Sorrento Therapeutics, Inc.
Form 10-K
March 15, 2019

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, 2018
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.)
4955 Directors Place San Diego, California	92121
(Address of Principal Executive Offices)	(Zip Code)

(858) 203-4100
(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 such filing requirements for the past 90 days. Yes No
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 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, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company” and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer	Accelerated filer

Non-accelerated filer Smaller reporting company
Emerging growth company
If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.
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, 2018 (the last trading day of the registrant's second fiscal quarter of 2018), as reported on the Nasdaq Capital Market, was approximately $836.9 million.
At February 21, 2019, the registrant had 122,280,092 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of our Proxy Statement for the 2019 Annual Meeting of Stockholders or an amendment to this Annual Report on Form 10-K, to be filed within 120 days of December 31, 2018, are incorporated by reference in Part III.

SORRENTO THERAPEUTICS, INC.
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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 Therapeutics, Inc. (Nasdaq: SRNE), together with its subsidiaries (collectively, the "Company", "we", "us" and "our") is a clinical stage and commercial biopharma company focused on delivering innovative and clinically meaningful therapies to patients and their families, globally, to address unmet medical needs. We primarily focus on therapeutics areas in Immune-Oncology and Non-Opioid Pain Management. We also have programs assessing the use of our technologies and products in autoimmune, inflammatory and neurodegenerative diseases.

At our core, we are an antibody-centric company and leverage our proprietary G-MAB™ library and targeted delivery modalities to generate the next generation of cancer therapeutics. Our fully human antibodies include PD-1, PD-L1, CD38, CD123, CD47, c-MET, VEGFR2, CCR2 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 chimeric antigen receptor T-cell therapy ("CAR-T"), dimeric antigen receptor T-cell therapy ("DAR-T"), antibody drug conjugates ("ADCs") as well as bispecific antibody approaches. Additionally, we acquired Sofusa®, a revolutionary drug delivery system, in July 2018, which delivers biologics directly into the lymphatic system to potentially achieve improved efficacy and fewer adverse effects than standard parenteral immunotherapy.

With each of our clinical and pre-clinical 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 focused 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 to entering the clinic. These include cellular therapies, an oncolytic virus and a palliative care program targeted to treat intractable

cancer pain. Our cellular therapy programs focus on 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”)-directed CAR-T program. We have treated five patients with stage 4, unresectable adenocarcinoma (four with pancreatic and one with colorectal cancer) and CEA-positive liver metastases with anti-CEA CAR-T and are currently expanding this study. We successfully submitted an Investigational New Drug application ("IND") for anti-CD38 CAR-T for the treatment of refractory or relapsed multiple myeloma ("RRMM") and obtained approval from the U.S. Food and Drug Administration (the "FDA") to commence a human clinical trial for this indication in early 2018. We have dosed two patients and are continuing the enrollment of additional patients.

Broadly speaking, we are one of the world’s leading CAR-T companies today due to our investments in technology and infrastructure, which have enabled significant progress in developing our next-generation non-viral, “off-the-shelf” allogeneic CAR-T solutions. With “off-the-shelf” solutions, CAR-T therapy can truly become a drug product rather than a treatment procedure. One of the approaches we have taken to develop the “off-the-shelf” allogeneic CAR-T solutions is through Celularity, our joint venture with Celgene, United Therapeutics and others. Celularity focuses on developing cell therapies with placenta-derived and cord blood T cells, which have natural allogeneic “off-the-shelf” characteristics. We are the single largest shareholder of Celularity with a stake of approximately 25%.

Outside of immune-oncology programs, as part of our global aim to provide a wide range of therapeutic products to meet underserved markets, we have made investments in non-opioid pain management. These include resiniferatoxin (“RTX”), which is a non-opioid-based neurotoxin that specifically ablates nerves that conduct pain signals while leaving other nerve functions intact and is being studied for chronic pain treatment. RTX has been granted orphan drug status for the treatment of intractable pain with end-stage cancer and a Phase I trial with the National Institutes of Health (“NIH”) is concluding. A Phase Ib trial studying tolerance and efficacy of RTX for the control of osteoarthritis knee pain was initiated in late 2018 and preliminary results have shown strong efficacy with no significant adverse effects. Other applications of RTX are expected to start Phase Ib trials in 2019.

Also in the area of non-opioid pain management, we have acquired proprietary technologies to responsibly develop next generation, branded pharmaceutical products to better manage patients’ medical conditions and maximize the quality of life of patients and healthcare providers. The flagship product of our majority-owned subsidiary, Scilex Pharmaceuticals Inc. (“Scilex”), ZTlido® (lidocaine topical system 1.8%), is a next-generation lidocaine delivery system which was approved by the FDA for the treatment of postherpetic neuralgia, a severe neuropathic pain condition, in February 2018, and was commercially launched in late October 2018. Scilex now has built a full commercial organization, which includes sales, marketing, market access, and medical affairs. ZTlido® is positioned as a best-in-class product with superior adhesion compared to Lidoderm and is manufactured by our Japanese partner in their state-of-the-art manufacturing facility.

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. Rapidly 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 and oncolytic virus immunotherapy in oncology and/or hematology indications. Our clinical-state RTX program will be developed in several pain indications with high-unmet medical needs.
2. Continuing the development of our preclinical programs with the aim of filing several new INDs over the next 12-18 months. These include moving our checkpoint inhibitors from our core antibody portfolio into the clinic either ourselves or with our strategic partners. Also, we will utilize our fully human antibody portfolio for the development of ADCs and bispecific antibodies ("BsAbs"). In addition, we plan to start several clinical trials with the Sofusa® device to explore safety and efficacy features of this innovative drug delivery system.
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 ("TSRI"), 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 quality control and quality assurance programs, which include 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 partnerships to share in the risk reward of our core franchises and to derive near term value from our non-core programs. 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

We have determined that we operate in one operating segment. See Note 3 in the Notes to Consolidated Financial Statements in this Form 10-K.

Clinical Programs

CD38 Directed CAR-T Program

Our proprietary, second generation anti-CD38 CAR-T therapy is being developed 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 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 estimated 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 and $1.2 billion in 2017. 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.

In a xenograft mouse model of human myeloma, we demonstrated that CD38-expressing multiple myeloma tumor cells were efficiently killed and tumors were completely eradicated by our anti-CD38 CAR-T. Importantly, these anti-CD38 CAR-T cells selectively killed 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 requiring a genetic CD38 knock-out or knock-down in our construct. We have successfully submitted an IND for anti-CD38 CAR-T for the treatment of RRMM and have obtained approval from the FDA to commence a human clinical trial for this indication. We began an anti-CD38 CAR-T clinical trial with RRMM patients in 2018 and recruitment continues in the dose-escalation phase of the study. There has been evidence of CAR-T cell activation and early signs of efficacy at low doses of the anti-CD38 CAR-T cells.

CEA Directed CAR-T Program

A second-generation anti-CEA CAR-T cell therapy is being developed for the regional treatment of liver metastases due to CEA-expressing pancreatic adenocarcinoma via pressure-enabled hepatic arterial infusion of CAR-T.

CEA is highly expressed in the majority of primary and metastatic cancers of gastrointestinal origin, including adenocarcinoma of the pancreas. In addition, liver metastases often express CEA at higher levels than the primary pancreatic tumor. However, CEA is also expressed on normal cells of the colonic epithelium and elsewhere in the gastrointestinal tract. Therefore, systemic intravenous infusions of anti-CEA CAR-T cells have been associated with colitis and symptoms of severe diarrhea. Regional infusions of anti-CEA CAR-T cells directly into the liver through the hepatic artery with a pressure-enabled device increases the delivery of the CAR-T cells directly to the metastatic tumors in the liver and reduces the risk of severe on-target/off-tumor effects, cytokine release syndrome, and neurotoxicity adverse events associated with intravenous infusions.

Pancreatic cancer is associated with a poor prognosis and is a high-unmet medical need. Most pancreatic cancer patients are asymptomatic until advanced disease develops. Up to 80% of patients with pancreatic cancer present with metastatic disease. The survival rates for pancreatic cancer patients at 1 and 5 years are only 29% and 7%, respectively. Liver metastases occur frequently and are a common cause of mortality and morbidity. Our early-phase clinical trial of anti-CEA CAR-T delivered to patients with pancreatic carcinoma and liver metastases via pressure-enabled hepatic artery infusion has demonstrated complete metabolic and radiologic responses within the liver in two of four patients by PET scans and CT scans, respectively. Based on these promising results, we are planning a randomized trial with FDA advice this year to study overall survival in patients with CEA-expressing pancreatic adenocarcinoma with liver metastases treated with regionally administered anti-CEA CAR-T cells.

Resiniferatoxin (RTX) Programs

RTX is a naturally occurring compound obtained from cactus-like succulents of the Euphorbia species. An ultra-potent TRPV1 agonist, RTX belongs to the same family as capsaicin, the active ingredient in red chili peppers. As an agonist, RTX produces a sustained opening of calcium channels located in the end-terminal or cell body of C-fiber nerves (depending upon the route of administration). This, in turn, generates a rapid and massive cation influx into the nerve and sustained depolarization results in cytotoxicity and ablation of TRPV1-positive cells that conduct pain signals, while leaving non-TPVR1 containing nerves (touch, motor control, joint position) intact. RTX is differentiated from other agonists, including capsaicin, in that it is significantly more potent at desensitizing than it is in inducing excitation of the neuron. In fact, it has been proposed that because RTX is several thousand times more potent than capsaicin at desensitization, the higher potency of RTX may lead to a briefer noxious (e.g., painful) period immediately after exposure.

RTX was tested in an investigator-sponsored Phase I clinical trial at the NIH under a Cooperative Research and Development Agreement (CRADA). To date, 13 patients with terminal cancer pain have been treated intrathecally at the NIH. A second sponsor-led trial for the control of intractable cancer pain is assessing the tolerance and efficacy of RTX administered epidurally. This dose-escalation trial is progressing and 4 patients have been enrolled thus far.

More recent studies in animals (translational work from our animal health subsidiary) have unveiled the clinical potential of RTX intra-articular injections for the control of pain associated with moderate to severe arthritis. Safety studies have been completed and a Phase I clinical trial in humans started in the second half of 2018. Significant activity in relieving pain associated with severe osteoarthritis of the knee was observed and RTX has been well tolerated at the doses administered. Two independent phase III pivotal trials are planned to start in the second half of 2019 and they could be completed in 12 to 18 months - advancing the program closer to a regulatory filing by 2021. RTX is being manufactured under cGMP and we have sufficient drug product to complete the clinical development programs across multiple additional indications. We have also secured enough raw materials for the drug production to cover the commercial needs for several years and additional contracts are in progress to ensure long-term commercial supplies.

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, BCMA), oncolytic virus program 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, BCMA, CTLA-4, CD123, CD47, c-MET, VEGFR2, CCR2 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:

Dimeric Antigen Receptor ("DAR") Technology

Chimeric antigen receptors ("CARs") have been created for commercial and clinical development programs in the industry, so there is strong proof-of-concept for this approach, but there are also disadvantages with this technology. The architecture of the CAR consists of a single fusion protein with several functional components: a single-chain variable fragment ("scFv") derived from an anti-tumor antibody fused to a structural support segment, a transmembrane portion, and one or more intracellular signaling domains. Potential drawbacks of the CAR technology are the use of scFv that often possess inferior biophysical stability and biochemical functionality compared to their parental antibodies.

We are addressing these potential weaknesses while building on the clinical experience generated within our current CAR-T programs with the design of DARs that are based on the complete antigen-binding fragment ("Fab") of the parental antibody. It is generally accepted that Fabs more closely mimic the functional and biophysical properties of natural antibodies. Utilizing the same antibody binding domain sequence, we have compared CAR constructs with a scFv binding domain to a DAR construct with an Fab or two chain binding domain. Our data showed that the DAR-T cells exhibited a higher functional activity with regards to cytokine production, and cytotoxicity against target-expressing tumor cells compared to CAR-T cells. In preclinical mouse models, the DAR-T cells demonstrated increased anti-tumor potency as well.

We are currently applying our DAR technology to our ongoing cell therapy programs for multiple hematological and solid tumor indications, including but not limited to: multiple myeloma, lymphoma, liver cancer, sarcoma, pancreatic cancer and glioma. Utilizing the vast portfolio of target-specific, fully human monoclonal antibodies discovered from our proprietary G-MAB library, we plan on submitting one or more INDs for our lead DAR-T programs in 2019.

Non-viral Knock-Out, Knock-In (“KOKI”) Technology

We have developed an innovative KOKI technology to introduce transgenes, for example CAR or DAR genes, into mammalian cells, such as T cells. These CAR-T cells have been evaluated and compared against CAR-T cells generated using current retrovirus transduction methodologies. Our data suggest that the non-virally generated CAR-T cells performed as well as retrovirally-transduced CAR-T cells with regard to CAR expression, cytokine production, and cytotoxicity against target-expressing tumor cells.

Our KOKI technology may offer several potential benefits over existing virus-based technology using transgene-encoding lentivirus, retrovirus or adeno-associated virus ("AAV") to introduce antigen receptor constructs into healthy donor (allogeneic) or cancer patient (autologous) T cells. These potential advantages of our non-viral KOKI technology include:

•site-specific integration of transgenes into a pre-selected locus in the T cell genome;

•streamlined method for transgene construct production without need for laborious and time-consuming virus production, release and validation processes, resulting in a shorter research and development timelines for IND-enabling activities; and

•applicability to both autologous and allogeneic cellular therapies.

We are developing our innovative KOKI technology for use in our CAR-T programs for the treatment of multiple hematological and solid tumor indications, including but not limited to: multiple myeloma, lymphoma, liver cancer, sarcoma, pancreatic cancer and glioma. We believe our KOKI technology has the potential to enable faster development timelines, more cost-effective cGMP manufacturing and possible removal of certain regulatory requirements for both autologous and allogeneic CAR-T and DAR-T therapies.

Sofusa®

Sofusa is a novel micro-epidermal infusion system that consists of a proprietary microneedle array and microfluidics reservoir for targeted lymphatic delivery of large molecules, such as antibodies. Abnormal lymphatic function is implicated in many conditions associated with immune suppression (oncology) and immune stimulation (autoimmune). Sofusa’s proprietary polymer nanotopography (draped over microneedles) has been shown to activate cellular pathways and enhance paracellular and transcellular transport across the epidermis. This enables efficient and direct absorption into both systemic and lymphatic microcapillaries just beneath the epidermis.

Sofusa’s unique biodistribution profile offers the potential for differentiated safety and efficacy versus IV and subcutaneous administration due to higher immune system concentrations and lower systemic concentrations of immune therapies. In 2018, pre-clinical animal models validated this hypothesis in oncology with an anti-CTLA4 (Yervoy®) and in rheumatoid arthritis with an anti-TNF- (Enbrel®). In addition, a Phase I study with an imaging agent gave visual confirmation of direct lymphatic targeting and provided important verification of device design parameters. Phase 1b human clinical studies are planned in 2019 to begin development of highly differentiated immunotherapies.

While checkpoint inhibitors have been a major advance in treatment of certain types of cancer, response rates and dose limiting toxicities are areas for improvement. Two checkpoint inhibitor development programs have been initiated to evaluate the impact of lymphatic targeting using anti-PD-1 and anti-CTLA-4 antibodies. Pilot trials are being designed to evaluate the feasibility of Sofusa delivery of anti-PD-1 and CTLA-4 antibodies in patients with melanoma and other skin cancers accessible to biopsies for intensive biomarker assessments. These trials will help assess whether the principles of better efficacy and safety seen in lymphatic administration of drugs in animal models can be replicated in patients.

Preclinical arthritis models with Sofusa and an anti-TNF alpha blocker (Enbrel®) have demonstrated a highly statistically significant efficacy signal and restoration of lymphatic flow, which is disrupted in some rheumatologic conditions. Given these encouraging findings, a Phase 1B clinical trial is being initiated in Rheumatoid Arthritis to evaluate the impact of lymphatic on suppression of overactive immune response. Patients who no longer respond to methotrexate will be treated with Sofusa lymphatic delivery vs traditional subcutaneous injections and evaluated for clinical response and lymphatic flow and function. If successful, the Sofusa® DoseDisc™ wearable (wear time 30 minutes to 2 hours) offers the potential for both improved clinical response and a more convenient dosing alternative to traditional injections for patients. The FDA has now approved an IND to proceed with this Phase 1b Sofusa-etanercept study which will advance our efforts to develop our biosimilar assets as bio-better therapeutics, and/or for potential licensing opportunities.

Scilex Pharmaceuticals: ZTlido® (lidocaine topical system 1.8%)

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 topical system 1.8%), is a next-generation lidocaine delivery system approved by the FDA in February 2018 for the treatment of postherpetic neuralgia ("PHN"), a severe neuropathic pain condition. Having raised $140.0 million in financing in September 2018, Scilex commercially launched ZTlido® in late October 2018. Scilex has built a full commercial organization with over 100 experienced pain medicine sales representatives, supported by teams in market access, medical affairs and marketing. Currently, approximately 100 million lives are covered by commercial payers for ZTlido®.

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

Chronic Pain recommends topical lidocaine for the treatment of neuropathic pain. The prescription lidocaine patch market for all indications totaled almost $700.0 million in 2015 in the U.S.

ZTlido® (lidocaine topical system 1.8%) is based on a novel and proprietary technology and contains only 36 mg of lidocaine but delivers the same amount of lidocaine compared to Endo Pharmaceuticals, Inc.'s Lidoderm® (lidocaine patch 5%), which holds 700 mg of lidocaine per patch. On February 28, 2018, the FDA approved ZTlido® (lidocaine topical system 1.8%) for the relief of pain associated with post-herpetic neuralgia. Scilex is exploring potential partnerships for the product in both European and Chinese markets.

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.

Recent Developments

2018 Securities Purchase Agreement in Private Placement and Amendments to Warrants

On March 26, 2018, we entered into a Securities Purchase Agreement, as amended by Amendment No. 1 thereto, dated as of June 13, 2018 (the "Securities Purchase Agreement") with certain accredited investors (the "Purchasers"). Pursuant to the Securities Purchase Agreement, we agreed to issue and sell to the Purchasers, in a private placement (the "Private Placement"), (1) convertible promissory notes in an aggregate principal amount of $37,848,750 (the "Notes"), and (2) warrants to purchase 2,698,662 shares of our common stock (the "Warrants").

On June 13, 2018, pursuant to the Securities Purchase Agreement, we issued and sold to the Purchasers, in the Private Placement, the Notes and the Warrants.

On November 7, 2018, we entered into an Agreement and Consent (the "Agreement and Consent") with the Purchasers. Pursuant to the Agreement and Consent, in consideration for certain of the Purchasers, in their capacity as holders of the Notes, providing a waiver and consent on behalf of all holders of the Notes, pursuant to which the Purchasers provided us with certain waivers of their rights and certain of our covenants under the Securities Purchase Agreement with respect to the Loan Agreement (as defined below) and the transactions contemplated thereby, we and the Purchasers agreed to amend the Warrants to reduce the exercise price per share of our common stock thereunder from $8.77 to $3.28.

Each Warrant has an exercise price of $3.28 per share, subject to adjustment for stock splits, reverse stock splits, stock dividends and similar transactions, became exercisable on December 11, 2018, has a term of five and a half years from the date of issuance and will be exercisable on a cash basis, unless there is not an effective registration statement covering the resale of the shares issuable upon exercise of the Warrants, in which case the Warrants shall also be exercisable on a cashless exercise basis.

2018 Purchase Agreements and Indenture for Scilex

On September 7, 2018, we entered into Purchase Agreements (the "2018 Purchase Agreements") with certain investors (collectively, the "Scilex Note Purchasers") and Scilex. Pursuant to the 2018 Purchase Agreements, on September 7, 2018, Scilex, among other things, issued and sold to the Scilex Note Purchasers senior secured notes due 2026 in an aggregate principal amount of $224,000,000 (the "Scilex Notes") for an aggregate purchase price of $140,000,000 (the "Offering"). In connection with the Offering, we also entered into an indenture (the "Indenture") governing the Scilex Notes with Scilex and U.S. Bank National Association, a national banking association, as trustee (the "Trustee") and collateral agent. Pursuant to the Indenture, we agreed to irrevocably and unconditionally guarantee, on a senior unsecured basis, the punctual performance and payment when due of all obligations of Scilex under the Indenture.

The net proceeds of the Offering were approximately $89.3 million, after deducting the Offering expenses payable by Scilex and funding a segregated reserve account with $20.0 million (the "Reserve Account") and a segregated collateral account with $25.0 million (the "Collateral Account") pursuant to the terms of the Indenture. The net proceeds of the Offering will be used by Scilex to support the commercialization of ZTlido® (lidocaine topical system 1.8%), for working capital and general corporate purposes in respect of the commercialization of ZTlido® (lidocaine topical system 1.8%). Funds in the Reserve Account will be released to Scilex upon receipt by the Trustee of an officer’s certificate from Scilex confirming receipt of a marketing approval letter from the United States Food and Drug Administration with respect to ZTlido® (lidocaine topical system 5.4%) or a similar product with a concentration of not less than 5% (the "Marketing Approval Letter") on or prior to July 1, 2023. Funds in the Collateral Account will be released upon receipt of a written consent authorizing such release from the holders of a majority in principal amount of the Scilex Notes issued.

The holders of the Scilex Notes will be entitled to receive quarterly payments of principal of the Scilex Notes equal to a percentage, in the range of 10% to 20% of the net sales of ZTlido® (lidocaine topical system 1.8%) for the prior fiscal quarter, beginning on February 15, 2019. If Scilex has not received the Marketing Approval Letter by March 31, 2021, the percentage of net sales payable shall be increased to be in the range of 15% to 25%. If actual cumulative net sales of ZTlido® (lidocaine topical system 1.8%) from October 1, 2022 through September 30, 2023 are less than 60% of a predetermined target sales threshold for such period, then Scilex will be obligated to pay an additional installment of principal of the Scilex Notes each quarter in an amount equal to an amount to be determined by reference to the amount of such deficiency.

The aggregate principal amount due under the Scilex Notes shall be increased by $28,000,000 on February 15, 2022 if actual cumulative net sales of ZTlido® (lidocaine topical system 1.8%) from the issue date of the Scilex Notes through December 31, 2021 do not equal or exceed 95% of a predetermined target sales threshold for such period. If actual cumulative net sales of ZTlido® (lidocaine topical system 1.8%) for the period from October 1, 2022 through September 30, 2023 do not equal or exceed 80% of a predetermined target sales threshold for such period, the aggregate principal amount shall also be increased on November 15, 2023 by an amount equal to an amount to be determined by reference to the amount of such deficiency.

The final maturity date of the Scilex Notes will be August 15, 2026. The Scilex Notes may be redeemed in whole at any time upon 30 days’ written notice at Scilex’s option prior to August 15, 2026 at a redemption price equal to 100% of the then-outstanding principal amount of the Scilex Notes. In addition, upon a change of control of Scilex (as defined in the Indenture), each holder of a Scilex Note shall have the right to require Scilex to repurchase all or any part of such holder’s Scilex Note at a repurchase price in cash equal to 101% of the then-outstanding principal amount thereof.

Oaktree Term Loan Agreement

On November 7, 2018, we and certain of our domestic subsidiaries (the “Guarantors”) entered into a Term Loan Agreement (the “Loan Agreement”) with certain funds and accounts managed by Oaktree Capital Management, L.P. (collectively, the “Lenders”) and Oaktree Fund Administration, LLC, as administrative and collateral agent, for an initial term loan of $100.0 million (the “Initial Loan”) and a second tranche of $50.0 million, subject to the achievement of certain commercial and financial milestones between August 7, 2019 and November 7, 2019, and the satisfaction of certain customary conditions (the “Conditional Loan”). The Initial Loan was funded on November 7, 2018. The net proceeds of the Initial Loan were approximately $91.3 million, after deducting estimated loan costs, commissions, fees and expenses, and will be used for general corporate purposes. In connection with the Loan Agreement, on November 7, 2018, we issued to the Lenders warrants to purchase 6,288,985 shares of our common stock (the “Initial Warrants”). The Initial Warrants have an exercise price per share of $3.28, subject to adjustment for stock splits, reverse stock splits, stock dividends and similar transactions, will be exercisable from May 7, 2019 through May 7, 2029 and will be exercisable on a cash basis, unless there is not an effective registration statement covering the resale of the shares issuable upon exercise of the Initial Warrants (the “Initial Warrant

Shares"), in which case the Initial Warrants shall also be exercisable on a cashless exercise basis. If the Conditional Loan is funded, we will issue to the Lenders additional warrants to purchase such number of shares of our common stock as is equal to 2% of our fully-diluted shares on the date the Conditional Loan is funded, subject to adjustment in certain circumstances (the "Conditional Warrants"). The Conditional Warrants will have an exercise price per share equal to the average volume-weighted average price of one share of our common stock for the ten trading days immediately preceding the date the Conditional Loan is funded, will be exercisable from the date that is six months following the date of issuance through the ten year anniversary of the date of issuance and will be exercisable on a cash basis, unless there is not an effective registration statement covering the resale of the shares issuable upon exercise of the Conditional Warrants (the "Conditional Warrant Shares"), in which case the Conditional Warrants shall also be exercisable on a cashless exercise basis. In connection with the Loan Agreement, on November 7, 2018, we and the Lenders entered into a Registration Rights Agreement (the "Registration Rights Agreement") pursuant to which, among other things, we agreed to file one or more registration statements with the Securities and Exchange Commission (the "SEC") for the purpose of registering for resale the Initial Warrant Shares and the shares of common stock issuable upon exercise of warrants. Under the Registration Rights Agreement, we agreed to file a registration statement with the SEC registering all of the Initial Warrant Shares and the shares of common stock issuable upon exercise of the Conditional Warrants for resale by no later than the 45th day following the issuance of the Initial Warrants and the Conditional Warrants, respectively. On December 13, 2018, we filed a registration statement with the SEC registering all of the Initial Warrant Shares for resale, and such registration statement was declared effective by the SEC on December 21, 2018.

Acquired In-process Research and Development of BDL

In August 2015, we and TNK entered into a Stock Purchase Agreement (the "Stock Purchase Agreement") with BDL Products, Inc. ("BDL") and the stockholders of BDL (the "Stockholders") pursuant to which the Stockholders sold all of their shares of capital stock in BDL to TNK for: (1) a cash payment of $100.00, and (2) $6.0 million in shares of TNK Class A Stock, subject to adjustment in certain circumstances, to be issued to the Stockholders upon a financing resulting in gross proceeds (individually or in the aggregate) to TNK of at least $50.0 million (a "Qualified Financing"). In accordance with subsequent amendments to the Stock Purchase Agreement, in the event a Qualified Financing did not occur by October 15, 2017 (subject to further extension as implied and based on previously amended dates) or TNK did not complete an initial public offering of shares of its capital stock by September 15, 2017, in lieu of receiving shares of TNK pursuant to the acquisition, the Stockholders would receive an aggregate of 309,916 shares of our common stock, subject to adjustment in certain circumstances. TNK did not complete a Qualified Financing by the financing deadline and we issued 309,916 shares of our common stock to the Stockholders on March 19, 2018.

Sofusa® Acquisition

On July 2, 2018, we entered into an Asset Purchase Agreement (the "Sofusa Purchase Agreement") with Kimberly-Clark Corporation ("KCC"), Kimberly-Clark Global Sales, LLC ("KCCGS"), and Kimberly-Clark Worldwide, Inc. ("KCCW" and together with KCC and KCCGS, "Kimberly-Clark") pursuant to which, among other things, we acquired certain of Kimberly-Clark's assets related to micro-needle drug delivery system, including the Sofusa® platform (the "Sofusa Assets") and related fixed assets, and assumed certain of Kimberly-Clark's liabilities related to the Sofusa Assets (the "Sofusa Acquisition"). The closing of the Sofusa Acquisition (the "Sofusa Closing") occurred on July 2, 2018. At the Sofusa Closing, we paid $10 million and agreed to pay additional consideration to Kimberly-Clark upon the achievement of certain regulatory and net sales milestones, as well as a percentage in the low double-digits of any non-royalty amounts received by us in connection with any license, sale or other grant of rights by us to develop or commercialize the Sofusa Assets (all such additional consideration, the "Sofusa Contingent Consideration"). Under the Sofusa Purchase Agreement, the aggregate amount of the Sofusa Contingent Consideration payable by us will not exceed $300.0 million. We also agreed to pay Kimberly-Clark a low single-digit royalty on all net sales with

respect to the first five products developed by us or our licensees that utilizes intellectual property included in the Sofusa Assets. The transaction was accounted for as an asset acquisition since substantially all the value of the gross assets was concentrated in a single asset. Under the Asset Purchase Agreement, we acquired the Sofusa DoseDisc micro-needle technology designed to increase the efficacy of drug delivery by way of transdermal drug delivery for cash consideration of $10.0 million which was allocated based on the relative fair value of the assets acquired. No contingent consideration was recorded as of December 31, 2018 since the related regulatory approval milestones are not deemed probable until they actually occur. As a result, $9.5 million was expensed as a component of acquired in-process research and development and the remaining $0.5 million was recorded primarily to fixed assets as of December 31, 2018.

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 and granted patents 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 subsidiaries. This ADC technology is the subject matter of pending patent applications and granted patents with potential patent coverage to at least 2033. 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 at least 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 was obtained by the acquisition of Scilex Pharmaceuticals Inc. Certain aspects of this technology are covered by several issued U.S. patents, which will not expire until at least 2031. Additional patent applications to improvements of this technology have been filed and have the potential to provide patent coverage to at least 2039 and may require the completion of clinical trials that compare the cost-effectiveness.

11) The Sofusa technology was acquired from Kimberly-Clark as a novel technology platform designed to deliver large molecules, such as antibodies, directly into lymphatic capillaries and tumor draining lymph nodes. This micro-epidermal infusion system features a proprietary microneedle array and microfluidics reservoir. The Sofusa technology is the subject of multiple granted and pending applications with potential patent coverage to at least 2037.

Certain factors can either extend patent terms 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:

- 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, distribution, shipping and storage 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.

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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

With the exception of our subsidiary, Scilex, we currently do not have any sales capabilities. We intend to license to, or enter into strategic alliances with, larger companies in the biopharmaceutical businesses or use the services of contract sales organizations ("CROs"), which are equipped to, market and/or sell our products, if any, through their well-developed 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. We may or may not manufacture the products we develop, if any. As of December 31, 2018, our Scilex ZTlido® product is manufactured by ITOCHU CHEMICAL FRONTIER Corporation. 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, 2018, we had 382 employees and 36 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.

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 4955 Directors Place, San Diego, CA 92121, and our telephone number at that address is (858) 203-4100. 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 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 primarily 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 Chimeric Antigen Receptor-T Cell ("CAR-T") for adoptive cellular immunotherapy and resiniferatoxin ("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 many 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 generated limited product related revenues to date, and, with the exception of our ZTlido® (lidocaine topical system 1.8%), 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, 2018 and December 31, 2017, we had an accumulated deficit of $367.8 million and $165.1 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, (vii) expand our corporate, development and manufacturing infrastructure, and (viii) support our subsidiaries, such as Scilex Pharmaceuticals Inc. ("Scilex"), in their commercialization efforts. 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 organization 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, recurring negative cash flows from operations and substantial cumulative losses, 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, 2018 included a "going concern" explanatory paragraph indicating that our recurring losses from operations, recurring negative cash flows from operations and substantial cumulative losses 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, including ZTlido® (lidocaine topical system 1.8%).

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 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. 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. Other than ZTlido® (lidocaine topical system 1.8%), 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 do not generate significant revenues from sales of any products, and we may not be able to develop or commercialize our product candidates.

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 can 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”), the United Kingdom’s Medicines and Healthcare Products Regulatory Agency (the “MHRA”), the European Medicines Agency (“EMA”) 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, the MHRA, the EMA or certain other foreign regulatory agencies before we may commercialize 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, but 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 Monitoring Committees (also known as Data and Safety Monitoring Board or Data and Safety Monitoring Committee) 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 MHRA, 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 MHRA, the 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. Other than ZTlido® (lidocaine topical system 1.8%), 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 MHRA, 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 MHRA, 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 MHRA, the EMA or comparable foreign regulatory authorities;
- the FDA, the MHRA, 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 United Kingdom, the European Union or elsewhere;
- the FDA, the MHRA, 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 MHRA, 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 MHRA, 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 U.S. new drug application submitted by Scilex for Scilex's lead product candidate, ZTlido® (lidocaine topical system 1.8%), which was approved by the FDA in February 2018, and an MAA filed in Europe (which was subsequently withdrawn in 2019), we have not previously submitted a BLA or an NDA to the FDA, an MAA to the MHRA or 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 United Kingdom, 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 MHRA, 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 some of 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.

With specific regard to ZTlido® (lidocaine topical system 1.8%) and other drug products we do not manufacture in-house, but rather through a third-party manufacturer, if a third-party manufacturer upon which we rely fails to produce drug candidates that we require on a timely basis, or to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the trials, regulatory submissions, required approvals or commercialization of our drug candidates. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, which include difficulties with production costs and yields, quality control and assurance and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. The third-party manufacturers we contract with may not perform as agreed or may terminate their agreements with us. Any of these factors could cause us to delay or suspend any future clinical trials, regulatory submissions, required approvals or commercialization of one or more of our drug candidates, entail higher costs and result in our being unable to effectively commercialize products.

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 products or product candidates in commercial quantities, which would prevent us from commercializing our products and 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 products and 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 products and product candidates. We expect our third-party manufacturers are capable of providing sufficient quantities of our products and 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 or face potential delays or shortages. While we believe that there are other contract manufacturers with the technical capabilities to manufacture our products and 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.

If we do not successfully commercialize our products, our business, financial condition and results of operations will be materially and adversely affected

With the exception of Scilex (which commercially launched ZTlido® (lidocaine topical system 1.8%) in late October 2018, using a contract sales organization to conduct its primary sales activities), 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.

Specifically relating to Scilex, Scilex has a limited internal commercial infrastructure (with most of the sales organization provided by a third party, contract sales organization)and since ZTlido® (lidocaine topical system 1.8%)

only recently launched in late October 2018, Scilex has limited experience in the commercialization, sale, marketing or distribution of pharmaceutical products, like ZTlido® (lidocaine topical system 1.8%). Scilex's commercialization efforts for ZTlido® (lidocaine topical system 1.8%) have been primarily focused in the United States. Commercialization of ZTlido® (lidocaine topical system 1.8%) and other future product candidates outside of the United States, to the extent pursued, is likely to require collaboration with one or more third parties.

In late October 2018, Scilex began commercial sales of ZTlido® (lidocaine topical system 1.8%). In addition to the risks discussed elsewhere in this section, Scilex's ability to successfully commercialize and generate revenues from ZTlido® (lidocaine topical system 1.8%) depends on a number of factors, including, but not limited to, Scilex's ability to:

- develop and execute our sales and marketing strategies for Scilex's products;
- achieve, maintain and grow market acceptance of, and demand for, Scilex's products;
- obtain and maintain adequate coverage, reimbursement and pricing from managed care, government and other third-party payers;
- maintain, manage or scale the necessary sales, marketing, manufacturing, managed markets, and other capabilities and infrastructure that are required to successfully integrate and commercialize our products;
- obtain adequate supply of Scilex's products;
- maintain and extend intellectual property protection for Scilex's products; and
- comply with applicable legal and regulatory requirements.

If Scilex is unable to successfully achieve or perform these functions, Scilex will not be able to maintain or increase its product revenues and our business, financial condition and results of operations will be materially and adversely affected.

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.

With respect to ZTlido® (lidocaine topical system 1.8%) and any of our product candidates for which we may receive regulatory approvals, 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.

Our FDA approval for ZTlido® (lidocaine topical system 1.8%) and any other regulatory approvals that we may receive for our product candidates may 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, the MHRA, the 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.

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. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws govern the collection, use, disclosure and protection of health-related and other personal information. 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.

International data protection laws and regulations may also apply to some or all of our clinical data obtained outside of the U.S. For example, in April 2016, the EU approved a new data protection regulation, known as the General Data Protection Regulation (the “GDPR”), which became effective in May 2018. The GDPR includes new operational requirements for companies that receive or process personal data of EU residents, as well as significant penalties for non-compliance. Complying with the GDPR may cause us to incur substantial operational costs or require us to change our business practices.

Failure to comply with data protection laws and regulations could result in government enforcement actions, which may involve civil and criminal penalties, private litigation and/or adverse publicity and could negatively affect our operating results and business. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in

adverse publicity that could harm our business.

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.

Although 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, 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 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, and Jiong Shao, Executive Vice President and Chief Financial Officer. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel. The loss of any of our executive officers, key employees or key consultants and our inability to find suitable replacements could impede the achievement of our research and development objectives, and 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, as we have with ZTlido® (lidocaine topical system 1.8%) through our subsidiary, Scilex, 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 for the commercialization of any products, including ZTlido® (lidocaine topical system 1.8%), which is marketed and sold through our subsidiary, Scilex. 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 and in Scilex with commercialization efforts. 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.

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.

Other than with respect to ZTlido® (lidocaine topical system 1.8%), we have not completed a corporate-sponsored clinical trial. Phase I trials are ongoing for RTX for knee osteoarthritis, RTX for cancer-related pain, anti-CD38 CAR-T for multiple myeloma and anti-CEA CAR-T for intrahepatic CEA positive metastases and for intraperitoneal tumor implantation (malignant ascites). Despite this, 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 RTX, clinical trials of CAR-T including targeting CD38 using a CAR-T cell therapy, 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, Biologics License Application 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.

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 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. If our facilities are 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 material legal claims and liability, damage to our reputation, suffer loss or harm to our intellectual property rights and the further research, development and commercial efforts of our products and product candidates could be delayed. If we are held liable for a claim against which we are not insured or for damages exceeding the limits of our insurance coverage, whether arising out of cybersecurity matters, or from some other matter, that claim could have a material adverse effect on our results of operations.

