

**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, 2021

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

(State or Other Jurisdiction of
Incorporation or Organization)

**4955 Directors Place
San Diego, California**

(Address of Principal Executive Offices)

33-0344842

(I.R.S. Employer
Identification No.)

92121

(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
Common Stock, par value \$0.0001 per share

Trading Symbol (s)
SRNE

Name of exchange on which registered
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 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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

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, 2021 (the last trading day of the registrant's second fiscal quarter of 2021), as reported on the Nasdaq Capital Market, was approximately \$2.8 billion.

At February 28, 2022, the registrant had 342,335,102 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

SORRENTO THERAPEUTICS, INC.
ANNUAL REPORT ON FORM 10-K
FISCAL YEAR ENDED DECEMBER 31, 2021

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this “Form 10-K”) contains “forward-looking statements” that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially and adversely from those expressed or implied by such forward-looking statements. The forward-looking statements are contained principally in Item 1—“Business,” Item 1.A—“Risk Factors” and Item 7—“Management’s Discussion and Analysis of Financial Condition and Results of Operations” but appear throughout the Form 10-K. Examples of forward-looking statements include, but are not limited to our expectations, beliefs or intentions regarding our potential product offerings, business, financial condition, results of operations, strategies or prospects and other matters that do not relate strictly to historical facts or statements of assumptions underlying any of the foregoing. These statements are often identified by the use of words such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “ongoing,” “opportunity,” “plan,” “potential,” “predicts,” “seek,” “should,” “will,” or “would,” and similar expressions and variations or negatives of these words. These forward-looking statements are based on the expectations, estimates, projections, beliefs and assumptions of our management based on information currently available to management, all of which are subject to change. Such forward-looking statements are subject to risks, uncertainties and other factors that are difficult to predict and could cause our actual results and the timing of certain events to differ materially and adversely from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed under Item 1.A—“Risk Factors” in this Annual Report on Form 10-K. Furthermore, such forward-looking statements speak only as of the date of this Annual Report on 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 biopharmaceutical company focused on delivering innovative and clinically meaningful therapies to address unmet medical needs.

At our core, we are antibody-centric 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, CD47, BCMA, CTLA-4, CD123, CD47, LAG3, ROR1, VEGFR2, CCR2 and CD137 and SARS-CoV-2 neutralizing antibodies, among others. We also have programs assessing the use of our technologies and products in autoimmune, inflammatory, viral and neurodegenerative diseases.

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”), lymphatic drug targeting (SOFUSA®), as well as bispecific antibody approaches. We acquired SOFUSA, a revolutionary drug delivery technology, in July 2018, which delivers biologics directly into the lymphatic system to potentially achieve improved efficacy and reduce adverse effects compared to standard parenteral immunotherapy. Additionally, our majority-owned subsidiary, Scilex Holding Company (“Scilex Holding”), acquired the assets of Semnur Pharmaceuticals, Inc. (“Semnur”) in March 2019. Semnur’s SEMDEXA™ (“SP-102”) compound has the potential to become the first U.S. Food and Drug Administration (“FDA”)–approved epidural steroid product for the treatment of sciatica. In response to the global SARS-CoV-2 (“COVID-19”) pandemic, we are utilizing the Bruton’s tyrosine kinase (“BTK”) inhibitor (Abivertinib, acquired from ACEA Therapeutics, Inc.) to treat the cytokine storm associated with a COVID-19 infection. We are also internally developing and conducting clinical studies for potential coronavirus antiviral therapies and vaccines, including COVI-MSC™, COVI-AMG™, COVIDROPS™, and COVISHIELD™, and diagnostic test solutions, such as COVI-STIX™ and COVITRACK™.

With each of our clinical and preclinical programs, we aim to tailor our therapies to treat specific stages in the evolution of a disease, from elimination to equilibrium and escape. In addition, our objective in our immuno-oncology programs 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, oncolytic viruses (Seprehvec™) and a palliative care program targeted to treat intractable pain in advanced cancer (resiniferatoxin, or “RTX”). Our cellular therapy programs focus on our allogeneic DAR-T platform for adoptive cellular immunotherapy to treat both solid and liquid tumors.

From the start of the COVID-19 pandemic, our mission has been to leverage our deep expertise in developing targeted antibodies for cancer immunotherapy to create best-in-category treatments and diagnostics to ease suffering and assist in the global response to COVID-19. We have leveraged, and continue to leverage, our G-MAB library and antibody development engineering capabilities to advance promising diagnostics and neutralizing antibody candidates to test for and treat COVID-19 and the immune reactions associated with SARS-CoV-2 infection.

STI-2020, or pluvavimab, is a highly potent neutralizing antibody (“nAb”) to COVID-19 that is currently being developed for intranasal (“IN”) instillation as STI-2099, or COVIDROPS. In preclinical studies, STI-2020/2099 was highly effective against the original Washington strain and early variants of concern (“VoCs”), including the delta VoC. STI-2020, the intravenous (“IV”) formulation and COVIDROPS were both cleared by the FDA for Phase I healthy volunteer studies which were completed and demonstrated that the nAbs were well-tolerated (IV up to 200 mg and intranasal up to 60 mg) without dose limiting toxicity or severe or serious adverse events (“AEs”). Most AEs were mild and unrelated. Phase II studies of COVIDROPS in outpatients with COVID-19 have begun enrollment in Mexico, the United Kingdom and the U.S. The United Kingdom study reached the planned interim analysis threshold in the first half of January 2022. The study in Mexico began pediatric enrollment in early 2022. We are also developing a broad-spectrum neutralizing antibody, STI-9167 (COVISHIELD), to be formulated both for IV and IN administration. STI-9167 (IV formulation) and STI-9199 (IN formulation using STI-9167 drug substance) have not only been broadly effective in preclinical studies for prior VoCs but are highly potent against the Omicron VoC. A healthy subject study for STI-9167/9199 is expected to begin in the first quarter of 2022 with Phase II studies of COVISHIELD to follow.

We have also developed two promising potential rescue treatments with Abivertinib (STI-5656), an oral next generation dual epidermal growth factor receptor (“EGFR”) (including mutant forms)/BTK inhibitor, or epidermal growth factor receptor/BTK inhibitor, to treat hospitalized COVID-19 patients and COVI-MSC™ (samtonadstrocel or STI-8282), human allogeneic adipose-derived mesenchymal stromal cells for patients suffering from COVID-19-induced acute respiratory distress (“ARD”). Both have been

cleared by the FDA and Abivertinib has completed Phase II clinical studies in the U.S. and Brazil of Abivertinib to treat COVID-19-induced acute respiratory distress syndrome (“ARDS”). While all patient groups improved with treatment, the U.S. study identified an At-Risk population who were the best responders: those who required oxygen supplementation with non-invasive ventilation or high flow oxygen at baseline. Although the Brazil study did not enroll a population as sick as those in the U.S. study, the results were similarly supportive. In the U.S. study, the At-Risk patients were discharged on average two days sooner from the intensive care unit. In both studies, there was nearly a 50% reduction of death and/or mechanical ventilation or extracorporeal membrane oxygenation by day 29. This data was used to power a pivotal Phase III Abivertinib study which is expected to begin enrollment in the second quarter of 2022. Two separate Phase II COVI-MSC studies are currently enrolling in Brazil and the U.S. in patients with COVID-19-induced ARDS. We are also working with Brazilian regulators (ANVISA) to conduct a COVID-19 study with COVI-MSCs in pulmonary long-haul patients post-recovery from the acute infection.

In furtherance of our goal to enable early detection and treatment across the entire continuum of COVID-19 solutions, we are further developing a number of highly sensitive and rapid diagnostic tests. COVISTIX™ is a lateral flow antigen test that uses a proprietary platinum-based colloid and antibody combination, resulting in high sensitivity and accuracy. This is a simple and rapid (15-minute) test with a shallow nasal swab and is designed for point-of-care and at-home use. This product has been approved under emergency use authorization for use in Mexico and Brazil as a point-of-care test and has also received its Conformité Européenne (“CE”) mark.

We previously have reported early data from Phase I trials of our carcinoembryonic antigen (“CEA”)-directed CAR-T program. We treated five patients with stage 4, unresectable adenocarcinoma (four with pancreatic cancer and one with colorectal cancer) and CEA-positive liver metastases with anti-CEA CAR-T. During 2021, we decided to pivot away from an autologous CAR-T platform to allogeneic DAR-T and successfully submitted an Investigational New Drug application (“IND”) for our CD38 DAR-T candidate for relapsed or refractory multiple myeloma (“RRMM”). We anticipate the first patient enrollment in the first quarter of 2022.

