as depicted below:

RTX

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 TRPV1 receptors without affecting normal sensation (touch and vibration sense) or muscle function. RTX has been extensively tested in animals and was tested in an investigator-sponsored Phase I clinical trial at the NIH under a Cooperative Research and Development Agreement (CRADA). To date, 12 patients with terminal cancer pain have been treated at the NIH.

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, TRPV1 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 TRPV1 receptors expressed by specific neurons in dorsal root ganglia and the superficial layers of the dorsal horn of the spinal column. RTX binding to TRPV1 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 TRPV1 positive neurons.

We expect to initiate a dose finding study using epidural administration of RTX in 2017. Given our prior clinical experience with RTX, we expect that the drug will be very well tolerated at all doses and that we will see a dose response. We have hired a contract manufacturer to produce the current good manufacturing practices (“cGMP”) drug substance and have sufficient material to complete the clinical development. We have also secured enough raw materials to cover the commercial needs for several years, including the drug product, also produced by a contract manufacturer, for which we have sufficient vials in storage to complete clinical development. Our plan is to apply for FDA Breakthrough Therapy Designation and potentially initiate pivotal Phase II trials by the end of 2017.

Scilex Pharmaceuticals: ZTlido™

Scilex leverages its core, proprietary technologies to responsibly develop next generation, branded pharmaceutical products to better manage critical conditions and maximize the quality of life of patients and healthcare providers. Scilex’s lead product candidate, ZTlido™ (lidocaine patch 1.8%), is a next-generation lidocaine patch currently in development for the treatment of postherpetic neuralgia (“PHN”), a severe neuropathic pain condition. ZTlido™ is manufactured by our collaboration partner in their state of the art manufacturing facility.

The elderly population, individuals that have suffered a shingles infection, HIV/AIDS and cancer patients are at highest risk of contracting PHN. In the 2016 Centers for Disease Control and Prevention Guideline for Prescribing Opioids in Chronic Pain, topical

lidocaine is recommended for the treatment of neuropathic pain. The prescription lidocaine patch market for all indications totaled almost $700 million in 2015 in the U.S.

ZTlido™'s anhydrous patch is based on a novel and proprietary technology that contains only 36 mg of lidocaine versus Lidoderm® (lidocaine patch 5%), which holds 700 mg of lidocaine per patch. In December 2016 and January 2017, Scilex reported key endpoints were met in the pivotal bioequivalence clinical trials for ZTlido™. The full data package is expected to be resubmitted to the FDA as part of the 505(b)(2) new drug application ("NDA") in mid-2017 (the initial filing was not accepted by the FDA) and filed with the Medicines and Healthcare products Regulatory Agency ("MHRA") in the United Kingdom as part of a hybrid Marketing Authorization Application ("MAA") in mid-2017.

Recent Developments

Yuhan Agreement

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

3SBio Term Sheet

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

Servier License and Collaboration Agreement

In July 2016, we announced a license and collaboration agreement with Les Laboratoires Servier, SAS, a corporation incorporated under the laws of France, and Institut de Recherches Internationales Servier, a company duly organized and existing under the laws of France (individually and collectively, "Servier") for the development, manufacture and commercialization of products using our fully human immuno-oncology anti-PD-1 mAb STI-A1110. The financial terms of the agreement include, among other things, a non-refundable upfront payment to us of €25 million, or $27.4 million, which we received in July 2016. We may also receive development milestone payments for the initial product and each additional product. We may receive up to €710 million in various payments based on commercial sales milestones related to annual net sales levels for the initial product and then also for each additional product. In addition to the commercial sales milestones, we will be entitled to receive variable royalties on the sales of all commercialized products ranging from high single-digit to double-digit percentages. During the twelve months ended December 31, 2016, we recognized $3.8 million in license fee revenue pursuant to the agreement.

CHA Biotech Term Sheet

In August 2016, we announced a binding term sheet to create a joint venture (the "JV") with CHA Biotech Co., LTD. ("CBT") of South Korea to develop and commercialize proprietary CAR modified cellular therapies based on CBT's

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

Scilex Acquisition

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

Celularity Transaction

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

Binding Term Sheet Regarding Acquisition of Semnur Pharmaceuticals, Inc.