Further, a cybersecurity attack, data breach or privacy violation that leads to disclosure or modification of, or prevents access to, patient information, including personally identifiable information or protected health information, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal data, resulting in increased costs or loss of revenue. Our ability to effectively manage and maintain our internal business information, and to ship products to customers and invoice them on a timely basis, depends significantly on our enterprise resource planning system and other information systems. Portions of our information technology systems may experience interruptions, delays or cessations of service or produce errors in connection with ongoing systems

implementation work. Cybersecurity attacks in particular are evolving and include, but are not limited to, threats, malicious software, ransom ware, attempts to gain unauthorized access to data and other electronic security breaches that could lead to disruptions in systems, misappropriation of confidential or otherwise protected information and corruption of data. If we are unable to prevent such cybersecurity attacks, data security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive patient data. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

The terms of our outstanding convertible promissory notes 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 June 13, 2018, we issued and sold convertible promissory notes in an aggregate principal amount of $37.8 million (the "Convertible Notes") to certain accredited investors pursuant to a Securities Purchase Agreement, as amended (the "Securities Purchase Agreement"). The Convertible Notes accrue interest at a rate equal to 5.0% per annum and mature upon the earlier to occur of June 13, 2023 and the date of the closing of a change of control (the "Maturity Date"). At any time and from time to time before the Maturity Date, the holders of the Convertible Notes have the option to convert any portion of the outstanding principal amount of the Convertible Notes that is equal to or greater than the lesser of: (1) $4,000,000, and (2) the then-outstanding principal amount of the Convertible Note being converted into shares of common stock at a price per share of $7.0125, subject to adjustment for stock splits, reverse stock splits, stock dividends and similar transactions. Any conversion of the Convertible Notes could result in material dilution to our existing stockholders. Accrued but unpaid interest on the Convertible Notes shall be paid in cash semi-annually in arrears on or prior to the 30th day of June and 31st day of December of each calendar year commencing with the year ended December 31, 2018. If a holder elects to convert any of the principal amount of their Convertible Note, then all accrued but unpaid interest on such portion of the principal amount shall become due and payable in cash. The Securities Purchase Agreement and the Convertible Notes contain customary restrictive covenants, which will remain in effect so long as the aggregate outstanding principal amount of the Convertible Notes is at least $18.8 million, including significant limitations on incurring additional indebtedness, liens, declaring cash dividends or making cash distributions and dispositions of our assets, in each case subject to customary exceptions. The breach of such covenants or the occurrence of certain other events would result in the occurrence of an event of default. Upon the occurrence of an event of default and following any applicable cure periods, the interest rate under the Convertible Notes will automatically increase to 12.0% per annum, effective until the day after such default is cured, and the holders of the Convertible Notes may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Convertible Notes, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Any declaration by the holders of the Convertible Notes of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

On September 7, 2018, Scilex issued and sold senior secured notes due 2026 in an aggregate principal amount of $224,000,000 (the "Scilex Notes") for an aggregate purchase price of $140,000,000 (the "Scilex Offering"). In connection with the Scilex Offering, we also entered into an indenture (the "Scilex Indenture") governing the Scilex Notes with U.S. Bank National Association, a national banking association, as trustee (the "Trustee") and collateral agent, and Scilex. Pursuant to the Scilex Indenture, we agreed to irrevocably and unconditionally guarantee, on a senior unsecured basis, the punctual performance and payment when due of all obligations of Scilex under the Scilex Indenture.

The Scilex Indenture governing the Scilex Notes contains customary events of default with respect to the Scilex Notes (including a failure to make any payment of principal on the Scilex Notes when due and payable), and, upon certain

events of default occurring and continuing, the Trustee by notice to Scilex, or the holders of at least 25% in principal amount of the outstanding Scilex Notes by notice to Scilex and the Trustee, may (subject to the provisions of the Scilex Indenture) declare 100% of the then-outstanding principal amount of the Scilex Notes to be due and payable. Upon such a declaration of acceleration, such principal will be due and payable immediately. In the case of certain events, including bankruptcy, insolvency or reorganization involving us or Scilex, the Scilex Notes will automatically become due and payable.

Pursuant to the Scilex Indenture, we and Scilex must also comply with certain covenants with respect to the commercialization of ZTlido® (lidocaine topical system 1.8%), as well as customary additional affirmative covenants, such as furnishing financial statements to the holders of the Scilex Notes, minimum cash requirements and net sales reports, and negative covenants, including limitations on the following: the incurrence of debt, the payment of dividends, the repurchase of shares and, under certain conditions, making certain other restricted payments, the prepayment, redemption or repurchase of subordinated debt, a merger, amalgamation or consolidation involving Scilex, engaging in certain transactions with affiliates; and the making of investments other than those permitted by the Scilex Indenture.

On November 7, 2018, we and certain of our domestic subsidiaries (the "Guarantors") entered into a Term Loan Agreement (the "Loan Agreement") with certain funds and accounts managed by Oaktree Capital Management, L.P. (collectively, the "Lenders") and Oaktree Fund Administration, LLC, as administrative and collateral agent, for an initial term loan of $100.0 million (the "Initial Loan") and a second tranche of $50.0 million, subject to the achievement of certain commercial and financial milestones between August 7, 2019 and November 7, 2019, and the satisfaction of certain customary conditions. The Initial Loan was funded on November 7, 2018. The Loan Agreement contains customary affirmative and restrictive covenants and representations and warranties, including financial reporting obligations and minimum liquidity requirements and limitations on indebtedness, liens, negative pledges, certain restricted payments, subsidiary distributions, investments, fundamental transactions, dispositions of assets and transactions with affiliates. The Loan Agreement also contains other customary provisions, such as expense reimbursement and confidentiality obligations, as well as indemnification rights for the benefit of the Lenders.

If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Our ability to utilize our net operating loss and tax credit carryforwards may be limited.

Section 382 of the Internal Revenue Code of 1986, as amended, and the rules and regulations thereunder ("Section 382") limit a corporation's ability to utilize existing net operating loss and tax credit carryforwards once the corporation experiences an ownership change as defined in Section 382. We have undergone an ownership change for purposes of Section 382 in a prior year. For the year ended December 31, 2018, there was no impact of such limitations on our income tax provision. Since our last ownership change we have had equity offerings or acquisitions that have equity as a component of the purchase price, which increases our likelihood of experiencing a future ownership change under Section 382. Future equity offerings or acquisitions that have equity as a component of the purchase price could constitute an ownership change under Section 382. If and when any other ownership change occurs, utilization of our net operating loss and tax credit carryforwards may be limited by Section 382, which could potentially result in increased future tax liability to us.

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. For example, the U.S. government has called for substantial changes to foreign trade policy with China and has recently raised, and has proposed to further raise in the future, tariffs on several Chinese goods. China has retaliated with increased tariffs on U.S. goods, which we anticipate will increase our cost of doing business in China. Any further changes in U.S. trade policy could trigger retaliatory actions by affected countries, including China, resulting in trade wars and in increased costs for goods imported into the United States and our ability to sell goods and services in the affected countries. Such an outcome may reduce customer demand for our products and services, especially if parties required to pay those tariffs increase their prices, or if trading partners limit their trade with the United States. If these consequences are realized, this may materially and adversely affect our sales and our business.

Additionally, the biopharmaceutical industry 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, some of which may be enhanced by our recent acquisition of Virttu Biologics Limited.

On April 27, 2017, we acquired Virttu Biologics Limited, which is based in the United Kingdom. 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;
- the inability to obtain necessary foreign regulatory or pricing approvals of products in a timely manner;
- fluctuations in foreign currency exchange rates;
- difficulties in staffing and managing international operations;
- less favorable intellectual property or other applicable laws;
- the effects of the implementation of the United Kingdom's decision to voluntarily depart from the European Union;
- currency controls that restrict or prohibit the payment of funds or the repatriation of earnings to the United States;
- increased costs of compliance with general business and tax regulations in these countries or regions;
- 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.

Uncertainty relating to the determination of LIBOR and the potential phasing out of LIBOR after 2021 may adversely affect our results of operations, financial condition, liquidity and net worth.

We routinely engage in transactions involving financial instruments, such as the purchase of loans, securities or derivatives indexed to LIBOR and the sale of LIBOR-indexed securities. In July 2017, the United Kingdom's Financial Conduct Authority, which regulates LIBOR, announced its intention to stop persuading or compelling the group of major banks that sustain LIBOR to submit rate quotations after 2021. As a result, it is uncertain whether LIBOR will continue to be quoted after 2021.

Efforts are underway to identify and transition to a set of alternative reference rates. The transition may lead to disruption, including yield volatility on LIBOR-based securities. In addition, our use of an alternative reference rate may be subject to judicial challenges. If LIBOR ceases or changes in a manner that causes regulators or market participants to question its viability, financial instruments indexed to LIBOR could experience disparate outcomes based on their contractual terms, ability to amend those terms, market or product type, legal or regulatory jurisdiction, and a host of other factors. There can be no assurance that legislative or regulatory actions will dictate what happens if LIBOR ceases or is no longer viable. In addition, while the Alternative Reference Rates Committee was created to identify best practices for market participants regarding alternative interest rates, there can be no assurance that broadly adopted industry practices will develop. Divergent industry or market participant actions could result after LIBOR is no longer available or viable. It is uncertain what effect any divergent industry practices will have on the performance of financial instruments, including ones that we own or have issued. Additionally, if an alternative method or index to LIBOR is selected, there can be no assurance that the alternative method or index will yield the same or similar economic results over the lives of the financial instruments. These developments could have a material impact on our debt securities, which could adversely affect our business, financial condition, liquidity, net worth or results of operations.

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., which remains a stand-alone company. We also acquired Virttu Biologics Limited in 2017 and Sofusa®, a revolutionary drug delivery system, in July 2018, and we are in the process of integrating this company and technology with ours. The success of any acquisition depends 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. 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.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Our long-term success depends on intellectual property protection; if our intellectual property rights are invalidated or circumvented, our business will be adversely affected.

Our long-term success depends on our ability to continually discover, develop, and commercialize innovative new pharmaceutical products. Without strong intellectual property protection, we would be unable to generate the returns necessary to support the enormous investments in research and development and capital as well as other expenditures required to bring new drugs to the market and for commercialization.

Intellectual property protection varies throughout the world and is subject to change over time. In the U.S., for small molecule drug products, such as ZTlido® (lidocaine topical system 1.8%) (which is held by our subsidiary, Scilex),

the Hatch-Waxman Act provides generic companies powerful incentives to seek to invalidate our pharmaceutical patents. As a result, we expect that our U.S. patents on major pharmaceutical products will be routinely challenged, and there can be no assurance that our patents will be upheld. We face generic manufacturer challenges to our patents outside the U.S. as well. In addition, competitors or other third parties may claim that our activities infringe patents or other intellectual property rights held by them. If successful, such claims could result in our being unable to market a product in a particular territory or being required to pay damages for past infringement or royalties on future sales.

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 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 can defend our position, the cost of doing so may adversely affect our ability to grow, generate revenue or become profitable. 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 related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent published applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtain a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtain a license, limit our uses, or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all.

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

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

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

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

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

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

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

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

For example, certain of our joint development and/or licensing agreements, including but not limited to our agreement with City of Hope, set forth diligence milestones including timelines in which certain clinical trials should be initiated. Due to the uncertainty of drug development and clinical trials as set forth above, we may not be able to meet these diligence milestones, which could result in loss of exclusivity or loss of our rights to develop certain products or services pursuant to those agreements.

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

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

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

- Others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- We or our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- We or our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions;
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- Our pending patent applications may not lead to issued patents;
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- We may not develop additional proprietary technologies that are patentable; and

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

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

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

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

We remain responsible for payments of all milestone and license fees to Samyang Biopharmaceuticals Corporation pursuant to our agreement with NantPharma.

As a result of our acquisition of IgDraSol, Inc. in September 2013, we became a party to an Exclusive Distribution Agreement, as amended, with Samyang Biopharmaceuticals Corporation ("Samyang") in connection with our development of Cynviloq™ which contained various milestone and license fees to be paid to Samyang. On May 14, 2015, we sold all our equity interests in IgDrasol, Inc. to NantPharma, LLC ("NantPharma"). As part of the sale, we agreed with NantPharma to be responsible for and pay all milestone and license fees required to be paid to Samyang under the Exclusive Distribution Agreement following notification from NantPharma when such milestone and license fees become due and payable. If such milestone or licenses fees become due and payable, the payment thereof could materially harm our business and financial condition.

Risks Related to Ownership of Our Common Stock

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

The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. For example, from January 2, 2018 to December 31, 2018, our closing stock price ranged from $2.01 to $9.95 per share. The market price of our common stock may fluctuate significantly in response to numerous factors, some of which are beyond our control, such as:

- actual or anticipated adverse results or delays in our clinical trials;
- our failure to commercialize our product candidates, if approved;
- unanticipated serious safety concerns related to the use of any of our product candidates;
- adverse regulatory decisions;
- changes in laws or regulations applicable to our product candidates, including but not limited to clinical trial requirements for approvals;
- legal disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our product candidates, government investigations and the results of any proceedings or lawsuits, including, but not limited to, patent or stockholder litigation;
- our decision to initiate a clinical trial, not initiate a clinical trial or to terminate an existing clinical trial;
- our dependence on third parties, including CROs;
- announcements of the introduction of new products by our competitors;
- market conditions in the pharmaceutical and biotechnology sectors;
- announcements concerning product development results or intellectual property rights of others;
- future issuances of common stock or other securities;
- the addition or departure of key personnel;
- failure to meet or exceed any financial guidance or expectations regarding development milestones that we may provide to the public;
- actual or anticipated variations in quarterly operating results;
- our failure to meet or exceed the estimates and projections of the investment community;
- overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- introduction of new products offered by us or our competitors;

- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- issuances of debt or equity securities;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;

- ineffectiveness of our internal controls;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- failure to effectively integrate the acquired companies' operations;
- general political and economic conditions;
- effects of natural or man-made catastrophic events; and
- other events or factors, many of which are beyond our control.

Further, the equity markets in general have recently experienced extreme price and volume fluctuations. Continued market fluctuations could result in extreme volatility in the price of our common stock, which could cause a decline in the value of our common stock. Price volatility of our common stock might worsen if the trading volume of our common stock is low. The realization of any of the above risks or any of a broad range of other risks, including those described in these "Risk Factors," could have a dramatic and material adverse impact on the market price of our common stock.

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

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future. The Loan Agreement prohibits us from paying any dividends without the prior written consent of the Lenders. In addition, pursuant to our outstanding convertible notes issued in June 2018, so long as the outstanding principal amount under all such notes is at least $18,845,851, we are prohibited from paying any dividends without the prior written consent of the holders of such notes. The payment of dividends on our capital stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as the board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if the common stock price appreciates.

Our strategic investments may result in losses.

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

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

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

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

Our quarterly operating results may fluctuate significantly.

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

- variations in the level of expenses related to our development programs;
-

- the addition or termination of clinical trials;
- any intellectual property infringement lawsuit in which we may become involved;

- regulatory developments affecting our product candidates; and
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements.

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

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

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

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

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

As of December 31, 2018, our directors and executive officers beneficially owned, in the aggregate, approximately 5% of our outstanding voting securities. As a result, if some or all of them acted together, they would have the ability to exert significant influence over the election of our board of directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may also have the effect of delaying or preventing a change in control of our company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

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

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

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

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

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

Provisions in our certificate of incorporation, as amended, and bylaws may discourage, delay or prevent a merger or acquisition involving us that our stockholders may consider favorable. For example, our certificate of incorporation,

as amended, authorizes our board of directors to issue up to 100,000,000 shares of “blank check” preferred stock. As a result, without further stockholder approval, the board of directors has the authority to attach special rights, including voting and

dividend rights, to this preferred stock. With these rights, preferred stockholders could make it more difficult for a third party to acquire us.

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

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

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

There have been changing laws, regulations and standards relating to corporate governance and public disclosure, including the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act"), the Sarbanes-Oxley Act of 2002 ("Sarbanes-Oxley"), new regulations promulgated by the U.S. Securities and Exchange Commission (the "SEC") and rules promulgated by the national securities exchanges. The Dodd-Frank Act, enacted in July 2010, expanded federal regulation of corporate governance matters and imposes requirements on public companies to, among other things, provides stockholders with a periodic advisory vote on executive compensation and also adds compensation committee reforms and enhanced pay-for-performance disclosures. While some provisions of the Dodd-Frank Act were effective upon enactment, others have been and will be implemented upon the SEC's adoption of related rules and regulations. The scope and timing of the adoption of such rules and regulations is uncertain and, accordingly, the cost of compliance with the Dodd-Frank Act is also uncertain. Additionally, while campaigning, President Trump made statements suggesting he may seek to adopt legislation that could significantly affect the regulation of United States financial markets. Areas subject to potential change, amendment or repeal include the Dodd-Frank Act, including § 619 (12 U.S.C. § 1851) known as the Volcker Rule and various swaps and derivatives regulations, the authority of the Federal Reserve and the Financial Stability Oversight Council, and renewed proposals to separate banks' commercial and investment banking activities.

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

We have identified material weaknesses in our internal control over financial reporting, and our financial controls and procedures may not in the future be sufficient to ensure timely and reliable reporting of financial information, which could materially harm our stock price and exchange listing, could cause our stock price to decline significantly and could make it more difficult for us to raise capital.

Sarbanes-Oxley specifically requires, among other things, that we maintain effective internal controls for financial reporting and disclosure of controls and procedures. In particular, we must perform system and process evaluation and

testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of Sarbanes-Oxley.

In March 2018, in connection with the preparation of our 2017 financial statements, we identified that the accounting implications of terms in certain unusual or non-recurring and significant agreements were not identified and assessed on a timely basis. Further, valuation of certain associated assets or liabilities were not properly reassessed at the end of each

reporting period. The material weakness did not result in a restatement of previously issued annual consolidated financial statements or condensed interim consolidated financial statements.

In connection with the preparation of our consolidated financial statements for the year ended December 31, 2018 there were multiple errors identified related to management's review of significant agreements. We believe the errors identified are due to deficiencies in our internal control environment resulting from insufficient competent accounting resources, including a Chief Accounting Officer, to effectively operate internal controls over financial reporting in a timely manner.

This ineffective control environment contributed to the following material weaknesses: (i) management did not adequately evaluate the underlying assumptions associated with the accounting for key terms identified in significant agreements, which in the current year included convertible notes and debt agreements and (ii) management did not accurately assess the significant assumptions in order to properly estimate the fair value of contingent consideration liabilities. We also identified the following deficiencies in our internal control environment resulting from insufficient accounting resources that collectively represent a material weakness: Management did not properly assess significant assumptions through the performance of precise reviews of accounting estimates including probability of occurrence and assumptions used in evaluating the fair value of embedded derivatives, fair value of indefinite-lived intangible assets, and income tax related balances. Such material weaknesses could result in material misstatements of the aforementioned account balances or disclosures in the annual or interim consolidated financial statements that would not be prevented or detected.

We have initiated and will continue to implement remediation measures to address the underlying causes of the material weaknesses described above and to improve and strengthen our internal control over financial reporting. We cannot assure you that the measures we have taken to date or any measures we may take in response to the material weaknesses in the future will be sufficient to remediate such material weakness or to avoid potential future material weaknesses. Even if we develop effective controls, these new controls may become inadequate because of changes in conditions or the degree of compliance with these policies or procedures may deteriorate.

Our compliance with Section 404 of Sarbanes-Oxley requires that we incur substantial accounting expense and expend significant management efforts. We will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Moreover, if we are not able to comply with the requirements of Section 404 of Sarbanes-Oxley in a timely manner, if we fail to remediate the material weaknesses in internal control over financial reporting or if we or our independent registered public accounting firm identifies additional deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We currently have leases in San Diego, California of approximately 130,584 square feet of corporate office and laboratory space, approximately 1,405 square feet of laboratory and office space at a second location as well as approximately 36,400 square feet for offices and cGMP fill and finish and storage space. In November 2018, we entered into a new lease in San Diego, California for approximately 61,200 square feet of additional corporate office and laboratory space, which commences in the first quarter of 2019 and expires in October 2029. In December 2018, we entered into a new lease in Broomfield, Colorado, for approximately 4,500 square feet of additional office space, which is expected to commence in the second quarter of 2019 and expires in 2024.

Our lease agreement in San Diego, for our corporate office and laboratory space expires in October 2029. The leases for our second laboratory and office space and our cGMP fill and finish and storage space expire in September 2020 and November 2022, respectively. We also lease 25,381 square feet of office and laboratory space in Suzhou, China, which lease expires in June 30, 2021. We lease 2,312 square feet of office, laboratory, and storage space in Scotland, which lease expires in March 2021. We sublease in New York, New York approximately 4,550 square feet of additional corporate office space. The sublease began in July of 2017 and expires in December 2020. We also lease approximately 3,432 square feet of office and laboratory space in Atlanta, Georgia which began in October of 2018

and expires in September 2024.

Item 3. Legal Proceedings.

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

In the normal course of business, we may be named as a defendant in one or more lawsuits. We are not a party to any outstanding material litigation and management is currently not aware of any legal proceedings that, individually or in the aggregate, are deemed to be material to our financial condition or results of operations.

Immunomedics Litigation

On June 26, 2015, Immunomedics, Inc. ("Immunomedics") filed a complaint in the United States District Court for the District of New Jersey (the "New Jersey Case") against the Board of Directors of RWMC, Dr. Richard P. Junghans, Dr. Steven C. Katz, the Office of the Board of Advisors of Tufts University School of Medicine, and one or more individuals or entities to be identified later. This complaint (the "Initial Complaint") alleged, among other things: (1) breach of contract; (2) breach of covenant of good faith and fair dealing; (3) tortious interference with prospective economic gain; (4) tortious interference with contracts; (5) misappropriation; (6) conversion; (7) bailment; (8) negligence; (9) vicarious liability; and (10) patent infringement. Overall, the allegations in the Initial Complaint were generally directed to an alleged material transfer agreement dated December 2008 and Immunomedics' alleged request for the return of certain alleged research material, as well as the alleged improper use and conversion of such research materials outside the scope of the material transfer agreement.

On October 22, 2015, Immunomedics filed an amended complaint (the "First Amended Complaint"), which, among other things, no longer named the Board of Directors of RWMC and The Office of the Board of Advisors of Tufts University School of Medicine as defendants. RWMC and Tufts Medical Center were added as new defendants. On January 14, 2016, Immunomedics filed a second amended complaint (the "Second Amended Complaint"), which, among other things, no longer named Tufts Medical Center as a defendant. In addition, the Second Amended Complaint contained allegations directed to two additional alleged material transfer agreements dated September 1993 and May 2010, respectively, and also added an allegation of unjust enrichment. The Second Amended Complaint also no longer asserted claims for (1) breach of covenant of good faith and fair dealing; (2) misappropriation; (3) bailment; (4) negligence; and (5) vicarious liability.

On October 12, 2016, Immunomedics filed a third amended complaint (the "Third Amended Complaint"), which added us, TNK, BDL and CARgenix as defendants. TNK is our subsidiary and purchased BDL and CARgenix in August 2015. The Third Amended Complaint included, among other things, allegations against us, TNK, BDL and CARgenix regarding (1) conversion; (2) tortious interference; and (3) unjust enrichment. On December 2, 2016, we, TNK, BDL, and CARgenix filed a motion to dismiss Immunomedics' complaint against them for lack of personal jurisdiction. On January 25, 2017, the District of New Jersey granted this motion, and we, TNK, BDL and CARgenix were dismissed as defendants from the New Jersey Case. Under various agreements, TNK has certain indemnification obligations to RWMC, Dr. Richard P. Junghans and Dr. Steven C. Katz that may be implicated by the New Jersey Case.

On April 27, 2018, Immunomedics filed a Complaint against us and TNK in San Diego Superior Court, Case No. 37-2018-00021006-CU-NP-CTL (the "San Diego Case"). The Complaint includes, among other things, allegations against us and TNK regarding (1) conversion; (2) tortious interference; and (3) inducing breach of contract.

On October 25, 2018, the parties to the New Jersey Case and the San Diego Case entered into a Mutual General Release and Settlement Agreement resolving both matters. Pursuant to the terms of the settlement, among other things, both the New Jersey Case and San Diego Case were dismissed with prejudice upon payment by us to Immunomedics of $2.35 million, which payment was timely made as called for by the agreement.

Cantor Fitzgerald & Co. Litigation

On May 25, 2018, Cantor Fitzgerald & Co. (“CF&Co.”) filed a complaint against us in the Supreme Court of the State of New York, County of New York, Index No. 652633/2018. The complaint includes, among other things, allegations against us for breach of contract arising out of a letter agreement whereby CF&Co. was to supply certain services to us in exchange for a fee (the “CF & Co. Litigation”). We filed an Answer and Counterclaim for breach of contract against CF&Co claiming that CF&Co. did not perform under the letter agreement.

Following a mediation held on December 19, 2018, the parties entered into a settlement agreement resolving the matter. Pursuant to the terms of the agreement, the litigation was dismissed with prejudice upon payment by us to CF&Co. of $1.0 million, which payment was timely made as called for by the agreement.

Item 4. Mine Safety Disclosures.

None.

PART II

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

Market Information

Our common stock is listed on the Nasdaq Capital Market under the symbol "SRNE".

Holders of Record

As of February 21, 2019, there were 225 holders of record of our common stock.

Recent Sales of Unregistered Securities

On November 7, 2018, we and certain of our domestic subsidiaries (the "Guarantors") entered into a Term Loan Agreement (the "Loan Agreement") with certain funds and accounts managed by Oaktree Capital Management, L.P. (collectively, the "Lenders") and Oaktree Fund Administration, LLC, as administrative and collateral agent. In connection with the Loan Agreement, on November 7, 2018, we issued to the Lenders warrants to purchase 6,288,985 shares of our common stock (the "Initial Warrants"). The Initial Warrants have an exercise price per share of $3.28, subject to adjustment for stock splits, reverse stock splits, stock dividends and similar transactions, will be exercisable from May 7, 2019 through May 7, 2029 and will be exercisable on a cash basis, unless there is not an effective registration statement covering the resale of the shares issuable upon exercise of the Initial Warrants (the "Initial Warrant Shares"), in which case the Initial Warrants shall also be exercisable on a cashless exercise basis.

We issued to the Lenders the Initial Warrants in reliance on the exemption from registration provided for under Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). We relied on this exemption from registration for private placements based in part on the representations made by the Lenders, including the representations with respect to each of the Lender's status as an accredited investor, as such term is defined in Rule 501(a) of the Securities Act, and such Lender's investment intent.

Performance Graph

The following graph compares the cumulative total stockholder return on our common stock from December 31, 2012 to December 31, 2018 with the cumulative total return of (i) the Nasdaq Market Index and (ii) the Nasdaq Biotechnology Index. This graph assumes the investment of $100.00 after the market closed on December 31, 2012 in our common stock, and in the Nasdaq Market Index and the Nasdaq Biotechnology Index, and it assumes any dividends are reinvested. The stock price performance included in this graph is not necessarily indicative of future stock price performance.

Item 6. Selected Financial Data.

You should read the selected consolidated financial data presented below in conjunction with the audited consolidated financial statements appearing elsewhere in this Form 10-K and the notes to those statements and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The selected consolidated financial data as of December 31, 2018 and 2017, and for each of the years in the three-year period ended December 31, 2018, have been derived from our audited consolidated financial statements which appear elsewhere in this Form 10-K. The selected consolidated financial data as of December 31, 2016, 2015 and 2014 and for the years ended December 31, 2015 and 2014 have been derived from our audited consolidated financial statements which are not included in this Form 10-K. The historical results are not necessarily indicative of the operating results to be expected in the future. All financial information presented has been prepared in United States dollars and in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

	Year Ended December 31,				
(In thousands, except per share data)	2018	2017	2016	2015	2014
Income Statement Data:					
Revenues:					
Grant	$356	$206	$1,033	$1,530	$488
Royalties and licenses	480	140,381	4,017	3,010	3,337
Sales and services	20,357	11,269	3,102	50	—
Total revenues	21,193	151,856	8,152	4,590	3,825
Income (Loss) from operations (1)	(150,425)	25,335	(96,777)	(74,005)	(34,742)
Net income (loss)	$(212,526)	$11,109	$(63,937)	$(50,074)	$(34,657)
Net loss per share - basic	$(1.92)	$0.13	$(1.21)	$(1.24)	$(1.30)
Net loss per share - diluted	$(1.92)	$0.13	$(1.21)	$(1.24)	$(1.30)
Weighted average number of shares during the period - basic	106,150	69,742	50,360	36,909	26,679
Weighted average number of shares during the period - diluted	106,150	70,381	50,360	36,909	26,679

(1) Year-over-year increase in 2017 is primarily due to revenue recognized from the intangibles transferred to Celularity as a result of closing the Contribution Agreement in 2017.

	As of December 31,				
(In thousands)	2018	2017	2016	2015	2014
Balance Sheet Data:					
Cash and cash equivalents	$158,738	$20,429	$82,398	$39,038	$71,902
Intangibles, net	66,283	71,013	64,776	3,912	4,357
Goodwill	38,298	38,298	41,548	20,626	24,041
Total assets	624,087	431,613	401,586	343,519	141,541
Total liabilities	416,587	225,003	315,084	202,581	32,828
Stockholders' equity	207,500	206,610	86,502	140,938	108,713
Net Working Capital	117,943	(49,255)	13,569	110,145	64,358

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

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

Overview

Sorrento Therapeutics, Inc. (Nasdaq: SRNE), together with its subsidiaries (collectively, the “Company”, “we”, “us” and “our”) is a clinical stage and commercial biopharma company focused on delivering innovative and clinically meaningful therapies to patients and their families, globally, to address unmet medical needs. We primarily focus on therapeutics areas in Immune-Oncology and Non-Opioid Pain Management. We also have programs assessing the use of our technologies and products in autoimmune, inflammatory and neurodegenerative diseases.

At our core, we are an antibody-centric company and leverage our proprietary G-MAB™ library and targeted delivery modalities to generate the next generation of cancer therapeutics. Our fully human antibodies include PD-1, PD-L1, CD38, CD123, CD47, c-MET, VEGFR2, CCR2 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 chimeric antigen receptor T-cell therapy (“CAR-T”), dimeric antigen receptor T-cell therapy (“DAR-T”), antibody drug conjugates (“ADCs”) as well as bispecific antibody approaches. Additionally, we acquired Sofusa®, a revolutionary drug delivery system, in July 2018, which delivers biologics directly into the lymphatic system to potentially achieve improved efficacy and fewer adverse effects than standard parenteral immunotherapy.

With each of our clinical and pre-clinical 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 focused 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 to entering the clinic. These include cellular therapies, an oncolytic virus and a palliative care program targeted to treat intractable cancer pain. Our cellular therapy programs focus on 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”)-directed CAR-T program. We have treated five patients with stage 4, unresectable adenocarcinoma (four with pancreatic and one with colorectal cancer) and CEA-positive liver metastases with anti-CEA CAR-T and are currently expanding this study. We successfully submitted an Investigational New Drug application ("IND") for anti-CD38 CAR-T for the treatment of refractory or relapsed multiple myeloma ("RRMM") and obtained approval from the U.S. Food and Drug Administration (the "FDA") to commence a human

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clinical trial for this indication in early 2018. We have dosed two patients and are continuing the enrollment of additional patients.

Broadly speaking, we are one of the world's leading CAR-T companies today due to our investments in technology and infrastructure, which have enabled significant progress in developing our next-generation non-viral, "off-the-shelf" allogeneic CAR-T solutions. With "off-the-shelf" solutions, CAR-T therapy can truly become a drug product rather than a treatment procedure. One of the approaches we have taken to develop the "off-the-shelf" allogeneic CAR-T solutions is through Celularity, our joint venture with Celgene, United Therapeutics and others. Celularity focuses on developing cell therapies with placenta-derived and cord blood T cells, which have natural allogeneic "off-the-shelf" characteristics. We are the single largest shareholder of Celularity with a stake of approximately 25%.

Outside of immune-oncology programs, as part of our global aim to provide a wide range of therapeutic products to meet underserved markets, we have made investments in non-opioid pain management. These include resiniferatoxin ("RTX"), which is a non-opioid-based neurotoxin that specifically ablates nerves that conduct pain signals while leaving other nerve functions intact and is being studied for chronic pain treatment. RTX has been granted orphan drug status for the treatment of intractable pain with end-stage cancer and a Phase I trial with the National Institutes of Health ("NIH") is concluding. A Phase Ib trial studying tolerance and efficacy of RTX for the control of osteoarthritis knee pain was initiated in late 2018 and preliminary results have shown strong efficacy with no significant adverse effects. Other applications of RTX are expected to start Phase Ib trials in 2019.

Also in the area of non-opioid pain management, we have acquired proprietary technologies to responsibly develop next generation, branded pharmaceutical products to better manage patients' medical conditions and maximize the quality of life of patients and healthcare providers. The flagship product of our majority-owned subsidiary, Scilex Pharmaceuticals Inc. ("Scilex"), ZTlido® (lidocaine topical system 1.8%), is a next-generation lidocaine delivery system which was approved by the FDA for the treatment of postherpetic neuralgia, a severe neuropathic pain condition, in February 2018, and was commercially launched in late October 2018. Scilex now has built a full commercial organization, which includes sales, marketing, market access, and medical affairs. ZTlido® is positioned as a best-in-class product with superior adhesion compared to Lidoderm and is manufactured by our Japanese partner in their state-of-the-art manufacturing facility.

Significant Developments

2018 Securities Purchase Agreement in Private Placement and Amendment to Warrants

On March 26, 2018, we entered into a Securities Purchase Agreement, as amended by Amendment No. 1 thereto, dated as of June 13, 2018 (the "Securities Purchase Agreement") with certain accredited investors (the "Purchasers"). Pursuant to the Securities Purchase Agreement, we agreed to issue and sell to the Purchasers, in a private placement (the "Private Placement"), (1) convertible promissory notes in an aggregate principal amount of $37,848,750 (the "Notes"), and (2) warrants to purchase 2,698,662 shares of our common stock (the "Warrants").

On June 13, 2018, pursuant to the Securities Purchase Agreement, we issued and sold to the Purchasers, in the Private Placement, the Notes and the Warrants.

On November 7, 2018, we entered into an Agreement and Consent (the "Agreement and Consent") with the Purchasers Pursuant to the Agreement and Consent, in consideration for certain of the Purchasers, in their capacity as holders of the Notes, providing a waiver and consent on behalf of all holders of the Notes, pursuant to which the Purchasers provided us with certain waivers of their rights and certain of our covenants under the Securities Purchase Agreement with respect to the Loan Agreement (as defined below) and the transactions contemplated thereby, we and the Purchasers agreed to amend the Warrants to reduce the exercise price per share of our common stock thereunder from $8.77 to $3.28.

Each Warrant has an exercise price of $3.28 per share, subject to adjustment for stock splits, reverse stock splits, stock dividends and similar transactions, became exercisable on December 11, 2018, has a term of five and a half years from the date of issuance and will be exercisable on a cash basis, unless there is not an effective registration statement covering the resale of the shares issuable upon exercise of the Warrants, in which case the Warrants shall also be exercisable on a cashless exercise basis.

2018 Purchase Agreements and Indenture for Scilex

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On September 7, 2018, we entered into Purchase Agreements (the "2018 Purchase Agreements") with certain investors (collectively, the "Scilex Note Purchasers") and Scilex. Pursuant to the 2018 Purchase Agreements, on September 7, 2018, Scilex, among other things, issued and sold to the Scilex Note Purchasers senior secured notes due 2026 in an aggregate principal amount of $224,000,000 (the "Scilex Notes") for an aggregate purchase price of $140,000,000 (the "Offering"). In connection with the Offering, we also entered into an indenture (the "Indenture") governing the Scilex Notes with Scilex and U.S. Bank National Association, a national banking association, as trustee (the "Trustee") and collateral agent (the "Collateral Agent"). Pursuant to the Indenture, we agreed to irrevocably and unconditionally guarantee, on a senior unsecured basis, the punctual performance and payment when due of all obligations of Scilex under the Indenture (the "Guarantee").

The net proceeds of the Offering were approximately $89.3 million, after deducting the Offering expenses payable by Scilex and funding a segregated reserve account with $20.0 million (the "Reserve Account") and a segregated collateral account with $25.0 million (the "Collateral Account") pursuant to the terms of the Indenture. The net proceeds of the Offering will be used by Scilex to support the commercialization of ZTlido® (lidocaine topical system 1.8%), for working capital and general corporate purposes in respect of the commercialization of ZTlido® (lidocaine topical system 1.8%). Funds in the Reserve Account will be released to Scilex upon receipt by the Trustee of an officer's certificate under the Indenture from Scilex confirming receipt of a marketing approval letter from the FDA with respect to ZTlido® (lidocaine topical system 5.4%) or a similar product with a concentration of not less than 5% (the "Marketing Approval Letter") on or prior to July 1, 2023. Funds in the Collateral Account will be released to Scilex upon receipt of a written consent authorizing such release from the holders of a majority in principal amount of the Scilex Notes issued, upon the occurrence and during the continuance of an event of default at the direction of the holders of a majority in principal amount of the Scilex Notes issued or upon the repayment in full of all amounts owed under the Scilex Notes.

The holders of the Scilex Notes will be entitled to receive quarterly payments of principal of the Scilex Notes equal to a percentage, in the range of 10% to 20% of the net sales of ZTlido® (lidocaine topical system 1.8%) for the prior fiscal quarter, beginning on February 15, 2019. If Scilex has not received the Marketing Approval Letter by March 31, 2021, the percentage of net sales payable shall be increased to be in the range of 15% to 25%. If actual cumulative net sales of ZTlido® (lidocaine topical system 1.8%) from October 1, 2022 through September 30, 2023 are less than 60% of a predetermined target sales threshold for such period, then Scilex will be obligated to pay an additional installment of principal of the Scilex Notes each quarter in an amount equal to an amount to be determined by reference to the amount of such deficiency.