With respect to Abivertinib for the treatment of non-small cell lung cancer (NSCLC), our oral small molecule combined EGFR/BTK inhibitor, a final imaging read of Phase III data is pending with additional follow-up from patients who continued on treatment in the years since the last update presented at the American Society of Clinical Oncology (ASCO) 2019 Annual Meeting. It is anticipated that a pre-new drug application (“NDA”) meeting will be requested to discuss the pathway to a planned NDA filing. Finally, we intend to start studies in castrate resistant prostate cancer with Abivertinib in the U.S. in the first quarter of 2022 and in Brazil in the second quarter of 2022.

With respect to our anti-CD38 ADC program, we began enrolling patients in the first quarter of 2021 in a Phase Ib ascending dose study for systemic Amyloid light-chain (“AL”) amyloidosis. We intend to start a new study to target RRMM in a partnership with Columbia University in the first quarter of 2022 and are planning collaborations with Columbia to target metastatic esophageal and lung cancer and with MD Anderson to treat T-cell acute lymphoblastic leukemia (“T-ALL”).

Additionally, based upon our exclusive licensing arrangement with Mayo Clinic for its antibody-drug-nanoparticle albumin-bound (“ADNAB™”) platform, the next generation in ADC technology, we intend to file several INDs in 2022 to treat various cancer targets. We also have an ongoing partnership with Mayo Clinic, directed to the use of lymphatic delivery using a hollow core microneedle array device manufactured by our SOFUSA unit, to explore whether lymphatic delivery of products traditionally delivered by IV administration can improve the pharmacokinetic profile and efficacy while reducing their AE profile. We also have an active program using the SOFUSA delivery system to treat rheumatoid arthritis patients resistant to etanercept and expect to announce preliminary results from an ongoing study in the first quarter of 2022.

Broadly speaking, we believe we are among the world’s leading cellular therapy 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 DAR-T solutions. DAR-T therapy can become a versatile drug product platform capable of delivering multiple targeted therapeutic approaches.

Outside of immuno-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 RTX, a non-opioid naturally-occurring product that specifically targets transient receptor potential vanilloid-1 (“TRPV1”). Depending on the site of injection, RTX can ablate or destroy targeted nerves (e.g., an epidural injection) or temporarily defunctionalize them (peripheral injections such as intra-articular). TRPV1 largely is responsible for the noxious chronic and inflammatory pain signaling that can occur post trauma but leaves other nerve functions intact. RTX has been granted orphan drug status for the treatment of intractable pain with end-stage or advanced cancer and two Phase Ib first-in-human trials (intrathecal and epidural routes) were completed. A Phase Ib trial studying the safety and efficacy of RTX to treat moderate to severe osteoarthritis (“OA”) knee pain was completed in early 2021 with one year follow-up data and preliminary results showed the potential for long-term efficacy with no dose-limiting toxicity. We have received clearance to proceed with Phase II clinical trials of RTX to treat severe cancer pain (epidural) and moderate-to-severe OA of the knee

pain (intra-articular). The knee OA study began enrolling in the fourth quarter of 2021 and the epidural cancer pain study is expected to start enrolling in the first quarter of 2022.

Also, in this area, we have developed in-house and acquired proprietary technologies to responsibly develop next generation, branded pharmaceutical products to better manage patients' medical conditions, maximize the quality of life of patients and assist healthcare providers. The flagship product of our subsidiary, Scilex Pharmaceuticals Inc., ("Scilex Pharma"), ZTlido® (lidocaine topical system 1.8%) ("ZTlido") 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 October 2018. Scilex Pharma has now built a full commercial organization, which includes sales, marketing, market access and medical affairs.

Recent Developments

Positive Top-Line Results for Phase III SP-102 Pivotal Trial

In December 2021, Scilex Holding Company announced highly statistically significant positive top-line results from its Phase III SP-102 (SEMDEXA™) Pivotal Trial C.L.E.A.R Program for its novel, non-opioid, corticosteroid formulation, injectable dexamethasone sodium phosphate viscous gel product for the treatment of lumbosacral radicular pain (sciatica). SP-102 (SEMDEXA™) has received Fast Track status from the FDA.

Enrollment was completed in the second half of 2021. The Pivotal Phase III trial has met the primary efficacy and key secondary efficacy endpoints with highly statistical significance:

- For the primary endpoint of change in average daily pain (as measured by the Numeric Pain Rating Scale) in the affected leg over 4 weeks following the initial injection the LS Mean (SE) group difference of -1.08 (0.17) compared to placebo with a p-value <0.001.
- The two key secondary endpoints assessing Oswestry Disability Index (ODI) and Time to open-label repeat injection have also demonstrated highly statistically significant results for SP-102. The LS Mean (SE) group difference in ODI compared to placebo at week 4 was -6.28 (1.49) with a p-value <0.001. A Cox proportional hazard model showed significantly longer duration of initial SP-102 (SEMDEXA™) treatment compared to placebo Hazard Ratio (95% CI) 0.49 (0.36, 0.65), with a p-value <0.001.

Virex Acquisition

On February 1, 2022, we completed the acquisition of Virex Health, Inc. ("Virex") pursuant to that certain Agreement and Plan of Merger (the "Virex Merger Agreement"), dated as of January 14, 2022, among us, Virex, VH Merger Sub I, Inc., our wholly owned subsidiary ("Merger Sub"), VH Merger Sub II, LLC, our wholly owned subsidiary ("Merger LLC"), and Fortis Advisors LLC, as representative of the equityholders of Virex (the "Stockholders' Representative"). Pursuant to the terms of the Merger Agreement, Merger Sub was merged with and into Virex (the "Initial Merger"), with Virex continuing as the surviving corporation in such merger, and subsequent to the Initial Merger, Virex was merged with and into Merger LLC (the "Subsequent Merger"), with Merger LLC surviving as our wholly owned subsidiary. At the effective time of the Subsequent Merger, the name of Merger LLC as the surviving company in the Subsequent Merger was changed to Virex Health, LLC.

Upon completion of the Initial Merger, the equityholders of Virex (the "Virex Equityholders") became entitled to receive the following amounts (to be paid in cash and stock as further described below): (i) \$12,000,000, as such amount was adjusted to \$11,566,275 (and may be further adjusted post-closing) pursuant to the terms of the Virex Merger Agreement for indebtedness, transaction expenses and cash (the "Closing Consideration") and (ii) subject to achievement of certain regulatory milestones, up to \$10,000,000 in additional consideration (the "Milestone Payment" and together with the Closing Consideration, the "Merger Consideration").

Pursuant to the Merger Agreement, the Merger Consideration shall be paid as follows: (i) 59% in cash; and (ii) 41% in shares of our common stock. Upon completion of the Initial Merger, the Virex Equityholders became entitled to receive an aggregate of \$6,824,126 in cash and an aggregate of 1,281,662 shares of our common stock based on a price per share equal to \$3.70 (representing the volume weighted average closing price per share of our common stock for the eleven consecutive trading days ending on the date that was three trading days prior to the closing date). Ten percent of the Closing Consideration was deposited into an escrow account (in the form of cash and stock) as partial security for the indemnification obligations of the Virex Equityholders under the Merger Agreement and \$150,000 was set aside for expenses that may be incurred by the Stockholders' Representative.

At any time shares of our common stock are issued in respect of a Milestone Payment, the number of shares to be issued will be based on a price per share equal to the volume weighted average closing price per share of our common stock for the eleven

consecutive trading days ending on the date that is three trading days prior to the applicable issuance date. The aggregate number of shares of our common stock issuable pursuant to the Virex Merger Agreement as Merger Consideration shall not exceed 19.99% of the total number of shares of our common stock issued and outstanding at the closing date.

Our Strategy

Our primary goal is to leverage our fully human antibody development expertise to address significant unmet medical needs that can significantly improve a patient's quality of life. In the face of the ongoing COVID-19 pandemic, we marshalled our resources to generate antibody-based treatments and diagnostic initiatives for COVID-19 in addition to acquiring other treatment assets to treat the entire spectrum of COVID-19 infections, from outpatients with mild infections, to hospitalized patients with moderate or severe infections. Despite the COVID-19 pandemic, we continue to make progress in our oncology programs and programs for refractory chronic pain conditions, such as intractable pain due to advanced cancer or knee osteoarthritis.