On August 15, 2016, we, Scintilla and Semnur Pharmaceuticals, Inc. ("Semnur") entered into a binding term sheet (the "Semnur Binding Term Sheet") setting forth the terms and conditions by which Scintilla will, through a subsidiary, purchase all of the issued and outstanding equity of Semnur (the "Semnur Acquisition"). The Semnur Binding Term Sheet provides that, contingent upon the execution of a definitive agreement between the parties (the "Definitive Agreement") and subject to certain conditions, Scintilla will, at the closing of the Semnur Acquisition (the "Semnur Closing"), make an initial payment of $60.0 million (the "Initial Consideration") to the equityholders of Semnur in exchange for all of the issued and outstanding equity of Semnur. The Initial Consideration will consist of $40.0 million in cash and $20.0 million in shares of our common stock (the "Semnur Stock Consideration"). The Semnur Binding Term Sheet also provides that the number of shares of our common stock comprising the Semnur Stock Consideration will be calculated based on the volume weighted average closing price of our common stock for the 30 consecutive trading days ending on the date that is three days prior to the execution of the Definitive Agreement. $6.0 million of the Semnur Stock Consideration will be placed into escrow, a portion of which will be held for a period of up to six or 12 months to secure certain obligations of Semnur and its equityholders in connection with the Semnur Acquisition. At the Semnur Closing, we will enter into a registration rights agreement with certain of Semnur's equityholders, pursuant to which we will agree to seek the registration for resale of the shares of our common stock comprising the Semnur Stock Consideration.

In addition to the Initial Consideration, Scintilla may pay additional consideration of up to $140.0 million to Semnur's equityholders upon Scintilla's completion of certain clinical studies and trials, receipt of certain regulatory approvals and the achievement of certain sales targets following the Semnur Closing.

Under the Semnur Binding Term Sheet, either party may terminate the Semnur Binding Term Sheet.

As of December 31, 2016, the Semnur Acquisition had not closed. The final terms of the Semnur Acquisition are subject to the negotiation and finalization of the Definitive Agreement and any other agreements relating to the Semnur Acquisition, and the material terms of the Semnur Acquisition are expected to differ from those set forth in the Semnur Binding Term Sheet. In addition, the Semnur Closing will be subject to various customary and other

closing conditions.

A member of our board of directors is Semnur's Chief Executive Officer and a member of Semnur's Board of Directors and currently owns approximately 5.5% of Semnur's total outstanding capital stock. Joseph Gunnar & Co., LLC provided an opinion to our board of directors opining that the consideration to be paid by Scintilla in the Semnur Acquisition is fair, from a financial point of view, to our stockholders.

Binding Term Sheet Regarding Acquisition of Virttu Biologics Limited

On November 15, 2016, we, TNK and Virttu Biologics Limited ("Virttu") entered into a binding term sheet (the "Virttu Binding Term Sheet") setting forth the terms and conditions by which TNK will purchase all of the issued and outstanding equity of Virttu (the "Virttu Acquisition"). Subject to certain conditions, at the closing of the Virttu Acquisition (the "Virttu Closing"), we will issue to the equityholders of Virttu an aggregate of $5.0 million of shares of our common stock (the "Closing Shares"). The number of Closing Shares issuable shall be determined based on the closing price of our common stock on the date of the Virttu Closing. Further, upon the occurrence of the closing of the next third party equity financing of TNK in which TNK receives at least $50.0 million in

proceeds (a "Financing"), TNK will issue to the equityholders of Virttu an aggregate of $20.0 million of shares of the same class and series of capital stock of TNK as is issued in such Financing, based upon the valuation of TNK achieved in such Financing (the "TNK Financing Shares"). If a Financing has not occurred within twelve months of the Virttu Closing (the "Financing Due Date"), the equityholders of Virttu will be issued an aggregate of $20.0 million of shares of our common stock in lieu of the TNK Financing Shares (the "Sorrento Financing Shares"). The number of Sorrento Financing Shares issuable shall be determined based on the closing price of our common stock on the Financing Due Date. In the event that the TNK Financing Shares are issued, 20% of the TNK Financing Shares will be placed into escrow until the Financing Due Date to secure the indemnification obligations of Virttu and its equityholders for breaches of their representations, warranties or covenants under the definitive agreements governing the Virttu Acquisition. The Closing Shares and the TNK Financing Shares or the Sorrento Financing Shares will be issued to the Virttu equityholders on a pro rata basis based on each such equityholder's equity interest in Virttu as of the Virttu Closing.