The aggregate principal amount due under the Scilex Notes shall be increased by $28,000,000 on February 15, 2022 if actual cumulative net sales of ZTlido® (lidocaine topical system 1.8%) from the issue date of the Scilex Notes through December 31, 2021 do not equal or exceed 95% of a predetermined target sales threshold for such period. If actual cumulative net sales of ZTlido® (lidocaine topical system 1.8%) for the period from October 1, 2022 through September 30, 2023 do not equal or exceed 80% of a predetermined target sales threshold for such period, the aggregate principal amount shall also be increased on November 15, 2023 by an amount equal to an amount to be determined by reference to the amount of such deficiency.

The final maturity date of the Scilex Notes will be August 15, 2026. The Scilex Notes may be redeemed in whole at any time upon 30 days' written notice at Scilex's option prior to August 15, 2026 at a redemption price equal to 100% of the then-outstanding principal amount of the Scilex Notes. In addition, upon a change of control of Scilex (as defined in the Indenture), each holder of a Scilex Note shall have the right to require Scilex to repurchase all or any part of such holder's Scilex Note at a repurchase price in cash equal to 101% of the then-outstanding principal amount thereof.

Oaktree Term Loan Agreement

On November 7, 2018, we and certain of our domestic subsidiaries (the "Guarantors") entered into a Term Loan Agreement (the "Loan Agreement") with certain funds and accounts managed by Oaktree Capital Management, L.P.

(collectively, the "Lenders") and Oaktree Fund Administration, LLC, as administrative and collateral agent, for an initial term loan of $100.0 million (the "Initial Loan") and a second tranche of $50.0 million, subject to the achievement of certain commercial and financial milestones between August 7, 2019 and November 7, 2019, and the satisfaction of certain customary conditions (the "Conditional Loan"). The Initial Loan was funded on November 7, 2018. The net proceeds of the Initial Loan were approximately $91.3 million, after deducting estimated loan costs, commissions, fees and expenses, and will be used for general corporate purposes. In connection with the Loan Agreement, on November 7, 2018, we issued to the Lenders warrants to purchase 6,288,985 shares of our common stock (the "Initial Warrants"). The Initial Warrants have an exercise price per share of $3.28, subject to adjustment for stock splits, reverse stock splits, stock dividends and similar transactions, will be exercisable from May 7, 2019 through May 7, 2029 and will be exercisable on a cash basis, unless there is not an effective registration statement covering the resale of the shares issuable upon exercise of the Initial Warrants (the "Initial Warrant Shares"), in which case the Initial Warrants shall also be exercisable on a cashless exercise basis. If the Conditional Loan is

funded, we will issue to the Lenders additional warrants to purchase such number of shares of our common stock as is equal to 2% of our fully-diluted shares on the date the Conditional Loan is funded, subject to adjustment in certain circumstances (the "Conditional Warrants"). The Conditional Warrants will have an exercise price per share equal to the average volume-weighted average price of one share of our common stock for the ten trading days immediately preceding the date the Conditional Loan is funded, will be exercisable from the date that is six months following the date of issuance through the ten year anniversary of the date of issuance and will be exercisable on a cash basis, unless there is not an effective registration statement covering the resale of the shares issuable upon exercise of the Conditional Warrants (the "Conditional Warrant Shares"), in which case the Conditional Warrants shall also be exercisable on a cashless exercise basis. In connection with the Loan Agreement, on November 7, 2018, we and the Lenders entered into a Registration Rights Agreement (the "Registration Rights Agreement") pursuant to which, among other things, we agreed to file one or more registration statements with the Securities and Exchange Commission (the "SEC") for the purpose of registering for resale the Initial Warrant Shares and the shares of common stock issuable upon exercise of the Conditional Warrants. Under the Registration Rights Agreement, we agreed to file a registration statement with the SEC registering all of the Initial Warrant Shares and the shares of common stock issuable upon exercise of the Conditional Warrants for resale by no later than the 45th day following the issuance of the Initial Warrants and the Conditional Warrants, respectively. On December 13, 2018, we filed a registration statement with the SEC registering all of the Initial Warrant Shares for resale, and such registration statement was declared effective by the SEC on December 21, 2018.

Acquired In-process Research and Development of BDL

In August 2015, we and TNK entered into a Stock Purchase Agreement (the "Stock Purchase Agreement") with BDL Products, Inc. ("BDL") and the stockholders of BDL (the "Stockholders") pursuant to which the Stockholders sold all of their shares of capital stock in BDL to TNK for: (1) a cash payment of $100.00, and (2) $6.0 million in shares of TNK Class A Stock, subject to adjustment in certain circumstances, to be issued to the Stockholders upon a financing resulting in gross proceeds (individually or in the aggregate) to TNK of at least $50.0 million (a "Qualified Financing"). In accordance with subsequent amendments to the Stock Purchase Agreement, in the event a Qualified Financing did not occur by October 15, 2017 (subject to further extension as implied and based on previously amended dates) or TNK did not complete an initial public offering of shares of its capital stock by September 15, 2017, in lieu of receiving shares of TNK pursuant to the acquisition, the Stockholders would receive an aggregate of 309,916 shares of our common stock, subject to adjustment in certain circumstances. TNK did not complete a Qualified Financing by the financing deadline and we issued 309,916 shares of our common stock to the Stockholders on March 19, 2018.

Sofusa® Acquisition

On July 2, 2018, we entered into an Asset Purchase Agreement (the "Sofusa Purchase Agreement") with Kimberly-Clark Corporation ("KCC"); Kimberly-Clark Global Sales, LLC ("KCCGS"); and Kimberly-Clark Worldwide, Inc. ("KCCW" and together with KCC and KCCGS, "Kimberly-Clark") pursuant to which, among other things, we acquired certain of Kimberly-Clark's assets related to micro-needle drug delivery system, including the Sofusa® platform (the "Sofusa Assets") and related fixed assets, and assumed certain of Kimberly-Clark's liabilities related to the Sofusa Assets (the "Sofusa Acquisition"). The closing of the Sofusa Acquisition (the "Sofusa Closing") occurred on July 2, 2018. At the Sofusa Closing, we paid $10 million and agreed to pay additional consideration to Kimberly-Clark upon the achievement of certain regulatory and net sales milestones, as well as a percentage in the low double-digits of any non-royalty amounts received by us in connection with any license, sale or other grant of rights by us to develop or commercialize the Sofusa Assets (all such additional consideration, the "Sofusa Contingent Consideration"). Under the Sofusa Purchase Agreement, the aggregate amount of the Sofusa Contingent Consideration payable by us will not exceed $300.0 million. We also agreed to pay Kimberly-Clark a low single-digit royalty on all net sales with respect to the first five products developed by us or our licensees that utilizes intellectual property included in the Sofusa Assets. The transaction was accounted for as an asset acquisition since substantially all the value of the gross assets was concentrated in a single asset. Under the Asset Purchase Agreement, we acquired the Sofusa DoseDisc

micro-needle technology designed to increase the efficacy of drug delivery by way of transdermal drug delivery for cash consideration of $10.0 million which was allocated based on the relative fair value of the assets acquired. No contingent consideration was recorded as of December 31, 2018 since the related regulatory approval milestones are not deemed probable until they actually occur. As a result, $9.5 million was expensed as a component of acquired in-process research and development and the remaining $0.5 million was recorded primarily to fixed assets as of December 31, 2018.

Results of Operations

The following discussion of our operating results explains material changes in our results of operations for the years ended December 31, 2018, 2017 and 2016. The discussion should be read in conjunction with the consolidated financial statements and related notes included elsewhere in this Form 10-K.

Comparison of the Years Ended December 31, 2018 and 2017

Revenues. Revenues were $21.2 million for the year ended December 31, 2018, as compared to $151.9 million for the year ended December 31, 2017. The net decrease of $130.7 million is primarily due to higher royalty and licensing activities in the prior year. Royalties and license revenues decreased $139.9 million for the year ended December 31, 2018 as compared to the same period of 2017 primarily due to higher licensing revenue associated with collaboration arrangements in the prior year including from the intangibles transferred to Celularity of approximately $116.2 million as a result of closing the Contribution Agreement in 2017 as well as the cancellation of the Servier agreement, which resulted in revenue of approximately $16.7 million. Sales and service revenues increased by $9.1 million as a result of the product launch of ZTlido® (lidocaine topical system 1.8%), which accounted for $2.6 million of the increase, as well as increased revenue generated from contract manufacturing services due to increased volume.

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

Cost of revenues. Cost of revenues for the years ended December 31, 2018 and 2017 were $7.1 million and $3.9 million, respectively. The increase is due primarily to increased contract manufacturing activities and higher direct materials and overhead costs for the year ended December 31, 2018 compared to the prior year period. The costs generally include employee salaries and benefits, direct materials and overhead costs including rent, depreciation, utilities, facility maintenance and insurance. The increase of approximately $3.1 million is primarily attributable to increased indirect costs associated with the higher sales and service revenues for next generation homogenous antibody drug conjugate development.

Research and Development Expenses. Research and development expenses for the years ended December 31, 2018 and 2017 were $77.0 million and $55.5 million, respectively. Research and development expenses include expenses associated with the ramp up of ZTlido® (lidocaine topical system 1.8%) as well as the costs related to our RTX program activities towards entering into future clinical trials, costs to identify, isolate and advance human antibody drug candidates derived from our libraries as well as advancing our ADC preclinical drug candidates, preclinical testing expenses and the expenses associated with fulfilling our development obligations related to the NIH grant awards (collectively the “NIH Grants”). Such expenses consist primarily of salaries and personnel related expenses, stock-based compensation expense, clinical development expenses, preclinical testing, lab supplies, consulting costs, depreciation and other expenses. The increase of approximately $21.4 million is attributable to increased clinical activities related to consulting and lab supply costs incurred in connection with our expanded research and development activities and activities to advance RTX into clinical trials and potentially pursue other development activities and regulatory related activities associated with ZTlido® (lidocaine topical system 1.8%). We expect research and development expenses to increase in absolute dollars 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 in connection with supporting all of our programs, (v) invest in our joint ventures, collaborations or other third party agreements, and (vi) expand our corporate infrastructure.

Acquired In-process Research and Development Expenses. Acquired in-process research and development expenses for the years ended December 31, 2018 and 2017 were $11.3 million and $26.1 million, respectively, with the decrease due to higher levels of acquisition related activities in the prior year. Acquired in-process research and development expenses for the year ended December 31, 2018 include costs associated with the acquisition of acquired in-process research and development from the Sofusa Purchase Agreement. Acquired in-process research and development expenses for the year ended December 31, 2017 include costs associated with the acquisition of acquired in-process research and development from Mabtech Limited.

General and Administrative Expenses. General and administrative expenses for the years ended December 31, 2018 and 2017 were $63.6 million and $38.3 million, respectively. General and administrative expenses consist primarily of salaries and personnel related expenses for executive, finance and administrative personnel, stock-based compensation

expense, professional fees, infrastructure expenses, legal and accounting expenses and other general corporate expenses. The increase of $25.3 million is primarily attributable to higher employee related costs associated with additional headcount, stock-based compensation, legal costs related to acquisitions, general corporate and intellectual property matters, consulting and business development expenses and higher compliance costs associated with our public reporting obligations.

Intangible Amortization. Intangible amortization for the years ended December 31, 2018 and 2017 was $3.0 million and $2.6 million, respectively. The increase in the year ended December 31, 2018 as compared to the same period in 2017 is primarily due to the amortization of acquired in-process research and development upon commercialization of ZTlido® (lidocaine topical system 1.8%).

Gain on derivative liability. Gain on derivative liability for the year ended December 31, 2018 was $2.8 million compared to a derivative liability of $0 for the year ended December 31, 2017. The increase in the year ended December 31, 2018 as compared to the same period in 2017 is due to the change in fair value of the Conditional Warrants associated with the Oaktree Term Loan Agreement as further described in Note 12 in the Notes to Consolidated Financial Statements in this Form 10-K.

Loss (gain) on Contingent Liabilities. Contingent liabilities for the years ended December 31, 2018 and 2017 was $12.0 million and $54.3 million, respectively. The decrease in the year ended December 31, 2018 as compared to the same period in 2017 is primarily due to the settlements of Scilex and BDL liabilities for $38.2 million and $2.3 million, respectively, and the $11.3 million partial settlement of the Virttu financing milestone in shares of our common stock. The decrease was partially offset by a re-measurement of fair value resulting in a loss on contingent liabilities of $9.6 million during the year ended December 31, 2018.

Interest Expense. Interest expense for the years ended December 31, 2018 and 2017 was $57.6 million and $5.0 million, respectively. The increase in the year ended December 31, 2018 as compared to the same period in 2017 resulted primarily from the conversion during the year of the convertible notes issued in December 2017. The unamortized discount remaining at the date of conversion of $44.3 million was recognized immediately at that date as interest expense. An additional increase is primarily attributed to interest expense associated with the 2018 Securities Purchase Agreement in the Private Placement and Amendment to Warrants, the 2018 Oaktree Term Loan Agreement and Scilex Notes entered into in 2018.

Interest Income. Interest income for the years ended December 31, 2018 and 2017 was $0.9 million and $0.2 million, respectively.

Income tax benefit. Income tax benefit for the year ended December 31, 2018 was $6.3 million. Income tax benefit for the year ended December 31, 2017 was $36.0 million. The decrease in the year ended December 31, 2018 as compared to the same period in 2017 is primarily due to the reduction in deferred tax liabilities for Scilex.

Loss (income) on equity method investments. Loss on equity investments for the year ended December 31, 2018 was $5.0 million compared to a loss on equity investments of $40.2 million for the year ended December 31, 2017. (See Note 9 in the Notes to Consolidated Financial Statements in this Form 10-K).

Net (loss) income. Net loss for the year ended December 31, 2018 was $212.5 million as compared to net income of $11.1 million for 2017. The decrease in net income is mainly attributable to revenue recognized from the intangibles transferred to Celularity as a result of closing the contribution agreement in 2017.

Comparison of the Years Ended December 31, 2017 and 2016

Revenues. Revenues were $151.9 million for the year ended December 31, 2017, as compared to $8.2 million for the year ended December 31, 2016. The net increase of $143.7 million is primarily due to an increase in royalty and licensing activities for the year ended December 31, 2017 compared to the corresponding period of 2016. Royalties and license revenues increased $136.4 million for the year ended December 2017 as compared to the same period of 2016 primarily due to revenue recognized from the intangibles transferred to Celularity of approximately $116.2 million as a result of closing the Contribution Agreement in 2017 as well as the cancellation of the Servier agreement which resulted in revenue of approximately $16.0 million. Sales and service revenues generated from the sale of customized reagents and providing contract development services increased $8.2 million for the year ended December 2017 as compared to the same period of 2016.

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

Cost of revenues. Cost of revenues for the years ended December 31, 2017 and 2016 were $3.9 million and $0.8 million, respectively. The increase is due primarily to increased contract manufacturing activities and higher direct materials and overhead costs for the year ended December 31, 2017 compared to the prior year period. The costs

generally include employee

salaries and benefits, direct materials and overhead costs including rent, depreciation, utilities, facility maintenance and insurance. We expect cost of revenues to fluctuate with related sales and service revenues

Research and Development Expenses. Research and development expenses for the years ended December 31, 2017 and 2016 were $55.5 million and $42.2 million, respectively. Research and development expenses include expenses associated with the ramp up of ZTlido® (lidocaine topical system 1.8%) as well as the costs related to our RTX program activities towards entering into future clinical trials, costs to identify, isolate and advance human antibody drug candidates derived from our libraries as well as advancing our ADC preclinical drug candidates, preclinical testing expenses and the expenses associated with fulfilling our development obligations related to the NIH grant awards (collectively the "NIH Grants"). Such expenses consist primarily of salaries and personnel related expenses, stock-based compensation expense, clinical development expenses, preclinical testing, lab supplies, consulting costs, depreciation and other expenses. The increase of $13.4 million is attributable to increased clinical activities related to consulting and lab supply costs incurred in connection with our expanded research and development activities and activities to advance RTX into clinical trials and potentially pursue other development activities and regulatory related activities associated with ZTlido® (lidocaine topical system 1.8%). We expect research and development expenses to increase in absolute dollars 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, and (vi) expand our corporate infrastructure.

Acquired In-process Research and Development Expenses. Acquired in-process research and development expenses for the years ended December 31, 2017 and 2016 were $26.1 million and $45.0 million, respectively, with the decrease to due to higher levels of acquisition related activities in the prior year. Acquired in-process research and development expenses for the year ended December 31, 2017 include costs associated with the acquisition of acquired in-process research and development from Mabtech. Acquired in-process research and development expenses for the year ended December 31, 2016 include costs associated with the acquisition of acquired in-process research and development from Mabtech Limited and LA Cell.

General and Administrative Expenses. General and administrative expenses for the years ended December 31, 2017 and 2016 were $38.3 million and $24.2 million, respectively. General and administrative expenses consist primarily of salaries and personnel related expenses for executive, finance and administrative personnel, stock-based compensation expense, professional fees, infrastructure expenses, legal and accounting expenses and other general corporate expenses. The increase of $14.1 million is primarily attributable to higher salaries and related compensation expenses, stock-based compensation, legal costs related to acquisitions, general corporate and intellectual property matters, consulting and business development expenses and higher compliance costs associated with our public reporting obligations. We expect general and administrative expenses to increase in absolute dollars as we: (i) incur incremental expenses associated with expanded operations and development efforts, (ii) expand our efforts to ensure continued compliance with our public reporting obligations, (iii) build our infrastructure, and (iv) invest in our joint ventures, collaborations or other third party agreements.

Intangible Amortization. Intangible amortization for the years ended December 31, 2017 and 2016 was $2.6 million and $0.8 million, respectively. The increase in the year ended December 31, 2017 as compared to the same period in 2016 is due to the impact of the acquisition of Scilex and the start of patent right amortization in 2017.

Gain on derivative liability. Gain on derivative liability for the year ended December 31, 2017 was $0 compared to a gain on derivative liability of $5.5 million for the year ended December 31, 2016. The decrease in the year ended December 31, 2017 as compared to the same period in 2016 is due to the expiration of the unexercised derivative liability on March 31, 2016 associated with the cancelled call option on shares of NantKwest, Inc. stock.

Interest Expense. Interest expense for the years ended December 31, 2017 and 2016 was $5.0 million and $1.6 million, respectively.

Interest Income. Interest income for the years ended December 31, 2017 and 2016 was $0.2 million and $0.3 million, respectively.

Income tax benefit. Income tax benefit for the year ended December 31, 2017 was $36.0 million. Income tax benefit for the year ended December 31, 2016 was $0.9 million. The increase in the year ended December 31, 2017 as compared to the same period in 2016 is primarily due to re-measurement adjustments related to the impact of U.S. tax reform under the Tax Cut and Jobs Act which was enacted on December 22, 2017.

Loss on equity method investments. Loss on equity investments for the year ended December 31, 2017 was $40.2 million compared to a gain on equity investments of $0.4 million for the year ended December 31, 2016. The decrease was primarily due to the recognition of other-than-temporary impairment associated with our equity method investment in NANTibody for the year ended December 31, 2017. (See Note 9 in the Notes to Consolidated Financial Statements in this Form 10-K).

Net (loss) income. Net income (loss) for the years ended December 31, 2017 and 2016 was $11.1 million and $(63.9) million, respectively. The increase in net income is mainly attributable to revenue recognized from the intangibles transferred to Celularity as a result of closing the Contribution Agreement in 2017.

Liquidity and Capital Resources

As of December 31, 2018, we had $158.7 million in cash and cash equivalents attributable in part to the following financing arrangements:

On June 13, 2018, pursuant to the Securities Purchase Agreement, we issued and sold to the Purchasers, in the Private Placement (1) Notes in an aggregate principal amount of $37,848,750, and (2) Warrants to purchase an aggregate of 2,698,662 shares of our common stock.

On September 7, 2018, Scilex entered into the 2018 Purchase Agreements with the Purchasers and us. Pursuant to the 2018 Purchase Agreements, on September 7, 2018, Scilex, among other things, issued and sold to the Purchasers the Notes with an aggregate principal of $224.0 million for an aggregate purchase price of $140.0 million. The net proceeds of the Offering were approximately $89.3 million, after deducting the Offering expenses payable by Scilex and funding the Reserve Account ($20.0 million) and the Collateral Account ($25.0 million) pursuant to the terms of the Indenture. In connection with the Offering, Scilex also entered into the Indenture governing the Notes with the Trustee and Collateral Agent and us. Pursuant to the Indenture, we agreed to the Guarantee.

On November 7, 2018, we and the Guarantors entered into the Loan Agreement with the Lenders and Oaktree Fund Administration, LLC, as administrative and collateral agent, for the Initial Loan and the Conditional Loan. The Initial Loan was funded on November 7, 2018. The net proceeds of the Initial Loan were approximately $91.3 million, after deducting estimated loan costs, commissions, fees and expenses.

Cash Flows from Operating Activities. Net cash used for operating activities was $111.8 million for the twelve months ended December 31, 2018 as compared to $99.2 million for the twelve months ended December 31, 2017. Net cash used in 2018 reflects a net loss of $212.5 million, which was partially offset by non-cash interest expense charges of $52.8 million, as well as other non-cash charges totaling $41.9 million, primarily related to depreciation and amortization, stock based compensation, charges related to acquired IPR&D, loss on debt extinguishment, loss on equity investments and loss on contingent liabilities. Net cash used for operating activities was $99.2 million for 2017 and was primarily due to an increase in cash flow associated with accrued payroll, deferred rent, accrued expenses and other operating activities.

We expect to continue to incur substantial and increasing losses and negative net cash flows from operating activities as we seek to expand and support our clinical and pre-clinical development and research activities, and continue to support the commercial launch of ZTlido® and fund our joint ventures, collaborations and other third party agreements.

Cash Flows from Investing Activities. Net cash used for investing activities was $21.2 million for 2018 as compared to $16.5 million for 2017. Our investing activities used $11.2 million to acquire equipment and building improvements. Additionally, we used $10.0 million for the Sofusa Purchase Agreement. In 2017, investing activities used $11.0 million to acquire equipment and building improvements as well as $5.0 million related to our investment in Celularity.

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

Cash Flows from Financing Activities. Net cash provided by financing activities was $326.0 million for 2018, which was primarily attributed to the net proceeds from the issuance of convertible notes in connection with the Securities Purchase Agreement, net proceeds from the issuance of the Scilex Notes, and net proceeds from the Initial Loan related to the Loan Agreement. Additional cash was provided by the issuance of common stock upon the exercise of stock options. Net cash provided by financing activities was $53.7 million for 2017, which was primarily from the net

proceeds from the issuance of common stock and the issuance of the Notes in the Private Placement partially offset by the repayment of the Hercules loan.

Future Liquidity Needs. We have principally financed our operations through underwritten public offerings and private equity financings with aggregate net proceeds of $295.1 million since inception, as we have not generated any significant product related revenue from our principal operations to date, and do not expect to generate significant revenue for several years, if ever. We will need to raise additional capital before we exhaust our current cash resources in order to continue to fund our research and development, including our plans for clinical and preclinical trials and new product development, as well as to fund operations generally. As and if necessary, we will seek to raise additional funds through various potential sources, such as equity and debt financings or through corporate collaboration and license agreements. We can give no assurances that we will be able to secure such additional sources of funds to support our operations, or, if such funds are available to us, that such additional financing will be sufficient to meet our needs. These conditions, among others, 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 issue additional equity securities to raise funds, the ownership percentage of existing stockholders would be reduced. New investors may demand rights, preferences or privileges senior to those of existing holders of common stock. 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. These factors raise substantial doubt about our ability to continue as a going concern. Our financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K do not include any adjustments that might result from the outcome of this uncertainty.

We anticipate that we will continue to incur net losses into the foreseeable future as we: (i) advance RTX and other product candidates into clinical trials, (ii) continue to identify and advance a number of potential mAb and ADC product candidates into preclinical development activities, (iii) continue our development of, and seek regulatory approvals for, our product candidates, (iv) expand our corporate infrastructure, including the costs associated with being a Nasdaq listed public company, and (v) incur our share of joint venture and collaboration costs for our products and technologies.

We plan to continue to fund our operating losses and capital funding needs through public or private equity or debt financings, strategic collaborations, licensing arrangements, asset sales, government grants or other arrangements.

In November 2017, we filed a universal shelf registration statement on Form S-3 (the “2017 Shelf Registration Statement”) with the SEC, which was declared effective by the SEC in December 2017. The 2017 Shelf Registration Statement provides us with the ability to offer up to $350 million of securities, including equity and other securities as described in the registration statement. Included in the 2017 Shelf Registration Statement is a sales agreement prospectus covering the offering, issuance and sale by us of up to a maximum aggregate offering price of $100.0 million of our common stock that may be issued and sold under a sales agreement with B. Riley FBR, Inc. (the “ATM Facility”). During the twelve months ended December 31, 2018, we sold approximately $83.6 million in shares of common stock under the ATM Facility. We can offer up to $15.5 million of additional shares of common stock under the ATM Facility, subject to certain limitations.

Pursuant to this Shelf Registration Statement, we may offer such securities from time to time and through one or more methods of distribution, subject to market conditions and our capital needs. Specific terms and prices will be determined at the time of each offering under a separate prospectus supplement, which will be filed with the SEC at the time of any offering.

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

Uses of Cash. We have and plan to expand our business and intellectual property portfolio through the acquisition of new businesses and technologies as well as entering into licensing arrangements.

Acquisition of Virttu Biologics Limited

On April 27, 2017, we entered into a Share Purchase Agreement (the "Virttu Purchase Agreement") with TNK Therapeutics, Inc., a majority-owned subsidiary of ours ("TNK"), Virttu Biologics Limited ("Virttu"), the shareholders of Virttu (the "Virttu Shareholders") and Dayspring Ventures Limited, as the representative of the Virttu Shareholders, pursuant to which, among other things, TNK acquired from the Virttu Shareholders 100% of the outstanding ordinary shares of Virttu (the "Virttu Acquisition").

We issued an aggregate of 1,795,011 shares of our common stock to the Virttu Shareholders on April 27, 2018 for a value of $11.3 million. As of December 31, 2018, approximately $9.9 million payable in cash related to acquisition consideration has not been paid as of the date of this filing. See further discussion in Note 4 in the Notes to Consolidated Financial Statements in this Form 10-K.

Acquisition of Scilex Pharmaceuticals Inc.

On November 8, 2016, we entered into a Stock Purchase Agreement (the "Scilex Purchase Agreement") with Scilex and a majority of the stockholders of Scilex (the "Scilex Stockholders") pursuant to which, on November 8, 2016, we acquired from the Scilex Stockholders, and the Scilex Stockholders sold to us, approximately 72% of the outstanding capital stock of Scilex (the "Scilex Acquisition"), which remains a stand-alone company. The remainder of the outstanding capital stock of Scilex represents a noncontrolling interest of which approximately 19.3% continues to be held by ITOCHU CHEMICAL FRONTIER CORPORATION following the Scilex Acquisition.

Under the terms of the Scilex Purchase Agreement, we agreed to provide additional consideration to the Accredited Scilex Stockholders upon the achievement of certain milestones, as further discussed in Note 4 in the Notes to Consolidated Financial Statements in this Form 10-K. In 2018, we paid $22.5 million of remaining contingent consideration for regulatory milestones related to the Scilex Purchase Agreement.

Sofusa® Acquisition

On July 2, 2018, we entered into an Asset Purchase Agreement (the "Sofusa Purchase Agreement") with Kimberly-Clark Corporation ("KCC"); Kimberly-Clark Global Sales, LLC ("KCCGS"); and Kimberly-Clark Worldwide, Inc. ("KCCW" and together with KCC and KCCGS, "Kimberly-Clark") pursuant to which, among other things, we acquired certain of Kimberly-Clark's assets related to micro-needle drug delivery system, including the Sofusa® platform (the "Sofusa Assets") and related fixed assets, and assumed certain of Kimberly-Clark's liabilities related to the Sofusa Assets (the "Sofusa Acquisition"). The closing of the Sofusa Acquisition (the "Sofusa Closing") occurred on July 2, 2018. At the Sofusa Closing, we paid $10 million and agreed to pay additional consideration to Kimberly-Clark upon the achievement of certain regulatory and net sales milestones, as well as a percentage in the low double-digits of any non-royalty amounts received by us in connection with any license, sale or other grant of rights by us to develop or commercialize the Sofusa Assets (all such additional consideration, the "Sofusa Contingent Consideration"). Under the Sofusa Purchase Agreement, the aggregate amount of the Sofusa Contingent Consideration payable by us will not exceed $300.0 million. We also agreed to pay Kimberly-Clark a low single-digit royalty on all net sales with respect to the first five products developed by us or our licensees that utilizes intellectual property included in the Sofusa Assets. The transaction was accounted for as an asset acquisition since substantially all the value of the gross assets was concentrated in a single asset. Under the Asset Purchase Agreement, we acquired the Sofusa DoseDisc micro-needle technology designed to increase the efficacy of drug delivery by way of transdermal drug delivery for cash consideration of $10.0 million which was allocated based on the relative fair value of the assets acquired. No contingent consideration has been recorded at December 31, 2018 since the related regulatory approval milestones are not deemed probable until they actually occur. As a result, $9.5 million was expensed as a component of acquired in-process research and development and the remaining $0.5 million was recorded primarily to fixed assets as of December 31, 2018.

Critical Accounting Policies

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

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

Stock-Based Compensation. We account for stock-based compensation in accordance with authoritative guidance for stock-based compensation, which requires us to measure the cost of employee services received in exchange for equity incentive awards, including stock options, based on the grant date fair value of the award. The fair value is

estimated using the Black-Scholes option pricing model. The resulting cost is recognized over the period during which the employee is required to provide services in exchange for the award, which is usually the vesting period. We recognize compensation expense over the vesting period using the straight-line method and classify these amounts in the consolidated statements of operations based on the department to which the related employee reports. To the extent that we issue future stock incentive awards to employees,

our stock-based compensation expense will be increased by the additional unearned compensation resulting from such additional issuances. (See Note 13 in the Notes to the Consolidated Financial Statements in this Form 10-K).

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

Revenue Recognition. Our revenues are generated from various NIH grant awards, license fees, product sales, the sale of customized reagents and other materials, and the provision of contract manufacturing and other services. We do not have significant costs associated with costs to obtain contracts with our customers. Substantially all of our grants and accounts receivable result from contracts with customers.

License fees for the licensing of product rights are recorded as deferred revenue upon receipt of cash and recognized as revenue on a straight-line basis over the license period, with the exception of license agreements with no remaining performance obligations or undelivered obligations.

Revenues from sales and services are generated from product sales, the sale of customized reagents and providing contract manufacturing services. Reagents are used for preparing ADCs, these reagents include industrial standard cytotoxins, linkers, and linker-toxins. The contract development services include providing synthetic expertise to customer’s synthesis by delivering them proprietary cytotoxins, linkers and linker-toxins and ADC service using industry standard toxin and antibodies provided by customers. Product sales include the sale of ZTlido® (lidocaine topical system 1.8%).

We recognize revenue when control of the products is transferred to the customers in an amount that reflects the consideration we expect to receive from the customers in exchange for those products and services. This process involves identifying the contract with a customer, determining the performance obligations in the contract and the contract price, allocating the contract price to the distinct performance obligations in the contract and recognizing revenue when the performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. We consider a performance obligation satisfied once we have transferred control of a good or service to the customer, meaning the customer has the ability to use and obtain the benefit of the good or service. We recognize revenue for satisfied performance obligations only when we determine there are no uncertainties regarding payment terms or transfer of control. (See Note 3 in the Notes to Consolidated Financial Statements in this Form 10-K).

For Scilex product sales, we record gross-to-net sales adjustments for government and managed care rebates, chargebacks, wholesaler fees, sales returns and prompt payment discounts. These are generally accounted for as variable consideration estimated in the same period the related sales occur. Government and other rebates and chargebacks represent the majority of our variable consideration and require complex and significant judgment. Estimates are assessed each period and updated to reflect current information. There was no material variable consideration for Scilex product sales during the year ended December 31, 2018.

Investments in Other Entities. We hold a portfolio of investments in equity securities that are accounted for under either the equity method or cost method. Investments in entities over which we have significant influence but not a controlling interest are accounted for using the equity method, with our share of earnings or losses reported in loss on equity investments.

All investments are reviewed on a regular basis for possible impairment. If an investment's fair value is determined to be less than its net carrying value and the decline is determined to be other-than-temporary, the investment is written

down to its fair value. Such an evaluation is judgmental and dependent on specific facts and circumstances. Factors considered in determining whether an other-than-temporary decline in value has occurred include: the magnitude of the impairment and length of time that the estimated market value was below the cost basis; financial condition and business prospects of the investee; our intent and ability to retain the investment for a sufficient period of time to allow for recovery in market value of the investment; issues that raise concerns about the investee's ability to continue as a going concern; any other information that

we may be aware of related to the investment. We do not report the fair value of our equity investments in non-publicly traded companies because it is not practical to do so. (See Note 9 in the Notes to Consolidated Financial Statements in this Form 10-K).

Debt, Including Debt With Detachable Warrants. Debt with detachable warrants are evaluated for the classification of warrants as either equity instruments, derivative liabilities, or liabilities depending on the specific terms of the warrant agreement. In circumstances in which debt is issued with equity-classified warrants, the proceeds from the issuance of convertible debt are first allocated to the debt and the warrants at their relative estimated fair values. The portion of the proceeds so allocated to the warrants are accounted for as paid-in capital and a debt discount. The remaining proceeds, as further reduced by discounts created by the bifurcation of embedded derivatives and beneficial conversion features, are allocated to the debt. We account for debt as liabilities measured at amortized cost and amortize the resulting debt discount from the allocation of proceeds, to interest expense using the effective interest method over the expected term of the debt instrument. We consider whether there are any embedded features in debt instruments that require bifurcation and separate accounting as derivative financial instruments pursuant to ASC 815, Derivatives and Hedging.

If the amount allocated to the convertible debt results in an effective per share conversion price less than the fair value of our common stock on the commitment date, the intrinsic value of this beneficial conversion feature is recorded as a discount to the convertible debt with a corresponding increase to additional paid in capital. The beneficial conversion feature discount is equal to the difference between the effective conversion price and the fair value of our common stock at the commitment date, unless limited by the remaining proceeds allocated to the debt.

We may enter financing arrangements, the terms of which involve significant assumptions and estimates, including future net product sales, in determining interest expense, amortization period of the debt discount, as well as the classification between current and long-term portions. In estimating future net product sales, we assess prevailing market conditions using various external market data against our anticipated sales and planned commercial activities. See Note 12 in the Notes to Consolidated Financial Statements in this Form 10-K for our discussion of the Scilex Notes, which include repayments based on a percentage of net sales of ZTlido® (lidocaine topical system 1.8%). Consequently, we impute interest on the carrying value of the debt and record interest expense using an imputed effective interest rate. We reassess the expected payments each reporting period and account for any changes through an adjustment to the effective interest rate on a prospective basis, with a corresponding impact to the classification of our current and long-term portions.

Income Taxes. The provisions of the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) Topic 740-10, Uncertainty in Income Taxes, address the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under ASC Topic 740-10, we may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by taxing authorities, based on the technical merits of the position. We have determined that we have uncertain tax positions.

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

We have deferred tax assets, which are subject to periodic recoverability assessments. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount that more likely than not will be realized. As of December 31, 2018, we maintained a full valuation allowance against our deferred tax assets, with the exception of an amount equal to our deferred tax liabilities.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation referred to as the Tax Cuts and Jobs Act (the “Tax Act’’), which significantly revises the Internal Revenue Code of 1986, as amended. The Tax Act contains, among other things, significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21% for tax years beginning after December 31, 2017, limitations on the deduction for net operating losses to 80% of current year taxable income, indefinite carryover period for net operating losses and limitations on the deductibility of interest to 30% of adjusted taxable income.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 (“SAB 118”), which allowed us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. As of

December 22, 2018, our accounting for the Tax Act was complete and there were no material changes to the provisional amounts previously recorded.

Goodwill and Other Long-Lived Assets. Goodwill, which has an indefinite useful life, represents the excess of cost over fair value of net assets acquired. Goodwill is reviewed for impairment at least annually during the fourth quarter, or more frequently if events occur indicating the potential for impairment. During our goodwill impairment review, we may assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount, including goodwill. The qualitative factors include, but are not limited to, macroeconomic conditions, industry and market considerations, and the overall financial performance of the Company. If, after assessing the totality of these qualitative factors, we determine that it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, then no additional assessment is deemed necessary. Otherwise, we proceed to perform the two-step test for goodwill impairment. The first step involves comparing the estimated fair value of the reporting unit with its carrying value, including goodwill. If the carrying amount of the reporting unit exceeds its fair value, we perform the second step of the goodwill impairment test to determine the amount of loss, which involves comparing the implied fair value of the goodwill to the carrying value of the goodwill. We may also elect to bypass the qualitative assessment in a period and elect to proceed to perform the first step of the goodwill impairment test. We performed an annual assessment for goodwill impairment in the fourth quarter of 2018, noting no impairment and that the fair value of the goodwill exceeded the carrying value by a significant margin. There have not been any triggering events indicating the potential for impairment through December 31, 2018.

In determining the fair value utilized in the goodwill impairment assessment, we consider qualitative factors such as changes in strategy, cash flows and the regulatory environment as well as the market capitalization of our publicly traded common stock. Our share price is highly volatile and although there was significant excess of fair value over book value at the annual impairment assessment date as well as December 31, 2018, there have been subsequent declines in the market share price and there could be risk of impairment in the future.