Our core strategic objectives and resources are:

1. Using a deliberate process to optimize our lead product candidates to fill identified unmet needs and advance them rapidly into the clinic for initiation of Phase I studies. Once demonstrated to be safe and efficacious, we plan to continue to drive through later phase (II and III) studies toward a NDA filing. Early in this process, we evaluate each program for potential accelerated approval or breakthrough therapy designation to fast-track development.
2. Collaborating with key opinion leaders and leading clinical and research institutes to enhance our clinical development plans and achieve our goals. We currently have such agreements in place with the Mayo Clinic, Karolinska Institute, The Scripps Research Institute, The Icahn School of Medicine at Mount Sinai, the National Institutes of Health ("NIH") and Tufts Medical School, among others.
3. Having active programs that utilize our antibodies for DAR-T, our antibody-drug conjugate platform (using our covalent linker technology), ADNAB platform, and our SOFUSA[®] DoseConnect[™] lymphatic delivery device to treat various oncology indications. Additionally, we have active programs to treat the spectrum of COVID-19 infections with our highly potent neutralizing antibodies ("nAbs") to treat outpatients with mild COVID-19 symptoms (IV COVI-AMG and intranasal COVIDROPS[™]) and hospitalized patients with moderate respiratory compromise (Abivertinib) or with severe ARDS (COVI-MSC). We are also developing a broad-spectrum neutralizing antibody, STI-9167 (IV) / STI-9199 (IN) (COVISHIELD), to treat outpatients with mild symptoms and for post-exposure prophylaxis. Finally, we continue to progress RTX, an ultrapotent TRPV-1 agonist, into Phase III for the treatment of intractable pain in advanced cancer and moderate-to-severe knee osteoarthritis. Our subsidiary, Scilex Holding, is working towards an NDA submission for SP-102 (SEMDEXA) in the treatment of lumbar radiculopathy.
4. Continuing, through our preclinical programs, to generate development candidates with exciting potential to meet unmet needs. We anticipate generating data to support more than a dozen new INDs in 2022. These include moving our checkpoint inhibitors from our core antibody portfolio into the clinic with our strategic key opinion leaders and institutional partners. We will continue to develop our fully human monoclonal antibody ("mAb") portfolio for new ADCs and bispecific mAbs. In addition, we expect to commence several clinical trials with our SOFUSA device to explore the safety and efficacy features of this innovative drug delivery technology.
5. Manufacturing our preclinical and clinical trial materials to support Phase I and II trial manufacturing needs in-house. We have established quality control and quality assurance programs to ensure that our products are produced under current good manufacturing practices ("cGMPs"), and other applicable domestic and foreign regulations.
6. Continuing 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

Effective January 1, 2019, we realigned our business into two new operating and reportable segments, Sorrento Therapeutics and Scilex.

Sorrento Therapeutics. The Sorrento Therapeutics segment is organized around our Immune-Oncology therapeutic area, leveraging our proprietary G-MAB[™] antibody library and targeted delivery modalities to generate the next generation of cancer therapeutics. These modalities include proprietary CAR-T, DAR-T, ADCs as well as bispecific antibody approaches. Additionally, this segment also includes Abivertinib, an oral next generation dual EGFR/BTK inhibitor, SOFUSA, a drug delivery technology that delivers biologics directly into the lymphatic system to potentially achieve improved efficacy and fewer adverse effects than standard parenteral immunotherapy, and RTX, which is a non-opioid-based neurotoxin currently in clinical trials for late stage cancer pain and

moderate to severe osteoarthritis of the knee pain. This segment further includes the full suite of COVID-19 treatments, diagnostics and vaccines under development, including COVIDROPS, COVISHIELD, COVI-MSC, COVISTIX and COVITRACK.

Scilex. The Scilex segment is largely organized around our non-opioid pain management operations and clinical pipeline. Revenues from the Scilex segment are exclusively derived from the sale of ZTlido.

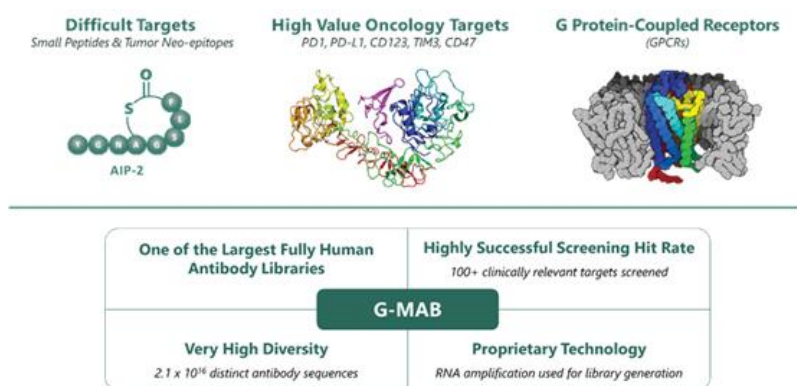
Clinical Programs

G-MAB™: Fully Human Antibody Library Platform

Our G-MAB library (“G-MAB”), 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 therapeutics 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 (PD-L1, CD47), ADCs (CD38), components of bispecific antibodies, and as part of our adoptive immunotherapy (CD38, BCMA), oncolytic virus program (Seprehvec) 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, CD47, BCMA, CTLA-4, CD123, CD47, LAG3, ROR1, 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.

COVID-19 (SARS-CoV-2)

COVID-19 is a pandemic disease caused by a single-stranded RNA virus termed SARS-CoV-2. Infection with COVID-19 may cause severe disease requiring hospitalization, including progression to ARDS and its associated high mortality rate due to a virus-induced hyperinflammatory response or “cytokine storm”. Patients with COVID-19 may develop elevated blood levels of multiple inflammatory cytokines and chemokines and those who are admitted to intensive care have even higher levels of these cytokines, which may indicate a far worse outcome.

We have leveraged our expertise in producing fully human monoclonal antibodies and our extensive G-MAB antibody library to develop potent neutralizing antibodies directed to the spike protein of SARS-CoV-2 or COVID-19. In addition, we have acquired or licensed assets that target the entire spectrum of COVID-19 infections, from outpatients who are asymptomatic or with mild symptoms to hospitalized patients with moderate symptoms to patients with severe or critical COVID-19 in intensive care units. Paired with our highly sensitive and specific diagnostic tests for COVID-19 in development, we have developed the ability to diagnose early and effectively treat every stage of this pandemic infection.

COVISTIX is a lateral flow rapid diagnostic test that offers early and accurate SARS-CoV-2 detection and treatment to not only protect the population, but also to facilitate early treatment, resulting in improved outcomes for patients who become infected. Using Sorrento’s unique capability to rapidly screen and develop highly potent antibodies, we developed COVISTIX, a highly sensitive 15-minute antigen test for detection of the SARS-CoV-2 virus. The test uses a proprietary platinum nano-catalyst core (“PtNC”) plus 2 antibody combination which yields up to 100-fold increases in sensitivity over conventional lateral flow colloidal gold assays. COVISTIX has also demonstrated high sensitivity across all variants, including Omicron, and maintained its sensitivity even in an all-comers (asymptomatic and symptomatic) patient population. This technology is ideally suited for either rapid point-of-care testing or at-home use. COVISTIX has been EUA cleared in, and is being marketed in, Mexico (COFEPRIS) and Brazil (ANVISA), and is CE-marked in Europe for IVD professional point-of-care use. EUA submissions have been completed and we are awaiting regulatory clearance from WHO, Canada (Health Canada), and the FDA.

STI-2020 (COVI-AMG) is the affinity-matured neutralizing antibody developed from STI-1499 (COVI-GUARD) which has been shown *in vitro* to be effective against the original Wuhan, China COVID-19 strain and the delta VoC. STI-2020, formulated for intravenous administration, blocks viral interactions with the ACE-2 receptor to prevent cell entry and replication and was engineered to lack any antibody-dependent enhancement (“ADE”) and tissue cross-reactivity (including possible hypersensitivity), neither of which has been observed in *in vitro* or *in vivo* preclinical studies. In the Syrian Golden hamster model, intravenous STI-2020 rapidly reversed COVID-19 infection and cleared viral particles from lung tissues. After a successful IND submission, intravenous STI-2020 (administered as a slow intravenous push) completed a healthy subject study demonstrating a benign safety profile. Further development of STI-2020 was deferred in favor of STI-2099 (COVIDROPS).

STI-2099 (COVIDROPS) is STI-2020 formulated for intranasal delivery. The neutralizing potency of STI-2020 lends itself to intranasal delivery, which may be an effective way of rapidly reducing infectivity and clearing viral burden from the nasopharynx and lung airways. STI-2099 may be a preferred treatment for children who may not be willing to receive an injection. After a successful IND clearance, we completed a healthy subject study demonstrating a benign safety profile for intranasal STI-2099. Phase II studies have begun in the U.S., United Kingdom and Mexico to demonstrate proof-of-concept. The U.S. study was completed early in the first quarter of 2022 and the UK study reached its interim analysis threshold (50% enrollment) early in the first quarter of 2022.