As of December 31, 2016, the Virttu Acquisition had not closed. The final terms of the Virttu Acquisition are subject to the negotiation and finalization of the definitive agreements relating to the Virttu Acquisition and the material terms of the Virttu Acquisition may differ from those set forth in the Virttu Binding Term Sheet. In addition, the Virttu Closing will be subject to various customary and other closing conditions.

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.

Patents and Other 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, is effectively maintained as a trade secret, or is protected by confidentiality agreements. Accordingly, patents and other proprietary rights are essential elements of our business.

We have multiple issued patents and pending patent applications in the U.S. and in selected foreign jurisdictions that cover our G-MAB™ technology, G-MAB™-derived antibodies, other proprietary antibody-centric technologies, and pain management compounds, including, but not limited to, the following:

1) The G-MAB™ discovery antibody library technology. Certain aspects of this technology are covered by issued patents and are the subject matter of pending patent applications with potential patent coverage to at least 2023.
2) The G-MAB™-derived immuno-oncology antibody candidate portfolio. Certain of these antibody candidates are covered by issued patents and are the subject matter of pending applications with potential patent coverage to at least 2033.
3) The bispecific antibody technology directed to the combination of one or more different monoclonal antibodies or fragments that can target multiple or different antigens. The bispecific antibody technology is the subject matter of pending applications with potential patent coverage to at least 2035.
4) The ADC technology using proprietary conjugation chemistries (called C-Lock and K-Lock), initially developed by Concortis Biosystems, Corp., (Concortis), one of our wholly-owned subsidiaries. This ADC technology is the subject matter of pending patent applications with potential patent coverage to at least 2034. Additional pending patent applications directed to different toxin derivatives, are the subject matter of pending applications with potential patent coverage to at least 2035.
5) The CAR T-Cell based technology is an immunotherapy platform and is the subject matter of pending patent applications with potential patent coverage to at least 2035. Candidates arising from the platform are the subject matter of pending applications with potential patent coverage to at least 2037.
6) The CAR adoptive cellular immunotherapy using T cells and NK immune cells is directed to helping a patient's immune system fight disease, including cancer. We have filed patent applications on the techniques for creating

such therapies based on our CAR combination therapies providing with potential patent coverage to at least 2036.

7) The intracellular targeting antibody (iTAb) technology (LA Cell) for targeting intracellular targets for treating disease is the subject matter of pending patent applications with potential patent coverage to at least 2036. We have filed patent applications on improvements to this technology with potential patent coverage to at least 2038.
8) The new biosimilar / biobetter antibody technology using manufacture in certain cells (for example, directed to antigen targets such as EGFR or TNF-alpha) is the subject matter of pending patent applications with potential patent coverage to at least 2035.

9) The RTX (resiniferatoxin)-based pain management technology. Certain aspects of this technology are covered by an issued patent in the U.S. providing patent protection to 2021 and are the subject matter of pending patent applications that will provide potential patent coverage to at least 2036.
10) The lidocaine-based pain management technology, obtained by acquisition of Scilex Pharmaceuticals Inc. Certain aspects of this technology are covered by an issued U.S. patent with patent coverage to 2031. Additional patent applications to improvements of this technology have been filed with potential patent coverage to at least 2038.

Certain factors can either extend patent term or provide other forms of exclusivity (e.g., data exclusivity) for varying periods depending on the date of patent filing, date of grant or the legal term of a patent in the various jurisdictions in which patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, also depends upon the type of patent, the scope of claim coverage and the availability of legal remedies in the particular 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 guarantee 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 interest in any 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. Accordingly, we cannot guarantee that employees, consultants or third parties will not breach the confidentiality provisions in our contracts, infringe or misappropriate our trade secrets or 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 (“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:

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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 ("GLP") regulations. Preclinical testing generally includes evaluation of our product candidates 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 ("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, import and export of materials and products, 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 chemical 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 ("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 institutional review board ("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 trial is a clinical trial that 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 trials are also Phase III trials but may be Phase II trials 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, 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 ("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 product candidates 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 ("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 European Medicines Agency ("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 ("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 trials 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, Special Protocol Assessment ("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 trials begin, or if the trial sponsor fails to follow the protocol that was agreed upon with the FDA. There is no guarantee that a trial will ultimately be adequate to support an approval even if the trial 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 ("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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "Healthcare Reform Law"), substantially changed the way healthcare is financed in the U.S. by both government and private insurers. Among other cost containment measures, the Healthcare Reform Law established:

- 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 Union, 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, amended 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 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 (“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 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.