It is not possible at this time to determine if an impairment charge would result from these factors, or, if it does, whether such charge would be material. We will continue to monitor the recoverability of goodwill.

We evaluate our long-lived and intangible assets with definite lives, such as property and equipment, acquired technology, customer relationships, patent and license rights, for impairment by considering competition by products prescribed for the same indication, the likelihood and estimated future entry of non-generic and generic competition with the same or similar indication and other related factors. The factors that drive the estimate of useful life are often uncertain and are reviewed on a periodic basis or when events occur that warrant review. Recoverability is measured by comparison of the assets' book value to future net undiscounted cash flows that the assets are expected to generate. There have not been any impairment losses of long-lived assets through December 31, 2018.

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

Acquired In-Process Research and Development Expense. We have acquired and may continue to acquire the rights to develop and commercialize new drug candidates. The up-front payments to acquire a new drug compound or drug delivery devices, as well as future milestone payments associated with asset acquisitions that do not meet the definition of derivative and are deemed probable to achieve the milestones, are immediately expensed as acquired in-process research and development provided that the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, have no alternative future use. The acquired in-process research and development related to the business combination of Virttu, for which certain products are under development and expected to be commercialized in the future, was capitalized and recorded within "Intangibles, net" on the accompanying consolidated balance sheet. We commenced amortization of acquired in-process research and development related to the business combination of Scilex upon commercialization of ZTlido® (lidocaine topical system 1.8%) in October 2018. Capitalized in-process research and development will be reviewed annually for impairment or more frequently as changes in circumstance or the occurrence of events suggest that the remaining value may not be recoverable. (See Note 4 in the Notes to Consolidated Financial Statements in this Form 10-K for further discussion of acquired

in-process research and development expense related to the Sofusa acquisition).

Acquisition Consideration Payable - Gain or Loss on Contingent Liabilities. Acquisition consideration payable relates to our acquisition of businesses and various other assets and is recorded on our consolidated balance sheets at fair value and is re-measured at each balance sheet date until such contingent liabilities have been settled, with changes in fair value recorded as gain on contingent liabilities. We estimate the fair value of contingent consideration based on level 3 inputs primarily driven by the probability of achieving certain financing or operating related milestones.

Contractual Obligations

As of December 31, 2018, our contractual obligations are as follows (in thousands):

	Payments Due by Fiscal Year				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Convertible Notes (1)	$47,311	$1,982	$3,784	$41,545	$—
Scilex Notes (1)	224,000	8,696	82,484	132,820	—
Oaktree Term Loan (1)	145,495	9,375	18,750	117,370	—
Operating leases	91,710	6,396	16,744	16,145	52,425
Total financial obligations	$508,516	$26,449	$121,762	$307,880	$52,425

(1) See Note 12 in the Notes to Consolidated Financial Statements in this Form 10-K.

Off-Balance Sheet Arrangements

From our inception through December 31, 2018, we did not engage in any off-balance sheet arrangements, as defined in Item 303(a)(4) of Regulation S-K.

Recent Accounting Pronouncements

Refer to Note 3, “Nature of Operations and Summary of Significant Accounting Polices,” in the Notes to Consolidated Financial Statements in this Form 10-K for a discussion of recent accounting pronouncements.

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

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

The fair market value of our Loan Agreement is subject to interest rate risk as a portion of the interest rate fluctuates based on the LIBOR. Generally, the fair market value of the debt will vary as interest rates increase or decrease. We had $100.0 million outstanding under our Loan Agreement at December 31, 2018. The weighted average stated interest rate on these borrowings is 9.38% as of December 31, 2018. A hypothetical 100 basis point adverse move in interest rates would increase our annual interest expense by approximately $1.0 million. We have determined that there was no material market risk exposure from such instruments to our consolidated financial position, results of operations or cash flows as of December 31, 2018.

We are not subject to interest rate risk on the Notes issued in 2018 in connection with our Securities Purchase Agreement as the Notes have a fixed rate of 5.00%. We are not subject to interest rate risk on the Scilex Notes associated with our 2018 Purchase Agreements as repayment of the Scilex Notes is determined by projected net sales as further discussed in Note 12 in the Notes to Consolidated Financial Statements in this Form 10-K. For both the Notes and Scilex Notes, changes in interest rates will generally affect the fair value of the debt instrument, but not our earnings or cash flows.

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

Item 8. Financial Statements and Supplementary Data.

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

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

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

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

In designing and evaluating the Company's disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. As required by Rule 13a-15(b) promulgated by the SEC under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Form 10-K. Based on the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were not effective as of the end of the period covered by this Form 10-K as a result of the material weaknesses described below.

Management's Annual Report on Internal Control Over Financial Reporting

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

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

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

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

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

We conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

In connection with the restatement of the Company's interim condensed consolidated financial statements for the three and nine months ended September 30, 2017 to correct a material error in our equity method investments, our management identified a material weakness in our review controls, that were not operating effectively to provide reasonable assurance that we timely identify and assess the accounting implications of transactions and events occurring at our equity method investees and properly report such investee financial information in our financial statements.

During 2018, the Company undertook remediation measures by enhancing existing internal controls with respect to our equity method investments. These include additional procedures to search for and assess information related to our equity method investees, including but not limited to financial statements and publicly available information, to evaluate related accounting implications. As a result of consistent and precise performance of these controls, the Company concluded that they were operating effectively and the related material weakness identified in prior year was remediated as of December 31, 2018.

In March 2018, in connection with the preparation of our 2017 financial statements, we identified that the accounting implications of terms in certain unusual or non-recurring and significant agreements were not identified and assessed on a timely basis. Further, valuation of certain associated assets or liabilities were not properly reassessed at the end of each reporting period. The material weakness did not result in a restatement of previously issued annual consolidated financial statements or condensed interim consolidated financial statements.

During 2018, the Company undertook remediation measures, including designing new controls and enhancing existing internal controls which, if effectively implemented, would provide reasonable assurance that we timely and precisely (1) identify and assess the accounting implications of terms in unusual or non-recurring and significant agreements and (2) reassess the valuation of associated assets or liabilities at the end of each reporting period. These included measures designed to improve centralized documentation control, improve the internal communication procedures between senior executive management, accounting personnel, and related business owners, leverage external

accounting experts as appropriate to perform the necessary reviews, and strengthen policies and procedures related to the transferring of responsibilities and the handoff of personnel duties. However, in connection with the preparation of our consolidated financial statements for the year ended December 31, 2018 there were multiple errors identified related to management's review of significant agreements. We believe the errors identified are due to deficiencies in our internal control environment resulting from insufficient competent

accounting resources, including a Chief Accounting Officer, to effectively operate internal controls over financial reporting in a timely manner.

This ineffective control environment contributed to the following material weaknesses: (i) management did not adequately evaluate the underlying assumptions associated with the accounting for key terms identified in significant agreements, which in the current year included convertible notes and debt agreements and (ii) management did not accurately assess the significant assumptions in order to properly estimate the fair value of contingent consideration liabilities. We also identified the following deficiencies in our internal control environment resulting from insufficient accounting resources that collectively represent a material weakness: Management did not properly assess significant assumptions through the performance of precise reviews of accounting estimates including probability of occurrence and assumptions used in evaluating the fair value of embedded derivatives, fair value of indefinite-lived intangible assets, and income tax related balances. Such material weaknesses could result in material misstatements of the aforementioned account balances or disclosures in the annual or interim consolidated financial statements that would not be prevented or detected.

Accordingly, our chief executive officer and chief financial officer concluded that, at December 31, 2018, our internal control over financial reporting was not effective. Notwithstanding the material weaknesses in our internal control over financial reporting, based on the additional analyses and procedures performed, we believe the consolidated financial statements included in our Annual Report on Form 10-K, are fairly presented in all material respects, in conformity with accounting principles generally accepted in the United States of America.

The effectiveness of our internal control over financial reporting at December 31, 2018 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Remediation Efforts to Address Material Weaknesses

As a result of the material weaknesses, we are in the process of implementing remediation measures including, but not limited to, performing a comprehensive assessment of accounting and finance resource requirements and hiring a Chief Accounting Officer and other personnel with sufficient accounting expertise to improve the operating effectiveness of the Company's review controls and monitoring activities, and utilizing external accounting experts as appropriate. We believe that our remediation measures, if effectively implemented, will provide reasonable assurance that we timely identify terms in agreements that could have material accounting implications, assess the accounting and disclosure implications of the terms, and account for such items in the financial statements appropriately. Any failure to implement these improvements to our internal control over financial reporting would result in continued material weaknesses in our internal control and could impact our ability to produce reliable financial reports, effectively manage the company or prevent fraud, and could potentially harm our business and our performance.

Changes in Internal Control Over Financial Reporting

Except the remediation of the prior year material weakness in relation to the review control of equity method investments, there has been no change in our internal control over financial reporting during the quarter ended December 31, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. As identified above under "Management's Annual Report on Internal Control Over Financial Reporting," material weaknesses were identified in our internal control over financial reporting as of December 31, 2018. Our plans for remediating such material weaknesses, which would constitute changes in our internal control over financial reporting prospectively when such controls are effectively implemented, are also enumerated above.

Item 9B. Other Information.

Effective as of March 15, 2019, we amended and restated our Bylaws (the "Amended and Restated Bylaws") to provide for, among other things the following changes from our Bylaws, as in effect immediately prior to the adoption of the Amended and Restated Bylaws:

Article I, Section 1(1): The Amended and Restated Bylaws delete the requirement that the annual meeting of stockholders be held within 13 months of the last annual meeting of stockholders and provide that such an annual meeting may be held at such place or by means of remote communication as our board of directors may determine in

its sole discretion.

Article I, Section 1(2): The Amended and Restated Bylaws add the requirement that a stockholder must be a stockholder of record entitled to vote at the time of the annual meeting in order to nominate a director or propose other business at such a meeting.
Article I, Sections 1(4)-1(9): The Amended and Restated Bylaws update the advance notice provisions by which a stockholder (the "Proposing Person") may propose business that is not submitted for inclusion in our proxy materials in connection with an annual meeting of the stockholders and nominations in connection with an annual or special meeting of the stockholders. The amendments require, among other things, (i) that the Proposing Person deliver a proxy statement and form of proxy to holders of at least the percentage of our stockholders required under applicable law to carry the relevant proposal, or in the case of a nomination, at least the percentage of our stockholders reasonably believed to be sufficient to elect such nominee, (ii) that the Proposing Person's notice to us contain certain information regarding the proposal and certain information, representations, consents and undertakings regarding the Proposing Person, (iii) that any proposed nominee for election provide a completed written questionnaire regarding such proposed nominee's background and qualifications, a written representation and agreement regarding the proposed nominee's voting, third party compensation and compliance with our policies and such proposed nominee's fiduciary duties and any other information our board may reasonably require, and (iv) that the Proposing Person must appear in person at the meeting to propose such business or nomination.
Article I, Section 2: The Amended and Restated Bylaws update the provisions regarding special meetings of the stockholders to implement the updated requirements of Article I, Section 1 of the Amended and Restated Bylaws.
Article I, Section 3: The Amended and Restated Bylaws allow the Board to postpone, reschedule, or cancel any previously scheduled special or annual meeting of stockholders before it is held.
Article I, Section 4: The Amended and Restated Bylaws clarify that any of our stock held, directly or indirectly, by us is not entitled to vote or counted for purposes of establishing a quorum; however, this limit does not apply to our ability to vote any stock held by us in a fiduciary capacity and count such stock for purposes of establishing a quorum.
Article I, Section 7: The Amended and Restated Bylaws clarify the duties of the inspector or inspectors of election appointed in connection with any meeting of our stockholders.
Article II, Sections 4 & 5: The Amended and Restated Bylaws provide that notices of regular and special meetings of the Board can be delivered in electronic format.
Article IV, Section 1: The Amended and Restated Bylaws provide for a Chief Financial Officer and an Assistant Secretary. The Amended and Restated Bylaws also provide that our board of directors may authorize our Chief Executive Officer to appoint any officer other than the Chairperson of the Board, the Chief Executive Officer, the President, the Chief Financial Officer or the Treasurer.
Article IV, Section 8: The Amended and Restated Bylaws provide for a Chairperson of the Board, who shall have the power to preside at all meetings of our board of directors and who shall have such other powers and duties provided in the Amended and Restated Bylaws and as our board of directors may from time to time prescribe.
Article V, Section 3: The Amended and Restated Bylaws provide that if the record date for a meeting of stockholders is not fixed by our board of directors, the record date shall be as provided by applicable law and, in the event of an adjournment, if our board of directors fixes a new record date for the adjourned meeting, such new record date shall not precede the date on which the resolution fixing such record date is adopted and shall not be more than 60 nor less than 10 days before the date of the adjourned meeting.
Article VI, Section 2: The Amended and Restated Bylaws provide that all stock and other securities of other corporations held by us will be voted by the person authorized to do so by our board, or in the absence of such authorization, by the Chairperson of our board of directors, our Chief Executive Officer, our President or any Vice President.
Article VII, Section 1: The Amended and Restated Bylaws modernize the forms that notice to the stockholders can take and provide the circumstances when notice is deemed given.
Article VII, Section 3: The Amended and Restated Bylaws provide that no notice shall be required to be given to persons with whom communication is unlawful.

Article VIII, Section 7: The Amended and Restated Bylaws provide for the Court of Chancery in the State of Delaware as the sole and exclusive forum for certain proceedings involving us, unless an alternative forum is approved by our board of directors.
Article IX: The Amended and Restated Bylaws expand the scope of our directors' and officers' right to indemnification.
Article X: The Amended and Restated Bylaws delete Article X, relating to loans to officers, in its entirety.
In addition to the changes summarized above, the Amended and Restated Bylaws also include certain other technical, conforming and clarifying changes.
The foregoing description of the Amended and Restated Bylaws is qualified in its entirety by reference to the full text of the Amended and Restated Bylaws, which are filed as Exhibit 3.3 to this Annual Report on Form 10-K and incorporated herein by reference.

PART III
Certain information required by Part III is omitted from this Annual Report on Form 10-K since we intend to file our definitive Proxy Statement for our next Annual Meeting of Stockholders, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended (the "2019 Proxy Statement"), no later than April 30, 2019, and certain information to be included in the 2019 Proxy Statement is incorporated herein by reference. To the extent that we do not file the 2019 Proxy Statement by April 30, 2019, we will file an amendment to this Annual Report on Form 10-K that includes the information required by Part III.
Item 10. Directors, Executive Officers and Corporate Governance.
The information required by this item regarding our directors, executive officers and corporate governance will be included in our 2019 Proxy Statement and is incorporated herein by reference.
Item 11. Executive Compensation.
The information required by this item regarding executive compensation will be included in our 2019 Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.
The information required by this item regarding security ownership of certain beneficial owners and management will be included in our 2019 Proxy Statement and is incorporated herein by reference.
Item 13. Certain Relationships and Related Transactions, and Director Independence.
The information required by this item regarding certain relationships and related transactions and director independence will be included in our 2019 Proxy Statement and is incorporated herein by reference.
Item 14. Principal Accounting Fees and Services.
The information required by this item regarding principal accounting fees and services will be included in our 2019 Proxy Statement and is incorporated herein by reference.
PART IV
Item 15. Exhibits, Financial Statement Schedules.
(a)(1) Financial Statements
Reference is made to the Index to Consolidated Financial Statements of Sorrento Therapeutics, Inc. appearing on page F-1 of this Form 10-K.

(a)(2) Financial Statement Schedules

Schedule II – Valuation of Qualifying Accounts

All other schedules not listed above have been omitted because of the absence of conditions under which they are required, or because the required information is included in the consolidated financial statements or the notes thereto.

(a)(3) Exhibits

Exhibit No.	Description
2.1*	Agreement and Plan of Merger between Sorrento Therapeutics, Inc. and IgDraSol, Inc. dated September 9, 2013 (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed with the SEC on September 11, 2013).
2.2*	Stock Purchase Agreement, dated November 8, 2016, by and among Sorrento Therapeutics, Inc., Scilex Pharmaceuticals Inc., the stockholders of Scilex Pharmaceuticals Inc. party thereto and SPI Shareholders Representative, LLC, as representative of the stockholders of Scilex Pharmaceuticals Inc. party thereto (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed with the SEC on November 8, 2016).
2.3*	Share Purchase Agreement, dated April 27, 2017, by and among Sorrento Therapeutics, Inc., TNK Therapeutics, Inc., Virttu Biologics, Limited, the shareholders of Virttu Biologics Limited and Dayspring Ventures Limited as representative of the shareholders of Virttu Biologics Limited (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed with the SEC on April 28, 2017).
2.4	Amendment No. 1 to Share Purchase Agreement, effective April 27, 2018, by and among Sorrento Therapeutics, Inc., TNK Therapeutics, Inc. and Dayspring Ventures Limited, as representative of the shareholders of Virttu Biologics Limited (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2018).
3.1	Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 15, 2013).
3.2	Certificate of Amendment of the Restated Certificate of Incorporation of Sorrento Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on August 1, 2013).
3.3	Amended and Restated Bylaws of Sorrento Therapeutics, Inc.
3.4	Certificate of Designation of Rights, Preferences and Privileges of Series A Junior Participating Preferred Stock of Sorrento Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on November 12, 2013).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on October 23, 2009).
4.2	Amended and Restated Rights Agreement, dated as of December 21, 2015 by and between Sorrento Therapeutics, Inc. and Philadelphia Stock Transfer, Inc., as rights agent (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on December 21, 2015).
4.3	Common Stock Purchase Warrant issued to Cambridge Equities, LP. (incorporated by reference to Exhibit 4.4 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 16, 2015).
4.4	Securities Purchase Agreement, dated as of April 3, 2016, by and among Sorrento Therapeutics, Inc., ABG SRNE Limited and Ally Bridge LB Healthcare Master Fund Limited (incorporated by reference to Exhibit

	4.5 to the Registrant's Registration Statement on Form S-3 filed with the SEC on June 29, 2016).
4.5	Securities Purchase Agreement, dated as of April 3, 2016, by and between Sorrento Therapeutics, Inc. and FREJOY Investment Management Co., Ltd. (incorporated by reference to Exhibit 4.6 to the Registrant's Registration Statement on Form S-3 filed with the SEC on June 29, 2016).
4.6	Securities Purchase Agreement, dated as of April 3, 2016, by and between Sorrento Therapeutics, Inc. and Beijing Shijilongxin Investment Co., Ltd. (incorporated by reference to Exhibit 4.7 to the Registrant's Registration Statement on Form S-3 filed with the SEC on June 29, 2016).
4.7	Securities Purchase Agreement, dated as of April 3, 2016, by and between Sorrento Therapeutics, Inc. and Yuhan Corporation (incorporated by reference to Exhibit 4.8 to the Registrant's Registration Statement on Form S-3 filed with the SEC on June 29, 2016).
4.8	Form of Common Stock Purchase Warrant issued to investors pursuant to the Securities Purchase Agreement, dated as of April 3, 2016, by and among Sorrento Therapeutics, Inc., ABG SRNE Limited and Ally Bridge LB Healthcare Master Fund Limited (incorporated by reference to Exhibit 4.9 to the Registrant's Registration Statement on Form S-3 filed with the SEC on June 29, 2016).

Exhibit No.	Description

4.9	Form of Common Stock Purchase Warrant issued to investors pursuant to the Securities Purchase Agreement, dated as of April 3, 2016, by and between Sorrento Therapeutics, Inc. and FREJOY Investment Management Co., Ltd. and Securities Purchase Agreement, dated as of April 3, 2016, by and between Sorrento Therapeutics, Inc. and Beijing Shijilongxin Investment Co., Ltd. (incorporated by reference to Exhibit 4.10 to the Registrant's Registration Statement on Form S-3 filed with the SEC on June 29, 2016).
4.10	Common Stock Purchase Warrant issued to Yuhan Corporation on April 29, 2016 (incorporated by reference to Exhibit 4.11 to the Registrant's Registration Statement on Form S-3 filed with the SEC on June 29, 2016).
4.11	Voting Agreement, dated as of April 29, 2016, by and between Sorrento Therapeutics, Inc. and Yuhan Corporation (incorporated by reference to Exhibit 4.12 to the Registrant's Registration Statement on Form S-3 filed with the SEC on June 29, 2016).
4.12	Registration Rights Agreement, dated November 8, 2016, by and among Sorrento Therapeutics, Inc. and the persons party thereto (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on November 8, 2016).
4.13	Warrant Agreement, dated November 23, 2016, issued to Hercules Capital, Inc. (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on November 29, 2016).
4.14	Registration Rights Agreement, dated April 27, 2017, by and among Sorrento Therapeutics, Inc. and the persons party thereto (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on April 28, 2017).
4.15	Form of Common Stock Purchase Warrant issued to investors pursuant to the Securities Purchase Agreement, dated as of December 11, 2017, by and among Sorrento Therapeutics, Inc. and the purchasers identified on Schedule A thereto (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the SEC on December 21, 2017).
4.16	Registration Rights Agreement, dated December 21, 2017, by and among Sorrento Therapeutics, Inc. and the purchasers identified on Schedule A thereto (incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K filed with the SEC on December 21, 2017).
4.17	Form of Convertible Promissory Note issued to investors pursuant to the Securities Purchase Agreement, dated as of June 13, 2018, by and among Sorrento Therapeutics, Inc. and the purchasers identified on Schedule A thereto (incorporated by reference to Exhibit 4.1 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2018).
4.18	Form of Common Stock Purchase Warrant issued to investors pursuant to the Securities Purchase Agreement, dated as of June 13, 2018, by and among Sorrento Therapeutics, Inc. and the purchasers identified on Schedule A thereto (incorporated by reference to Exhibit 4.2 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2018).
4.19	Registration Rights Agreement, dated June 13, 2018, by and among Sorrento Therapeutics, Inc. and the purchasers identified on Schedule A thereto (incorporated by reference to Exhibit 4.3 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2018).
4.20	

	Form of Warrant, dated November 7, 2018, issued by Sorrento Therapeutics, Inc. (incorporated by reference to Exhibit 4.1 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2018).
4.21	Registration Rights Agreement, dated November 7, 2018, by and among Sorrento Therapeutics, Inc. and the parties identified on Schedule A thereto (incorporated by reference to Exhibit 4.2 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2018).
10.1+	Exclusive License and Development Agreement between Sorrento Therapeutics, Inc. and China Oncology Focus Limited dated October 3, 2014 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q/A filed with the SEC on November 25, 2014).
10.2+	License Agreement, dated January 8, 2010, by and between The Scripps Research Institute and Sorrento Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 14, 2010).
10.3±	Form of Stock Option Agreement (incorporated by reference to Exhibit 10.11 to the Registrant's Current Report on Form 8-K/A filed with the SEC on September 22, 2009).
10.4±	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on September 7, 2012).
10.5±	2009 Amended and Restated Stock Incentive Plan, and forms of agreements related thereto (incorporated by reference to Appendix A to the definitive proxy statement filed by Sorrento Therapeutics, Inc. with the Securities and Exchange Commission on May 13, 2016).
10.6±	2009 Equity Incentive Plan, and forms of agreement related thereto (incorporated by reference to Exhibit 10.17 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 25, 2010).

10.7	Option Agreement between Sorrento Therapeutics, Inc. and B.G, Negev Technologies and Applications Ltd. (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 13, 2013).

Exhibit No.	Description
10.8+	Exclusive License Agreement dated as of April 21, 2015 by and between NantCell, Inc. and Sorrento Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 7, 2015).
10.9*	Stock Sale and Purchase Agreement dated as of May 14, 2015 by and between NantPharma, LLC and Sorrento Therapeutics, Inc. (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 7, 2015).
10.10	Binding Term Sheet for License Between Cytolumina/Fetolumina and TNK Therapeutics, Inc. (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 16, 2015).
10.11+	Exclusive License Agreement dated September 25, 2015 by and between LA Cell, Inc. and City of Hope (incorporated by reference to Exhibit 10.26 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 15, 2016).
10.12±	Employment Agreement, dated December 8, 2014, by and between Sorrento Therapeutics, Inc. and George Ng (incorporated by reference to Exhibit 10.28 to the Registrant's Annual Report on Form 10-K/A filed with the SEC on April 29, 2016).
10.13	Letter Agreement, dated June 30, 2016, among Chan Soon-Shiong Family Foundation, Cambridge Equities, L.P. and Sorrento Therapeutics, Inc. (incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 8, 2016).
10.14	Lease Agreement, dated September 12, 2016, between Sorrento Therapeutics, Inc. and HCP Life Science REIT, Inc. (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2016).
10.15	First Amendment to Office Lease, dated October 19, 2018, between Sorrento Therapeutics, Inc. and HCP Life Science REIT, Inc.
10.16	Unit Purchase Agreement dated August 5, 2016, by and among MedoveX Corporation and the purchasers party thereto (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed by MedoveX Corporation (File No. 001-36763) with the SEC on August 8, 2016).

Exhibit No.	Description
10.17	Registration Rights Agreement, dated August 5, 2016, by and among MedoveX Corporation and the investors party thereto (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed by MedoveX Corporation (File No. 001-36763) with the SEC on August 8, 2016).

10.18±	Amended and Restated Employment Agreement between Sorrento Therapeutics, Inc. and Henry Ji, Ph.D. dated May 9, 2017 (incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 15, 2017).
10.19+	Contribution Agreement, dated as of June 12, 2017, by and among Sorrento Therapeutics, Inc., TNK Therapeutics, Inc. and Celularity, Inc. (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2017).
10.20+	Amendment No. 1 to Contribution Agreement, dated as of June 30, 2017, by and among Sorrento Therapeutics, Inc., TNK Therapeutics, Inc. and Celularity, Inc. (incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2017).
10.21	Amendment No. 2 to Contribution Agreement, dated as of August 10, 2017, by and among Sorrento Therapeutics, Inc., TNK Therapeutics, Inc. and Celularity, Inc. (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2017).

10.22+	License and Transfer Agreement dated August 15, 2017 by and among Sorrento Therapeutics, Inc., TNK Therapeutics, Inc. and Celularity, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2017).
10.23	At Market Issuance Sales Agreement, dated as of November 9, 2017, by and between Sorrento Therapeutics, Inc. and B. Riley FBR, Inc. (incorporated by reference to Exhibit 1.2 to the Registrant's Registration Statement on Form S-3 filed with the SEC on November 9, 2017).
10.24	Offer Letter, dated March 15, 2018, by and between Sorrento Therapeutics, Inc. and Jiong Shao (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 10, 2018).
10.25+	Indenture and form of Note issued thereunder, dated as of September 7, 2018, by and among Scilex Pharmaceuticals Inc., as issuer, Sorrento Therapeutics, Inc., as parent guarantor, and U.S. Bank National Association, as trustee and collateral agent (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2018).
10.26	Form of Purchase Agreement, dated as of September 7, 2018, by and among Scilex Pharmaceuticals Inc., Sorrento Therapeutics, Inc. and the purchasers party thereto (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2018).
10.27	Collateral Agreement, dated as of September 7, 2018, by and between Scilex Pharmaceuticals Inc. and U.S. Bank National Association, as trustee and collateral agent (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2018).
10.28+	Irrevocable Standby Letter of Credit, dated September 7, 2018, issued by Sorrento Therapeutics, Inc. (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2018).
10.29+	Term Loan Agreement, dated November 7, 2018, by and among Sorrento Therapeutics, Inc., certain subsidiaries of Sorrento Therapeutics, Inc., the lenders party thereto and Oaktree Fund Administration, LLC, as administrative and collateral agent (incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2018).
10.30	Lease Agreement, dated November 13, 2018, between Sorrento Therapeutics, Inc. and HCP Life Science Estates, Inc.
10.31	Agreement and Consent, dated November 7, 2018, by and among Sorrento Therapeutics, Inc. and the Warrant Holders party thereto (incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2018).
21.1	List of Subsidiaries
23.1	Consent of Deloitte & Touche LLP

24	Power of Attorney (included on signature page hereto)
31.1	Certification of Henry Ji, Ph.D., Principal Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.
31.2	Certification of Jiong Shao, Principal Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.
32.1	Certification of Henry Ji, Ph.D., Principal Executive Officer and Jiong Shao, Principal Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, as amended.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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

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

± Management contract or compensatory plan.

The following financial statement schedule is filed as part of this Annual Report on Form 10-K:

Schedule Number	Description
II	Valuation and Qualifying Accounts

SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS

(in thousands)	Balance at Beginning of Period	Reserves Acquired	Additions	Deductions	Balance at End of Period
Fiscal Year 2018:					
Income tax valuation allowance	43,405	—	31,565	—	74,970
	$ 43,405	$ —	$ 31,565	$ —	$ 74,970
Fiscal Year 2017:					
Income tax valuation allowance	81,039	797	—	(38,431)	43,405
	$ 81,039	$ 797	$ —	$ (38,431)	$ 43,405
Fiscal Year 2016:					
Income tax valuation allowance	39,605	—	41,434	—	81,039
	$ 39,605	$ —	$ 41,434	$ —	$ 81,039

Item 16. Form 10-K Summary.

None.

SIGNATURES

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

Date: March 15, 2019 SORRENTO THERAPEUTICS, INC.

By: /s/ Henry Ji
Henry Ji, Ph.D.
Chairman of the Board of Directors, Chief Executive Officer & President

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints, jointly and severally, Henry Ji, Ph.D., and Jiong Shao, and each of them acting individually, as his attorney-in-fact, each with full power of substitution and resubstitution, for him in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact, or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title(s)	Date
/s/ Henry Ji, Ph.D. Henry Ji, Ph.D.	Chairman of the Board of Directors, Chief Executive Officer & President (Principal Executive Officer)	March 15, 2019
/s/ Jiong Shao Jiong Shao	Chief Financial Officer (Principal Financial and Accounting Officer)	March 15, 2019
/s/ Dorman Followwill Dorman Followwill	Director	March 15, 2019
/s/ Yue Alexander Wu Yue Alexander Wu, Ph.D.	Director	March 15, 2019
/s/ Kim D. Janda, Ph.D. Kim D. Janda, Ph.D.	Director	March 15, 2019
/s/ Jaisim Shah Jaisim Shah	Director	March 15, 2019
/s/ David Lemus David Lemus	Director	March 15, 2019

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Reports of Independent Registered Public Accounting Firm

To the stockholders and Board of Directors of Sorrento Therapeutics, Inc.

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Sorrento Therapeutics, Inc. and subsidiaries (the "Company") as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, because of the effect of the material weaknesses identified below on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements and financial statement schedule as of and for the year ended December 31, 2018, of the Company and our report dated March 15, 2019, expressed an unqualified opinion on those consolidated financial statements and financial statement schedule and included an explanatory paragraph regarding substantial doubt about the Company's ability to continue as a going concern.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

Definition and Limitations of Internal Control over Financial Reporting

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

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Material Weaknesses

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company’s annual or interim financial statements will not be prevented or detected on a timely basis. The following material weaknesses have been identified and included in management's assessment:

As required by COSO Principles 4 and 12, the Company did not attract, develop, and retain sufficient accounting resources, including a Chief Accounting Officer, with appropriate knowledge and expertise commensurate with the Company's corporate structure and financial reporting requirements to effectively operate internal controls over financial reporting in a timely manner. As a result of the lack of sufficient and appropriate resources, the Company's control activities in certain process or control areas did not operate effectively. Areas where we identified deficiencies resulting from the lack of sufficient accounting department resources included a lack of precise reviews of significant assumptions underlying fair value of embedded derivatives, fair value of indefinite-lived intangible assets, and income tax related balances.

The Company's failure to establish an effective control environment also contributed to the following individual material weaknesses: (i) a deficiency in evaluating the underlying assumptions associated with the accounting for key terms identified in significant transactions, which in the current year included convertible note and debt agreements; and (ii) a deficiency in reviewing and assessing assumptions underlying the determination of fair value of contingent consideration liabilities.

/s/ DELOITTE & TOUCHE LLP
San Diego, California
March 15, 2019

Reports of Independent Registered Public Accounting Firm
To the stockholders and the Board of Directors of Sorrento Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Sorrento Therapeutics, Inc. and subsidiaries (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and the schedule listed in the Index at Item 15 (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.
We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 15, 2019, expressed an adverse opinion on the Company's internal control over financial reporting because of material weaknesses.

Going Concern
The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company’s recurring losses from operations, recurring negative cash flows from operations and substantial cumulative net losses raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion
These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.
We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ DELOITTE & TOUCHE LLP

San Diego, California
March 15, 2019

We have served as the Company's auditor since 2016.