STI-5656 (abivertinib maleate) is a potent, small molecule third-generation tyrosine kinase inhibitor (“TKI”) of epidermal growth factor receptor (“EGFR”) and, importantly, also a BTK receptor. It inhibits the gatekeeper mutation of EGFR; T790M, as well as the common activating mutations (L858R, 19del), and has minimal inhibitory activity against the wild type (“WT”) receptor, contributing to its observed safety. Additionally, STI-5656 irreversibly binds to the BTK receptor at nanomolar potency, preventing the phosphorylation of the receptor and has shown potent immunomodulatory activities by inhibiting key pro-inflammatory cytokine production, including IL-1beta, IL-6 and TNF-alpha, all of which are correlated with higher morbidity and mortality in ARDS and “cytokine storm” due to COVID-19 infections. STI-5656 has completed enrollment in two Phase II studies in the U.S. and Brazil in subjects with COVID-19-induced respiratory compromise. These studies identified an “At-Risk” population likely to respond to treatment with STI-5656, those requiring non-invasive ventilation or high flow oxygen supplementation for which no treatments other than supportive care are available. A pivotal study is planned for 2022.

STI-8282(COVI-MSC): After acquiring an allogeneic culture-expanded adipose-derived mesenchymal stem cell (“MSC”) asset from Personalized Stem Cells, Inc., we transitioned the open IND and completed a Phase Ib single site (Fresno, CA) study of subjects with severe COVID-19 infections and acute respiratory failure or frank ARDS who received up to three infusions of STI-8282. In this study, all 10 subjects enrolled were able to be discharged from the hospital within several days of treatment. Phase II studies in the U.S. and Brazil started enrollment in the fourth quarter of 2021 and are expected to be completed in the first or second quarter of 2022.

STI-8472 (COVI-GeneMAB™): Finally, while not directly a “treatment” for COVID-19, the acquisition of SmartPharm Therapeutics, Inc. in September 2020 gave us the ability to use non-viral DNA and RNA gene delivery platforms to create a gene-encoded therapeutic product candidate using our STI-2020 neutralizing antibody. With this combination, an intramuscular injection can cause a person’s own body to produce the neutralizing antibody, for possibly months, instead of having to rely on intermittent injections of externally manufactured antibodies, such as STI-2020. STI-8472 is the combination of the non-viral DNA plasmid with gene-encoded STI-2020. We are in the process of completing the IND-enabling preclinical and chemistry, manufacturing and controls steps necessary to file an IND in 2022. We envision a combination of an STI-2020 injection to “treat” and STI-8472 to “prevent” reinfection in those positive for COVID-19, or in subjects negative for COVID-19, to prevent infection. This may be a valuable option for those who cannot or refuse to be vaccinated for health or other reasons. This program received approved funding from the Defense Advanced Research Projects Agency (“DARPA”), an advanced-technology branch of the U.S. Department of Defense.

Anti-CD38 CAR-T Program

Chimeric antigen receptors (“CARs”) have been created for commercial and clinical development programs. 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 scFvs, which often possess inferior biophysical stability and biochemical functionality compared to their parental antibodies.

The membrane glycoprotein CD38 is widely found on the surface of lymphoid and myeloid lineages, including B, T and NK cells, but is 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.

STI-2798 and STI-5171 (anti-CD38 CAR-T): Our proprietary, second generation anti-CD38 CAR-T therapy was being developed for the treatment of RRMM. Our anti-CD38 CAR-T is based on a fully human anti-CD38 monoclonal antibody derived from our G-MAB antibody library. We completed a Phase Ib ascending dose safety study of STI-5171, which began in 2018 with the initial anti-CD38 CAR-T platform. While long-term follow up is continuing, in the last two dose cohorts (10^6 or 10^7 cells/kg body weight), we achieved a 50% overall response rate. We improved on the CAR-T construct by removing the “myc tag” (which cannot be used in Europe) from the CAR-T product candidate (STI-2798) and made changes to the lymphodepletion protocol in hopes of improving long-term cell persistence. We completed a successful IND submission for STI-2798, our new anti-CD38 CAR-T (-myc), for subjects with RRMM but elected to pivot to our new allogeneic anti-CD38 knock-out/knock-in (“KOKI”) DAR-T (STI-1492).

Anti-CD38 KOKI DAR-T Program

We have addressed the potential weaknesses of CAR constructs while building on the clinical experience generated within our current CAR-T programs with the design of dimeric antigen receptors 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 a 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-T 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.

STI-1492 (anti-CD38 DAR-T) is an allogeneic non-viral anti-CD38 A2 KOKI DAR-T cell agent (second generation anti-CD38 “knock-out knock-in” dimeric antigen receptor 4-1BB ζ - engineered T cells), which is IND-cleared and is pending enrollment. STI-1492 consists of allogeneic donor T cells that are engineered to express an anti-CD38 antigen receptor for the treatment of patients with RRMM. The DAR consists of a Fab variable region instead of the scFv utilized by CARs. During the production of STI-1492, there is a “knock-in” of the DAR into the T-cell receptor (“TCR”) alpha constant region (“TRAC”) gene. The TCR alpha is simultaneously inactivated (“knock-out”) by this DAR knock-in process, allowing allogeneic T cells to be administered therapeutically without the development of graft versus host disease. In addition, STI-1492 utilizes a 4-1BB co-stimulatory domain. The anti-CD38 DAR design is associated with enhanced cytotoxic activity, longer persistence and potentially less toxicity compared with the anti-CD38 CAR design in preclinical studies. The ability to administer this agent as modified allogeneic T cells allows STI-1492 to be stored as an off-the-shelf agent that eliminates the need for leukapheresis and the treatment delay for the manufacturing process for each individual patient associated with autologous cellular therapy.

Our non-viral KOKI technology may offer several potential benefits over existing virus-based technology using transgene-encoding lentivirus, retrovirus or adeno-associated virus to introduce antigen receptor constructs into healthy donor (allogeneic) or cancer patient (autologous) T cells. These potential advantages of our 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 intend to use our G- MAB library to generate a number of monoclonal antibodies that can be used with our KOKI DAR-T platform to target a number of difficult to treat cancers.

Anti-CD38 Antibody-Drug Conjugate (ADC) Program

AL amyloidosis is an incurable disease that is characterized by a clonal population of bone marrow plasma cells that produces a monoclonal light chain immunoglobulin. The clonal plasma cells often make up less than 10% of the nucleated cells in the bone marrow in patients with AL amyloidosis. The light chain immunoglobulin is of a κ or λ type and is produced as either an intact molecule or a fragment. The light chain protein produced by the dysfunctional plasma cells associated with AL amyloidosis is misfolded, forming β -pleated sheets that deposit in tissues in the form of amyloid fibrils. The insoluble tissue protein deposits interfere with organ function and the soluble circulating light chains may be toxic to organs as well. The clinical features of AL amyloidosis depend on which organs are involved and may include restrictive cardiomyopathy, nephrotic syndrome, hepatic dysfunction, peripheral and/or autonomic neuropathy and signs or symptoms of an atypical multiple myeloma.

STI-6129 (anti-CD38 ADC) is composed of a human monoclonal anti-CD38 A2 antibody (STI-5171) covalently bound by a chemical linker to a dolastatin tubulin inhibitor chemotherapeutic derivative (duostatin 5.2). STI-5171 was generated from Sorrento's proprietary G-MAB antibody library. The binding affinity of STI-5171 to CD38 is comparable to that of daratumumab but it binds to different epitopes (Sorrento data on file). The STI-6129 ADC is produced by conjugation of the drug-linker-duostatin moiety to the parent STI-5171 monoclonal antibody. The heavy chain of the STI-5171 parent antibody included in the STI-6129 ADC has been modified by a C246 \rightarrow S mutation that substitutes a serine amino acid for cysteine. This substitution results in an antibody with 3 inter-chain disulfide bonds instead of the 4 disulfide bonds present in wild type IgG1 antibodies and provides an ADC with drug to antibody ratio of 3 (Sorrento data on file). Upon binding to CD38 target cell surface antigen, the STI-6129 ADC is internalized by the cell and undergoes lysosomal degradation resulting in the release of the duostatin 5.2 chemotherapeutic agent. This targeted delivery of potent chemotherapeutic agents is designed to enhance activity against the aberrant plasma cells in AL amyloidosis, minimize toxicity in normal tissues, and provide sustained delivery of the chemotherapy over time. The proprietary stable covalent linker technology reduces premature systemic release of duostatin, which may reduce or eliminate ocular toxicity and other adverse events. After a successful IND submission, STI-6129 is currently enrolling patients in an ascending dose study to identify the maximum tolerated dose to be used for the treatment of AL amyloidosis. To date, no ocular toxicity has been observed. Once a recommended Phase II dose is identified, an expansion cohort will be enrolled. Additionally, we are partnering with Columbia University in New York City to assess STI-6129 in the treatment of RRMM and metastatic esophageal cancer, and with MD Anderson to assess STI-6129 in the treatment of T-ALL.