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 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, marketing and sales teams 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 manufacture the majority of our preclinical and clinical materials in-house, and use contract manufacturers for the manufacture of some of our product candidates. Our internal manufacturing and 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 cGMPs. We have established a quality control and quality assurance program, which includes a set of standard operating procedures and specifications designed to ensure that our products are manufactured in accordance with cGMPs, and other applicable domestic and foreign regulations.

Employees

As of December 31, 2016, we had 154 employees and 21 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, excluding acquired in-process research and development expenses, totaled $42.2 million and $31.3 million in the years ended December 31, 2016 and 2015, respectively.

Corporate Information

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

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

Address

Our principal executive offices are located at 9380 Judicial Drive, San Diego, CA 92121, and our telephone number at that address is (858) 210-3700. Our website is www.sorrentotherapeutics.com. Any information contained on, or that can be accessed through, our website is not incorporated by reference into, nor is it in any way part of this Form 10-K.

Available Information

We file electronically with the U.S. Securities and Exchange Commission (the "SEC") our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and 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 to stockholders 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 clinical stage company subject to significant risks and uncertainties, including the risk that we or our partners may never develop, obtain regulatory approval or market any of our product candidates or generate product related revenues.

We are a clinical stage biotechnology company that began operating and commenced research and development activities in 2009. Pharmaceutical 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 or any of our other product candidates in development 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 product candidates in development, including, but not limited to, our fully-human mAbs, biosimilars/biobetters, fully human anti-PD-L1 and anti-PD-1 checkpoint inhibitors derived from our proprietary G-MAB™ library platform, antibody drug conjugates ("ADCs"), BsAbs, as well as CAR-T for adoptive cellular immunotherapy and RTX 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 from most of our product candidates in the foreseeable future, if ever.

We have not generated any product related revenues to date, and, with the exception of our ZTlido™ lidocaine patch product, 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, 2016 and December 31, 2015, we had an accumulated deficit of $174.3 million and $113.3 million, respectively. We continue to incur significant research and development and other expenses related to our ongoing 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) advance RTX and our other product candidates into clinical trials and pursue other development, acquire, develop and manufacture clinical trial materials and increase other regulatory operating activities, (ii) incur incremental expenses associated with our efforts to further advance a number of potential product candidates into preclinical development activities, (iii) continue to identify and advance a number of fully human therapeutic antibody and ADC preclinical product candidates, (iv) incur higher salary, lab supply and infrastructure costs incurred in connection with supporting all of our programs, (v) invest in our joint ventures, collaborations or other third party agreements, (vi) incur expenses in conjunction with defending and enforcing our rights in various litigation matters, and (vii) expand our corporate, development and manufacturing infrastructure. 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.

As a result of our recurring losses from operations and stockholders' capital deficiency, there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, which raises substantial doubt about our ability to continue as a going concern. If we are unsuccessful in our efforts to raise outside financing, we may be required to significantly reduce or cease operations. The report of our independent registered public accounting firm on our audited financial statements for the year ended December 31, 2016 included a "going concern" explanatory paragraph indicating that our recurring losses from operations and availability of working capital raise substantial doubt about our ability to continue as a going concern.

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 mAbs, including biosimilars/biobetters, fully human anti-PD-L1 and anti-PD-1 checkpoint inhibitors derived from our proprietary G-MAB™ library platform, ADCs, BsAbs, as well as CAR-T for adoptive cellular immunotherapy and RTX;
- 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, joint ventures, public or private equity or debt financing, bank lines of credit, asset sales, government grants or other arrangements. We cannot be sure that any additional funding, if needed, will be available on terms favorable to us or at all. Furthermore, any additional equity or equity-related financing may be dilutive to our stockholders, and debt or equity financing, if available, may subject us to restrictive covenants and significant interest costs. If we obtain funding through a strategic collaboration or licensing arrangement, we may be required to relinquish our rights to certain of our product candidates or marketing territories.