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CONSOLIDATED BALANCE SHEETS
(In thousands, except for share amounts)

	December 31,	
	2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	$158,738	$20,429
Restricted cash	9,592	—
Marketable securities	297	441
Grants and accounts receivables, net	3,833	2,211
Income tax receivable	526	1,715
Prepaid expenses and other, net	6,578	4,904
Total current assets	179,564	29,700
Property and equipment, net	24,384	19,345
Intangibles, net	66,283	71,013
Goodwill	38,298	38,298
Cost method investments	237,008	237,008
Equity method investments	27,980	32,999
Restricted cash	45,000	—
Other, net	5,570	3,250
Total assets	$624,087	$431,613
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$13,817	$9,911
Accrued payroll and related	10,236	4,485
Accrued expenses	13,403	7,274
Current portion of deferred revenue	2,703	3,864
Current portion of deferred rent	—	212
Acquisition consideration payable	11,312	53,209
Current portion of debt	10,150	—
Total current liabilities	61,621	78,955
Long-term debt, net of discount	223,136	5,211
Deferred tax liabilities, net	9,416	15,535
Deferred revenue	116,274	119,287
Deferred rent and other	6,140	6,015
Total liabilities	416,587	225,003
Commitments and contingencies		
Equity:		
Sorrento Therapeutics, Inc. equity		
Preferred stock, $0.0001 par value; 100,000,000 shares authorized and no shares issued or outstanding	—	—
Common stock, $0.0001 par value; 750,000,000 shares authorized and 122,280,092 and 82,903,567 shares issued and outstanding at December 31, 2018 and 2017, respectively	13	9
Additional paid-in capital	626,658	413,901
Accumulated other comprehensive income	15	242
Accumulated deficit	(367,750)	(165,120)
Treasury stock, 7,568,182 shares and 7,568,182 shares at cost at December 31, 2018 and 2017, respectively	(49,464)	(49,464)

Total Sorrento Therapeutics, Inc. stockholders' equity	209,472	199,568
Noncontrolling interests	(1,972)	7,042
Total equity	207,500	206,610
Total liabilities and equity	$624,087	$431,613

See accompanying notes

SORRENTO THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
For the Years Ended December 31, 2018, 2017 and 2016
(In thousands, except for per share amounts)

	2018	2017	2016
Revenues:			
Grant	$356	$206	$1,033
Royalties and licenses	480	140,381	4,017
Sales and services	20,357	11,269	3,102
Total revenues	21,193	151,856	8,152
Operating costs and expenses:			
Costs of revenues	7,060	3,945	811
Research and development	76,963	55,532	42,175
Acquired in-process research and development	11,304	26,102	45,000
General and administrative	63,638	38,332	24,219
Intangible amortization	3,009	2,610	845
Loss (gain) on contingent liabilities	9,644	—	(8,121)
Total costs and operating expenses	171,618	126,521	104,929
(Loss) income from operations	(150,425)	25,335	(96,777)
Gain on derivative liabilities	2,830	—	5,520
Gain on marketable securities	—	—	27,193
Loss on foreign currency exchange	(1,243)	(178)	—
(Loss) gain on trading securities	(144)	(665)	356
Interest expense	(57,631)	(4,980)	(1,610)
Interest income	921	241	272
Loss on debt extinguishment	(8,089)	(4,275)	(222)
Loss on receivable	—	(163)	—
(Loss) income before income tax (benefit) loss and (loss) income on equity method investments	(213,781)	15,315	(65,268)
Income tax benefit	(6,274)	(36,038)	(896)
(Loss) income on equity method investments	(5,019)	(40,244)	435
Net (loss) income	(212,526)	11,109	(63,937)
Net (loss) income attributable to noncontrolling interests	(8,986)	1,977	(3,014)
Net (loss) income attributable to Sorrento	$(203,540)	$9,132	$(60,923)
Net (loss) income per share - basic per share attributable to Sorrento	$(1.92)	$0.13	$(1.21)
Net (loss) income per share - diluted per share attributable to Sorrento	$(1.92)	$0.13	$(1.21)
Weighted-average shares used during period - basic per share attributable to Sorrento	106,150	69,742	50,360
Weighted-average shares used during period - diluted per share attributable to Sorrento	106,150	70,381	50,360

See accompanying notes

SORRENTO THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
For the Years Ended December 31, 2018, 2017 and 2016
(In thousands, except for share amounts)

	2018	2017	2016
Net (loss) income	$(212,526)	$11,109	$(63,937)
Other comprehensive income:			
Unrealized loss on marketable securities, net of tax of $0, $0, and $(14,294)	—	—	(73,579)
Foreign currency translation adjustments	(227)	360	(118)
Total other comprehensive (loss) income	(227)	360	(73,697)
Comprehensive (loss) income	(212,753)	11,469	(137,634)
Comprehensive (loss) income attributable to noncontrolling interests	(8,986)	1,977	(3,014)
Comprehensive (loss) income attributable to Sorrento	$(203,767)	$9,492	$(134,620)

See accompanying notes

SORRENTO THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the Years Ended December 31, 2018, 2017 and 2016
(In thousands, except for share amounts)

	Common Stock		Treasury Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Noncontrolling	
	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Deficit	Interest	Total
Balance, December 31, 2015	37,771,459	4	—	—	184,898	73,579	(113,329)	(4,214)	140,938
Issuance of common stock with exercise of options	204,668	—	—	—	524	—	—	—	527
Issuance of common stock for private placement and investments, net	27,598,235	3	—	—	108,298	—	—	—	108,301
Issuance of common stock upon acquisition of Scilex	754,911	1	—	—	5,368	—	—	13,693	19,061
Cancellation of stock issuance	(15,446,417)	(2)	7,568,182	(49,464)	(1,341)	—	—	—	(50,807)
Stock-based compensation	—	—	—	—	4,741	—	—	—	4,741
Change in unrealized gain on marketable securities	—	—	—	—	—	(73,579)	—	—	(73,579)
Foreign currency translation adjustment	—	—	—	—	—	(118)	—	—	(118)
Hercules warrant	—	—	—	—	1,377	—	—	—	1,377
Net loss	—	—	—	—	—	—	(60,923)	(3,014)	(63,937)
Balance, December 31, 2016	50,882,856	6	7,568,182	(49,464)	303,865	(118)	(174,252)	6,465	86,502
Scilex acquisition adjustment	—	—	—	—	(627)	—	—	(1,400)	(2,027)
Issuance of common stock for public placement and investments, net	30,468,700	3	—	—	57,925	—	—	—	57,928
	—	—	—	—	32,062	—	—	—	32,062

Beneficial conversion feature recorded on convertible notes									
Warrants issued in connection with convertible notes	—	—	—	—	12,669	—	—	—	12,669
Issuance of common stock for business combinations	1,552,011	—	—	—	3,055	—	—	—	3,055
Stock-based compensation	—	—	—	—	4,952	—	—	—	4,952
Foreign currency translation adjustment	—	—	—	—	—	360	—	—	360
Net loss	—	—	—	—	—	—	9,132	1,977	11,109
Balance, December 31, 2017	82,903,567	9	7,568,182	(49,464)	413,901	242	(165,120)	7,042	206,610
Adoption impact of ASC 606	—	—	—	—	—	—	910	—	910
Issuance of common stock with exercise of options	57,690	—	—	—	211	—	—	—	211
Issuance of common stock for BDL settlement	309,916	—	—	—	2,340	—	—	—	2,340
Issuance of common stock for Scilex settlement	1,381,346	—	—	—	13,744	—	—	—	13,744
Issuance of common stock for public placement, net	13,793,997	2	—	—	83,608	—	—	—	83,610
Issuance of common stock for Virttu settlement	1,795,011	—	—	—	11,308	—	—	—	11,308
Issuance of common stock related to conversion of notes payable	22,038,565	2	—	—	49,998	—	—	—	50,000
Beneficial conversion	—	—	—	—	12,006	—	—	—	12,006

feature recorded on convertible notes									
Warrants issued in connection with convertible notes	—	—	—	—	9,646	—	—	—	9,646
Warrants issued in connection with Term Loan Agreement	—	—	—	—	21,746	—	—	—	21,746
Loss on debt extinguishment	—	—	—	—	1,916	—	—	—	1,916
Stock-based compensation	—	—	—	—	6,234	—	—	(28)	6,206
Foreign currency translation adjustment	—	—	—	—	—	(227)	—	—	(227)
Net loss	—	—	—	—	—	—	(203,540)	(8,986)	(212,526)
Balance, December 31, 2018	122,280,092	$ 13	7,568,182	$(49,464)	$626,658	$ 15	$(367,750)	$ (1,972)	$207,500

See accompanying notes

SORRENTO THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
For the Years Ended December 31, 2018, 2017 and 2016
(In thousands, except for share amounts)

	2018	2017	2016
Operating activities			
Net income (loss)	$(212,526)	$11,109	$(63,937)
Adjustments to reconcile net loss to net cash provided by and (used for) operating activities:			
Depreciation and amortization	9,054	7,079	2,885
Non-cash interest expense	52,841	1,326	164
Amortization of debt issuance costs	550	477	—
Loss (gain) on sale of marketable securities	—	—	(27,193)
Loss on trading securities	144	665	—
Stock-based compensation	6,206	4,952	4,741
Acquired in-process research and development	9,895	—	—
Loss on disposal for property and equipment	440	59	—
Loss on receivable	—	163	—
Loss on debt extinguishment	8,089	4,275	—
(Gain) on derivative liability	(2,830)	—	(5,520)
Loss (income) on equity method investments	5,019	40,244	(435)
Non-cash income on cost method investments	—	(116,249)	—
Loss (Gain) on contingent liabilities	9,644	—	(8,121)
Loss on IPR&D impairment	1,826	—	—
Deferred tax provision	(6,119)	(35,679)	982
Changes in operating assets and liabilities; net of dispositions:			
Grants and other receivables	(1,623)	(515)	(472)
Accrued payroll	5,751	920	—
Prepaid expenses and other	(1,674)	(1,902)	40
Deposits and other assets	(1,130)	233	(448)
Accounts payable	3,578	1,592	3,714
Deferred revenue	(3,263)	(20,891)	23,534
Deferred rent and other	251	639	(2,535)
Acquisition consideration payable	(2,020)	—	—
Accrued expenses and other liabilities	6,130	2,323	1,673
Net cash used for operating activities	(111,767)	(99,180)	(70,928)
Investing activities			
Purchases of property and equipment	(11,195)	(10,972)	(6,860)
Purchase of assets related to Sofusa	(10,000)	—	—
Investment in SiniWest	—	—	(1,000)
Investment in Celularity	—	(5,000)	(5,000)
Purchase of business, net of cash acquired	—	(557)	(3,842)
Purchase of MedoveX Investment	—	—	(750)
Net cash used for investing activities	(21,195)	(16,529)	(17,452)
Financing activities			
Net borrowings under loan and security agreement	—	49,916	—
Payments on short term bridge loan	(20,000)	—	—
Bridge loan for Scilex settlement	20,000	—	—
Bridge loan for Scilex settlement repayment	(20,000)	—	—

Proceeds from loan agreement	1,586	—	—

Short-term bridge loan, net of issuance costs	19,675	—	—
Scilex consideration for regulatory milestones	(22,466)	—	—
Proceeds from issuance of common stock, net	83,608	57,928	107,986
Proceeds from issuance of Scilex notes	140,000	—	—
Scilex notes issuance of Scilex notes	(5,725)	—	—
Proceeds from issuance of convertible notes	37,849	—	—
Cash payments for treasury shares	—	—	(15,639)
Proceeds from loan and security agreement, net of fees	—	—	48,320
Payments of debt on retired note	—	(53,157)	(9,451)
Net payments of deferred compensation	—	(1,012)	—
Proceeds from Oaktree term loan	100,000	—	—
Oaktree issuance cost	(8,740)	—	—
Proceeds from exercise of stock options	211	—	524
Net cash provided by financing activities	325,998	53,675	131,740
Net change in cash, cash equivalents and restricted cash	193,036	(62,034)	43,360
Net effect of exchange rate changes on cash	(135)	65	—
Cash, cash equivalents and restricted cash at beginning of period	20,429	82,398	39,038
Cash, cash equivalents and restricted cash at end of period	$213,330	$20,429	$82,398
Supplemental disclosures:			
Cash paid during the period for:			
Income taxes	6	34	2
Interest	1,620	3,499	1,342
Supplemental disclosures of non-cash investing and financing activities:			
Virttu acquisition non-cash consideration	11,308	15,465	—
Scilex acquisition non-cash consideration	—	—	(45,368)
Scilex non-cash consideration for regulatory milestone	13,744	1,380	—
SiniWest non-cash consideration	—	—	(2,832)
Roger Williams Medical Center non-cash consideration	—	—	(3,398)
Investment in ImmuneOncia	—	—	(9,608)
BDL stock issuance	2,340	—	—
Conversion of 2017 convertible notes	50,000	—	—
Loss on debt extinguishment	1,916	—	—
Property and equipment costs incurred but not paid	328	37	—
Reconciliation of cash, cash equivalents and restricted cash within the Company's consolidated balance sheets:			
Cash and cash equivalents	158,738	20,429	82,398
Restricted cash	54,592	—	—
Cash, cash equivalents, and restricted cash	$213,330	$20,429	$82,398

SORRENTO THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Operations and Business Activities
Nature of Operations and Basis of Presentation

Sorrento Therapeutics, Inc. (Nasdaq: SRNE), together with its subsidiaries (collectively, the "Company") is a clinical stage and commercial biopharma company focused on delivering innovative and clinically meaningful therapies to patients and their families, globally, to address unmet medical needs. The Company primarily focuses on therapeutics areas in Immune-Oncology and Non-Opioid Pain Management. The Company also has programs assessing the use of its technologies and products in auto-immune, inflammatory and neurodegenerative diseases.
At its core, the Company is an antibody-centric company and leverages its proprietary G-MAB™ library and targeted delivery modalities to generate the next generation of cancer therapeutics. the Company's fully human antibodies include PD-1, PD-L1, CD38, CD123, CD47, c-MET, VEGFR2, CCR2 and CD137 among others.
The Company's 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 chimeric antigen receptor T-cell therapy ("CAR-T"), dimeric antigen receptor T-cell therapy ("DAR-T"), antibody drug conjugates ("ADCs") as well as bispecific antibody approaches. Additionally, the Company acquired Sofusa®, a revolutionary drug delivery system, in July 2018, which delivers biologics directly into the lymphatic system to potentially achieve improved efficacy and fewer adverse effects than standard parenteral immunotherapy.
With each of the Company's clinical and pre-clinical programs, it aims to tailor its therapies to treat specific stages in the evolution of cancer, from elimination, to equilibrium and escape. In addition, the Company's objective is to focus on tumors that are resistant to current treatments and where it can design focused trials based on a genetic signature or biomarker to ensure patients have the best chance of a durable and significant response. The Company has several immuno-oncology programs that are in or near to entering the clinic. These include cellular therapies, an oncolytic virus and a palliative care program targeted to treat intractable cancer pain.
Through December 31, 2018, the Company had devoted substantially all of its efforts to product development, raising capital and building infrastructure, and had not realized revenues from its planned principal operations.
The accompanying consolidated financial statements include the accounts of the Company's subsidiaries. For consolidated entities where the Company owns or is exposed to less than 100% of the economics, the Company records net income (loss) attributable to noncontrolling interests in its consolidated statements of operations equal to the percentage of the economic or ownership interest retained in such entities by the respective noncontrolling parties. All intercompany balances and transactions have been eliminated in consolidation.

2. Liquidity and Going Concern
The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has recurring losses from operations, recurring negative cash flows from operations and substantial cumulative net losses to date and anticipates that it will continue to do so for the foreseeable future as it continues to identify and invest in advancing product candidates, as well as expanding corporate infrastructure.
The Company has plans in place to obtain sufficient additional fundraising to fulfill its operating and capital requirements for the next 12 months. The Company's plans include continuing to fund its operating losses and capital funding needs through public or private equity or debt financings, strategic collaborations, licensing arrangements, asset sales, government grants or other arrangements. Although management believes such plans, if executed, should provide the Company sufficient financing to meet its needs, successful completion of such plans is dependent on factors outside of the Company's control. As such, management cannot conclude that such plans will be effectively implemented within one year after the date that the financial statements are issued. As a result, management has concluded that the aforementioned conditions, among others, raise substantial doubt about the Company's ability to

continue as a going concern within one year after the date the financial statements are issued.

As of December 31, 2018, the Company had $361.8 million of long term debt outstanding under the 2018 Securities Purchase Agreement in Private Placement and Amendment to Warrants, 2018 Purchase Agreements and Indenture for Scilex and 2018 Oaktree Term Loan Agreement (collectively, the "Debt Arrangements") (See Note 12).

Each of the Debt Arrangements provide that, upon the occurrence of an event of default, the Purchasers thereof may, by written notice to the Company, declare all of the outstanding principal and interest under such Note immediately due and payable. For purposes of the Debt Arrangements, an event of default includes, among other things, one or more events that have, or could reasonably be expected to have, a material adverse effect on (i) the business, assets, financial condition or operations of the Company, (ii) the Company's ability to comply with its obligations under the agreements, or (iii) the legality, validity or enforceability of the agreements. The Company believes that it is not probable that the material adverse event clause under the Debt Arrangements will be exercised.

If the Company is unable to raise additional capital in sufficient amounts or on terms acceptable, the Company may have to significantly delay, scale back or discontinue the development or commercialization of one or more of its product candidates. The Company may also seek collaborators for one or more of its 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. The consolidated financial statements do not reflect any adjustments that might be necessary if the Company is unable to continue as a going concern.

Universal Shelf Registration

In November 2014, the Company filed a universal shelf registration statement on Form S-3 (the "2014 Shelf Registration Statement") with the SEC, which was declared effective by the SEC in December 2014. This 2014 Shelf Registration Statement provided the Company with the ability to offer up to $250 million of securities, including equity and other securities as described in the registration statement. Included in the 2014 shelf registration is a sales agreement prospectus covering the offering, issuance and sale by the Company of up to a maximum aggregate offering price of $50.0 million of the Company's common stock that may be issued and sold under a sales agreement with MLV & Co. LLC (the "2014 ATM Facility"). During the twelve months ended December 31, 2017 and 2016, the Company sold approximately $13.9 million and $3.6 million in shares of common stock under the 2014 ATM Facility, respectively.

In April 2017, the Company completed a public offering of $47.5 million of shares of common stock pursuant to the 2014 Shelf Registration Statement for net proceeds of approximately $43.1 million.

In November 2017, the Company filed a universal shelf registration statement on Form S-3 (the "2017 Shelf Registration Statement") with the SEC, which was declared effective by the SEC in December 2017. The 2014 Shelf Registration Statement expired on December 6, 2017 when the 2017 Shelf Registration was declared effective. This 2017 Shelf Registration Statement provides the Company with the ability to offer up to $350 million of securities, including equity and other securities as described in the registration statement. Included in the 2017 Shelf Registration Statement is a sales agreement prospectus covering the offering, issuance and sale by the Company of up to a maximum aggregate offering price of $100.0 million of the Company's common stock that may be issued and sold under a sales agreement with B. Riley FBR, Inc. (the "ATM Facility"). During the twelve months ended December 31, 2018, the Company sold approximately $83.6 million in shares of common stock under the ATM Facility. The Company can offer up to $15.5 million of additional shares of common stock under the ATM Facility, subject to certain limitations.

Pursuant to the 2017 Shelf Registration Statement, the Company may offer such securities from time to time and through one or more methods of distribution, subject to market conditions and the Company's capital needs. Specific terms and prices will be determined at the time of each offering under a separate prospectus supplement, which will be filed with the SEC at the time of any offering. However, the Company cannot be sure that such additional funds will be available on reasonable terms, or at all.

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

3. Significant Accounting Policies

Use of Estimates

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The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Management believes that these estimates are reasonable; however, actual results may differ from these estimates.

Cash and Cash Equivalents

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

Restricted Cash

Restricted cash in the Company's consolidated balance sheet as of December 31, 2018, included approximately $45.0 million of restricted cash related to the Scilex Notes in the form of both the Reserve Account and the Collateral Account (See Note 12). Restricted cash in the Company's consolidated balance sheet as of December 31, 2018 also included approximately $9.6 million of restricted cash related to the Loan Agreement in the form of a Reserve Account (See Note 12).

Fair Value of Financial Instruments

The Company follows accounting guidance on fair value measurements for financial instruments measured on a recurring basis, as well as for certain assets and liabilities that are initially recorded at their estimated fair values. Fair value is defined as the exit price, or the amount that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company uses the following three-level hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs to value its financial instruments:

- Level 1: Observable inputs such as unadjusted quoted prices in active markets for identical instruments.

- Level 2: Quoted prices for similar instruments that are directly or indirectly observable in the marketplace.

- Level 3: Significant unobservable inputs which are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

Financial instruments measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires it to make judgments and consider factors specific to the asset or liability. The use of different assumptions and/or estimation methodologies may have a material effect on estimated fair values. Accordingly, the fair value estimates disclosed or initial amounts recorded may not be indicative of the amount that the Company or holders of the instruments could realize in a current market exchange.

The carrying amounts of cash equivalents and marketable securities approximate their fair value based upon quoted market prices. Certain of the Company's financial instruments are not measured at fair value on a recurring basis, but are recorded at amounts that approximate their fair value due to their liquid or short-term nature, such as cash, accounts receivable and payable, and other financial instruments in current assets or current liabilities.

Marketable Securities

Marketable securities are designated either as trading or available-for-sale securities and are accounted for at fair value. Marketable securities are classified as short-term or long-term based on the nature of the securities and their availability to meet current operating requirements. Marketable securities that are readily available for use in current operations and are classified as short-term available-for-sale securities are reported as a component of current assets in the accompanying consolidated balance sheets. Marketable securities that are not trading securities and are not considered available for use in current operations are classified as long-term available-for-sale securities and are

reported as a component of long-term assets in the accompanying consolidated balance sheets.

Securities that are classified as trading are carried at fair value, with changes to fair value reported as a component of income. Securities that are classified as available-for-sale are carried at fair value, with temporary unrealized gains and losses reported as a component of stockholders' equity until their disposition. The cost of securities sold is based on the specific identification method.

All of the Company’s marketable securities are subject to a periodic impairment review. The Company recognizes an impairment charge when a decline in the fair value of its investments below the cost basis is judged to be other-than-temporary. For the year ended December 31, 2018, no other-than-temporary impairment charges were recorded for marketable securities.

Grants and Accounts Receivable

Grants receivable at December 31, 2018 and 2017 represent amounts due under several federal contracts with the National Institute of Allergy and Infectious Diseases (“NIAID”), a division of the National Institutes of Health (“NIH”) (collectively, the “NIH Grants”). The Company considers the grants receivable to be fully collectible; accordingly, no allowance for doubtful amounts has been established. If amounts become uncollectible, they are charged to operations.

Accounts receivable at December 31, 2018, 2017 and 2016 consists of trade receivables from sales and services provided to certain customers, which are generally unsecured and due within 30 days. Estimated credit losses related to trade accounts receivable are recorded as general and administrative expenses and as an allowance for doubtful accounts within grants and accounts receivable, net. The Company reviews reserves and makes adjustments based on historical experience and known collectability issues and disputes. When internal collection efforts on accounts have been exhausted, the accounts are written off by reducing the allowance for doubtful accounts. As of December 31, 2018, 2017 and 2016, the allowance for doubtful accounts was $20 thousand, $20 thousand and $26 thousand, respectively.

Inventory

The Company determines inventory cost on a first-in, first-out basis. The Company reduces the carrying value of inventories to a lower of cost or market basis for those items that are potentially excess, obsolete or slow-moving. The Company reserves for excess and obsolete inventory based upon historical experience, sales trends, and specific categories of inventory and age of on-hand inventory. As of December 31, 2018, the Company's inventory is primarily comprised of finished goods and is recorded as a component of Prepaid expenses and other, net on the consolidated balance sheets.

Property and Equipment

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

Acquisitions and Intangibles

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

Goodwill and Other Long-Lived Assets

Goodwill, which has an indefinite useful life, represents the excess of cost over fair value of net assets acquired. Goodwill is reviewed for impairment at least annually during the fourth quarter, or more frequently if events occur indicating the potential for impairment. During its goodwill impairment review, the Company may assess qualitative factors to determine whether it is more likely than not that the fair value of its reporting unit is less than its carrying amount, including goodwill. The qualitative factors include, but are not limited to, macroeconomic conditions, industry and market considerations, and the overall financial performance of the Company. If, after assessing the totality of these qualitative factors, the Company determines that it is not more likely than not that the fair value of its reporting unit is less than its carrying amount, then no additional assessment is deemed necessary. Otherwise, the

Company proceeds to perform the two-step test for goodwill impairment. The first step involves comparing the estimated fair value of the reporting unit with its carrying value, including

goodwill. If the carrying amount of the reporting unit exceeds its fair value, the Company performs the second step of the goodwill impairment test to determine the amount of loss, which involves comparing the implied fair value of the goodwill to the carrying value of the goodwill. The Company may also elect to bypass the qualitative assessment in a period and elect to proceed to perform the first step of the goodwill impairment test. The Company performed its annual assessment for goodwill impairment in the fourth quarter of 2018, noting no impairment and that the fair value of the goodwill exceeded the carrying value by a significant margin. There have not been any triggering events indicating the potential for impairment through December 31, 2018.

In determining the fair value utilized in the goodwill impairment assessment, the Company considers qualitative factors such as changes in strategy, cash flows and the regulatory environment as well as the market capitalization of the Company's publicly traded common stock. The Company's share price is highly volatile and although there was significant excess of fair value over book value at the annual impairment assessment date as well as December 31, 2018, there have been subsequent declines in the market share price and there could be risk of impairment in the future.

It is not possible at this time to determine if an impairment charge would result from these factors, or, if it does, whether such charge would be material. The Company will continue to monitor the recoverability of its goodwill.

The Company evaluates its long-lived and intangible assets with definite lives, such as property and equipment, acquired technology, customer relationships, patent and license rights, for impairment by considering competition by products prescribed for the same indication, the likelihood and estimated future entry of non-generic and generic competition with the same or similar indication and other related factors. The factors that drive the estimate of useful life are often uncertain and are reviewed on a periodic basis or when events occur that warrant review. Recoverability is measured by comparison of the assets' book value to future net undiscounted cash flows that the assets are expected to generate. There have not been any impairment losses of long-lived assets through December 31, 2018.

Acquisition Consideration Payable - Gain or Loss on Contingent Liabilities

Acquisition consideration payable relates to the Company's acquisition of businesses and various other assets and is recorded on the Company's consolidated balance sheets at fair value and is re-measured at each balance sheet date until such contingent liabilities have been settled, with changes in fair value recorded as gain or loss on contingent liabilities. The Company estimates the fair value of contingent consideration based on level 3 inputs primarily driven by the probability of achieving certain financing or operating related milestones.

The Company estimates the fair value of contingent consideration based on level 3 inputs, which, for acquisition consideration payable related to asset acquisitions, are primarily driven by the probability of achieving certain financing or operating related milestones.

Debt, Including Debt With Detachable Warrants

Debt with detachable warrants are evaluated for the classification of warrants as either equity instruments, derivative liabilities, or liabilities depending on the specific terms of the warrant agreement. In circumstances in which debt is issued with equity-classified warrants, the proceeds from the issuance of convertible debt are first allocated to the debt and the warrants at their relative estimated fair values. The portion of the proceeds so allocated to the warrants are accounted for as paid-in capital and a debt discount. The remaining proceeds, as further reduced by discounts created by the bifurcation of embedded derivatives and beneficial conversion features, are allocated to the debt. The Company accounts for debt as liabilities measured at amortized cost and amortizes the resulting debt discount from the allocation of proceeds, to interest expense using the effective interest method over the expected term of the debt instrument. The Company considers whether there are any embedded features in debt instruments that require bifurcation and separate accounting as derivative financial instruments pursuant to ASC 815, Derivatives and Hedging.

If the amount allocated to the convertible debt results in an effective per share conversion price less than the fair value of the Company's common stock on the commitment date, the intrinsic value of this beneficial conversion feature is recorded as a discount to the convertible debt with a corresponding increase to additional paid in capital. The beneficial conversion feature discount is equal to the difference between the effective conversion price and the fair value of the Company's common stock at the commitment date, unless limited by the remaining proceeds allocated to the debt.

The Company may enter financing arrangements, the terms of which involve significant assumptions and estimates, including future net product sales, in determining interest expense, amortization period of the debt discount, as well as the classification between current and long-term portions. In estimating future net product sales, the Company assesses prevailing

market conditions using various external market data against the Company's anticipated sales and planned commercial activities. See Note 12 for discussion of the Scilex Notes, which include repayments based on a percentage of net sales of ZTlido® (lidocaine topical system 1.8%). Consequently, the Company imputes interest on the carrying value of the debt and record interest expense using an imputed effective interest rate. The Company reassesses the expected payments each reporting period and account for any changes through an adjustment to the effective interest rate on a prospective basis, with a corresponding impact to the classification of the Company's current and long-term portions.

Investments in Other Entities

The Company holds a portfolio of investments in equity securities that are accounted for under either the equity method or cost method. Investments in entities over which the Company has significant influence but not a controlling interest are accounted for using the equity method, with the Company's share of earnings or losses reported in loss on equity method investments.

All investments are reviewed on a regular basis for possible impairment. If an investment's fair value is determined to be less than its net carrying value and the decline is determined to be other-than-temporary, the investment is written down to its fair value. Such an evaluation is judgmental and dependent on specific facts and circumstances. Factors considered in determining whether an other-than-temporary decline in value has occurred include: the magnitude of the impairment and length of time that the estimated market value was below the cost basis; financial condition and business prospects of the investee; the Company's intent and ability to retain the investment for a sufficient period of time to allow for recovery in market value of the investment; issues that raise concerns about the investee's ability to continue as a going concern; any other information that the Company may be aware of related to the investment.

Research and Development Costs and Collaborations

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

Acquired In-Process Research and Development Expense

The Company has acquired and may continue to acquire the rights to develop and commercialize new drug candidates. The up-front payments to acquire a new drug compound or drug delivery devices, as well as future milestone payments associated with asset acquisitions that do not meet the definition of derivative and are deemed probable to achieve the milestones, are immediately expensed as acquired in-process research and development provided that the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, have no alternative future use. The acquired in-process research and development related to the business combination of Virttu Biologics Limited ("Virttu"), for which certain products are under development and expected to be commercialized in the future, was capitalized and recorded within "Intangibles, net" on the accompanying consolidated balance sheet. The Company commenced amortization of acquired in-process research and development related to the business combination of Scilex upon commercialization of ZTlido® (lidocaine topical system 1.8%) in October 2018. Capitalized in-process research and development will be reviewed annually for impairment or more frequently as changes in circumstance or the occurrence of events suggest that the remaining value may not be recoverable. (See Note 4 for further discussion of acquired in-process research and development expense related to the Sofusa acquisition).

Income Taxes

The provisions of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 740 "Income Taxes," addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under ASC Topic 740-10, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by taxing authorities, based on the technical merits of the position. The Company has determined that it has uncertain tax positions.

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

The Company has deferred tax assets, which are subject to periodic recoverability assessments. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount that more likely than not will be realized. As of December 31, 2018, the Company maintained a full valuation allowance against its deferred tax assets, with the

exception of an amount equal to its deferred tax liabilities.

Revenue Recognition

The Company’s revenues are generated from various NIH grant awards, license fees, product sales, the sale of customized reagents and other materials, and the provision of contract manufacturing and other services. The Company does not have significant costs associated with costs to obtain contracts with its customers. Substantially all of the Company’s revenues and accounts receivable result from contracts with customers.

Grant Revenues

The revenue from the NIH grant awards is based upon subcontractor and internal costs incurred that are specifically covered by the grant, and where applicable, a facilities and administrative rate that provides funding for overhead expenses. These revenues are recognized when expenses have been incurred by subcontractors or when the Company incurs internal expenses that are related to the grant. Grant revenues were not material for the twelve months ended December 31, 2018.

Royalty and License Revenues

License fees for the licensing of product rights are recorded as deferred revenue upon receipt of cash and recognized as revenue on a straight-line basis over the license period, with the exception of license agreements with no remaining performance obligations or undelivered obligations. The Company applies judgment in determining the timing of revenue recognition related to contracts that include multiple performance obligations. The total transaction price of the contract is allocated to each performance obligation in an amount based on the estimated relative standalone selling prices of the promised goods or services underlying each performance obligation. For goods or services for which observable standalone selling prices are not available, the Company develops an estimated standalone selling price of each performance obligation.

As of December 31, 2018, the future performance obligations for royalty and license revenues relate to the ImmuneOncia Therapeutics, LLC (“ImmuneOncia”) and NantCell, Inc. (“NantCell”) license agreements.

The total consideration for the ImmuneOncia license performance obligation, effective September 1, 2016, represented $9.6 million. The estimated revenue expected to be recognized for future performance obligations, as of December 31, 2018 was approximately $8.5 million. The Company expects to recognize license revenue of approximately $0.5 million of the remaining performance obligation annually through the remaining term. The Company applied judgment in estimating the 20-year contract term, analogous to the expected life of the patent, over which revenue is recognized over time given the ongoing performance obligation related to the Company's participation on a steering committee for the technologies under the agreement.

As of December 31, 2018 and December 31, 2017, the NantCell license agreement, effective April 21, 2015, represented $110 million of contract liabilities reflected in long-term deferred revenue. See Note 11 for additional information regarding the remaining performance obligation for the agreement.

Sales and Services Revenues

Sales and services revenues are comprised of Scilex product sales of ZTlido® (lidocaine topical system 1.8%), contract manufacturing associated with sales of customized reagents at Concortis Biosystems Corp. ("Concortis"), materials and supply agreements, contract manufacturing services at BioServ Corporation, and the Company’s joint development agreement with Celularity Inc.

The Company does not disclose the value of unsatisfied performance obligations for (i) contracts with an original expected length of one year or less and (ii) contracts for which it recognizes revenue at the amount to which it has the right to invoice for services performed. The Company applied the practical expedient in ASC Topic 606-10-50-14 to the revenue contracts for Concortis sales and services and materials and supply agreements due to the short-term length of such contracts.

The following table shows sales and service revenues disaggregated by product and services type for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	Years Ended December 31,		
	2018	2017	2016
Scilex product sales	2,606	—	—
Concortis sales and services	5,159	4,049	2,223
Materials and supply agreements	3,267	553	879
Bioserv sales and services	5,992	5,000	—
Joint development agreement	3,333	1,667	—
	$20,357	$11,269	$3,102

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

Scilex Pharmaceuticals Inc. (“Scilex”)

Revenues from Scilex product sales include sales of its ZTlido® (lidocaine topical system 1.8%). Scilex’s performance obligation with respect to Scilex product sales is satisfied at a point in time, which transfers control upon delivery of product to the customer. The Company considers control to have transferred upon delivery because the customer has legal title to the asset, physical possession of the asset has been transferred to the customer, the customer has significant risks and rewards of ownership of the asset, and the Company has a present right to payment at that time. The Company identified a single performance obligation. Invoicing typically occurs upon shipment and the length of time between invoicing and when payment is due is not significant. The aggregate dollar value of unfulfilled orders as of December 31, 2018 was not material.

For Scilex product sales, the Company records gross-to-net sales adjustments for government and managed care rebates, chargebacks, wholesaler fees, sales returns and prompt payment discounts. Such variable consideration are estimated in the period of the sale and are estimated using a most likely amount approach based primarily upon provisions included in the Company’s customer contract, customary industry practices and current government regulations and was not significant for the year ended December 31, 2018. There were no significant changes during the year ended December 31, 2018.

Concortis Biosystems Corporation (“Concortis”)

Contract manufacturing associated with sales of customized reagents for Concortis operations relate to providing synthetic expertise to customers’ synthesis by delivering proprietary cytotoxins, linkers and linker-toxins and ADC service using industry standard toxin and antibodies provided by customers which are recognized at a point in time upon the transfer of control, which is generally upon shipment given the short contract terms which are generally three months or less.

Materials and Supply Agreements

Revenues from the sale of materials associated with the Company's research and development arrangements are recognized at a point in time upon the transfer of control, which is generally, upon shipment. As of December 31, 2018, outstanding performance obligations related to materials and supply agreements was $0.9 million, of which $0.6 million is expected to be fulfilled during the next twelve months.

Bioserv Corporation (“Bioserv”)

Revenues from contract manufacturing services associated with the Company's Bioserv operations related to finish and fill activities for drug products and reagents are recognized ratably over the contract term based on a time-based measure, which reflects the transfer of services to the customer, because the manufactured products are highly customized and do not have an alternative use to the Company. As of December 31, 2018 and 2017, the Company had approximately $0.4 million and $0.5 million of unbilled accounts receivable for which revenue has been recognized but not billed at the reporting date, respectively. As of December 31, 2018 and 2017, the Company had approximately $0.2 million and $0.4 million of upfront payments related to its contract manufacturing services included in deferred revenue, respectively.

As of December 31, 2018 and 2017, the estimated revenue expected to be recognized for future performance obligations associated with contract manufacturing services was approximately $1.6 million and $3.0 million, respectively.

The following table includes Bioserv sales and services revenue expected to be recognized in the future related to performance obligations that are undelivered or partially delivered at the end of the reporting period and do not include

contracts with original durations of one year or less (in thousands):

	2019	2020 and thereafter
Contract manufacturing services	$1,118	$529

Joint Development Agreement

On September 26, 2017, the Company entered into a joint development agreement with Celularity Inc. whereby the Company agreed to provide research services to Celularity Inc. through June 30, 2018 in exchange for an upfront payment of $5.0 million. The revenue related to the joint development agreement of $5.0 million was recognized over the length of the service agreement as services were performed. The Company recorded sales and services revenues under the joint development agreement of $3.3 million and $1.7 million for the years ended December 31, 2018 and 2017, respectively.

Stock-Based Compensation

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

The Company accounts for equity instruments, including restricted stock or stock options, issued to non-employees in accordance with authoritative guidance for equity based payments to non-employees. Stock options issued to non-employees are accounted for at their estimated fair value determined using the Black-Scholes option-pricing model. The fair value of options and restricted stock granted to non-employees is re-measured over the vesting period, and the resulting changes in fair value are recognized as expense in the period of the change in proportion to the services rendered to date.

Comprehensive (Loss) Income

Comprehensive (loss) income is primarily comprised of net income (loss) and adjustments for the change in unrealized gains and losses on the Company’s investments in available-for-sale marketable securities, net of taxes. The Company displays comprehensive (loss) income and its components in its consolidated statements of comprehensive (loss) income.

Net Income (Loss) per Share

Basic net income (loss) per share is computed by dividing net loss for the period by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share reflects the additional dilution from potential issuances of common stock, such as stock issuable pursuant to the exercise of stock options or the exercise of outstanding warrants. The treasury stock method and if-converted method are used to calculate the potential dilutive effect of these common stock equivalents. Potentially dilutive shares are excluded from the computation of diluted net loss per share when their effect is anti-dilutive. In periods where a net loss is presented, all potentially dilutive securities are anti-dilutive and are excluded from the computation of diluted net loss per share.

During 2018, 2017 and 2016, the Company had securities outstanding which could potentially dilute basic earnings per share in the future, but were excluded from the computation of diluted net loss per share, as their effect would have been anti-dilutive.

These outstanding securities consist of the following:

	Years Ended December 31,		
	2018	2017	2016
Outstanding options	10,523,075	6,321,400	4,332,876
Outstanding warrants	25,635,117	4,708,860	7,740,340

Segment Information

The Company is engaged primarily in the discovery and development of innovative therapies focused on oncology and the treatment of chronic cancer pain as well as immunology and infectious diseases based on its platform technologies. Accordingly, the Company has determined that it operates in one operating segment.

Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. ASU No. 2014-09 was originally effective for annual reporting periods beginning after December 15, 2016, and interim periods thereafter. In August 2015, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which delayed the effective date of the new standard for annual reporting periods beginning after December 15, 2017, and interim periods thereafter. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. The standard allows for either a full retrospective or modified retrospective method of adoption. The Company adopted this standard on its effective date, January 1, 2018 under the modified retrospective method of adoption. Under this method, entities recognize the cumulative impact of applying the new standard at the date of adoption without restatement of prior periods presented. The cumulative effect of applying the new standard to contracts that were not completed as of January 1, 2018 did not have a material impact on the Company's consolidated financial position, results of operations or cash flows. Had ASC 605 continued to be applied for the year ended December 31, 2018, the effect of applying ASC 605 would not have had a material impact on the Company's consolidated financial position, results of operations or cash flows.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments-Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. The ASU amends the guidance in GAAP on the classification and measurement of financial instruments. Changes to the current guidance primarily affect the accounting for equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. ASU No. 2016-01 was effective for fiscal years and interim periods beginning after December 15, 2017, and upon adoption, an entity should apply the amendments by means of a cumulative-effect adjustment to the balance sheet at the beginning of the first reporting period in which the guidance is effective. Early adoption is not permitted except for the provision to record fair value changes for financial liabilities under the fair value option resulting from instrument-specific credit risk in other comprehensive income. The adoption of this standard did not have a material impact on the Company's consolidated financial position, results of operations or cash flows.

In February 2016, the FASB issued ASU No. 2016-02, Leases. ASU No. 2016-02 is aimed at making leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. ASU No. 2016-2 is effective for financial statements issued for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. In July 2018, the FASB issued ASU No. 2018-11, which allows for an alternative method to adopt the lease standard by recognizing a cumulative-effect adjustment to the opening balance sheet of retained earnings in the period of adoption, with no adjustment to prior comparative periods. ASU No. 2016-02 and all subsequent amendments (collectively, "ASC 842") were effective for public entities for annual reporting periods beginning after December 15, 2018, including interim periods therein. The Company will adopt ASC 842 during the first quarter of 2019 and has elected to apply the cumulative-effect adjustment to the opening balance sheet and optional transition method to not present comparable prior periods as allowed under ASU No. 2018-11. The Company also expects to make the following transitional practical expedients elections: (1) elect the short term lease exception, (2) not elect hindsight and (3) elect to not separate its non-lease components for its real estate, vehicle and equipment leases. While substantially complete, the Company is still in the process of finalizing its evaluation of the effect of ASC 842 on the Company's financial statements, disclosures, and internal controls and has determined that ASC 842 will have a material impact on its consolidated financial position. The Company is finalizing its determination of the incremental borrowing rate to be applied in the calculation of the operating right-of-use assets and operating lease liabilities. The Company will continue to report financial information for fiscal years ending

before December 31, 2018 under the current lease accounting standard.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments to improve financial reporting by requiring timelier recording of credit losses on loans and other financial instruments held by financial institutions and other organizations. The ASU requires the measurement of all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecasts. The ASU also requires enhanced disclosures to help investors and other financial statement users better understand significant estimates and judgments used in estimating credit losses, as well as the credit quality and underwriting standards of an organization’s portfolio. The ASU is effective for fiscal years beginning after

December 15, 2019, including interim periods within those fiscal years. Early application will be permitted for all organizations for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company is currently evaluating the impact that the adoption of ASU No. 2016-13 will have on its consolidated financial position, results of operations and cash flows.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments, to improve financial reporting in regards to how certain transactions are classified in the statement of cash flows. The ASU requires that (1) debt extinguishment costs be classified as cash outflows for financing activities and provides additional classification guidance for the statement of cash flows, (2) the classification of cash receipts and payments that have aspects of more than one class of cash flows to be determined by applying specific guidance under generally accepted accounting principles, and (3) each separately identifiable source or use within the cash receipts and payments be classified on the basis of their nature in financing, investing or operating activities. The ASU was effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The adoption of this standard did not have a material impact on the Company's consolidated financial position, results of operations or cash flows.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash (a consensus of the FASB Emerging Issues Task Force). The ASU requires the statement of cash flows to explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents are to be included with cash and cash equivalents when reconciling the beginning of period and end of period amounts shown on the statement of cash flows. The ASU was effective for the Company for annual reporting periods beginning after December 15, 2017 and was required to be adopted using a retrospective approach, if applicable, with early adoption permitted. The Company adopted the new standard on January 1, 2018. The adoption of this ASU impacted the presentation of cash flows with the inclusion of restricted cash for the year ended December 31, 2018.