Anti-CD47 Fully Human Monoclonal Antibody Program (STI-6643)

Several studies have described the role of cluster of differentiation 47/Signal regulatory protein-alpha ("CD47/SIRP α ") interaction in regulating macrophage-mediated phagocytosis and dendritic cell-mediated cross-priming of T cells. CD47 is a ubiquitously expressed immuno-regulatory glycoprotein (also known as integrin-associated protein) of the immunoglobulin superfamily best known for its so called '*don't eat me*' function that prevents phagocytic removal of healthy cells by the body's immune system. Many cancers present high levels of this signal on their cell surface, thereby disrupting anti-cancer immune responses. Given CD47's essential role as a negative checkpoint for innate immunity and subsequent adaptive immunity, the CD47-SIRP α axis has been explored as a new target for cancer immunotherapy and its disruption has demonstrated great therapeutic promise in reestablishing antitumor activity *in vivo*. However, significant anemia and thrombocytopenia has plagued early product candidates (e.g., Hu5F9-G4 or magrolimab, a humanized IgG₄ monoclonal antibody) due to CD47 expression on normal cells, particularly aging red blood cells which may lose this 'marker of self' becoming susceptible to clearance by splenic macrophages. This major 'on-target' dose limiting toxicity was seen with magrolimab in preclinical studies and required complicated priming methodologies to reduce this risk.

STI-6643 (anti-CD47 antibody) is our novel fully human CD47 monoclonal antibody that blocks CD47/SIRP α to promote *in vitro* anti-tumor phagocytic activity. When incubated with human peripheral blood mononuclear cells in a mixed lymphocyte reaction assay, STI-6643 demonstrated minimal T, B or NK cell depletion as opposed to reference clones (prepared based on sequence

analysis) which could result in improved efficacy by preserving the infiltrating anti-tumor immune cells. Additionally, STI-6643 showed 15- to 30-fold reduction in observed hemagglutination in human and cynomolgus monkey red blood cells, respectively, and despite its high binding to canine red blood cells, it showed reduced hemagglutination in comparison to magrolimab (clone prepared based on the sequence analysis). After a successful IND submission, the Phase Ib study has begun enrollment.

Antibody-Drug Nanoparticle Albumin Bound (ADNAB) Platform

We have partnered with Svetomir Markovic, MD, Ph.D. at Mayo Clinic Rochester to use the nanoparticle human serum albumin bound paclitaxel (or other chemotherapeutic agents) platform to bind various monoclonal antibodies to the external surface of the albumin micelles to form stable complexes that can be designed to target specific cancers for delivery directly to the tumor microenvironment. This partnership would leverage our existing antibody library, PD-1, PD-L1, CD38, CD47, BCMA, CTLA-4, CD123, CD47, LAG3, ROR1, VEGFR2, CCR2 and CD137, among others, to create ADNAB products that may enhance tumor response. The first programs (B cell lymphomas, melanoma and gynecological cancers) are already ongoing under investigator-initiated INDs that we support. We intend to use our PD-L1 (STI-3031) mAb in an investigator-initiated IND submission in the second quarter of 2022.

SOFUSA® Lymphatic Delivery System (S-LDS)

SOFUSA is a novel technology platform designed for targeted drug delivery to lymphatic vessels and lymph nodes. Abnormal immune system function is implicated in many conditions such as cancer and autoimmune diseases (e.g., rheumatoid arthritis, multiple sclerosis and psoriasis). SOFUSA's proprietary nanotopography draped microneedles have been shown to reversibly open tight junctions in the skin and facilitate paracellular and transcellular transport across the epidermis. In preclinical biodistribution studies, this proprietary microneedle and microfluidics system has consistently demonstrated the ability to deliver over 40-fold in drug concentration to lymph nodes (with lower drug concentration in systemic organs) when compared to traditional IV and subcutaneous ("SC") injections. For drugs that target the immune system, SOFUSA offers the potential to achieve a superior clinical response with potentially lower doses and/or side effects versus systemic injections or infusions.

Phase I clinical safety studies have now been completed, and two Phase 1b studies are underway to evaluate safety and pilot efficacy in our first human proof of concept studies. The first study is in autoimmune diseases with an anti-TNF α in rheumatoid arthritis ("RA") and the second study in cancer with a checkpoint inhibitor (anti-PD-1) in cutaneous T-cell lymphoma ("CTCL"). Early results are quite promising in the RA study in that the first four patients who were non-responders to full dose subcutaneous injections were switched to a 50% dose using SOFUSA, and all patients showed Disease Activity Score ("DAS") improvement. The first patient has completed the 12-week study and demonstrated an approximately 40% improvement in DAS and a 91% improvement in tender joints (from 11 tender joints to one). The study is now 50% enrolled and should be completed in the second quarter of 2022. The anti-PD-1 CTCL study is expected to start in the first quarter of 2022. We are also conducting multiple intention-to-treat studies to explore additional drugs (anti-CTLA-4) and indications (e.g., melanoma and non-Hodgkin's lymphoma).

Based upon our SOFUSA core microneedle technology, we have also developed the SOFUSA MuVaxx™ device for the administration of small volume peptides and vaccines. The skin (rich in dendritic cells) and lymph nodes are the primary organs for generating both humoral immunity (IgG and IgM) and cellular immunity (memory T-Cells) for long-term protection. In a preclinical study using a model Ovalbumin ("OVA") protein antigen, SOFUSA MuVaxx demonstrated a 60-100 fold increase in anti-OVA IgG antibodies vs intramuscular ("IM") injections, and in another preclinical COVID-19 vaccine study, the SOFUSA device resulted in 10-40X higher T-Cell response versus IM and intradermal injections. The SOFUSA MuVaxx device is designed to be a simple low-cost attachment to a standard syringe for rapid large-scale deployment of our vaccine candidates and, due to the small needle size, is expected to result in a pain-free injection.

Oncolytic Virus Program (Seprehvir[®] and Seprehvec[®])

We previously completed two trials using Herpes simplex virus lacking infected cell protein 34.5 (“HSV1716”) or Seprehvir to treat solid pediatric or young adult non-central nervous system tumors or malignant pleural mesothelioma with intratumoral, intravenous or intrapleural administration. A second-generation product, STI-1386 (Seprehvec), is a platform that can generate a number of possible product candidates. We successfully completed an IND submission in the fourth quarter of 2021 and are expecting enrollment to begin in the first quarter of 2022, targeting pancreatic cancer, soft tissue sarcomas and hepatic metastases.

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 general TRPV1 family as capsaicin, the active ingredient in red chili peppers, but is a thousand-fold more potent. As an agonist, RTX produces a sustained opening of calcium channels expressed on neurons, either in the end-terminals or cell bodies, of unmyelinated C-fibers or thinly myelinated A-delta fibers. The effect from this sustained calcium influx depends on the location that RTX is injected. When injected peripherally near end-terminals (for example intra-articularly), a sustained defunctionalization or desensitization occurs resulting in reduction in noxious chronic pain symptoms that can last for months. When injected neuraxially (intrathecally or epidurally) rapid programmed cell death of TRPV1-expressing neurons targeted by the RTX injection can produce long-lasting improvement in noxious chronic pain that has been refractory to treatment (e.g., cancer related pain). RTX does not interact with and leaves unaffected non-TRPV1-expressing nerves (touch, motor control and position sense).

An investigator-sponsored Phase I clinical trial of intrathecal RTX has been ongoing at the NIH under a Cooperative Research and Development Agreement. To date, 16 patients with terminal cancer pain have been treated intrathecally at the NIH. Additional enrollment in this study is planned for 2022.

A Phase Ib clinical trial with epidural RTX was completed in 2020 in 17 subjects with intractable pain due to advanced cancer. No dose limiting toxicity was observed at doses up to 25 mcg RTX and RTX demonstrated promising efficacy in relieving intractable pain associated with advanced cancer. A Phase II study was cleared to proceed and enrollment is expected to commence in the second quarter of 2022.

Another Phase Ib clinical trial with intra-articular RTX administration for moderate-to-severe osteoarthritis of the knee was completed with no dose-limiting toxicities at any of the administered doses. A total of 94 patients were enrolled at RTX doses from 5 mcg to 25 mcg; 40 subjects enrolled in the placebo-controlled ascending dose portion of the study; 38 subjects received 12.5 mcg and 16 subjects received 25 mcg. The preliminary efficacy results in this study showed promising evidence of a significant improvement lasting well beyond six months. A Phase II study was cleared to proceed and began enrolling in the fourth quarter of 2021. It is expected to fully enroll in mid-2022 with one year follow up to provide clarity on long-term safety and efficacy.