Further, there is uncertainty related to future National Institutes of Health (“NIH”) grant funding, and the NIH’s 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;
- seeking and obtaining intellectual property and/or proprietary rights to our technology and/or the technology of others;
- 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 (the “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.

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 risky and 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 pharmaceutical 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 ZTlido™, RTX, CAR-T, our biosimilar/biobetters antibodies and other product candidates, 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 New Drug Application ("NDA"), Biologics License Application ("BLA") or other application for

marketing based on such pivotal trial. The FDA may require additional clinical trials as a condition for approving our product candidates.

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 RTX, CAR-T, and biosimilar/biobetter antibodies and other product candidates, 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 ("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 ("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 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, the EMA 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 from the FDA, the European Medicines Agency ("EMA") 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.

We may fail to receive regulatory approval for our product candidates for many reasons, including the following:

- the FDA, the EMA 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, the EMA 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 for approval by the FDA, the EMA or comparable foreign regulatory authorities;
- the FDA, the EMA 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, a marketing authorization application ("MAA") or other submission or to obtain regulatory approval in the U.S., the European Union or elsewhere;
- the FDA, the EMA 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, the EMA 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, the EMA 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.

Other than a new drug application submitted by Scilex for Scilex's lead product candidate, ZTlido™, we have not previously submitted a BLA or an NDA to the FDA, an MAA to the EMA 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 our clinical trials are successful. 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 some instances, 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 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. Further, the United Kingdom has voted to withdraw from the European Union. We

cannot predict what consequences the withdrawal of the United Kingdom from the European Union might have on the regulatory frameworks of the United Kingdom or the European Union, or on our future operations, if any, in these jurisdictions.

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

ADCs and intracellular targeting antibodies ("iTAbs") are emerging technologies and, consequently, it is conceivable that such technologies may ultimately fail to identify commercially viable products to treat human patients with cancer or other diseases. Due to the unproven nature of ADCs and iTAbs, significant further research and development activities will be required. We may incur substantial costs in connection with such research and development activities and there is no guarantee that these activities will lead to the identification of commercially viable products.

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. 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 we receive marketing approval for one or more of our product candidates, 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 ("cGCP"), which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, and comparable foreign regulatory authorities for all of our

product candidates 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 EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications or may not approve 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 ("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.

If we fail to comply with manufacturing regulations, our financial results and financial condition will be adversely affected.

We currently manufacture our preclinical and clinical materials in-house. However, we only recently began manufacturing such materials and do not have significant prior experience manufacturing preclinical or clinical materials or product candidates. Before we can begin commercial manufacture of our product candidates, regulatory authorities must approve marketing applications that identify manufacturing facilities operated by us or our contract manufacturers that have passed regulatory inspection and manufacturing processes that are acceptable to the regulatory authorities. In addition, our pharmaceutical manufacturing facilities are continuously subject to scheduled and unannounced inspection by the FDA and international regulatory authorities, before and after product approval, to monitor and ensure compliance with cGMP and other regulations. Additionally, we may use contract manufacturers for the manufacture of our product candidates from time to time based on capacity needs. Although we are not involved in the day-to-day operations of our contract manufacturers, we are ultimately responsible for ensuring that our products are manufactured in accordance with cGMP regulations.

Due to the complexity of the processes used to manufacture our product candidates, we may be unable to continue to pass or initially pass federal or international regulatory inspections in a cost-effective manner. For the same reason, any potential third-party manufacturer of our product candidates may be unable to comply with cGMP regulations in a cost-effective manner and may be unable to initially or continue to pass a federal or international regulatory inspection.

If we, or third-party manufacturers with whom we contract, are unable to comply with manufacturing regulations, we may be subject to delay of approval of our product candidates, warning or untitled letters, fines, unanticipated compliance expenses, recall or seizure of our products, total or partial suspension of production and/or enforcement actions, including injunctions, and criminal or civil prosecution. These possible sanctions would adversely affect our financial results and financial condition.

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.

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 us. We typically 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 obtain or replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If 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 may not be able to manufacture our product candidates in commercial quantities, which would prevent us from commercializing our product candidates.

We are largely 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 with 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.

The complexities and regulations related to our manufacturing and development services businesses subject us to potential risks.