In January 2017, the FASB issued ASU No. 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business, to clarify the definition of a business to add guidance for evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. Specifically, this ASU provides a screen to assist entities in determining when a set should not be considered a business, which screen provides that if substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or group of similar assets, the set is not a business. The ASU was effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The Company applied this standard in the evaluation of the Sofusa acquisition. (See Note 4).

In January 2017, the FASB issued ASU No. 2017-04, Simplifying the Test for Goodwill Impairment (Topic 350). This standard eliminates Step 2 from the goodwill impairment test, instead requiring an entity to recognize a goodwill impairment charge for the amount by which the goodwill carrying amount exceeds the reporting unit's fair value. This guidance is effective for interim and annual goodwill impairment tests in fiscal years beginning after December 15, 2019 with early adoption permitted. This guidance must be applied on a prospective basis. The Company is currently evaluating the impact that the adoption of ASU No. 2017-04 will have on the Company's consolidated financial position, results of operations or cash flows.

In May 2017, the FASB issued ASU No. 2017-09, Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting, to provide clarity and reduce both the diversity in practice and cost of complexity when applying the guidance. Specifically, the ASU provides additional modification conditions in determining whether or not modification accounting should be applied. The ASU was effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The adoption of this standard did not have a material impact on the Company's consolidated financial position, results of operations or cash flows.

In February 2018, the FASB issued ASU No. 2018-02, Income Statement - Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income, to allow a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Jobs Act and improves the usefulness of information reported to financial statement users. The ASU is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal

years. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial position, results of operations or cash flows.

In June 2018, the FASB issued ASU No. 2018-07, Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting, to include share-based payment transactions for acquiring goods and services from nonemployees. The ASU is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company is currently evaluating the impact that the adoption of ASU No. 2018-07 will have on the Company's consolidated financial position, results of operations or cash flows.

In August 2018, the FASB issued ASU No. 2018-13, Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement, to improve the effectiveness of the disclosure requirements for fair value measurements. The ASU is effective for fiscal years and interim periods beginning after December 15, 2019. Amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements and the narrative description of measurement uncertainty will be applied prospectively as of the beginning of the fiscal year of adoption with all other amendments being applied retrospectively to all periods presented upon their effective date. Early adoption is permitted. The Company is evaluating the impact the standard will have on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-15, Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract. The amendments in this update align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). The amendments in this update are effective for interim and annual periods for the Company beginning on January 1, 2020, with early adoption permitted. The amendments in this update may be applied either retrospectively or prospectively. The Company is evaluating the impact the standard will have on its consolidated financial statements.

In November 2018, the FASB issued ASU No. 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606. The amendments in this update provide guidance on how to assess whether certain transactions between collaborative arrangement participants should be accounted for within the revenue recognition standard. The amendments in this update are effective for interim and annual periods for the Company beginning on January 1, 2020, with early adoption permitted. The Company is evaluating the impact the standard will have on its consolidated financial statements.

4. Acquisitions

Sofusa® Acquisition

On July 2, 2018, the Company entered into an Asset Purchase Agreement (the "Sofusa Purchase Agreement") with Kimberly-Clark Corporation ("KCC"); Kimberly-Clark Global Sales, LLC ("KCCGS"); and Kimberly-Clark Worldwide, Inc. ("KCCW" and together with KCC and KCCGS, "Kimberly-Clark") pursuant to which, among other things, the Company acquired certain of Kimberly-Clark's assets related to micro-needle drug delivery system, including the Sofusa® platform (the "Sofusa Assets") and related fixed assets, and assumed certain of Kimberly-Clark's liabilities related to the Sofusa Assets (the "Sofusa Acquisition"). The closing of the Sofusa Acquisition (the "Sofusa Closing") occurred on July 2, 2018. At the Sofusa Closing, the Company paid $10.0 million and agreed to pay additional consideration to Kimberly-Clark upon the achievement of certain regulatory and net sales milestones, as well as a percentage in the low double-digits of any non-royalty amounts received by the Company in connection with any license, sale or other grant of rights by the Company to develop or commercialize the Sofusa Assets (all such additional consideration, the "Sofusa Contingent Consideration"). Under the Sofusa Purchase Agreement, the aggregate amount of the Sofusa Contingent Consideration payable by the Company will not exceed $300.0 million. The Company also agreed to pay Kimberly-Clark a low single-digit royalty on all net sales with respect to the first five products developed by the Company or its licensees that utilizes intellectual property included in the Sofusa Assets. The transaction was accounted for as an asset acquisition since substantially all the value of the gross assets was concentrated in a single asset. Under the Asset Purchase Agreement, the Company acquired the Sofusa DoseDisc micro-needle technology designed to increase the efficacy of drug delivery by way of transdermal drug delivery for cash consideration of $10.0 million which was allocated based on the relative fair value of the assets acquired. No contingent consideration was recorded as of December 31, 2018 since the related regulatory approval milestones are not deemed probable until they actually occur. As a result, $9.5 million was expensed as a component of acquired in-process research and development and the remaining $0.5 million was recorded primarily to fixed assets.

Acquisition of Virttu Biologics Limited

On April 27, 2017, the Company entered into a Share Purchase Agreement (the "Virttu Purchase Agreement") with TNK Therapeutics, Inc., a majority-owned subsidiary of the Company ("TNK"), Virttu Biologics Limited ("Virttu"), the shareholders of Virttu (the "Virttu Shareholders") and Dayspring Ventures Limited, as the representative of the Virttu Shareholders, pursuant to which, among other things, TNK acquired from the Virttu Shareholders 100% of the outstanding ordinary shares of Virttu (the "Virttu Acquisition").

Virttu focuses on the development of oncolytic viruses that infect and selectively multiply in and destroy tumor cells without damaging healthy tissue. Its lead oncolytic virus candidate, Seprehvir, infects and replicates in cancer cells selectively, leaving normal cells unharmed.

Under the Virttu Purchase Agreement, the total amount of the consideration payable to the Virttu Shareholders in the Virttu Acquisition is equal to $25 million, less Virttu's net debt (the "Virttu Base Consideration"). An additional $10 million contingent consideration is payable upon the achievement of certain regulatory milestones (as described below) (the "Regulatory Approval Consideration").

At the closing of the Virttu Acquisition (the "Closing"), the Company issued to the Virttu Shareholders consideration valued at approximately $2.2 million, which consisted primarily of an aggregate of 797,081 shares (the "Virttu Closing Shares") and approximately $557,000 in cash (the "Cash Consideration"). The issuance of the Virttu Closing Shares and the payment of the Cash Consideration satisfied TNK's obligation to pay 20% of the Virttu Base Consideration at the Closing. Under the terms of the Virttu Purchase Agreement, the Company agreed to provide additional consideration to the Virttu Shareholders, as follows:

(1) Upon a financing resulting in gross proceeds (individually or in the aggregate) to TNK of at least $50.0 million (a "Qualified Financing"), TNK agreed to issue to the Virttu Shareholders an aggregate number of shares of its capital stock ("TNK Capital Stock") as is equal to the quotient obtained by dividing 80% of the Virttu Base Consideration by the lowest per share price paid by investors in the Qualified Financing (the "TNK Financing Consideration"); provided, however, that 20% of the TNK Financing Consideration was to be held in escrow until April 27, 2018 (the "Financing Due Date"), to be used to, among other things, satisfy the indemnification obligations of the Virttu Shareholders. In the event that a Qualified Financing did not occur, then on the Financing Due Date, the Company agreed to issue to the Virttu Shareholders an aggregate number of shares of the Company's common stock as is equal to the quotient obtained by dividing 80% of the Virttu Base Consideration, by $5.55 (as adjusted, as appropriate, to reflect any stock splits or similar events affecting the Company's common stock after the Closing).

(2) Within 45 business days after Virttu becomes aware that certain governmental bodies in the United States, the European Union, the United Kingdom or Japan have approved for commercialization, on or before October 26, 2024, Seprehvir (or any enhancement, combination or derivative thereof) as a monotherapy or in combination with one or more other active components (each of the first two such approvals by a governmental body being a "Regulatory Approval"), TNK shall pay half of the Regulatory Approval Consideration to the Virttu Shareholders, in a combination of (a) up to $5.0 million in cash (the "Regulatory Approval Cash") and/or (b) (i) such number of shares of the Company's common stock as is equal to the quotient obtained by dividing $5.0 million less the Regulatory Approval Cash (the "Regulatory Approval Share Value") by the 30 Day VWAP (as defined below) of one share of the Company's common stock; (ii) if TNK has completed its first public offering of TNK Capital Stock, the number of shares of TNK Capital Stock as is equal to the quotient obtained by dividing the Regulatory Approval Share Value by the 30 Day VWAP of one share of TNK Capital Stock; or (iii) such number of shares of common stock of a publicly traded company as is equal to the quotient obtained by dividing the Regulatory Approval Share Value by the volume weighted average price of the relevant security, as reported on the Nasdaq Capital Market (or other principal stock exchange or securities market on which the shares are then listed or quoted) for the thirty trading days immediately following the receipt of Regulatory Approval (the "30 Day VWAP"), with the composition of the Regulatory Approval Consideration to be at TNK's option. In order for a second regulatory approval to qualify as a Regulatory Approval under the Purchase Agreement, the second approval must be granted by a different governmental body in a different jurisdiction than that which granted the first Regulatory Approval.

At April 27, 2017, the 80% of the Virttu Base Consideration was valued at $12.8 million. The fair value of the 80% of the Virttu Base Consideration is recorded as a current liability and will be adjusted quarterly for changes in fair value or as events and circumstances arise. At April 27, 2017, the contingent Regulatory Approval Consideration was valued at $1.0 million. The fair value of the contingent Regulatory Approval Consideration is recorded as a non-current liability within "Deferred rent and other" on the accompanying consolidated balance sheet and will be adjusted quarterly for changes in fair value or as events and circumstances arise.

The consolidated financial statements include the results of operations from this transaction, which have been accounted for as a business combination, and require, among other things, that assets acquired and liabilities assumed

be recognized at their fair values as of the acquisition date. The valuation of the acquired assets and liabilities resulted in the recognition of identifiable assets of approximately $16.0 million comprised mainly of in-process research and development of approximately $15.4 million, deferred tax liabilities of $0.8 million and goodwill of approximately $1.4 million. Various factors contributed to the establishment of goodwill, including an assembled workforce. There is no tax deductible goodwill for Virttu.

In connection with the Virttu transaction, the Company recorded acquisition costs of approximately $0.9 million in general and administrative expenses for the twelve months ended December 31, 2017, for legal and related costs. Acquisition costs are expensed as incurred.

The acquisition of Virttu was not significant to the Company's consolidated financial statements.

TNK did not complete a Qualified Financing prior to the Financing Due Date and on April 27, 2018. The Company, TNK and Dayspring entered into the Amendment, pursuant to which, among other things, the Company agreed that the acquisition consideration, otherwise payable on April 27, 2018 to the Virttu Shareholders, shall be as follows: (1) an issuance of 1,795,011 shares of the Company's common stock to the Virttu Shareholders and (2) $9.9 million payable in cash.

The Company issued an aggregate of 1,795,011 shares of the Company's common stock to the Virttu Shareholders on April 27, 2018 for a value of $11.3 million. The approximately $9.9 million payable in cash is recorded on the Company's consolidated balance sheet under Acquisition Consideration Payable and has not been paid as of the date of this filing.

Acquisition of Scilex Pharmaceuticals Inc.

On November 8, 2016, the Company entered into a Stock Purchase Agreement (the “Scilex Purchase Agreement”) with Scilex and a majority of the stockholders of Scilex (the “Scilex Stockholders”) pursuant to which, on November 8, 2016, the Company acquired from the Scilex Stockholders, and the Scilex Stockholders sold to the Company, approximately 72% of the outstanding capital stock of Scilex (the “Scilex Acquisition”). The remainder of the outstanding capital stock of Scilex represents a noncontrolling interest of which approximately 19.3% continues to be held by ITOCHU CHEMICAL FRONTIER CORPORATION following the Scilex Acquisition.

Scilex focuses on the development and commercialization of specialty pharmaceutical products for the treatment of pain; its lead product, ZTlido® (lidocaine topical system 1.8%), is a branded lidocaine topical system formulation for the treatment of chronic pain. As discussed in Note 17, ITOCHU CHEMICAL FRONTIER Corporation serves as the sole manufacturer and supplier to Scilex for the ZTlido® product.

At the closing of the Scilex Acquisition, the Company issued to the Scilex Stockholders that were accredited investors (the “Accredited Scilex Stockholders”) consideration valued at $4.8 million which consisted primarily of an aggregate of 754,911 shares of the Company’s common stock (the “Common Stock”). Under the terms of the Scilex Purchase Agreement, the Company agreed to provide additional consideration to the Accredited Scilex Stockholders upon the achievement of certain milestones, as follows:

(1) Upon receipt of notice from the U.S. Food and Drug Administration (the “FDA”) that the FDA has accepted Scilex’s resubmitted new drug application for ZTlido® (lidocaine topical system 1.8%) for the treatment of postherpetic neuralgia (the “NDA”), the Company agreed to deliver to the Accredited Scilex Stockholders a number of shares of Common Stock equal to the quotient obtained by dividing 10% of the total undiscounted purchase consideration of approximately $47.8 million (the “Adjusted Base Consideration”) by a price (the “FDA Acceptance Price”) equal to the closing market price of one share of Common Stock, as reported by The Nasdaq Stock Market LLC (“Nasdaq”) on the date of Scilex’s receipt of the FDA notice or, if no closing price is reported for such date, the closing price on the last preceding date for which such quotation exists; provided, however, that in no event was the FDA Acceptance Price to be greater than $25.32 or less than $6.33 (in each case as adjusted, as appropriate, to reflect any stock splits or similar events affecting the Common Stock).

On September 11, 2017, the Company received notice from the FDA that the FDA had accepted the NDA and the Company issued to the Accredited Scilex Stockholders consideration valued at $1.4 million, which consisted primarily of an aggregate of 754,930 shares of Common Stock.

(2) Upon receipt of notice from the FDA that the FDA has approved the NDA for commercialization, the Company will deliver to the Accredited Scilex Stockholders cash and shares of Common Stock in such proportion to be determined in the Company’s sole discretion, with a total value equal to 80% of the Adjusted Base Consideration (the “FDA Approval Consideration”). To the extent that the Company elects to pay any portion of the FDA Approval Consideration in shares of Common Stock, the number of shares shall be equal to the quotient obtained by dividing (a) the portion of the FDA Approval Consideration to be paid in shares of Common Stock by (b) a price (the “FDA

Approval Price") equal to the closing market price of one share of Common Stock, as reported by Nasdaq on the date of the Scilex's receipt of the FDA notice or, if no closing price is reported for such date, the closing price on the last preceding date for which such quotation exists; provided, however, that in no event shall the FDA Approval Price be greater than $25.32 or less than $6.33 (in each case as adjusted, as appropriate, to reflect any stock splits or similar events affecting the Common Stock). However, in no event may the Company make an election with respect to the FDA Approval Consideration so as to cause the total number of shares of Common Stock issued in connection with the Scilex Acquisition to exceed 4.99% of the total number of shares of Common Stock of the Company outstanding as of immediately prior to the Closing (as adjusted, as appropriate, to reflect any stock splits or similar

events affecting the Common Stock), unless the Company has obtained stockholder approval to issue a greater number of shares.

On February 28, 2018, the Company received notice that the FDA had approved the NDA and the Company issued the Accredited Scilex Stockholders consideration valued at $38.2 million, which included an aggregate of 1,381,346 shares of Common Stock.

At November 8, 2016, the contingent consideration was valued at $33.5 million, resulting in a total purchase consideration of approximately $38.2 million. The fair value of the contingent consideration is recorded as a current liability and will be periodically adjusted for changes in fair value or as events and circumstances arise. The remainder of the outstanding capital stock of Scilex represents a noncontrolling interest which was valued at $12.3 million at November 8, 2016.

The consolidated financial statements include the results of operations from this transaction, which have been accounted for as a business combination, and require, among other things, that assets acquired and liabilities assumed be recognized at their fair values as of the acquisition date. The valuation of the acquired assets resulted in the recognition of identifiable assets of approximately $54.9 million comprised mainly of in-process research and development of $21.9 million and patents of $32.6 million. The valuation of the acquired liabilities resulted in the recognition of liabilities of approximately $17.9 million comprised mainly deferred tax liabilities of $13.9 million. The Company recorded goodwill of $13.5 million associated with the acquisition. The amounts in this Note reflect the adjustment described above. Various factors contributed to the establishment of goodwill, including an assembled workforce. There is no tax deductible goodwill for Scilex.

Acquired In-process Research and Development of BDL

In August 2015, the Company and TNK entered into a Stock Purchase Agreement (the “Stock Purchase Agreement”) with BDL Products, Inc. (“BDL”) and the stockholders of BDL (“Stockholders”) pursuant to which the Stockholders sold all of their shares of capital stock in BDL to TNK for: (1) a cash payment of $100.00, and (2) $6.0 million in shares of TNK Class A Stock, subject to adjustment in certain circumstances, to be issued to the Stockholders upon a financing resulting in gross proceeds (individually or in the aggregate) to TNK of at least $50.0 million (a “Qualified Financing”). In accordance with subsequent amendments to the Stock Purchase Agreement, in the event a Qualified Financing did not occur by October 15, 2017 (which is subject to further extension as implied and based on previously amended dates) or TNK did not complete an initial public offering of shares of its capital stock by September 15, 2017, in lieu of receiving shares of TNK pursuant to the acquisition, the Stockholders were entitled to receive an aggregate of 309,916 shares of the Company’s common stock, subject to adjustment in certain circumstances.

A Qualified Financing did not occur by October 15, 2017 and TNK did not complete an initial public offering by September 15, 2017 and the Company issued 309,916 shares of its common stock to the Stockholders on March 19, 2018.

Acquired In-process Research and Development of Cargenix

In August 2015, the Company and TNK Therapeutics, Inc., its subsidiary (“TNK”) entered into a Membership Interest Purchase Agreement (the “Membership Interest Purchase Agreement”) with CARgenix Holdings LLC (“CARgenix”) and the members of CARgenix (the “Members”) pursuant to which the Members sold all of their membership interests in CARgenix to TNK for: (1) a cash payment of $100.00, and (2) $6.0 million in shares of TNK Class A common stock (“TNK Class A Stock”), subject to adjustment in certain circumstances, to be issued to the Members upon a financing resulting in gross proceeds (individually or in the aggregate) to TNK of at least $50.0 million (a “Qualified Financing”). In accordance with an amendment to the Membership Interest Purchase Agreement entered into in March 2016, in the event a Qualified Financing did not occur by September 15, 2016 or TNK did not complete an initial public offering of shares of its capital stock by October 15, 2016, in lieu of receiving shares of TNK pursuant to the acquisition, the Members would receive an aggregate of 309,917 shares of the Company’s common stock, subject to adjustment in certain circumstances. TNK did not complete a Qualified Financing by the amended financing deadline and the Company issued 309,917 shares of its common stock to the Members on October 7, 2016.

5. Fair Value Measurements

Fair value measurement is defined as the price that would be received to sell an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. A fair value hierarchy is established, which prioritizes the inputs used in measuring fair value into three broad levels as follows:

Level 1—Quoted prices in active markets for identical assets or liabilities.

Level 2—Inputs, other than quoted prices in active markets, that are observable either directly or indirectly.
Level 3—Unobservable inputs based on the Company's own assumptions.

The following table presents the Company’s financial assets and liabilities that are measured at fair value on a recurring basis (in thousands):

	Fair Value Measurements at December 31, 2018			
	Balance	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	$158,738	$158,738	$ —	$ —
Restricted cash	54,592	54,592	—	—
Marketable securities	297	247	—	50
Total assets	$213,627	$213,577	$ —	$ 50
Liabilities:				
Acquisition consideration payable	$11,312	$—	$ —	$ 11,312
Acquisition consideration payable, non-current	725	—	—	725
Total liabilities	$12,037	$—	$ —	$ 12,037

	Fair Value Measurements at December 31, 2017			
	Balance	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash and Cash Equivalents	$20,429	$20,429	$ —	$ —
Marketable securities	441	356	—	85
Total assets	$20,870	$20,785	$ —	$ 85
Liabilities:				
Acquisition consideration payable	$53,209	$—	$ —	$ 53,209
Acquisition consideration payable, non-current	1,063			1,063
Total liabilities	$54,272	$—	$ —	$ 54,272

The Company's financial assets and liabilities carried at fair value are comprised of cash, cash equivalents, restricted cash, marketable securities and acquisition consideration payable. Cash and cash equivalents consist of money market accounts and bank deposits which are highly liquid and readily tradable. These investments are valued using inputs observable in active markets for identical securities. Marketable securities are valued using inputs observable in active markets for identical securities. The fair value of the contingent consideration is measured on a recurring basis using significant unobservable inputs (Level 3). Contingent consideration is measured using the income approach and discounting to present value the contingent payments expected to be made based on assessment of the probability that the company would be required to make such future payment.

In connection with the issuance of the Loan Agreement as described in Note 12, the Company recorded a derivative liability associated with the Conditional Warrants in the amount of $2.8 million, which balance was immaterial as of

December 31, 2018 based on the probability of achieving certain milestones and resulted in a $2.8 million gain on derivative liability recorded during the quarter ended December 31, 2018. Such derivative liability was valued using a Monte Carlo simulation model using significant unobservable inputs (Level 3) related to the probability of achieving certain commercial and financial milestones as outlined in the Loan Agreement.

The following is a summary of the contingent consideration liabilities associated with acquisitions entered into during the years ended 2017 and 2016. During the year ended December 31, 2018, the fair value remeasurement adjustments related to the Company's acquisitions resulted in an increase to the contingent consideration liabilities by $9.6 million and there were $51.9 million in settlements of contingent consideration related to such liabilities. Settlements of contingent consideration for the twelve months ended December 31, 2018 include the settlements of Scilex and BDL liabilities for $38.2 million and $2.3 million, respectively, and the $11.3 million partial settlement of the Virttu financing milestone in common stock of the Company ($9.9 million of the Virttu contingent liability remains to be paid in cash).

The following tables includes a summary of the changes to contingent consideration liabilities during the year ended December 31, 2018, 2017 and 2016. The contingent consideration is measured at fair value using significant unobservable inputs (Level 3) during the twelve months ended December 31, 2018, 2017 and 2016:

(in thousands)	2018
Beginning Balance at December 31, 2017	54,272
Re-measurement of Fair Value	9,644
Settlements of current year contingent consideration	(51,879)
Ending Balance at December 31, 2018	$12,037

(in thousands)	2017
Beginning Balance at December 31, 2016	48,362
Scilex acquisition adjustment (See Note 4)	(6,500)
Acquisition consideration payable - current year acquisitions (See Note 4)	12,807
Contingent consideration (Non-current) - current year acquisitions (See Note 4)	983
Re-measurement of Fair Value	—
Payment of shares for current year contingent consideration	(1,380)
Ending Balance at December 31, 2017	$54,272

(in thousands)	2016
Beginning Balance at December 31, 2015	—
Contingent consideration - current year acquisitions (1)	50,137
Re-measurement of Fair Value – current year acquisitions	(1,775)
Payment of current year contingent consideration	—
Ending Balance at December 31, 2016	$48,362

(1) Includes the BDL contingent consideration of 309,917 shares.

The following table includes a summary of the Company's contingent and financing liabilities, related inputs used to determine fair value, and the valuation methodologies used for the fair value measurements using significant unobservable inputs (Level 3) at December 31, 2018:

(in thousands)	Fair Value Measurements at December 31, 2018	Valuation Methodology	Significant Unobservable Input	Weighted Average (range, if applicable)
Virttu Contingent Consideration (Non-Current)	$ 725	Multiple outcome discounted cash flow	Discount Rate Probability of Regulatory Milestone	19.2% 16%
Concortis Contingent Consideration	511	Multiple outcome discounted cash flow	Discount Rate Percent probabilities assigned to scenarios	19.2% 20%
Shanghai Three Contingent Consideration	336	Multiple outcome discounted cash flow	Discount Rate Percent probabilities assigned to scenarios	19.2% 10%

RWMC Contingent Consideration	503	Multiple outcome discounted cash flow	Discount Rate, Percent probabilities assigned to scenarios	19.2% 10%

The principal significant unobservable inputs used in the valuations of the contingent considerations are the discount rates, and probabilities assigned to scenario outcomes. An increase in the discount rate will cause a decrease in the fair value of the contingent consideration. Conversely, a decrease in the discount rate will cause an increase in the fair value of the contingent consideration. An increase in the probabilities assigned to certain scenarios will cause the fair value of contingent consideration to increase. Conversely, a decrease in the probabilities assigned to certain scenarios will cause the fair value of contingent considerations to decrease.

6. Marketable Securities

Marketable securities consisted of the following as of December 31, 2018 (in thousands):

	December 31, 2018		
	Cost	Gross Realized Gains (Losses)	Fair Value
Trading securities:			
MedoveX common shares and warrants	$750	$ (453)	$ 297

	December 31, 2017		
	Cost	Gross Realized Gains (Losses)	Fair Value
Trading securities:			
MedoveX common shares and warrants	$750	$ (309)	$ 441

Trading Securities

On August 5, 2016, the Company entered into a Unit Purchase Agreement (the “Unit Purchase Agreement”) with MedoveX Corporation (“MedoveX”). Pursuant to the terms of the Unit Purchase Agreement, the Company purchased three Units for $750 thousand. Each Unit had a purchase price of $250 thousand and consisted of (i) 208,333 shares of MedoveX common stock (the “MedoveX Common Stock”), and (ii) a warrant to purchase 104,167 shares of MedoveX Common Stock (the “MedoveX Warrant”). The MedoveX Warrant has an initial exercise price of $1.52 per share, subject to adjustment, and is initially exercisable six months following the date of issuance for a period of five years from the date of issuance. In addition, the Company entered into a Registration Rights Agreement with MedoveX pursuant to which MedoveX was required to file a registration statement registering for resale all shares of MedoveX Common Stock and shares of MedoveX Common Stock issuable pursuant to the MedoveX Warrant issued as part of the Units.

For the twelve months ended December 31, 2018 and 2017, the Company recorded a loss of $0.1 million and a loss of $0.7 million on trading securities, respectively. The Company’s investment in MedoveX will be revalued on each balance sheet date. The fair value of the Company’s holding in MedoveX Common Stock at December 31, 2018 is a Level 1 measurement. The fair value of the Company’s holdings in the MedoveX Warrant was estimated using the Black-Scholes option-pricing method. The risk-free rate was derived from the U.S. Treasury yield curve, matching the MedoveX Warrant’s term, in effect at the measurement date. The volatility factor was determined based on MedoveX’s historical stock prices. The warrant valuation is a Level 3 measurement.

The following table includes a summary of the warrant measured at fair value using significant unobservable inputs (Level 3) during the twelve months ended December 31, 2018 (in thousands):

	Total

Beginning balance at December 31, 2017	$84
Addition of warrant	—
Change in fair value of warrant	(34)
Ending balance at December 31, 2018	$50

Available-for-sale Securities

In July 2016, the Company completed the transactions contemplated by a letter agreement (the “Letter Agreement”) with the Chan Soon-Shiong Family Foundation (“Foundation”) and Cambridge Equities, LP (“Cambridge”). Pursuant to the terms of

the Letter Agreement, among other things, (i) the Company agreed to sell to Foundation, and Foundation agreed to purchase from the Company, an aggregate of 5,618,326 shares of common stock of NantKwest held by the Company (representing all shares of NantKwest held by the Company), (ii) Foundation agreed to sell to the Company, and the Company agreed to purchase all reported shares held by Foundation and Cambridge, constituting an aggregate of 7,878,098 shares of Common Stock, (iii) Cambridge agreed to forfeit its right to purchase 500,000 shares of Common Stock issuable pursuant to a warrant to purchase 1,724,138 shares of Common Stock issued by the Company, and (iv) the Company agreed to pay to Foundation an aggregate of approximately $15.6 million. Effective upon closing, the Company repurchased the 7,878,098 shares of Common Stock. The Company recognized a gain of $27.2 million on the sale of the NantKwest stock in its consolidated statement of operations for the twelve months ended December 31, 2016 as a result of the transaction.

7. Property and Equipment

Property and equipment consisted of the following as of December 31, 2018 and 2017 (in thousands):

	December 31,	
	2018	2017
Furniture and fixtures	$1,127	$1,035
Office equipment	632	493
Machinery and lab equipment	27,690	19,868
Leasehold improvements	9,001	7,327
Construction in progress	1,221	—
	39,671	28,723
Less accumulated depreciation	(15,287)	(9,378)
	$24,384	$19,345

Depreciation expense for the years ended December 31, 2018, 2017 and 2016 was $6.0 million, $4.5 million and $2.0 million, respectively.

8. Cost Method Investments

As of December 31, 2018 and 2017, the aggregate carrying amount of the Company's cost-method investments in non-publicly traded companies was $237.0 million and included an ownership interest in NantCell, Inc. ("NantCell"), NantBioScience, Inc. ("NantBioScience"), Globavir Biosciences, Inc., Brink Biologics, Inc., Coneksis, Inc., and Celularity Inc.

The Company's cost-method investments are assessed for impairment quarterly. The Company has determined that it is not practicable to estimate the fair value of its cost-method investments on a regular basis and does not reassess the fair value of cost-method investments if there are no identified events or changes in circumstances that may have a significant adverse effect on the fair value of the investments. No impairment losses were recorded during the years ended December 31, 2018, 2017 and 2016.

9. Equity Method Investments

NANTibody

In 2013, the Company acquired IgDraSol Inc. ("IgDraSol"), a private company focused on the development of oncologic agents for the treatment of cancer, from a third party unrelated to the NantWorks, LLC ("NantWorks") affiliated entities for 3 million shares of the Company's common stock and $380,000 of cash for a total purchase price of $29.1 million. This transaction included the acquisition of IgDraSol's lead compound, Cynviloq™, a micellar diblock copolymeric paclitaxel formulation drug product.

In May 2015, the Company entered into an agreement with NantPharma, LLC ("NantPharma"), a NantWorks company, pursuant to which the Company sold to NantPharma all of its equity interests in IgDraSol, which continued to hold the rights to Cynviloq™. Pursuant to the agreement, NantPharma paid the Company an upfront fee of $90.1 million, of which $60.0 million was required to be used by the Company to fund two joint ventures, as described below.

In April 2015, the Company and NantCell, a subsidiary of NantWorks, LLC (“NantWorks”), a private company owned by Dr. Patrick Soon-Shiong, established a new entity called Immunotherapy NANTibody, LLC (“NANTibody”) as a stand-alone biotechnology company with $100.0 million initial joint funding. NantCell owns 60% of the equity interest of

NANTibody and agreed to contribute $60.0 million to NANTibody. The Company owns 40% of NANTibody and in July 2015, the Company had NantPharma, LLC ("NantPharma") contribute its portion of the initial joint funding of $40.0 million to NANTibody from the proceeds of the sale of IgDraSol, Inc. ("IgDraSol"). Additionally, the Company and NantCell were allowed to appoint three and two representatives, respectively, to NANTibody's five-member Board of Directors. NANTibody will focus on accelerating the development of multiple immuno-oncology mAbs for the treatment of cancer, including but not limited to anti-PD-1, anti-PD-L1, anti-CTLA4mAbs, and other immune-check point antibodies as well as ADCs and bispecific antibodies.

NANTibody had been formed to advance pre-clinical and clinical immunology assets contributed by the Company and NantCell. The Company continues to hold 40% of the outstanding equity of NANTibody and NantCell holds the remaining 60%. Until July 2, 2017, NANTibody held approximately $100.0 million of cash and cash equivalents, and the Company recorded its investment in NANTibody at approximately $40.0 million. As an equity method investment, the Company's ratable portion of 40% of money expended for the development of intellectual property assets held by NANTibody would be reflected within income (loss) on equity method investments in its statement of operations. As a result of limited spending at NANTibody, the cash on hand at NANTibody remained at approximately $100.0 million since the inception of the NANTibody joint venture until July 2, 2017. Further, the Company's equity method investment in NANTibody remained at approximately $40.0 million until July 2, 2017. The financial statements of NANTibody are not received sufficiently timely for the Company to record its portion of earnings or loss in the current financial statements and therefore the Company reports its portion of earnings or loss on a quarter lag.

In February 2018, NANTibody notified the Company that on July 2, 2017, NANTibody acquired all of the outstanding equity of IgDraSol in exchange for $90.1 million in cash. NANTibody purchased IgDraSol from NantPharma, LLC, which is controlled by NantWorks, an entity with a controlling interest in NantCell and NantPharma.

Although the Company has had a designee serving on the Board of Directors of NANTibody since the formation of NANTibody in April 2015, and although the Company has held 40% of the outstanding equity of NANTibody since NANTibody's formation, neither the Company nor its director designee was given any advance notice of NANTibody's purchase of IgDraSol or of any board meeting or action to approve such purchase. As such, the Company's designee on NANTibody's Board of Directors was not given an opportunity to consider or vote on the transaction as a director and the Company was not given an opportunity to consider or vote on the transaction in its position as a significant (40%) equity holder of NANTibody.

As a result of the July 2, 2017 purchase of IgDraSol, NANTibody's cash and cash equivalents were reduced from $99.6 million as of June 30, 2017 to $9.5 million as of September 30, 2017, and NANTibody's contributed capital was reduced from $100.0 million as of June 30, 2017 to $10.0 million as of September 30, 2017, to effect the transfer of IgDraSol from NantPharma to NANTibody. No additional information was provided to the Company to explain why NANTibody's total assets as of September 30, 2017 were reduced by approximately $90.1 million. The Company requested, but did not receive, additional information from NANTibody for purposes of supporting the value of IgDraSol, including any information regarding clinical advancements in the entity since the sale of IgDraSol by the Company in May 2015.

Prior to the communication of the transfer of IgDraSol from NantPharma to NANTibody, the Company relied on the cash and cash equivalents of NANTibody for purposes of determining the value of its investment in NANTibody, which capital was expended by NANTibody to acquire IgDraSol on July 2, 2017. As a result of the transfer of IgDraSol, the Company reassessed the recoverability of its equity method investment in NANTibody as of July 2, 2017. In doing so, the Company considered the expected outcomes for the intellectual property assets held by NANTibody as of July 2, 2017. As a result of the lack of evidence of any development activity associated with any of the assets held in NANTibody, given the passage of time since the formation of the joint venture, many competitive products from other drug developers worldwide have advanced and/or commercialized for the targeted disease indications of the assets held in NANTibody, and given the Company's minority interest in NANTibody (the

investee), the Company concluded that it does not have the ability to recover the carrying amount of the investment and an other-than-temporary decline in the value of the investment had occurred. Accordingly, an impairment was recorded to the Company's equity method investment in NANTibody for the three and nine months ended September 30, 2017. The fair value of the Company’s investment in NANTibody was measured at fair value on July 2, 2017 using significant unobservable inputs (Level 3) due to the determination of fair value requiring significant judgment, including the potential outcomes of the intellectual property assets held by NANTibody. For these reasons, fair value was determined by applying the Company's 40% equity interest in NANTibody to the remaining cash and cash equivalents, which resulted in an impairment of $36.0 million. The impairment resulted in a revised carrying value of the Company's investment in NANTibody

of $3.7 million which approximates its ratable 40% ownership of the cash maintained by NANTibody expected to be used for future research and development.

NANTibody recorded net loss of $0.7 million, $1.1 million and $0.6 million for the twelve months ended September 30, 2018, 2017 and 2016, respectively. The Company recorded its portion of loss from NANTibody in (loss) income on equity investments on its consolidated statements of operations for the twelve months ended December 31, 2018 and 2017. As of September 30, 2018, NANTibody had $9.7 million in current assets, $0.8 million in current liabilities, and no noncurrent assets or noncurrent liabilities. As of September 30, 2017, NANTibody had $9.9 million in current assets and $0.6 million in current liabilities and no noncurrent assets or noncurrent liabilities.

NantStem

In July 2015, the Company and NantBioScience, a subsidiary of NantWorks, established a new entity called NantCancerStemCell, LLC ("NantStem") as a stand-alone biotechnology company with $100.0 million initial joint funding. As initially organized, NantBioScience was obligated to make a $60.0 million cash contribution to NantStem for a 60% equity interest in NantStem, and the Company was obligated to make a $40.0 million cash contribution to NantStem for a 40% equity interest in NantStem. Fifty percent of these contributions were funded in July 2015 and the remaining amounts were to be made by no later than September 30, 2015. The Company had NantPharma contribute its portion of the initial joint funding of $20.0 million to NantStem from the proceeds of the sale of IgDraSol. Pursuant to a Side Letter dated October 13, 2015, the NantStem joint venture agreement was amended to relieve the Company of the obligation to contribute the second $20.0 million payment, and its ownership interest in NantStem was reduced to 20%. NantBioScience's funding obligations were unchanged. The Side Letter was negotiated at the same time the Company issued a call option on shares of NantKwest that it owned to Cambridge, a related party to NantBioScience.