Portfolio	Key Programs	Indication	Preclinical	Phase I	Phase II	Phase III/Pivotal	FDA Approved	
COVID-19	COVISTIX™ (diagnostic)	Antigen Test	Emergency Use Authorisation (EUA), Approved in Mexico (COFEPRIS), Brazil (ANVISA), and CE Mark authorization in Europe.					
	COVIDROPS™ (treatment)	Neutralizing Antibody (Intranasal) in Outpatients						
	COVI-AMG™ (treatment)	Neutralizing Antibody (IV) in Outpatients						
	COVISHIELD™ (treatment)	Neutralizing Antibody (IV and IN) in Outpatients and Inpatients						
	ABIVERTINIB (treatment)	Severe COVID-19 in ICU Patients					Pivotal Trial Pending FDA Clearance	
	COVI-MSC (treatment)	ARDS due to COVID-19 in ICU Patients					Pivotal Trial in Brazil	
	Mpro Inhibitor (oral pill)	Anti-viral						
	Omicron mRNA Vaccine	Vaccine						
Immunotherapy	Abivertinib	NSCLC						
	Abivertinib	B Cell Lymphomas						
	Abivertinib	Prostate						
	Abivertinib	Lupus						
	Abivertinib	MS						
	Abivertinib	GvHD						
	PD-L1 (Socazolimab)*	SCLC					* In Partnership with Lee's Pharm in China	
	PD-L1 (5T1-3031)**	Cervical Cancer					** In US and in partnership with ImmuneOncia in Korea	
	CD47	Solid Tumors						
	CD38 DAR-T	Multiple Myeloma						
	CD38 ADC	Amyloidosis, Multiple Myeloma, T-ALL, and esophageal						
	TROP2 ADC*	Solid Tumors					* In China	
	Seprehvec™ oncolytic virus	Solid Tumors; CNS Tumors						
	BCMA ADC	Liquid Tumors						
Bevacizumab-ADNAB™	Endometrial Cancer					In partnership with Mayo Clinic		
Bevacizumab-ADNAB™	Ovarian Cancer					In partnership with Mayo Clinic		
Rituximab-ADNAB™	B-cell Lymphomas					In partnership with Mayo Clinic		
Pain	ZTlido™ 1.8%	Postherpetic Neuralgia - PHN						
	SP-102	Lumbar Radicular/Sciatica Pain						
	SP-103	Acute Back Pain						
	SP-104	Fibromyalgia						
	RTX (resiniferatoxin) – Epidural	Intractable Pain in Advanced Cancer					Orphan designation	
	RTX (resiniferatoxin) – Intra-	Moderate to Severe Knee OA Pain						
Lymphatic Delivery	Sofusa® anti-TNF	Autoimmune (RA)						
	Sofusa® anti-PD-1	Cutaneous T-Cell Lymphoma (CTCL)						
	Sofusa® anti-PD-1	Melanoma					In partnership with Mayo Clinic	

Scilex Holding

Scilex Holding is focused on cost-effectively developing and commercializing non-opioid therapies that will provide safe and substantial, localized pain relief for large market opportunities. The following chart illustrates the current product and product candidates for which Scilex Holding has worldwide commercialization rights, except with respect to Japan for ZTlido and SP-103:

Product and Product Candidates	Indication	Pilot PK	Phase 1	Phase 2	Phase 3	NDA Submission	Marketed	Milestones/Status	
ZTlido (lidocaine topical system) 1.896	Pain associated with postherpetic neuralgia (post-shingles pain)								<ul style="list-style-type: none"> NDA approval in February 2018 Launched in October 2018
SEMDEXA (10 mg, dexamethasone sodium phosphate viscous gel for injection)	Lumbosacral radicular pain (sciatica)								<ul style="list-style-type: none"> Phase 3 top-line results were highly positive
SP-103 (lidocaine topical system) 5.496	Acute low back pain								<ul style="list-style-type: none"> Initiation of Phase 2 trial anticipated in Q1-2022
SP-104 (Low-dose naltrexone hydrochloride)	fibromyalgia								<ul style="list-style-type: none"> Initiating multiple Phase 1 in Q1-2022

ZTlido

ZTlido is a lidocaine topical system approved for the relief of pain associated with post-herpetic neuralgia (“PHN”). PHN is a chronic neuropathic pain syndrome that results as a complication following an infection of herpes zoster, also known as shingles. Herpes zoster symptoms typically resolve after a few weeks, but the pain caused by the nerve injury can persist for months to years in the affected area. ZTlido is designed as a lighter, thinner product which has improved adhesion relative to Lidoderm (lidocaine patch 5%), while providing a bioequivalent delivery of lidocaine in an efficient drug delivery system.

We launched ZTlido in October 2018 with support from an integrated commercial organization using a dedicated contract sales force and our own sales management, marketing and managed care capabilities. We currently market ZTlido through a dedicated sales force of 60 individuals, targeting approximately 10,000 primary care physicians, pain specialists, neurologists and palliative care physicians. We are utilizing a multi-channel marketing strategy to expand awareness and utilization of ZTlido. There is coverage for ZTlido from national and regional pharmacy benefit managers, health maintenance organizations, Medicare and Medicaid plans for approximately 165 million covered lives.

SEMDEXA

SEMDEXA is a Phase III product candidate we are developing to be an injectable viscous gel formulation of a widely used corticosteroid designed to address the serious risks posed by off-label epidural steroid injections (“ESIs”) for the treatment of sciatica, a pathology of low back pain. We believe SEMDEXA, if successfully developed, has the potential to reduce the disability related to sciatica and help delay or avoid spine surgery. SEMDEXA has been granted fast track designation by the FDA and, if approved, could become the only FDA-approved alternative to off-label ESIs, which are administered over 10 million times annually in the United States. Enrollment for the Phase III trial was completed in the second half of 2021. We announced top-line data from this study in December 2021. The SP-102 pivotal Phase III trial 12-week data demonstrated a highly statistically significant greater effect over placebo for primary and secondary endpoints with no safety risks identified. The complete six-months data analysis is expected by March 2022. Based on the current results, we plan to submit a request to the FDA for Breakthrough Therapy Designation, which will help expedite the overall development program and potential market approval. We also expect to submit a pre-NDA meeting request to the FDA in the first half of 2022.

SP-103

SP-103 is an investigational, non-aqueous lidocaine topical system undergoing clinical development in low back pain conditions. SP-103 builds on the learnings from ZTlido because both products share a similar adhesive drug delivery formulation and manufacturing technology. If approved, we believe that SP-103 could become the first-in-class lidocaine topical product for low back pain indications. All current uses of topical lidocaine products for low back pain are off-label. SP-103 has three times the drug load of ZTlido (108 mg versus 36 mg) in the adhesive system to potentially deliver threefold level of the drug within a targeted area, still with

the convenience of a single topical system. Additionally, SP-103 is designed to deliver a localized dose of lidocaine that is threefold greater than any lidocaine topical product that we are aware of either on the market or in development. If approved, we believe SP-103 may be able to address the limitations of prescription lidocaine patches in treating low back pain by delivering a higher dose of lidocaine to the application site. We expect the Phase II trial to commence in the first half of 2022.

SP-104

We are developing SP-104, a novel low-dose delayed-release naltrexone hydrochloride formulation for the treatment of fibromyalgia. Fibromyalgia is considered a neurosensory disorder characterized in part by abnormalities in pain processing by the central nervous system. Increased understanding of the biological bases underlying fibromyalgia is rapidly leading to a new era of specific pharmacologic therapy for the condition. Fibromyalgia affects approximately ~3-6% of the adult population. There are estimated to be between 8-10 million individuals with fibromyalgia in the United States. Fibromyalgia is the second most common disorder that rheumatologists encounter, as it is seen in 15% of evaluated patients. Approximately 8% of patients cared for in primary care clinics have fibromyalgia. Women have a higher frequency of fibromyalgia. Prominent fibromyalgia researchers and specialists estimate the costs in the U.S. to be between \$12-14 billion each year and it accounts for a loss of 1-2% of the national overall productivity. Current FDA-approved treatments for fibromyalgia include duloxetine, pregabalin, and milnacipran. Despite the availability of these treatments, there is a large unmet need in the marketplace as these treatments have response rates of less than 50%, ranging from 27 to 40%. Two Phase I studies are ongoing and are designed to characterize the pharmacokinetics (PK) of SP-104 and the safety of SP-104 relative to the known naltrexone adverse effects. We plan to initiate a Phase II clinical trial in the second half of 2022.

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-MABTM-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 patent applications and granted patents with potential patent coverage to at least 2039.
- 3) The bispecific antibody technology directed to the combination of two 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 2040.
- 4) The COVID-19 technologies and product candidates, including neutralizing antibodies (COVI-AMG, COVIDROPS and COVISIELD), other therapeutic and/or product candidates and diagnostic platforms, are the subject of pending patent applications with potential patent coverage to at least 2042.
- 5) The ADC technology using proprietary conjugation chemistries (called C-LockTM and K-LockTM), initially developed by Concartis Biosystems, Corp., 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 ADC directed to different antigen targets and/or toxin derivatives are the subject matter of pending patent applications and granted patents with potential patent coverage to at least 2042.
- 6) The chimeric antigen receptor T-cell (CAR-T)-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 2038.
- 7) The dimeric antigen receptor T-cells (DAR-T)-based technology is an allogeneic immunotherapy platform and is the subject of pending patent applications with potential patent coverage to at least 2039. Candidates arising from the platform are the subject matter of pending applications with potential patent coverage to at least 2040.
- 8) The oncolytic virus technology is a human herpes simplex virus (HSV)-based immunotherapy platform designed to target and destroy tumor cells while also stimulating anti-tumor patient immune responses. It is the subject 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 2040.