Through certain subsidiaries, we offer development (e.g., conjugation) and manufacturing services that are highly complex, due in part to strict regulatory requirements. A failure of our quality control systems in our facilities could cause problems to arise in connection with facility operations for a variety of reasons, including equipment malfunction, contamination, failure to follow specific manufacturing instructions, protocols and standard operating procedures, problems with raw materials or environmental factors. Such problems could affect production of a single manufacturing run or a series of runs, requiring the destruction of products, or could halt manufacturing operations altogether. In addition, our failure to meet required quality standards may result in our failure to timely deliver products to our customers, which in turn could damage our reputation for quality and service. Any such incident could, among other things, lead to increased costs, lost revenue, reimbursement to customers for lost drug substance, damage to and possibly termination of existing customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other manufacturing runs. With respect to our commercial manufacturing, if problems are not discovered before the product is released to the market, we may be subject to regulatory actions, including product recalls, product seizures, injunctions to halt manufacture and distribution, restrictions on our operations, civil sanctions, including monetary sanctions, and criminal actions. In addition, such issues could subject us to litigation and/or liability for damages, the cost of which could be significant.

Regulatory agencies may periodically inspect our manufacturing facilities to ensure compliance with applicable legal, regulatory and local requirements, such as cGMP requirements. Failure to comply with these requirements may subject us to possible legal or regulatory actions, such as suspension of manufacturing, seizure of product or voluntary recall of a product.

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 (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 it believes 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 product 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;
- impairment of our ability to obtain intellectual property rights or rights to commercialize additional product candidates, or increased cost to obtain such rights;
- 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 product labeling or product insert required by the FDA or regulatory authority in other countries;
- the approval, availability, market acceptance and reimbursement for a companion diagnostic, if any;
- the prevalence and severity of adverse side effects; and
- the effectiveness of our sales and marketing efforts.

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

If we 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 and pain management markets, and other relevant markets, is intense. Even if we are able to develop our product candidates, proprietary platform technology and/or 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 or biosimilar 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;
- obtain and 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 product candidates, if approved, are competitive with other products.

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 changed the way healthcare is financed by both governmental and private insurers. Such government-adopted reform measures may adversely impact the pricing of healthcare products and services in the U.S. or internationally and the amount of reimbursement available from governmental agencies or other third-party payors.

There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. For example, there have been recent public announcements by members of the U.S. Congress, President Trump and his administration regarding their plans to repeal and replace the Healthcare Reform Law and Medicare. Although we cannot predict the ultimate content or timing of any healthcare reform legislation, potential changes resulting from any amendment, repeal or replacement of these programs, including any reduction in the future availability of healthcare insurance benefits, could adversely affect our business and future results of operations. 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.

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 typically 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, any 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. In such instances, 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 collaborations depend upon the efforts of third parties to fund and manage the development of many of our potential product candidates, and failure of those 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 has included the formation of joint ventures and 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;
    - seeking and obtaining intellectual property and/or other proprietary rights to technology; and
- successfully commercializing any future product candidates.

Our collaborations limit our ability to control the efforts devoted to many of our product candidates in such arrangements and our earlier stage pipeline is dependent upon identifying new potential collaborators. For example, our most recent joint ventures require us to conduct research and provide potential product candidates in addition to making capital contributions to continue the further development of those products. We generally do not have control over the management of the joint ventures and are minority holders in most of those ventures, which may result in limitations on our ability to successfully develop product candidates, obtain intellectual property and/or other proprietary rights and fund clinical trials through those joint ventures.

In addition, 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.

Although we are not subject to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as we are neither a Covered Entity nor Business Associate (as defined in HIPAA and the Health Information Technology and Clinical Health Act (the "HITECH Act")), 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 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 trials required to support regulatory applications for our product candidates. 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 ("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, 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.

The regulatory path forward for biosimilar/biobetter product candidates is not clear.

We have acquired and are assessing the regulatory and strategic path forward for our portfolio of late stage biosimilar/biobetter antibodies based on Erbitux®, Remicade®, Xolair® and Simulect®. While the enactment of the BPCIA created an abbreviated pathway for the approval of biosimilar and interchangeable biological products, there is still considerable uncertainty with respect to the FDA's approval process. While applications based on biosimilarity may not be required to duplicate the entirety of preclinical and clinical testing used to establish the underlying safety and effectiveness of the reference product, the FDA may refuse to approve an application if there is insufficient information to show that the active ingredients are the same or to demonstrate that any impurities or differences in

active ingredients do not affect the safety, purity or potency of the product. In addition, applications based on biosimilarity will not be approved unless the product is manufactured in facilities designed to assure and preserve the biological product's safety, purity and potency. Due to the uncertainty surrounding the approval of biosimilar/biobetter products, as well as other risk factors identified in this Form 10-K, our portfolio of late stage biosimilar/biobetter antibodies may never result in commercially viable products.