A loss related to other-than-temporary impairment of $0.5 million was recognized for the equity investment in NantStem for the year ended December 31, 2018. There was no loss related to other-than-temporary impairment recognized for the equity investment for the years ended December 31, 2017 or 2016.

The Company is accounting for its interest in NantStem as an equity method investment, due to the significant influence the Company has over the operations of NantStem through its board representation and 20% voting interest. The Company's investment in NantStem is reported in equity method investments on its consolidated balance sheets and its share of NantStem's loss is recorded in loss on equity investments on its consolidated statement of operations. As of December 31, 2018 and 2017, the carrying value of the Company's investment in NantStem was approximately $18.0 million and $18.7 million, respectively.

The financial statements of NantStem are not received sufficiently timely for the Company to record its portion of earnings or loss in the current financial statements and therefore the Company reports its portion of earnings or loss on a quarter lag.

NantStem recorded a net loss of $0.7 million for the twelve months ended September 30, 2018 and net income of $0.7 million and $0.9 million for the years ended 2017 and 2016, respectively. The Company recorded its portion of gain from NantStem in gain on equity investments on its consolidated statements of operations for the twelve months ended December 31, 2018 and 2017. As of September 30, 2018, NantStem had $74.1 million in current assets and $0.1 million in current liabilities and $6.9 million noncurrent assets and no noncurrent liabilities. As of September 30, 2017, NantStem had $82.5 million in current assets and no current liabilities and no noncurrent assets or noncurrent liabilities.

Yuhan Agreement

In March 2016, the Company 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. Under the terms of the joint venture agreement, Yuhan contributed an initial investment of $10.0 million to ImmuneOncia, and the Company granted ImmuneOncia an exclusive license to one of its 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 the Company's immuno-oncology antibody portfolio. Yuhan owns 51% of ImmuneOncia, while the Company owns 49%.

The Company is accounting for its interest in ImmuneOncia as an equity method investment, due to the significant influence the Company has over the operations of ImmuneOncia through its board representation and 49% voting interest while

not sharing joint control with Yuhan. The Company’s investment in ImmuneOncia is reported in equity method investments on its consolidated balance sheets and its share of ImmuneOncia’s loss is recorded in loss on equity investments on its consolidated statement of operations. As of December 31, 2018 and 2017, the carrying value of the Company’s investment in ImmuneOncia was approximately $2.7 million and $6.8 million, respectively. The difference between the Company’s investment in ImmuneOncia and the Company’s 49% interest in the net assets of ImmuneOncia was approximately $0.8 million at December 31, 2018.

ImmuneOncia recorded net loss of $8.4 million for the twelve months ended December 31, 2018. The Company recorded its portion (49% equity interest) of loss from ImmuneOncia in loss on equity investments on its consolidated statement of operations for the twelve months ended December 31, 2018. As of December 31, 2018, ImmuneOncia had $0.8 million in current assets, $1.1 million in current liabilities, $7.5 million in noncurrent assets, and $87 thousand in noncurrent liabilities. As of December 31, 2018, no material activity had occurred subsequent to the Company's initial investment.

ImmuneOncia recorded net loss of $5.4 million for the twelve months ended December 31, 2017. The Company recorded its portion (49% equity interest) of loss from ImmuneOncia in loss on equity investments on its consolidated statement of operations for the twelve months ended December 31, 2017. As of December 31, 2017, ImmuneOncia had $7.4 million in current assets, $129 thousand in current liabilities, $8.8 million in noncurrent assets, and $33 thousand noncurrent liabilities.

In April 2016, Yuhan purchased $10.0 million of shares of Common Stock, and warrants as part of the Company’s private placement offering. As of December 31, 2016, no material activity had occurred subsequent to the Company's initial investment.

Shanghai Three

On March 7, 2016, TNK agreed to issue to SiniWest Holdings, Inc. (“SiniWest Holdings”) $4.0 million in shares of TNK Class A Stock, subject to certain circumstances, to be issued upon a financing resulting in gross proceeds (individually or in the aggregate) to TNK of at least $10.0 million and a $1.0 million upfront cash payment in exchange for SiniWest Holdings transferring certain assets to TNK, including SiniWest Holdings’ 25% interest in Shanghai Three-Alliance Biotech Co. LTD, a China based company (“Shanghai Three”). The Company is accounting for its interest in Shanghai Three as an equity method investment, due to the significant influence the Company has over the operations of Shanghai Three through its 25% voting interest. The Company’s investment in Shanghai Three is reported in equity method investments on the consolidated balance sheets and its share of Shanghai Three’s income or loss is recorded in income (loss) on equity investments on the consolidated statement of operations. As of each of the years ended December 31, 2018 and 2017, the carrying value of the Company’s investment in Shanghai Three was approximately $3.8 million.

The financial statements of Shanghai Three are not received sufficiently timely for the Company to record its portion of earnings or loss in the current financial statements and therefore the Company reports its portion of earnings or loss on a quarter lag.

Shanghai Three incurred no operating expenses for the twelve months ended September 30, 2018 and 2017. As of September 30, 2018, Shanghai Three had approximately $0.3 million in current assets, $5.1 million in noncurrent assets, $2.6 million in current liabilities, and $2.0 million in noncurrent liabilities. As of December 31, 2017, Shanghai Three had approximately $0.4 million in current assets, $5.3 million in noncurrent assets, $2.8 million in current liabilities, and $2.0 million in noncurrent liabilities.

Fair Value of Equity Method Investment

The Company periodically evaluates the carrying value of the Company's equity method investments, when events and circumstances indicate that the carrying amount of an asset may not be recovered. The Company determines the fair value of its equity method investments to evaluate whether impairment losses shall be recorded using Level 3 inputs. These investments include the Company's holdings in privately held biotechnology companies that are not exchange traded and therefore not supported with observable market prices. However, these investments are valued by reference to their net asset values that can be market supported and unobservable inputs including future cash flows if available.

10. Goodwill and Intangible Assets

The Company had goodwill of $38.3 million for each of years ended December 31, 2018 and 2017. The Company performed a qualitative test for goodwill impairment as of December 31, 2018. Based upon the results of the qualitative testing

the Company concluded that it is more-likely-than-not that the fair values of the Company's goodwill was in excess of its carrying value and therefore performing the first step of the two-step impairment test was unnecessary. No goodwill impairment was recognized for the years ended December 31, 2018, 2017 and 2016.

The Company's intangible assets, excluding goodwill, include acquired license and patent rights, core technologies, customer relationships and acquired in-process research and development. Amortization for the intangible assets that have finite useful lives is generally recorded on a straight-line basis over their useful lives. A summary of the Company's identifiable intangible assets as of December 31, 2018 and 2017 is as follows (in thousands):

	December 31, 2018		
	Gross Carrying Amount	Accumulated Amortization	Intangibles, net
Customer relationships	$1,585	$ 1,373	$ 212
Acquired technology	3,410	885	2,525
Acquired in-process research and development	35,834	366	35,468
Patent rights	32,720	4,742	27,978
Assembled workforce	105	5	100
Total intangible assets	$73,654	$ 7,371	$ 66,283

	December 31, 2017		
	Gross Carrying Amount	Accumulated Amortization	Intangibles, net
Customer relationships	$1,585	$ 1,091	$ 494
Acquired technology	3,410	709	2,701
Acquired in-process research and development	37,660	—	37,660
Patent rights	32,720	2,562	30,158
Total intangible assets	$75,375	$ 4,362	$ 71,013

As of December 31, 2018, the remaining weighted average life for identifiable intangible assets is 15 years.

Patent rights are stated at cost and amortized on a straight-line basis over the estimated useful lives of the assets, determined to be approximately fifteen years or nineteen years from the date of transfer of the rights to the Company. Amortization expense for the years ended December 31, 2018, 2017 and 2016 was $2.2 million, $2.1 million and $0.4 million.

Acquired technology is stated at cost and amortized on a straight-line basis over the estimated useful lives of the assets, determined to be approximately nineteen years from the date of acquisition of the technology in December 2013. Amortization expense for the each of the years ended December 31, 2018, 2017 and 2016 was $0.2 million.

Customer relationships are stated at cost and amortized on a straight-line basis over the estimated useful lives of the assets and are generally determined to be approximately five years from the date of acquisition. Amortization expense for each of the years ended December 31, 2018, 2017 and 2016 was $0.3 million.

Acquired in-process research and development is stated at cost and may be immediately expensed if there is no alternative future use. The Company commenced amortization of acquired in-process research and development related to the business combination of Scilex upon commercialization of ZTlido® (lidocaine topical system 1.8%) in October 2018. Amortization expense for the year ended December 31, 2018 was $0.4 million and is being amortized on a straight-line basis over the estimated useful life of approximately fifteen years. The Company intends to begin amortization of acquired in-process research and development costs associated with the Virttu business combination upon commercialization of products. The acquired in-process research and development is reviewed annually for impairment or more frequently as changes in circumstance or the occurrence of events suggest that the remaining value may not be recoverable. The Company recorded an impairment charge of $1.8 million associated with Virttu

IPR&D for the quarter ended December 31, 2018.
Estimated future amortization expense related to intangible assets at December 31, 2018 is as follows (in thousands):

Years Ending December 31,	Amount
2019	$3,866
2020	3,866
2021	4,920
2022	4,920
2023	4,915
Thereafter	43,796
Total	$66,283

11. Significant Agreements and Contracts

License Agreement with Mabtech Limited

In August 2015, the Company entered into an exclusive licensing agreement to develop and commercialize multiple prespecified biosimilar and biobetter antibodies from Mabtech Limited. Under the terms of the agreement, the Company will develop and market four mAbs for the North American, European and Japanese markets. The Company made an initial license payment of $10.0 million and in February 2016, paid an additional $10.0 million license payment, both of which were recognized as acquired in-process research and development expense in the consolidated statements of operations as the Company determined there was no alternative future use for the license.

In June 2016, the Company agreed to accelerate and pay a $30.0 million milestone license payment which has been recognized as acquired in-process research and development expense in the consolidated statements of operations, in exchange for the purchase by Mabtech Limited in June 2016, of $10.0 million of common stock and warrants.

In December 2017, the Company agreed to accelerate and, as a result, paid a $25.0 million milestone license payment, which has been recognized as acquired in-process research and development expense in the consolidated statements of operations. The amended agreement includes additional milestone payments totaling $125.0 million payable following the completion of the technology transfer from Mabtech Limited and for payables to extend the license agreement. The Company is not obligated to extend the license agreement. Accordingly, the additional future milestone payments have not yet been accrued as of December 31, 2018.

Immunotherapy Research Collaboration Agreement with Roger Williams Medical Center

In April 2016, the Company entered into an immunotherapy research collaboration agreement with Roger Williams Medical Center to provide certain clinical trial, research and manufacturing services. Under the terms of the agreement, Roger Williams Medical Center will perform pre-clinical and clinical research related to the development and delivery of CAR-T immunotherapies. In exchange, the Company granted Roger Williams Medical Center $6.0 million in shares of TNK Class A Stock, subject to adjustment in certain circumstances, to be issued upon a financing resulting in gross proceeds (individually or in the aggregate) to TNK of at least $20.0 million. The Company determined the fair value of this obligation was $3.4 million as of the April 2016 agreement effective date, and the amount was recognized as prepaid expense and other and acquisition consideration payable in the consolidated balance sheet. The Company will recognize the upfront payment over the expected performance period of five years. During the twelve months ended December 31, 2018, 2017 and 2016 the Company recognized approximately $0.4 million, $0.7 million and $0.5 million in pre-clinical research and development expense pursuant to the agreement, respectively.

License Agreement with NantCell

In April 2015, the Company and NantCell entered into a license agreement. Under the terms of the agreement the Company granted an exclusive license to NantCell covering patent rights, know-how, and materials related to certain antibodies, ADCs and two CAR-TNK products. NantCell agreed to pay a royalty not to exceed five percent (5%) to the Company on any net sales of products (as defined) from the assets licensed by the Company to NantCell. In addition to the future royalties payable under this agreement, NantCell paid an upfront payment of $10.0 million to the Company and issued 10 million shares of NantCell common stock to the Company valued at $100.0 million based on a recent equity sale of NantCell common stock to a third party. As of December 31, 2018, the Company had not yet provided all of the items noted in the agreement, including research services for and on behalf of NantCell, and therefore has recorded the entire upfront payment and value of the equity interest received as deferred

revenue. Specifically, only a portion of the materials associated with the

licensed assets have been delivered while the majority of the licensed assets remain undelivered and the related research activities are still to be performed. The Company will recognize the upfront payment and the value of the equity interest received over the period beginning with the commencement of the last item delivered. The Company's ownership interest in NantCell does not provide the Company with control or the ability to exercise significant influence; therefore the $100.0 million investment is carried at cost in the consolidated balance sheets and evaluated for other-than-temporary impairment on a quarterly basis.

NIH Grants

In June 2014, the NIAID awarded the Company a Phase II Small Business Technology Transfer ("STTR") grant (the "Staph Grant III Award") to support the advanced preclinical development of human bispecific antibody therapeutics to prevent and treat Staphylococcus aureus ("S. aureus" or "Staph") infections, including methicillin-resistant S. aureus ("MRSA"). The project period for the Staph Grant III Award covered a two-year period which commenced in June 2014, which was subsequently extended by one year, with total funds available of approximately $1.0 million per year for up to two years. The Staph Grant III Award was not extended beyond June 30, 2017 and the remaining amounts for the award have been recorded as of December 31, 2017. The Company recorded $0 and $0.2 million of revenue associated with the Staph Grant III Award during the twelve months ended December 31, 2018 and 2017, respectively.

The Company recorded $0.4 million of revenue associated with other grants during the twelve months ended December 31, 2018.

12. Loan and Security Agreement and Convertible Notes

Loan and Security Agreement with Hercules Capital, Inc.

On November 23, 2016, the Company and certain of its domestic subsidiaries (together with the Company, the "Borrowers") entered into a Loan and Security Agreement (the "Hercules Loan Agreement") with Hercules Capital, Inc. ("Hercules"), as a lender and agent for several banks and other financial institutions or entities from time to time party to the Hercules Loan Agreement for a term loan of up to $75.0 million, subject to funding in multiple tranches (the "Term Loan"). The Term Loan would have matured on December 1, 2020. The proceeds of the Term Loan were used for general corporate purposes and coincided with the repayment of the outstanding debt financing arrangement with Oxford Finance LLC and Silicon Valley Bank.

The first tranche of $50.0 million was funded upon execution of the Hercules Loan Agreement on November 23, 2016. Pursuant to the terms of the third amendment to the Hercules Loan Agreement entered into on March 15, 2017, the Company paid Hercules $1.5 million for a portion of the backend fee. Pursuant to the terms of the fourth amendment to the Hercules Loan Agreement entered into on March 23, 2017 (the "Fourth Amendment"), the Company repaid Hercules, without repayment penalty, $20.0 million of the outstanding principal and unpaid interest accrued thereon on March 23, 2017. The Fourth Amendment also provided for the following: (1) Hercules reduced the minimum amount of unrestricted cash that the Company must maintain under the Hercules Loan Agreement, and (2) the parties agreed to change the date by which the Company must achieve a fundraising milestone.

Pursuant to the terms of the seventh amendment to the Hercules Loan Agreement entered into on November 6, 2017 (the "Seventh Amendment"), (i) the Company repaid Hercules, without repayment penalty, $10.0 million of the outstanding principal and unpaid interest accrued thereon on November 6, 2017, and (ii) Hercules agreed to reduce the minimum amount of unrestricted cash that the Company must maintain under the Hercules Loan Agreement from $20.0 million to $8.0 million.

On December 21, 2017, the Company paid off all obligations owing under, and terminated, the Hercules Loan Agreement. The secured interests under the Hercules Loan Agreement were terminated in connection with the Company's discharge of indebtedness thereunder.

In connection with the Hercules Loan Agreement, the Company issued Hercules a warrant, dated November 23, 2016 (the "Hercules Warrant"), to purchase up to 460,123 shares of Common Stock, at an initial exercise price of $4.89, subject to adjustment as provided in the Hercules Warrant. The Hercules Warrant is initially exercisable for 306,748 shares of common stock of the Company, and may automatically become exercisable for additional shares of common stock on such dates (if any) based upon the funding amounts of Tranche II or Tranche III of the Term Loan that may

be extended to the Borrowers. The Hercules Warrant will terminate, if not earlier exercised, on the earlier of November 23, 2023 and the closing of certain merger or other transactions in which the consideration is cash, stock of a publicly-traded acquirer or a combination thereof.

In connection with the extinguishment of the Hercules Loan Agreement on December 21, 2017, a loss of $4.3 million on the extinguishment of debt was recorded representing the difference between the reacquisition price of debt and the net carrying amount of the loan as of December 21, 2017.

2018 Chinese Yuan (“RMB”) Loan

In March 2018, the Company entered into a term loan in the aggregate principal amount of $1.6 million ("RMB10.0 million") with the Bank of China and the Agricultural Bank of China, which is guaranteed by Levena Suzhou Biopharma, Co. Ltd. This one year bank facility was used for working capital purposes. The proceeds from the loan agreement are reflected as financing activities in the consolidated statements of cash flows for the twelve months ended December 31, 2018. The outstanding balance is repayable from February 2018 to March 2019. The interest rate on this loan is 5%.

2016 Private Investment in Public Entity Financing

On April 3, 2016, the Company entered into a Securities Purchase Agreement (the “ABG Purchase Agreement”) with ABG SRNE Limited and Ally Bridge LB Healthcare Master Fund Limited (collectively, “Ally Bridge”), pursuant to which, among other things, the Company agreed to issue and sell to Ally Bridge and other purchasers that may be designated by Ally Bridge (collectively, the “ABG Purchasers”), in a private placement transaction (the “ABG Private Placement”), up to $50.0 million in shares of the Common Stock and warrants to purchase shares of Common Stock. Upon the closing of the ABG Private Placement, the Company issued to the ABG Purchasers (1) an aggregate of 9,009,005 shares (the “ABG Shares”) of Common Stock, and (2) warrants to purchase an aggregate of 2,702,700 shares of Common Stock (each, an “ABG Warrant”). Each ABG Warrant had an exercise price of $8.50 per share, was immediately exercisable upon issuance, had a term of three years and was exercisable on a cash or cashless exercise basis.

Under the terms of the ABG Purchase Agreement, the Company was obligated to prepare and file with the SEC, within 30 days of the closing date of the ABG Private Placement, a registration statement to register for resale the ABG Shares and the shares of Common Stock issuable upon exercise of each ABG Warrant (the “ABG Warrant Shares”), and may be required to effect certain registrations to register for resale the ABG Shares and the ABG Warrant Shares in connection with certain “piggy-back” registration rights granted to the ABG Purchasers.

On April 3, 2016, the Company also entered into a Securities Purchase Agreement (collectively, the “Additional Purchase Agreements”) with each of Beijing Shijilongxin Investment Co., Ltd. (“Beijing Shijilongxin”), FREJOY Investment Management Co., Ltd. (“Frejoy”) and Yuhan Corporation (“Yuhan”), pursuant to which, among other things, the Company agreed to issue and sell, in separate private placement transactions: (1) to Beijing Shijilongxin, 8,108,108 shares of Common Stock, and a warrant to purchase 1,176,471 shares of Common Stock, for an aggregate purchase price of $45.0 million; (2) to Frejoy, 8,108,108 shares of Common Stock, and a warrant to purchase 1,176,471 shares of Common Stock, for an aggregate purchase price of $45.0 million; and (3) to Yuhan, 1,801,802 shares of Common Stock, and a warrant to purchase 235,294 shares of Common Stock, for an aggregate purchase price of $10.0 million. The warrants to be issued pursuant to each of the Additional Purchase Agreements (collectively, the “Additional Warrants” and, together with each ABG Warrant, the “Warrants”) had an exercise price of $8.50 per share, were immediately exercisable upon issuance, had a term of three years and were exercisable on a cash or cashless exercise basis.

Under the terms of the Additional Purchase Agreements, each of Beijing Shijilongxin, Frejoy and Yuhan had the right to demand, at any time beginning six months after the closing of the transactions contemplated by the applicable Additional Purchase Agreement, that the Company prepare and file with the SEC a registration statement to register for resale such investor’s shares of Common Stock purchased pursuant to the applicable Additional Purchase Agreement and the shares of Common Stock issuable upon exercise of such investor’s Additional Warrant. In addition, the Company may be required to effect certain registrations to register for resale such shares in connection with certain “piggy-back” registration rights granted to Beijing Shijilongxin, Frejoy and Yuhan.

On May 2, 2016, the Company closed its private placement of common stock and warrants with Yuhan for gross proceeds of $10.0 million. Yuhan purchased 1,801,802 shares of common stock at $5.55 per share and a warrant to purchase 235,294 shares of common stock. The warrant was exercisable for three years at an exercise price of $8.50 per share.

Between May 31, 2016 and June 7, 2016, the Company closed on the remainder of the $150.0 million financing with the ABG Purchasers, Beijing Shijilongxin, and Frejoy. The ABG Purchasers led the financing and, together with Beijing Shijilongxin and Frejoy, collectively purchased 25,225,221 shares of common stock at $5.55 per share, and warrants to purchase 5,055,642 shares of common stock for total cash consideration of $86.5 million and secured promissory notes (the “2016 Notes”) in an aggregate principal amount of $53.5 million.

On December 31, 2016, the Company entered into Warrant and Note Cancellation and Share Forfeiture Agreements (the "Cancellation and Forfeiture Agreements") with certain investors (the "Investors") that held an aggregate of 7,838,259 shares of Common Stock and certain of the Warrants granting the right to purchase an aggregate of 1,137,316 shares of Common Stock. Pursuant to the Cancellation and Forfeiture Agreements, effective December 31, 2016, the Warrants held by the Investors and the 2016 Notes, of which $43.5 million was then outstanding, were cancelled and the shares of Common Stock held by the Investors were forfeited and returned to the Company.

2017 Securities Purchase Agreement in Private Placement

On December 11, 2017, the Company entered into a Securities Purchase Agreement (the "December 2017 Securities Purchase Agreement") with certain accredited investors (collectively, the "December 2017 Purchasers"). Pursuant to the December 2017 Securities Purchase Agreement, on December 21, 2017, the Company issued and sold to the December 2017 Purchasers, in a private placement transaction, (1) convertible promissory notes in an aggregate principal amount of $50,000,000 (the "December 2017 Notes"), which will accrue simple interest at a rate equal to 5.0% per annum and mature upon the earlier to occur of (a) December 21, 2022, and (b) the date of the closing of a change in control (the "December 2017 Maturity Date"), and (2) warrants (the "December 2017 Warrants") to purchase an aggregate of 12,121,210 shares of its common stock.

At any time and from time to time before the December 2017 Warrant Maturity Date, each December 2017 Purchaser had the option to convert any portion of the outstanding principal amount of such December 2017 Purchaser's December 2017 Note that was equal to or greater than the lesser of: (1) $4,000,000, and (2) the then-outstanding principal amount of such December 2017 Purchaser's December 2017 Note into shares of common stock at a price per share of $2.26875, subject to adjustment for stock splits, reverse stock splits, stock dividends and similar transactions. Accrued but unpaid interest on the December 2017 Notes was to be paid in cash semi-annually in arrears on or prior to the 30th day of June and 31st day of December of each calendar year commencing with the year ending December 31, 2018.

Each December 2017 Warrant has an exercise price of $2.61 per share, subject to adjustment for stock splits, reverse stock splits, stock dividends and similar transactions, became exercisable on June 20, 2018, has a term of five and a half years and is exercisable on a cash basis, unless there is not an effective registration statement covering the resale of the shares issuable upon exercise of the December 2017 Warrants, in which case the December 2017 Warrants shall also be exercisable on a cashless exercise basis.

The fair value of the Notes was estimated using a valuation model with Level 2 inputs including the stock price volatility, risk-free interest rate, and debt yield. As of December 31, 2017, the estimated fair value of the Notes was approximately $89.5 million, compared to the carrying value of $5.2 million.

On May 17, 2018, the December 2017 Purchasers converted in full the outstanding principal and accrued interest under the December 2017 Notes into 22,038,565 shares of the Company's common stock, and the Company paid to the December 2017 Purchasers cash in an aggregate amount of $1.0 million in accrued but unpaid interest. The unamortized discount remaining at the date of conversion of $44.3 million was recognized immediately at that date as interest expense.

See Note 3 for discussion of the Company's policies for accounting for debt with detachable warrants. In connection with the issuance of the December 2017 Notes and December 2017 Warrants, the Company recorded a debt discount of approximately $44.8 million based on an allocation of proceeds to the December 2017 Warrants of approximately $12.7 million and a beneficial conversion feature of approximately $32.1 million, before issuance costs.

Borrowings under the December 2017 Notes consisted of the following (in thousands):

Principal amount	$50,000
Debt discount - warrant	(12,669)
Debt discount - beneficial conversion feature	(32,062)
Capitalized debt issuance costs	(84)
Accretion of debt issuance costs and other	—
Accretion of debt discount	26
Balance at December 31, 2017	$5,211

2018 Securities Purchase Agreement in Private Placement and Amendment to Warrants

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On March 26, 2018, the Company entered into a Securities Purchase Agreement (the "March 2018 Securities Purchase Agreement") with certain accredited investors (the "March 2018 Purchasers"). Pursuant the March 2018 Securities Purchase Agreement, the Company agreed to issue and sell to the March 2018 Purchasers, in a Private Placement (the "March 2018 Private Placement"), (1) convertible promissory notes in an aggregate principal amount of $120,500,000 (the "Notes"), and (2) warrants to purchase 8,591,794 shares of the common stock of the Company (the "Warrants"). On June 13, 2018, the Company entered into an amendment (the "June 2018 Amendment") to the March 2018 Securities Purchase Agreement. Under the terms of the June 2018 Amendment, the Company and the March 2018 Purchasers agreed that the aggregate principal amount of the Notes was reduced to $37,848,750 and that the aggregate number of shares of Common Stock issuable upon exercise of the Warrants was reduced to 2,698,662, and also agreed to certain other adjustments to the threshold principal amount of the Notes required to remain outstanding in order for certain rights and obligations to apply to the Notes.

On June 13, 2018, pursuant to the March 2018 Securities Purchase Agreement, as amended by the June 2018 Amendment, the Company issued and sold to the March 2018 Purchasers, in the March 2018 Private Placement (1) Notes in an aggregate principal amount of $37,848,750, and (2) Warrants to purchase an aggregate of 2,698,662 shares of Common Stock. The Notes accrue interest at a rate equal to 5.0% per annum and mature upon the earlier to occur of June 13, 2023 and the date of the closing of a change of control (the "Maturity Date"). At any time and from time to time before the Maturity Date, each March 2018 Purchaser shall have the option to convert any portion of the outstanding principal amount of such March 2018 Purchaser's Note that is equal to or greater than the lesser of: (1) $4,000,000, and (2) the then-outstanding principal amount of such March 2018 Purchaser's Note into shares of common stock at a price per share of $7.0125, subject to adjustment for stock splits, reverse stock splits, stock dividends and similar transactions. Accrued but unpaid interest on the Notes shall be paid in cash semi-annually in arrears on or prior to the 30th day of June and 31st day of December of each calendar year commencing with December 31, 2018. Each Warrant has an exercise price of $3.28 per share, subject to adjustment for stock splits, reverse stock splits, stock dividends and similar transactions, became exercisable on December 11, 2018, has a term of five and a half years from the date of issuance and will be exercisable on a cash basis, unless there is not an effective registration statement covering the resale of the shares issuable upon exercise of the Warrants, in which case the Warrants shall also be exercisable on a cashless exercise basis. See Note 3 for discussion of the Company's policies for accounting for debt with detachable warrants. In connection with the issuance of the Notes and the Warrants, the Company recorded a debt discount of approximately $21.6 million based on an allocation of proceeds to the Warrants of approximately $9.6 million and a beneficial conversion feature of approximately $12.0 million, before issuance costs. The Company accounts for the debt at amortized cost and amortizes the debt discount to interest expense using the effective interest method over the expected term of the Notes. The fair value of the Notes was estimated using a lattice model with Level 3 inputs including the historical stock price volatility, risk-free interest rate, and debt yield.

On November 7, 2018, the Company entered into an Agreement and Consent (the "Agreement and Consent") with the March 2018 Purchasers. Pursuant to the Agreement and Consent, in consideration for certain of the March 2018 Purchasers, in their capacity as holders of the Notes, providing a waiver and consent on behalf of all holders of the Notes, pursuant to which the March 2018 Purchasers provided the Company with certain waivers of their rights and certain of the Company's covenants under the Securities Purchase Agreement, as amended by Amendment No. 1 thereto, with respect to the Loan Agreement (as defined below) and the transactions contemplated thereby, the Company and the March 2018 Purchasers agreed to amend the Warrants to reduce the exercise price per share of its common stock thereunder from $8.77 to $3.28. The amendment of the Warrants resulted in a loss on debt extinguishment of $1.9 million representing the incremental fair value of the modified Warrants along with the difference between the fair value and carrying value of the Notes at the modification date of November 7, 2018.

The Company determined that the amendment of the Warrants resulted in an extinguishment at the modification date. As a result, the Company recorded a loss on debt extinguishment for the difference between the fair value of $23.1 million and the carrying value of $17.0 million, or $6.1 million. The Company recorded the loss as of the date of modification, or November 7, 2018. As of December 31, 2018, the estimated fair value of the Notes was approximately $15.8 million, compared to the carrying value of $23.6 million.

Borrowings under the Notes consisted of the following (in thousands):

Face value of loan	$37,849
Unamortized debt discount	(14,804)
Accretion of debt discount	515
Balance at December 31, 2018	$23,560

Interest expense recognized on the Notes for the year ended December 31, 2018 totaled $1.0 million for the stated interest. Debt discount and debt issuance costs, which are presented as a direct reduction of the Notes in the consolidated balance sheets, are amortized as interest expense using the effective interest method. The amount of debt discount and debt issuance costs included in interest expense for the year ended December 31, 2018 was approximately $0.5 million.

2018 Purchase Agreements and Indenture for Scilex

On September 7, 2018, Scilex entered into Purchase Agreements (the "2018 Purchase Agreements") with certain investors (collectively, the "Scilex Note Purchasers") and the Company. Pursuant to the 2018 Purchase Agreements, on September 7, 2018, Scilex, among other things, issued and sold to the Scilex Note Purchasers senior secured notes due 2026 in an aggregate principal amount of $224,000,000 (the "Scilex Notes") for an aggregate purchase price of $140,000,000 (the "Offering"). In connection with the Offering, Scilex also entered into the Indenture governing the Scilex Notes with the Trustee and Collateral Agent, and the Company. Pursuant to the Indenture, the Company agreed to the Guarantee.

The net proceeds of the Offering were approximately $89.3 million, after deducting the Offering expenses payable by Scilex and funding the Reserve Account and the Collateral Account pursuant to the terms of the Indenture. The net proceeds of the Offering will be used by Scilex to support the commercialization of ZTlido® (lidocaine topical system 1.8%), for working capital and general corporate purposes in respect of the commercialization of ZTlido® (lidocaine topical system 1.8%). Funds in the Reserve Account will be released to Scilex upon receipt by the Trustee of an officer’s certificate under the Indenture from Scilex confirming receipt of the Marketing Approval Letter on or prior to July 1, 2023. Funds in the Collateral Account will be released upon receipt of a written consent authorizing such release from the holders of a majority in principal amount of the Scilex Notes issued, upon the occurrence and during the continuance of an event of default at the direction of the holders of a majority in principal amount of the Scilex Notes issued or upon the repayment in full of all amounts owed under the Scilex Notes.

The holders of the Scilex Notes will be entitled to receive quarterly payments of principal of the Scilex Notes equal to a percentage, in the range of 10% to 20% of the net sales of ZTlido® (lidocaine topical system 1.8%) for the prior fiscal quarter, beginning on February 15, 2019. If Scilex has not received the Marketing Approval Letter by March 31, 2021, the percentage of net sales payable shall be increased to be in the range of 15% to 25%. If actual cumulative net sales of ZTlido® (lidocaine topical system 1.8%) from October 1, 2022 through September 30, 2023 are less than 60% of a predetermined target sales threshold for such period, then Scilex will be obligated to pay an additional installment of principal of the Scilex Notes each quarter in an amount equal to an amount to be determined by reference to the amount of such deficiency.

The aggregate principal amount due under the Scilex Notes shall be increased by $28,000,000 on February 15, 2022 if actual cumulative net sales of ZTlido® (lidocaine topical system 1.8%) from the issue date of the Scilex Notes through December 31, 2021 do not equal or exceed 95% of a predetermined target sales threshold for such period. If actual cumulative net sales of ZTlido® (lidocaine topical system 1.8%) for the period from October 1, 2022 through September 30, 2023 do not equal or exceed 80% of a predetermined target sales threshold for such period, the aggregate principal amount shall also be increased on November 15, 2023 by an amount equal to an amount to be determined by reference to the amount of such deficiency.

The final maturity date of the Scilex Notes will be August 15, 2026. The Scilex Notes may be redeemed in whole at any time upon 30 days’ written notice at Scilex’s option prior to August 15, 2026 at a redemption price equal to 100% of the then-outstanding principal amount of the Scilex Notes. In addition, upon a change of control of Scilex (as defined in the Indenture), each holder of a Scilex Note shall have the right to require Scilex to repurchase all or any part of such holder’s Scilex Note at a repurchase price in cash equal to 101% of the then-outstanding principal amount

thereof.

The 2018 Purchase Agreements include the terms and conditions of the offer and sale of the Scilex Notes, representations and warranties of the parties, indemnification and contribution obligations and other terms and conditions customary in agreements of this type.

The Indenture governing the Scilex Notes contains customary events of default with respect to the Scilex Notes (including a failure to make any payment of principal on the Scilex Notes when due and payable), and, upon certain events of default occurring and continuing, the Trustee by notice to Scilex, or the holders of at least 25% in principal amount of the outstanding Scilex Notes by notice to Scilex and the Trustee, may (subject to the provisions of the Indenture) declare 100% of the then-outstanding principal amount of the Scilex Notes to be due and payable. Upon such a declaration of acceleration, such principal will be due and payable immediately. In the case of certain events, including bankruptcy, insolvency or reorganization involving the Company or Scilex, the Scilex Notes will automatically become due and payable.

Pursuant to the Indenture, the Company and Scilex must also comply with certain covenants with respect to the commercialization of ZTlido® (lidocaine topical system 1.8%), as well as customary additional affirmative covenants, such as furnishing financial statements to the holders of the Scilex Notes, minimum cash requirements and net sales reports; and negative covenants, including limitations on the following: the incurrence of debt; the payment of dividends, the repurchase of shares and under certain conditions making certain other restricted payments; the prepayment, redemption or repurchase of subordinated debt; a merger, amalgamation or consolidation involving Scilex; engaging in certain transactions with affiliates; and the making of investments other than those permitted by the Indenture.

The Scilex Notes and related Guarantee have not been, and will not be, registered under the Securities Act of 1933, as amended, or the securities laws of any other jurisdiction and may not be offered or sold in the United States without registration or an applicable exemption from registration requirements. The holders of the Scilex Notes do not have any registration rights.
Pursuant to a Collateral Agreement by and among Scilex, the Trustee and the Collateral Agent (the “Collateral Agreement”), the Scilex Notes will be secured by ZTlido® (lidocaine topical system 1.8%) and all of the existing and future property and assets of Scilex necessary for, or otherwise relevant to, now or in the future, the manufacture and sale of ZTlido® (lidocaine topical system 1.8%), on a worldwide basis (exclusive of Japan), including, but not limited to, the intellectual property related to ZTlido® (lidocaine topical system 1.8%), the marketing or similar regulatory approvals related to ZTlido® (lidocaine topical system 1.8%), any licenses, agreements and other contracts related to ZTlido® (lidocaine topical system 1.8%), and the current assets related to ZTlido® (lidocaine topical system 1.8%) such as inventory, accounts receivable and cash and any and all future iterations, improvements or modifications of such product made, developed or licensed (or sub-licensed) by Scilex or any of its affiliates or licensees (or sub-licensees) (including ZTlido® (lidocaine topical system 5.4%)).

Pursuant to the terms of the Indenture, the Company issued an irrevocable standby letter of credit to Scilex (the “Letter of Credit”), which provides that, in the event that (1) Scilex does not hold at least $35,000,000 in unrestricted cash as of the end of any calendar month during the term of the Scilex Notes, (2) actual cumulative net sales of ZTlido® (lidocaine topical system 1.8%) from the issue date of the Scilex Notes through December 31, 2021 are less than a specified sales threshold for such period, or (3) actual cumulative net sales of ZTlido® (lidocaine topical system 1.8%) for any calendar year during the term of the Scilex Notes, beginning with the 2022 calendar year, are less than a specified sales threshold for such calendar year, Scilex, as beneficiary of the Letter of Credit, will draw, and the Company will pay to Scilex, $35,000,000 in a single lump-sum amount as a subordinated loan. The Letter of Credit will terminate upon the earliest to occur of: (a) the repayment of the Scilex Notes in full, (b) the actual net sales of ZTlido® (lidocaine topical system 1.8%) for any calendar year during the term of the Scilex Notes exceeding a certain threshold, (c) the consummation of an initial public offering on a major international stock exchange by Scilex that satisfies certain valuation thresholds, and (d) the replacement of the Letter of Credit with another letter of credit in form and substance, including as to the identity and creditworthiness of issuer, reasonably acceptable to the holders of at least 80% in principal amount of outstanding Scilex Notes. The Company performed a level 3 based assessment for certain of these contingent features related to the Letter of Credit, which, included significant judgment and assumptions related to the likelihood of the aforementioned terms being achieved. Based on its assessment, it was concluded that the estimated fair value of these embedded features were not material as of December 31, 2018. As of December 31, 2018, the estimated fair value of the Notes was approximately $122.8 million compared to the carrying value of $141.1 million. The Company uses the discounted cash flow method under the income approach, which involves significant level 3 inputs and assumptions, combined with a Monte Carlo simulation, as appropriate. The value of the debt instrument is based on the present value of future interest and principal payments, discounted a rate of return reflective the Company's credit risk.