9) The corticosteroid injectable pain management technology, which is formulated as a viscous gel injection for the treatment of lumbosacral radicular pain/sciatica, was obtained by the acquisition of Semnur Pharmaceuticals in March 2019 and it is the subject matter of pending patent applications and granted patents with potential patent coverage to at least 2036.

10) The resiniferatoxin (RTX)-based pain management technology is an experimental TRPV1 agonist agent developed as a single injection pain treatment that ablates afferent nerves that conduct pain signals while sparing other nerve functions. Certain aspects of this technology are covered by an issued patent in the U.S. providing patent protection to at least 2022 and are the subject matter of pending patent applications that will provide potential patent coverage to at least 2040.

11) The lidocaine-based pain management technology was obtained by the acquisition of Scilex Pharma. 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.

12) The SOFUSA technology was acquired from Kimberly-Clark Corporation (“KCC”); Kimberly-Clark Global Sales, LLC (“KCCGS”); and Kimberly-Clark Worldwide, Inc. (“KCCW” and together with KCC and KCCGS, “Kimberly-Clark”) in July 2018 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 2040.

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.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition, a strong emphasis on proprietary products and intellectual property. While we believe that our scientific knowledge, technology and development experience provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, some or all of which may have greater access to capital or resources than we do. For any products that we may ultimately commercialize, not only will we compete with any existing therapies and those therapies currently in development, we will have to compete with new therapies that may become available in the future.

We expect that the market will become increasingly competitive in the future. Many of our competitors, either alone or together with their collaborative partners, operate larger research and development programs, and have substantially greater commercial and financial resources than we do, as well as significantly greater experience in: developing product candidates and technologies, undertaking preclinical studies and clinical trials, obtaining FDA and other regulatory approvals of product candidates, formulating

and manufacturing product candidates and launching, marketing and selling product candidates. As a result, these companies may obtain marketing approval more rapidly than we are able and may be more effective in developing, selling and marketing their products.

Immunotherapy

Immunotherapy is an active area of research and several immune-related products have been identified in recent years that modulate the immune system. Many of these products utilize dendritic cells, a form of immune cell that presents cancer target peptides to T cells and that can in turn result in T-cell activation. More recently, bispecific antibodies and checkpoint inhibitors (for instance PD-1/PD-L1 antibodies) have been identified as having utility in the treatment of cancer. Bi-specific antibodies commonly target both the cancer peptide and the TCR, thus bringing both cancer cells and T cells into close proximity to maximize the chance of TCR binding and hence an immune response to the cancer cells. Checkpoint inhibitors on the other hand, work by targeting receptors that inhibit T-cell effectiveness and proliferation and thereby essentially activate T cells. Other immunotherapies that are being actively investigated include: antibody drug complexes, TCR-mimic antibodies, oncolytic viruses, cancer vaccines.

We are aware of companies developing therapies in various areas related to our specific research and development programs. Specifically, there are a growing number of pharmaceutical, biotechnology, and academic institutions researching and developing autologous and allogeneic CAR-T therapies in both the solid and liquid tumor setting. These CAR-T cell therapies are at a variety of stages of preclinical, clinical development and approval. Such therapies are directed towards a broad target spectrum, including but not limited to: DLL3, EGFR, GD2, HER-2, IL13 α 2, Lewis Y, L1-CAM, Mesothelin, MUC16, PSCA, PSMA and ROR1. The two approved CAR-T therapies both target CD19. We are also aware of allogeneic CAR-T programs in development.

RTX

The pain management field in particular is a growing industry due to increased attention on opioid usage for pain, which has created a rapidly emerging market and has fueled an increased interest in opioid alternatives. The rise of various small and early-stage companies in the non-opioid pain management field may also prove to be significant competitors, particularly if they enter into collaborative arrangements with large, established companies.

COVID-19 Product Candidates

Neutralizing antibodies (“nAbs”): We have several nAbs either in development or in the clinic. These nAbs are directed against the COVID-19 spike protein and have varying degrees of effectiveness dependent on the VoC being targeted. The lead nAb during 2021, STI-2020, was shown to be effective in preclinical studies against the original Washington strain as well as the delta VoC. With the meteoric rise of the omicron VoC late in 2021, we identified a new highly potent nAb, STI-9167, which we initially obtained under an exclusive license from Mount Sinai and modified to be a fully-human nAb with modifications to reduce the potential for antibody-dependent enhancement or human tissue cross-reactivity. This nAb is highly effective in preclinical studies against Omicron and Omicron plus and we filed an IND early in the first quarter of 2022 to begin human safety studies of both the IV and intranasal formulations. There are several other companies which have nAbs in early development. In addition, companies that are involved in vaccine development are indirect competitors in this space, although the vaccines approved to date and known to be in development are not nAbs-based.

Bruton’s Tyrosine Kinase Inhibitors (“BTKi”): We have completed Phase II trials with Abivertinib, our dual EGFR/BTKi, to treat ARD due to COVID-19. There are several other BTKis approved for oncology conditions that could theoretically be used to treat COVID-19-induced ARD. For example, Acalabrutinib (Calquence) was used in two Phase II studies but failed to meet its primary endpoint.

Adipose-derived mesenchymal stromal or stem cells (AdMSCs): We are currently enrolling two Phase II studies treating COVID-19-induced ARD and ARDS in the U.S. and Brazil. There are a large number of companies and universities exploring various MSCs (adipose, bone marrow, cord blood, umbilical and other sources) in Phase I and II studies to treat moderate to severe COVID-19.

Scilex

ZTlido and our product candidate, SP-103, if approved, face and will likely face competition from prescription and generic topical lidocaine patches, including Lidoderm and generic lidocaine patches manufactured by Teva, Mylan and Par Pharmaceutical, Inc. Additionally, SP-103, if approved, will likely compete with various opioid pain medications, nonsteroidal anti-inflammatory drugs (“NSAIDs”), muscle relaxants, antidepressants and anticonvulsants, particularly as we seek approval for the treatment of chronic low back pain.

SEMDEXA, if approved, has the potential to become the first FDA-approved epidural steroid product for the treatment of sciatica. While there are currently no FDA approved ESIs indicated for the treatment of sciatica, we are aware of certain non-steroid product candidates in development. For example, Sollis Therapeutics, Inc. is developing its product candidate, a non-opioid, non-steroid clonidine micropellet to be administered through epidural injection, which is reported to be in Phase III development. SEMDEXA, if approved, will compete with various opioid pain medications, NSAIDs, muscle relaxants, antidepressants, anticonvulsants and surgical procedures. Procedures may include nerve blocks and transcutaneous electrical nerve stimulations. We may also face indirect competition from the off-label and unapproved use of branded and generic injectable steroids.

The key competitive factors affecting the success of ZTlido, SEMDEXA, SP-103 and SP-104 are likely to be their efficacy, durability, safety, price and the availability of reimbursement from government and other third-party payors.

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, 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:

- 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;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin and must be updated annually;
- 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 a 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 BLA or 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;
- satisfactory completion of an FDA pre-approval inspection of one or more of the clinical sites at which the clinical trials were conducted;
- at the discretion of the FDA, a public Advisory Committee Meeting where the data is reviewed by experts who discuss the data and give their opinion (which the FDA is not obliged to follow) of the adequacy of the data to support an approval; 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 pre-approval clinical investigation of a drug is generally divided into three phases (the numbers of subjects/patients are approximate and vary from indication to indication). 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. In general, two Phase III trials are needed for an approval.

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 BLA or 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.

During the evaluation of the BLA or NDA, the FDA conducts inspections of manufacturing facilities where the drug product and/or its API will be produced and some of the clinical sites that conducted the trials, and 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 BLA or NDA does not satisfy the criteria for approval. The FDA could also approve the BLA or 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 BLA or 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 (about every two years) 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 BLA or 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 can 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. Meetings with the FDA are free.

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

Orphan Drug Designation

The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the U.S., or, if it affects more than 200,000 individuals in the U.S., there is no reasonable expectation that the cost of developing and making the drug for this type of disease or condition will be recovered from sales in the U.S. In the European Union, the EMA’s Committee for Orphan Medicinal Products (“COMP”) grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than 5 in 10,000 persons in the European Union Community. Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product.