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, George Ng, Executive Vice President and Chief Administrative Officer, Kevin Herde, Executive Vice President and Chief Financial Officer, Jeffrey Su, Executive Vice President and Chief Operating Officer, Jerry Zeldis, President of Clinical Research and Regulatory and Chief Medical Officer, and Miranda Toledano, Executive Vice President of Corporate Development. 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, comply with laws and regulations (including, but not limited to the Foreign Corrupt Practices Act of 1977, as amended, 15 U.S.C. §§ 78dd-1 ("FCPA")) and internal policies restricting payments to government agencies and representatives, 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 HITECH Act, 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;
- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- 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 are subject to the U.S. Foreign Corrupt Practices Act and other anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures, and legal expenses, which could adversely affect our business, results of operations and financial condition.

Our operations are subject to certain anti-corruption laws, including the FCPA, and other anti-corruption laws that apply in countries where we do business. The FCPA and other anti-corruption laws generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We and our commercial partners operate in a number of jurisdictions that pose a high risk of potential FCPA violations and we participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations governing our international operations, including regulations administered in the U.S. and in the EU, including applicable import and export control regulations such as those regulations under the Convention on International Trade in Endangered Species of Wild Fauna and Flora, also known as the Washington Convention (“CITES”), economic sanctions on countries and persons, customs requirements and currency exchange regulations (collectively, “Trade Control Laws”).

There can be no assurance that we will be completely effective in ensuring our compliance with all applicable anticorruption laws, including the FCPA or other legal requirements, such as Trade Control Laws. Any investigation of potential violations of the FCPA, other anti-corruption laws or Trade Control Laws by U.S., EU or other authorities could have an adverse impact on our reputation, our business, results of operations and financial condition. Furthermore, should we be found not to be in compliance with the FCPA, other anti-corruption laws or Trade Control Laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, as well as the accompanying legal expenses, any of which could have a material adverse effect on our reputation and liquidity, as well as on our business, results of operations and financial condition.

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

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

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

Our principal executive offices, which house our research and development programs, are located in San Diego, California. Our facilities may be affected by natural or man-made disasters. Earthquakes are of particular significance

since our facilities are located in an earthquake-prone area. We are also vulnerable to damage from other types of disasters, including power loss, attacks from extremist organizations, fires, 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, cybersecurity attacks or hacking, 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.

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

On November 23, 2016, we and certain of our domestic subsidiaries (together with us, the “Borrowers”) entered into a Loan and Security Agreement , as amended (as so amended, the “Loan Agreement”) with Hercules Capital, Inc., as a lender and agent for several banks and other financial institutions or entities from time to time party to the Loan Agreement (collectively, the “Lenders”) for a term loan of up to $75.0 million, subject to funding in multiple tranches.

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

The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports and maintain insurance coverage. The negative covenants include, among others, restrictions on transferring collateral, changing our business, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments and creating other liens on our assets, in each case subject to customary exceptions. If we default under the 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 Lenders’ right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. The Lenders could declare a default upon the occurrence of any event that they interpret as a material adverse change as defined under the 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.

Our operations in China subject us to risks and uncertainties relating to the laws and regulations of China.

Certain of our operations are currently based in China. Under its current leadership, the government of China has been pursuing economic reform policies, including by encouraging foreign trade and investment. However, there is no assurance that the Chinese government will continue to pursue such policies, that such policies will be successfully implemented, that such policies will not be significantly altered, or that such policies will be beneficial to our operations in China. China's system of laws can be unpredictable, especially with respect to foreign investment and foreign trade. The promulgation of new laws and regulations and changes to existing laws and regulations may adversely affect foreign investors and foreign entities with operations in China.

Additionally, the biopharmaceutical industry in particular in China is strictly regulated by the Chinese government. Changes to Chinese regulations affecting biopharmaceutical companies are unpredictable and may have a material adverse effect on our Chinese operations and on our business and financial condition.