Borrowings of the Notes consisted of the following (in thousands):

Face value of loan	$224,000
Unamortized debt discount	(84,000)
Capitalized debt issuance costs	(5,748)
Accretion of debt discount	6,376
Accretion of debt issuance cost	435
Balance at December 31, 2018	$141,063

Future minimum payments under the Notes, based on a percentage of projected net sales of ZTlido® (lidocaine topical system 1.8%) are as follows (in thousands):

Year Ending December 31,	
2019	$8,696
2020	30,010
2021	52,474
2022	99,153
2023	33,667
Total future minimum payments	224,000
Unamortized debt discount	(77,624)
Unamortized capitalized debt issuance costs	(5,313)
Total minimum payment	141,063
Current portion	(8,696)
Long-term portion of Scilex Notes	$132,367

Debt discount and debt issuance costs, which are presented as a direct reduction of the Scilex Notes in the consolidated balance sheets, are amortized as interest expense using the effective interest method. As principal repayments on the Scilex Notes are based on a percentage of net sales of ZTlido® (lidocaine topical system 1.8% and lidocaine topical system 5.4%, if a Marketing Approval Letter is received), the Company has elected to account for changes in estimated cash flows from future net sales prospectively. Specifically, a new effective interest rate will be determined based on revised estimates of remaining cash flows and changes in expected cash flows will be recognized prospectively. The amount of debt discount and debt issuance costs included in interest expense for the fiscal year ended December 31, 2018 was approximately $6.8 million.

The Company identified a number of embedded derivatives that require bifurcation from the Scilex Notes and separate accounting as a single compound derivative. However, as the current fair value attributed to the bifurcated compound derivative is immaterial, The Company has not recorded this derivative within its consolidated financial statements. The Company re-evaluates this assessment each reporting period.

2018 Oaktree Term Loan Agreement

On November 7, 2018, the Company and certain of its domestic subsidiaries (the “Guarantors”) entered into a Term Loan Agreement (the “Loan Agreement”) with certain funds and accounts managed by Oaktree Capital Management, L.P. (collectively, the “Lenders”) and Oaktree Fund Administration, LLC, as administrative and collateral agent, for an initial term loan of $100.0 million (the “Initial Loan”) and a second tranche of $50.0 million, subject to the achievement of certain commercial and financial milestones between August 7, 2019 and November 7, 2019, and the satisfaction of certain customary conditions (the “Conditional Loan”). The Initial Loan matures on November 7, 2023 (the “Maturity Date”) and bears interest at a rate equal to the London Interbank Offered Rate ("LIBOR") plus the applicable margin, or 7%. The Initial Loan was funded on November 7, 2018. The net proceeds of the Initial Loan were approximately $91.3 million, after deducting estimated loan costs, commissions, fees and expenses, and will be used for general corporate purposes. In connection with the Loan Agreement, on November 7, 2018, the Company issued to the

Lenders warrants to purchase 6,288,985 shares of the Company's common stock (the "Initial Warrants"). The Initial Warrants have an exercise price per share of $3.28, subject to adjustment for stock splits, reverse stock splits, stock dividends and similar transactions, will be exercisable from May 7, 2019 through May 7, 2029 and will be exercisable on a cash basis, unless there is not an effective registration statement covering the resale of the shares issuable upon exercise of the Initial Warrants (the "Initial Warrant Shares"), in which case the Initial Warrants shall also be exercisable on a cashless exercise basis. In connection with the Loan Agreement, on November 7, 2018, the Company and

the Lenders entered into a Registration Rights Agreement (the "Registration Rights Agreement") pursuant to which, among other things, the Company agreed to file one or more registration statements with the Securities and Exchange Commission (the "SEC") for the purpose of registering for resale the Initial Warrant Shares and the shares of common stock issuable upon exercise of warrants that may be issued in connection with the Conditional Loan (the "Conditional Warrants"). Under the Registration Rights Agreement, the Company agreed to file a registration statement with the SEC registering all of the Initial Warrant Shares and the shares of common stock issuable upon exercise of the Conditional Warrants for resale by no later than the 45th day following the issuance of the Initial Warrants and the Conditional Warrants, respectively.

As of December 31, 2018, the estimated fair value of the Initial Loan was approximately $64.0 million compared to the carrying value of $67.2 million.

Borrowings under the Initial Loan consisted of the following (in thousands):

Face value of loan	$100,000
Debt discount - warrant	(26,659)
Capitalized debt issuance costs	(6,658)
Accretion of debt discount and issuance costs	526
Balance at December 31, 2018	$67,209

Interest expense recognized on the Initial Loan for the year ended December 31, 2018 totaled $1.4 million for the stated interest. Debt discount and debt issuance costs, which are presented as a direct reduction of the Loan Agreement in the consolidated balance sheets, are amortized as interest expense using the effective interest method. The amount of debt discount and debt issuance costs included in interest expense for the year ended December 31, 2018 was approximately $0.5 million.

The Company performed a level 3 based assessment and identified a number of embedded derivatives that require bifurcation from the Initial Loan and separate accounting as a single compound derivative. Certain of these embedded features include default interest due to non-credit-related events of default, mandatory prepayment upon a change of control, mandatory prepayment upon an asset disposition, mandatory prepayment upon non-permitted debt issuance, indemnified taxes, increased costs upon a change in law and automatic acceleration upon a non-bankruptcy event of default. As the current fair value attributed to the bifurcated compound derivative is immaterial, the Company has not recorded this derivative within its consolidated financial statements. The Company will re-evaluate this assessment each reporting period.

2018 Short-term Bridge Loan

On September 10, 2018, the Company entered into a Short-term Bridge Loan Agreement ("Bridge Loan) in which the Company received proceeds of approximately $19.6 million, net of approximately $0.3 million of commitment fees to facilitate the timing of a cash payment. Interest on the Bridge Loan was 8.5 percent annually and the maturity date is November 12, 2018. The Bridge Loan was paid in full as of December 31, 2018.

13. Stockholders' Equity

2009 Non-Employee Director Grants

In September 2009, prior to the adoption of the 2009 Stock Incentive Plan (the "2009 Plan"), the Company's board of directors approved the reservation and issuance of 8,000 nonstatutory stock options to the Company's non-employee directors. The outstanding options vested on the one year anniversary of the vesting commencement date in October 2010, and are exercisable for up to 10 years from the grant date. No further shares may be granted under this plan and, as of December 31, 2018, 3,200 options with a weighted-average exercise price of $1.12 were outstanding.

2009 Stock Incentive Plan

In October 2009, the Company's stockholders approved the 2009 Stock Incentive Plan. In August 2018, the Company's stockholders approved, among other items, the amendment and restatement of the 2009 Stock Incentive Plan (as amended and restated, the "Stock Plan") to increase the number of shares of the Company's common stock authorized to be issued pursuant to the Stock Plan to 18,860,000. Such shares of the Company's common stock are reserved for issuance to employees, non-employee directors and consultants of the Company. The Stock Plan provides for the grant of incentive stock options, non-incentive stock options, stock appreciation rights, restricted stock awards, unrestricted stock awards, restricted stock unit awards and performance awards to eligible recipients. Recipients of stock options shall be eligible to purchase shares of the

Company's common stock at an exercise price equal to no less than the estimated fair market value of such stock on the date of grant. The maximum term of options granted under the Stock Plan is ten years. Employee option grants generally vest 25% on the first anniversary of the original vesting commencement date, with the balance vesting monthly over the remaining three years. The vesting schedules for grants to non-employee directors and consultants will be determined by the Company's Compensation Committee. Stock options are generally not exercisable prior to the applicable vesting date, unless otherwise accelerated under the terms of the applicable stock plan agreement.
The following table summarizes stock option activity as of December 31, 2018, 2017 and 2016, and the changes for the years then ended (in thousands, except for share amounts):

	Options Outstanding	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2017	6,343,400	$ 4.74	$ 6,290
Options Granted	4,737,800	$ 5.23	
Options Canceled	(500,435)	$ 5.84	
Options Exercised	(57,690)	$ 3.69	
Outstanding at December 31, 2018	10,523,075	$ 4.91	$ 1,723

The aggregate intrinsic value of options exercised during the years ended December 31, 2018, 2017 and 2016 were $133 thousand, $0 thousand and $194 thousand, respectively. The Company uses the Black-Scholes valuation model to calculate the fair value of stock options. The fair value of employee stock options was estimated at the grant date using the following assumptions:

	Years Ended December 31,		
	2018	2017	2016
Weighted-average grant date fair value	$3.65	$1.28	$5.86
Dividend yield	—	—	—
Volatility	81 %	81 %	75 %
Risk-free interest rate	2.87 %	1.92 %	1.49 %
Expected life of options	6.1 years	6.1 years	6.1 years

The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. Due to the Company's limited historical data, the estimated volatility incorporates the historical and implied volatility of comparable companies whose share prices are publicly available. The risk-free interest rate assumption was based on the U.S. Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The weighted average expected life of options was estimated using the average of the contractual term and the weighted average vesting term of the options.
The total employee and director stock-based compensation recorded as operating expenses was $5,139 thousand, $4,423 thousand and $4,354 thousand for the years ended December 31, 2018, 2017 and 2016, respectively.
The total unrecognized compensation cost related to unvested employee and director stock option grants as of December 31, 2018 was $16,857 thousand and the weighted average period over which these grants are expected to vest is 3.0 years.
The Company records equity instruments issued to non-employees as expense at their fair value over the related service period as determined in accordance with the authoritative guidance and periodically revalues the equity instruments as they vest. Stock-based compensation expense related to non-employee consultants recorded as operating expenses was $1,055 thousand, $228 thousand, and $198 thousand for the years ended December 31, 2018, 2017 and 2016, respectively.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following at December 31, 2018:

Common stock warrants outstanding under the loan and security agreement	6,354,877
Common stock warrants outstanding under the Hercules securities agreement	306,748
Common stock warrants outstanding under the convertible notes	14,819,872
Common stock warrants outstanding under private placements	4,153,620
Common stock options outstanding under the Non-Employee Director Plan	3,200
Authorized for future grant or issuance under the 2009 Stock Incentive Plan	18,324,406
Shares issuable upon the conversion of the 2018 Notes	5,397,325
Issuable under assignment agreement based upon achievement of certain milestones	80,000
	49,440,048

2017 Stock Option Plan

In June 2017, the Company's subsidiary, Scilex, adopted the Scilex 2017 Stock Option Plan, reserved 4.0 million shares of Scilex common stock and awarded 1.0 million options to certain Company personnel, directors and consultants under such plan. Stock options granted under this plan typically vest 1/4th of the shares on the first anniversary of the vesting commencement date and 1/48th of the remaining options vest each month thereafter. As of December 31, 2018, 1.6 million shares were canceled. As of December 31, 2018, 0.7 million options were outstanding.

2015 Stock Option Plans

In May 2015, the Company's subsidiary, TNK, adopted the TNK 2015 Stock Option Plan and reserved 10.0 million shares of TNK class A common stock and awarded 3.6 million options to certain Company personnel, directors and consultants under such plan. In November 2015, TNK awarded 0.5 million options to certain Company personnel. Stock options granted under this plan typically vest a portion immediately upon grant and the remaining options over two to four years or monthly over four years from the grant date and have a contractual term of ten years. As of December 31, 2018, 2.1 million shares were canceled. As of December 31, 2018, 0.9 million options were outstanding.

In May 2015, TNK granted a warrant to the Company's CEO to purchase 9.5 million shares of TNK class B common stock which have 10 to 1 voting rights. Warrant shares totaling 4.0 million are exercisable evenly over forty months and the remaining warrant shares are exercisable if certain defined events occur within four years from date of issuance at an initial exercise price of $0.01 per share. This warrant was canceled in its entirety effective August 29, 2017.

In May 2015, the Company's subsidiary, LA Cell, adopted the LA Cell 2015 Stock Option Plan and reserved 10.0 million shares of LA Cell class A common stock and awarded 2.9 million options to certain Company personnel, directors and consultants under such plan. Stock options granted under this plan typically vest a portion immediately upon grant and the remaining options over two to four years or monthly over four years from the grant date and have a contractual term of ten years. As of December 31, 2018, 1.7 million shares were canceled. As of December 31, 2018, 0.3 million options were outstanding.

In May 2015, LA Cell granted a warrant to the Company's CEO to purchase 9.5 million shares of LA Cell class B common stock which have 10 to 1 voting rights. Warrant shares totaling 4.0 million are exercisable evenly over forty months and the remaining warrant shares are exercisable if certain defined events occur within four years from date of issuance at an initial exercise price of $0.01 per share. This warrant was canceled in its entirety effective August 29, 2017.

In October 2015, the Company's subsidiary, Concortis Biosystems, Corp., ("CBC"), adopted the CBC 2015 Stock Option Plan and reserved 10.0 million shares of CBC class A common stock and awarded 1.8 million options to certain Company personnel, directors and consultants under such plan. Stock options granted under this plan typically vest a portion immediately upon grant and the remaining options over two to four years or monthly over four years from the grant date and have a contractual term of ten years. As of December 31, 2018, 1.7 million shares were canceled. As of December 31, 2018, no options were outstanding.

In October 2015, CBC granted a warrant to the Company's CEO to purchase 9.5 million shares of CBC class B common stock which have 10 to 1 voting rights. Warrant shares totaling 4.0 million are exercisable evenly over forty

months and the remaining warrant shares are exercisable if certain defined events occur within four years from date of issuance at an initial exercise price of $0.25 per share. This warrant was canceled in its entirety effective August 29, 2017.

In October 2015, the Company's subsidiary, Scintilla, adopted the Scintilla 2015 Stock Option Plan and reserved 10.0 million shares of Scintilla class A common stock and awarded 2.1 million options to certain Company personnel, directors and consultants under such plan. Stock options granted under this plan typically vest a portion immediately upon grant and the remaining options over two to four years or monthly over four years from the grant date and have a contractual term of ten years. As of December 31, 2018, 0.9 million shares were canceled. As of December 31, 2018, no options were outstanding.

In October 2015, Scintilla granted a warrant to the Company's CEO to purchase 9.5 million shares of Scintilla class B common stock which have 10 to 1 voting rights. Warrant shares totaling 4.0 million are exercisable evenly over forty months and the remaining warrant shares are exercisable if certain defined events occur within four years from date of issuance at an initial exercise price of $0.01 per share. This warrant was canceled in its entirety effective August 29, 2017.

In October 2015, the Company's subsidiary, Sorrento Biologics, Inc. ("Biologics"), adopted the Biologics 2015 Stock Option Plan and reserved 10.0 million shares of Biologics class A common stock and awarded 2.6 million options to certain Company personnel, directors and consultants under such plan. Stock options granted under this plan typically vest a portion immediately upon grant and the remaining options over two to four years or monthly over four years from the grant date and have a contractual term of ten years. As of December 31, 2018, 1.4 million shares were canceled. As of December 31, 2018, no options were outstanding.

In October 2015, Biologics granted a warrant to the Company's CEO to purchase 9.5 million shares of Biologics class B common stock which have 10 to 1 voting rights. Warrant shares totaling 4.0 million are exercisable evenly over forty months and the remaining warrant shares are exercisable if certain defined events occur within four years from date of issuance at an initial exercise price of $0.01 per share. This warrant was canceled in its entirety effective August 29, 2017.

On August 29, 2017, the options and warrants were canceled in accordance with the terms of a settlement agreement and, as a result, unrecognized compensation expense of $281 thousand associated with these previously issued shares was accelerated and recognized upon cancellation.

The total director stock-based compensation recorded as operating expenses by the Company for TNK, LA Cell, CBC, Scintilla and Biologics for the year ended December 31, 2017 and 2016 was $0 and $166 thousand, respectively. Total unrecognized stock-based compensation expense related to unvested director stock option and warrant grants for these entities as of December 31, 2017 was $0, and the weighted-average period over which these grants are expected to vest is approximately 3.5 years. The Company records equity instruments issued to non-employees as expense at their fair value over the related service period as determined in accordance with the authoritative guidance and periodically revalues the equity instruments as they vest. Stock based compensation expense related to non-employee consultants recorded as operating expenses by the Company for TNK, LA Cell, CBC, Scintilla and Biologics for the year ended December 31, 2018 and 2017 was $655 thousand and $156 thousand, respectively.

The weighted-average assumptions used in the Black-Scholes option and warrant pricing model used by TNK, LA Cell, CBC, Scintilla and Biologics to determine the fair value of stock option grants for directors and non-employee consultants were as follows: expected dividend yield – 0%, risk-free interest rate – 1.39% to 2.24%, expected volatility – 76% to 77%, and expected term of 4.0 to 6.1 years.

2014 Stock Option Plan

In May 2014, the Company's subsidiary, Ark Animal Health, Inc. ("Ark"), adopted the Ark 2014 Stock Option Plan and reserved and awarded 600,000 options to certain directors and consultants under such plan. Stock options granted under such plan typically vest a portion immediately upon grant and the remaining options over one year from the grant date and have a contractual term of ten years. Effective August 29, 2017, options to purchase an aggregate of 135,000 shares were canceled. As of December 31, 2018, 88,000 options were outstanding.

There were no operating expenses recorded for total director and consultant stock-based compensation by the Company for Ark for each of the years ended December 31, 2018 and 2017. No unrecognized stock-based compensation expense remains related to stock option grants as of December 31, 2018.

14. Derivative Liability

On October 13, 2015, the Company wrote a call option to Cambridge, on up to 2.0 million shares of NantKwest common stock held by the Company (the “Option Agreement”). As of December 31, 2015, the Company held approximately

5.6 million shares of common stock of NantKwest, par value $0.0001 per share, which was classified as available-for-sale and reported in its consolidated financial statements as marketable securities. The Option Agreement gave Cambridge the right to purchase up to 2.0 million shares at a price of $15.295 per share from time to time in the first quarter of 2016. There was no contractual option premium associated with this Option Agreement. The Option Agreement was a derivative as defined in ASC Topic 815 and was recognized at fair value every reporting period the Option Agreement is in effect, with changes in fair value recognized in current operations. For the year ended December 31, 2015, the Company recorded a loss of $3.4 million on the derivative liability.

The call option expired unexercised on March 31, 2016 and the Company recorded a gain of $5.5 million upon the cancellation of the derivative liability.

As of December 31, 2018, no derivative liability was recorded on the Company’s consolidated balance sheets.

15. Commitments and Contingencies

Litigation

In the normal course of business, the Company may be named as a defendant in one or more lawsuits. The Company is not a party to any outstanding material litigation and management is currently not aware of any legal proceedings that, individually or in the aggregate, are deemed to be material to the Company’s financial condition or results of operations.

Immunomedics Litigation

On June 26, 2015, Immunomedics, Inc. (“Immunomedics”) filed a complaint in the United States District Court for the District of New Jersey (the “New Jersey Case”) against the Board of Directors of RWMC, Dr. Richard P. Junghans, Dr. Steven C. Katz, the Office of the Board of Advisors of Tufts University School of Medicine, and one or more individuals or entities to be identified later. This complaint (the "Initial Complaint") alleged, among other things: (1) breach of contract; (2) breach of covenant of good faith and fair dealing; (3) tortious interference with prospective economic gain; (4) tortious interference with contracts; (5) misappropriation; (6) conversion; (7) bailment; (8) negligence; (9) vicarious liability; and (10) patent infringement. Overall, the allegations in the Initial Complaint were generally directed to an alleged material transfer agreement dated December 2008 and Immunomedics’ alleged request for the return of certain alleged research material, as well as the alleged improper use and conversion of such research materials outside the scope of the material transfer agreement.

On October 22, 2015, Immunomedics filed an amended complaint (the “First Amended Complaint”), which, among other things, no longer named the Board of Directors of RWMC and The Office of the Board of Advisors of Tufts University School of Medicine as defendants. RWMC and Tufts Medical Center were added as new defendants. On January 14, 2016, Immunomedics filed a second amended complaint (the "Second Amended Complaint"), which, among other things, no longer named Tufts Medical Center as a defendant. In addition, the Second Amended Complaint contained allegations directed to two additional alleged material transfer agreements dated September 1993 and May 2010, respectively, and also added an allegation of unjust enrichment. The Second Amended Complaint also no longer asserted claims for (1) breach of covenant of good faith and fair dealing; (2) misappropriation; (3) bailment; (4) negligence; and (5) vicarious liability.

On October 12, 2016, Immunomedics filed a third amended complaint (the “Third Amended Complaint”), which added the Company, TNK, BDL and CARgenix as defendants. TNK is a subsidiary of the Company and purchased BDL and CARgenix in August 2015. The Third Amended Complaint included, among other things, allegations against the Company, TNK, BDL and CARgenix regarding (1) conversion; (2) tortious interference; and (3) unjust enrichment. On December 2, 2016, the Company, TNK, BDL, and CARgenix filed a motion to dismiss Immunomedics’ complaint against them for lack of personal jurisdiction. On January 25, 2017, the District of New Jersey granted this motion, and the Company, TNK, BDL and CARgenix were dismissed as defendants from the New Jersey Case. Under various agreements, TNK has certain indemnification obligations to RWMC, Dr. Richard P. Junghans and Dr. Steven C. Katz that may be implicated by the New Jersey Case.

On April 27, 2018, Immunomedics filed a Complaint against the Company and TNK in San Diego Superior Court, Case No. 37-2018-00021006-CU-NP-CTL (the "San Diego Case"). The Complaint includes, among other things, allegations against the Company and TNK regarding (1) conversion; (2) tortious interference; and (3) inducing breach of contract.

On October 25, 2018, the parties to the New Jersey Case and the San Diego Case entered into a Mutual General Release and Settlement Agreement resolving both matters. Pursuant to the terms of the settlement, among other things, both the New

Jersey Case and San Diego Case were dismissed with prejudice upon payment by Sorrento to Immunomedics of $2.35 million, which payment was timely made as called for by the agreement.

Cantor Fitzgerald & Co. Litigation

On May 25, 2018, Cantor Fitzgerald & Co. ("CF&Co.") filed a Complaint against the Company in the Supreme Court of the State of New York, County of New York, Index No. 652633/2018. The Complaint included, among other things, allegations against the Company for breach of contract arising out of a letter agreement whereby CF&Co. was to supply certain services to the Company in exchange for a fee (the "CF & Co. Litigation"). The Company filed an Answer and Counterclaim for breach of contract against CF&Co claiming that CF&Co. did not perform under the letter agreement.

Following a mediation held on December 19, 2018, the parties entered into a settlement agreement resolving the matter. Pursuant to the terms of the agreement, the litigation was dismissed with prejudice upon payment by Sorrento to CF&Co. of $1 million, which payment was timely made as called for by the agreement.

Operating Leases

The Company currently has leases in San Diego, California of approximately 130,584 square feet of corporate office and laboratory space, approximately 1,405 square feet of laboratory and office space at a second location as well as approximately 36,400 square feet for offices and cGMP fill and finish and storage space. In November 2018, the Company entered into a new lease in San Diego, California for approximately 61,200 square feet of additional corporate office and laboratory space. Operations for the new lease are expected to begin in the first quarter of 2019 and the lease expires in October 2029. In December 2018, the Company entered into a new lease in Broomfield, Colorado, for approximately 4,500 square feet of additional office space, which is expected to commence in the second quarter of 2019 and expires in 2024.

The Company's lease agreements in San Diego, as amended, for its corporate office and laboratory space expire in October 2029. Its second laboratory and office space and its cGMP fill and finish and storage space expire in September 2020 and November 2022, respectively. The Company also leases 25,381 square feet of office and laboratory space in Suzhou, China, which lease expires in June 30, 2021. The Company leases 2,312 square feet of office, laboratory, and storage space in Scotland, which lease expires in March 2021. The Company subleases in New York, New York for approximately 4,550 square feet of additional corporate office space. The sublease began in July of 2017 and expires in December 2020. The Company leases approximately 3,432 square feet of office and laboratory space in Atlanta, Georgia which began in October of 2018 and expires in September 2024.

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

2019	$6,396
2020	8,733
2021	8,011
2022	7,959
2023	8,186
Thereafter	52,425
	$91,710

Rent expense for operating leases totaled approximately $6.1 million, $3.2 million and $2.1 million, for the years ended December 31, 2018, December 31, 2017 and December 31, 2016, respectively.

16. Income Taxes

The components of the provision expense (benefit) were as follows for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	2018	2017	2016
Current:			
Federal	$(178)	$(366)	$(1,785)
State	23	14	(600)
Foreign	(44)	30	—
	(199)	(322)	(2,385)
Deferred:			
Federal	(3,499)	(33,178)	3,554
State	(2,421)	(2,538)	(2,065)
Foreign	(155)	—	—
	(6,075)	(35,716)	1,489
Totals	$(6,274)	$(36,038)	$(896)

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

The components of the Company's net deferred tax liabilities and related valuation allowance are as follows as of December 31, 2018 and 2017 (in thousands):

	2018	2017
Deferred tax assets:		
Amortization of intangibles	$27,075	$21,862
Deferred revenue	25,448	34,754
Tax credit carryforwards	13,720	10,160
Net operating loss carryforwards	43,542	21,172
Stock based compensation	1,786	1,743
Accrued expenses and other	14,037	1,877
Total deferred tax assets	125,608	91,568
Less valuation allowance	(74,970)	(43,405)
Total deferred tax assets	50,638	48,163
Deferred tax liabilities:		
Amortization of intangibles	(12,739)	(15,225)
Depreciation	(543)	(757)
Investment in common stock	(46,772)	(47,716)
Total deferred tax liabilities	(60,054)	(63,698)
Net deferred tax assets / liabilities	$(9,416)	$(15,535)

The reconciliation between U.S. federal income taxes at the statutory rate and the Company’s provision for income taxes are as follows for the years ended December 31 (in thousands):

	2018	2017
Income tax expense (benefit) at federal statutory rate	$(46,011)	$(8,725)
State, net of federal tax benefit	(3,075)	(834)
Other permanent differences	2,814	1,290
Debt discount	11,357	—
Incentive stock compensation	1,001	1,025
Transaction costs	102	408
Other	123	715
Return to provision adjustment	(8)	(42)
Acquired in-process research and development	677	71
Change in Federal rate	—	10,006
Change in State rate	(453)	810
Research tax credits	(4,664)	(4,051)
Uncertain tax positions	879	1,027
Prior year true-ups and carrybacks	(889)	(1,095)
Stock compensation true-up	308	1,788
Change in valuation allowance	31,565	(38,431)
Income tax provision	$(6,274)	$(36,038)

The Company has evaluated the available evidence supporting the realization of its gross deferred tax assets, including the amount and timing of future taxable income, and has determined that it is more likely than not that the deferred tax assets will not be realized. Due to such uncertainties surrounding the realization of the domestic deferred tax assets, the Company maintains a valuation allowance of $75.0 million against its deferred tax assets as of December 31, 2018. Realization of the deferred tax assets will be primarily dependent upon the Company's ability to generate sufficient taxable income prior to the expiration of its net operating losses.

As of December 31, 2018, the Company had net operating loss carryforwards of approximately $169.7 million and $77.1 million for federal and state income tax purposes, respectively. These may be used to offset future taxable income and will begin to expire in varying amounts in 2029 to 2038, except for a portion of the federal net operating loss that have an indefinite carryforward period. The Company also has research and development and orphan drug credits of approximately $12.2 million and $6.1 million for federal and state income taxes purposes, respectively. The federal credits may be used to offset future tax and will begin to expire in varying amounts in 2029 to 2038. The state credits may be used to offset future tax, such credits carryforward indefinitely.

Internal Revenue Code Section 382 rules apply to limit a corporation's ability to utilize existing net operating loss and tax credit carryforwards once the corporation experiences an ownership change as defined in Section 382. The Company has undergone an ownership change in a prior year. For the year ended December 31, 2018, there was no impact of such limitations on the income tax provision. Due to the existence of the valuation allowance, it is not expected that any possible limitation will have an impact on the results of operations or financial position of the Company.

The Company is subject to taxation in the U.S., various state tax jurisdictions and various foreign tax jurisdictions. The Company's tax years starting in December 31, 2007 through December 31, 2018 are open and subject to examination by the U.S. and state taxing authorities due to the carryforward of utilized net operating losses and research and development credits.

During 2018 the Company was notified by the Franchise Tax Board that its California income tax return for the 2015 and 2016 calendar year was selected for examination. The Company has responded to information requested.

The Company adopted the provisions of ASC Topic 740 regarding uncertain tax positions on January 1, 2009. Under ASC Topic 740, the impact of an uncertain income tax position taken on a tax return must be recognized at the largest amount that is cumulatively “more likely than not” to be sustained upon audit by relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained.

A reconciliation of the beginning and ending amount of unrecognized tax expense (benefits) is as follows (in thousands):

	Amount
Unrecognized tax benefits balance at December 31, 2017	$3,883
Increase related to current year tax positions	916
Increase related to prior year tax positions	150
Decrease related to prior year tax positions	(597)
Unrecognized tax benefits balance at December 31, 2018	$4,352

The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. No interest has been recognized as of and for the period ended December 31, 2018.

The Company believes that no material amount of the liabilities for uncertain tax positions will expire within 12 months of December 31, 2018.

U.S. Tax Reform

On December 22, 2017, the U.S. government enacted comprehensive tax legislation referred to as the Tax Cuts and Jobs Act (the "Tax Act''), which significantly revises the Internal Revenue Code of 1986, as amended. The Tax Act contains, among other things, significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21% for tax years beginning after December 31, 2017, limitations on the deduction for net operating losses to 80% of current year taxable income, indefinite carryover period for net operating losses and limitations on the deductibility of interest to 30% of adjusted taxable income.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118"), which allowed the Company to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. As of December 22, 2018, the Company's accounting for the Tax Act was complete and there were no material changes to the provisional amounts previously recorded.

17. Related Party Agreements and Other

During the year ended December 31, 2015, the Company entered into a joint venture called Immunotherapy NANTibody, LLC, with NantCell, a subsidiary of NantWorks. In July 2015, the Company contributed its portion of the initial joint funding of $40.0 million to the NANTibody joint venture. The Company and NantCell have also entered into a license agreement pursuant to which the Company received a $10.0 million upfront license payment and $100.0 million of vested NantCell common stock.

During the year ended December 31, 2015, the Company entered into a joint venture called NantCancerStemCell, LLC, with NantBioScience, a wholly-owned subsidiary of NantWorks. In connection with negotiated changes to the structure of NantStem the Company issued a call option on shares of NantKwest that it owned to Cambridge, a related party to the Company and to NantBioScience. In April 2015, the Company purchased 1.0 million shares of NantBioScience common stock for $10.0 million.

In March 2016, the Company and Yuhan entered into an agreement to form a joint venture company called ImmuneOncia Therapeutics, LLC, to develop and commercialize a number of immune checkpoint antibodies against undisclosed targets for both hematological malignancies and solid tumors. As of December 31, 2018, the carrying value of the Company's investment in ImmuneOncia Therapeutics, LLC was approximately $2.7 million. During the three months ended June 30, 2016, Yuhan purchased $10.0 million of Common Stock and warrants.

On August 15, 2017, the transactions contemplated by that certain Contribution Agreement, dated June 12, 2017, by and among the Company, TNK and Celularity Inc. ("Celularity"), pursuant to which, among other things, the Company and TNK agreed to contribute certain intellectual property rights related to their proprietary chimeric antigen receptor constructs and related CARs to Celularity in exchange for shares of Celularity's Series A Preferred Stock equal to 25% of Celularity's outstanding shares of capital stock, calculated on a fully-diluted basis closed. Dr. Henry Ji, the Company's Chairman of the Board, President and Chief Executive Officer, Jaisim Shah, a member of the Company's

Board of Directors and David Deming, a member of the Company's Board of Directors, were previously appointed as members of the board of directors of Celularity.

On November 8, 2016, the Company entered into the Scilex Purchase Agreement, pursuant to which the Company acquired from the Scilex Stockholders approximately 72% of the outstanding capital stock of Scilex. Dr. Henry Ji, the Company's President and Chief Executive Officer and a member of the Company's Board of Directors, and George K. Ng, the Company's Vice President, Chief Administrative Officer and Chief Legal Officer, were stockholders of Scilex prior to the acquisition transaction.

The remainder of the outstanding capital stock of Scilex represents a noncontrolling interest of which approximately 19.3% continues to be held by ITOCHU CHEMICAL FRONTIER Corporation following the Scilex acquisition. Scilex has entered into a product development agreement with ITOCHU CHEMICAL FRONTIER Corporation which serves as the sole manufacturer and supplier to Scilex for the ZTlido® product.

18. 401(k) Plan

The Company maintains a defined contribution 401(k) plan available to eligible employees. Employee contributions are voluntary and are determined on an individual basis, limited to the maximum amount allowable under federal tax regulations. The Company made matching contributions to the 401(k) plan totaling $898 thousand, $658 thousand and $424 thousand, for the years ended December 31, 2018, 2017 and 2016, respectively.

19. Quarterly Financial Data (Unaudited)

The following table sets forth selected quarterly data for the years presented, in thousands, except per share data.

2018	Quarter Ended December 31,	Quarter Ended September 30,	Quarter Ended June 30,	Quarter Ended March 31,	Year Ended December 31,
Revenues	$6,929	$4,105	$3,913	$6,246	$21,193
Operating costs and expenses	$48,530	$52,012	$32,284	$38,792	$171,618
Net loss attributable to Sorrento	$(49,774)	$(47,328)	$(73,864)	$(32,574)	$(203,540)
Net loss per share - basic	$(0.41)	$(0.40)	$(0.73)	$(0.38)	$(1.92)
Net loss per share - diluted	$(0.41)	$(0.40)	$(0.73)	$(0.38)	$(1.92)
Weighted-average shares - basic	121,552	117,021	100,563	84,941	106,150
Weighted-average shares - diluted	121,552	117,021	100,563	84,941	106,150

2017	Quarter Ended December 31, (1)	Quarter Ended September 30,	Quarter Ended June 30,	Quarter Ended March 31,	Year Ended December 31,
Revenues	$20,407	$121,910 [1]	$4,665	$4,874	$151,856
Operating costs and expenses	$55,205	$24,993	$18,123	$28,200	$126,521
Net income (loss) attributable to Sorrento	$48,444	$(2,061)	$(14,187)	$(23,064)	$9,132
Net income (loss) per share - basic	$0.60	$(0.03)	$(0.20)	$(0.45)	$0.13
Net income (loss) per share - diluted	$0.58	$(0.03)	$(0.20)	$(0.45)	$0.13
Weighted-average shares - basic	80,486	76,887	70,302	50,886	69,742
Weighted-average shares - diluted	82,996	76,888	70,302	50,886	70,381

(1) Quarter-over-quarter increase primarily due to revenue recognized from the intangibles transferred to Celularity as a result of closing the Contribution Agreement in 2017.

20. Earnings Per Share

For the years ended December 31, 2018, 2017, and 2016, basic earnings per share of common stock is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period. Diluted earnings per share of common stock is calculated to give effect to all dilutive securities, using the treasury stock method.

The following table sets forth the reconciliation of basic and diluted earnings per share for the years ended December 31, 2018, 2017 and 2016 (in thousands, except per share):

	Years Ended December 31,		
	2018	2017	2016
Net Income (Loss)	$(203,540)	$9,132	$(60,923)
Net Income Adjusted for Tax-Effected Interest on Convertible Notes	—	(71)	—
Adjusted Net Income	(203,540)	9,061	(60,923)
Denominator for Basic Earnings Per Share	106,150	69,742	50,360
Effect of Dilutive Securities:			
Stock Options	—	8	—
Convertible Notes	—	604	—
Convertible Notes - Warrants	—	27	—
Denominator for Diluted Earnings per Share – Adjusted for Dilutive Securities	106,150	70,381	50,360
Dilutive Earnings Per Share	$(1.92)	$0.13	$(1.21)

The potentially dilutive stock options that would have been excluded because the effect would have been antidilutive for years ended December 31, 2018, 2017, and 2016 were 10.5 million, 6.3 million, and 4.3 million, respectively. The potentially dilutive warrants that would have been excluded because the effect would have been antidilutive for years ended December 31, 2018, 2017, and 2016 were 25.6 million, 4.7 million, and 7.7 million, respectively. Basic and diluted per share amounts are computed independently in the consolidated statements of income. Therefore, the sum of per share components may not equal the per share amounts presented.

21. Subsequent Events

Scilex Non-binding Term Sheet for ZTlido® in Europe

Scilex Pharmaceuticals Inc. (“Scilex”), a subsidiary of Sorrento Therapeutics, Inc., recently executed a non-binding term sheet for the rights to ZTlido® (lidocaine medicated plaster 1.8%) in certain European countries with a major European pharmaceutical company. After discussions with such potential partner, Scilex also intends to withdraw its Marketing Authorization Application (“MAA”) for ZTlido® for the treatment of pain associated with post-herpetic neuralgia (PHN), and notified the Medicines and Healthcare Products Regulatory Agency in the United Kingdom (the application's Reference Member State) on January 23, 2019 of such intent. Scilex submitted its MAA in November 2017 through a hybrid regulatory pathway via the Decentralized Procedure. Scilex plans to resubmit the MAA in collaboration with such partner in the near future.