Our global operations are exposed to political and economic risks, commercial volatility and events beyond our control in the countries in which we operate.

In addition to challenges specific to the United States, our operations, including but not limited to our operations outside of the United States, are subject to a variety of political and economic risks, including risks arising from:

- unexpected changes in international or domestic legal, regulatory or governmental requirements or regulations, including related to intellectual property or the biopharmaceutical industry;
- unexpected increases in taxes or tariffs;
- trade protection measures or import or export licensing requirements;
- divergent legal systems and regulatory frameworks; and
- political and economic instability or corruption.

These risks and others may have a material adverse effect on our global operations and on our business and financial condition.

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.

We have and plan to continue to expand our business and intellectual property portfolio through the acquisition of new businesses and technologies. For example, we recently acquired approximately 72% of the outstanding capital stock of Scilex Pharmaceuticals Inc. and are in the process of integrating this company and its operations with ours. We have also announced binding term sheets to acquire Semnur Pharmaceuticals, Inc. and Virttu Biologics Limited. The success of any acquisitions depend on, among other things, our ability to combine our business with the acquired business 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 us and the acquired company will also divert management's attention from our core business and other opportunities that could have been beneficial to our stockholders. An inability to realize the full extent of, or any of, the anticipated benefits of the acquisition, as well as any delays encountered in the integration process, could have an adverse effect on our business and results of operations, which may affect the value of the shares of our common stock after the completion of the acquisition. If we are unable to achieve these objectives, the anticipated benefits of the acquisition may not be realized fully or at all or may take longer to realize than expected. In particular, the acquisition may not be accretive to our stock value or development pipeline in the near or long term.

We expect to incur additional costs integrating the operations of any companies we acquire, 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 exceed the anticipated benefits of the acquisition, our financial results could be adversely affected.

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 continue to 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, proprietary rights 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.

Any acquisitions we make could disrupt our business and seriously harm our financial condition.

We have in the past made (and may, from time to time, consider) acquisitions of complementary companies, products or technologies. Acquisitions involve numerous risks, including difficulties in the assimilation of the acquired businesses, the diversion of our management's attention from other business concerns and potential adverse effects on existing business relationships. In addition, any acquisitions could involve the incurrence of substantial additional indebtedness. We cannot assure you that we will be able to successfully integrate any acquisitions that we pursue or that such acquisitions will perform as planned or prove to be beneficial to our operations and cash flow. Any such failure could seriously harm our business, financial condition and results of operations.

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, exclude others from using our technology 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. Subsequently, we filed multiple antibody family patent applications. The first of the antibody family patent applications was issued in 2014 and we continue to file additional patent applications for our product candidates and technology.

We have commenced generating a patent portfolio 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 will cover our products or product candidates or that any resulting patents will be enforced. In addition, third parties may challenge, seek to invalidate, limit the scope of or circumvent any of our patents, once they are issued. Thus, any patents that we own or license from third parties or joint venture or development partners 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 or joint venture or development partners, may not result in patents being issued. Moreover, disputes between our licensing or joint development partners and us may arise over license scope, or ownership, assignment, inventorship and/or rights to use or commercialize patent or other proprietary rights, which may adversely impact our ability to obtain and protect our proprietary technology and products. Also, patent rights may not provide us with adequate proprietary protection or competitive advantages against competitors with similar technologies or products.

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

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, or prior to seeking patent protection, we rely on trade secret protection and confidentiality agreements. Unlike some of our competitors, in addition to certain manufacturing processes, we maintain our proprietary libraries for ourselves as trade secrets. 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. Moreover, our third party licensing partners may retain rights in some of our proprietary or joint trade secrets, know-how, patented inventions or other proprietary information, including rights to sublicense and rights of publication, which may adversely impact our ability to obtain patents and protect trade secrets, know-how or other proprietary information. In addition, the U.S. government may retain rights in some of our patents or other proprietary information.

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 product candidates or 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, product candidates or potential products that are claimed to infringe a third party's intellectual property unless that party grants us or our strategic partners' or licensees' rights to use its intellectual property. Ultimately, we may be unable to develop some of our technologies or potential products or may have to discontinue development of a product candidate or cease some of our business operations as a result of patent infringement claims, which could severely harm our business.

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

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

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

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 PTO administrative proceedings, such as inter partes reviews, and reexamination proceedings before the 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 r