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

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

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

Authorization Procedures in the European Union

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

- *Centralized procedure.* The EMA implemented the centralized procedure for the approval of human medicines to facilitate marketing authorizations that are valid throughout the European Union. This procedure results in a single marketing authorization issued by the EMA that is valid across the European Union, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human medicines that are: derived from biotechnology processes, such as genetic engineering, contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, and officially designated orphan medicines.
- For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.
- *National authorization procedures.* There are also two other possible routes to authorize medicinal products in several countries, which are available for investigational drug products that fall outside the scope of the centralized procedure:

- *Decentralized procedure.* Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one European Union country of medicinal products that have not yet been authorized in any European Union country and that do not fall within the mandatory scope of the centralized procedure.
- *Mutual recognition procedure.* In the mutual recognition procedure, a medicine is first authorized in one European Union Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other European Union countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

Priority Review/Standard Review (U.S.) and Accelerated Review (European Union)

Based on results of the Phase III clinical trial(s) submitted in a BLA or NDA, upon the request of an applicant, the FDA may grant the BLA or 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 BLA or 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 \$11,803 to \$23,607 (each subject to adjustment for inflation) 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 biopharmaceutical industry to help us advance the clinical development of select product candidates.

Marketing and Sales

With the exception of our subsidiary, Scilex Holding, 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, 2021, our 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, 2021, we had 799 employees and 22 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. We focus on identifying, recruiting, developing and retaining a team of highly talented and motivated employees. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, as well providing our employees with the opportunity to participate in our employee stock purchase plan, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives. The success of our business is fundamentally connected to the well-being, health and safety of our employees. In an effort to protect the health and safety of our employees, we took proactive action from the earliest signs of the COVID-19 outbreak, which included implementing social distancing policies at our facilities, facilitating remote working arrangements and imposing employee travel restrictions.

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”).

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 Annual Report on 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.

Risk Factor Summary

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the Securities and Exchange Commission before making investment decisions regarding our common stock.

- We are a clinical and commercial stage company subject to significant risks and uncertainties, including the risk that we or our partners may fail to develop, obtain regulatory approval or market our product candidates or generate product related revenues.
- We have incurred significant losses since inception and anticipate that we will incur continued losses for the foreseeable future.
- 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.
- 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.
- 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.
- We may expend our limited resources to pursue a particular product, product candidate or indication and fail to capitalize on products, product candidates or indications that may be more profitable or for which there is a greater likelihood of success.
- 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.
- 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 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.
- With respect to ZTlido, COVISTIX 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 failure to successfully discover, acquire, develop and market additional product candidates or approved products would impair our ability to grow.
- 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.
- 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.
- Price controls may be imposed, which may adversely affect our future profitability.
- 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.
- 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 will need to increase the size of our company and may not effectively manage our growth.
- 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.
- There can be no assurance that the product candidates we are developing for the detection and treatment of COVID-19 will be granted an Emergency Use Authorization by the FDA or comparable foreign authorities. If no Emergency Use Authorization is granted or, once granted, it is terminated, we will be unable to sell our product candidates in the near future and will be required to pursue the drug approval process, which is lengthy and expensive.
- Interim “top-line” and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- We are involved, and may become involved in the future, in disputes and other legal or regulatory proceedings that, if adversely decided or settled, could materially and adversely affect our business, financial condition and results of operations.
- We have acquired, and plan to continue to acquire, assets, businesses and technologies and may fail to realize the anticipated benefits of the acquisitions, and acquisitions can be costly and dilutive.
- Any acquisitions we make could disrupt our business and seriously harm our financial condition.
- Our long-term success depends on intellectual property protection; if our intellectual property rights are invalidated or circumvented, our business will be adversely affected.
- 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.
- 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.
- 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.
- 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.
- 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.
- Our strategic investments may result in losses.

Risks Related to Our Financial Position and Capital Requirements

We are a clinical and commercial stage company subject to significant risks and uncertainties, including the risk that we or our partners may fail to develop, obtain regulatory approval or market our product candidates or generate product related revenues.

We are primarily a clinical and commercial 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 therapeutic 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 derived from our proprietary G-MAB library platform (e.g., PD-L1, CD47), antibody drug conjugates (“ADCs”), bispecific antibodies (“BsAbs”), as well as Chimeric Antigen Receptor T Cells (“CAR-T”) and Dimeric Antigen Receptor T Cells (“DAR-T”) for adoptive cellular immunotherapy, resiniferatoxin (“RTX”), higher strength lidocaine topical system (SP-103), non-opioid corticosteroid formulated as a viscous gel injection (SP-102) (“SEMDEXATM”) and lymphatic drug delivery system (SOFUSA) to be commercially available for a few years, if at all. Additionally, our COVID-19 related product candidates, including STI-2020 (affinity matured neutralizing antibody; COVI-AMG), STI-2099 (intranasal affinity matured neutralizing antibody; COVIDROPS), STI-9167 (broad-spectrum neutralizing antibody; COVISHIELD), STI-5656 (Abivertinib), STI-8282 (allogeneic adipose-derived mesenchymal stem cells; COVI-MSC), serological IgM/IgG antibody diagnostic test (COVITRACK) and lateral flow viral antigen diagnostic test for SARS-CoV-2 (COVISTIX), are subject to uncertainties relating to product development, regulatory approval and commercialization, and further risks based on the constantly evolving situation affecting the United States and the international community. 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 ZTlido® (lidocaine topical system 1.8%) (“ZTlido”), 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, 2021 and 2020, we had an accumulated deficit of \$1,386.6 million and \$958.3 million, respectively. We continue to incur significant research and development and other expenses related to our ongoing operations. We have incurred operating losses since our inception, expect to continue to incur significant operating losses for the foreseeable future, and we expect these losses to increase as we: (i) advance RTX, STI-6129 (anti-CD38 ADC), STI-1492 (anti-CD38 DAR-T), STI-6643 (anti-CD47 antibody), SP-103, SEMDEXA™ and our other product candidates, including our COVID-19 related product candidates, STI-2099 (COVIDROPS), STI-9167 (COVISHIELD), STI-8282 (COVI-MSD) and STI-5656 (Abivertinib), into further clinical trials and pursue other development, acquire, develop and manufacture clinical trial materials and increase other regulatory operating activities, (ii) conduct further studies for our preclinical COVID-19 related product candidates to advance to clinical trials and seek regulatory approval; (iii) incur incremental expenses associated with our efforts to further advance a number of potential product candidates into preclinical development activities, (iv) continue to identify and advance a number of fully human therapeutic antibody and ADC preclinical product candidates, (v) incur higher salary, lab supply and infrastructure costs incurred in connection with supporting all of our programs, (vi) invest in our joint ventures, collaborations or other third party agreements, (vii) incur expenses in conjunction with defending and enforcing our rights in various litigation matters, (viii) expand our corporate, development and manufacturing infrastructure, and (ix) support our subsidiaries, including Bioserv Corporation, Levena Biopharma US Inc., Scilex Holding Company (“Scilex Holding”) and SmartPharm Therapeutics, Inc., in their clinical trial, development and 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, 2021 included a “going concern” explanatory paragraph indicating that our recurring losses from operations, negative working capital, recurring negative cash flows from operations and substantial cumulative net 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, derived from our proprietary G-MAB library platform, ADCs, BsAbs, CAR-T and DAR-T for adoptive cellular immunotherapy, Abivertinib, GeneMAb, RTX, SOFUSA, SP-103 and SEMDEXA™ and our COVID-19 product candidates;

- the number of product candidates we pursue;
- our ability to develop and advance our current product candidates and programs into, and successfully complete, clinical studies;
- 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;
- our obligations under our debt arrangements;
- the time and costs involved in defending and enforcing our rights in various litigation matters;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified personnel;
- the effect of the COVID-19 pandemic; and
- our revenues, if any, from successful development and commercialization of our product candidates, including ZTlido.

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.

In addition, as discussed in the risk factor under the heading “The terms of our outstanding debt 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” below, the Scilex Indenture includes negative covenants that place limitations on the following: the incurrence of debt, the payment of dividends by Scilex Pharma, 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 Pharma, engaging in certain transactions with affiliates; and the making of investments other than those permitted by the Scilex Indenture.

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.

Our portfolio of marketable securities is subject to market, interest and credit risk that may reduce its value.

We maintain a portfolio of marketable securities. Changes in the value of our portfolio of marketable securities could adversely affect our earnings. In particular, the value of our investments may decline due to increases in interest rates, downgrades of the bonds and other securities included in our portfolio, instability in the global financial markets that reduces the liquidity of securities included in our portfolio, declines in the value of collateral underlying the securities included in our portfolio and other factors. In addition, the COVID-19 pandemic has and may continue to adversely affect the financial markets in some or all countries worldwide. Each of these events may cause us to record charges to reduce the carrying value of our investment portfolio or sell investments for less than our acquisition cost. Although we attempt to mitigate these risks through diversification of our investments and continuous monitoring of our portfolio’s overall risk profile, the value of our investments may nevertheless decline.

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, 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 (the “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 currently engaging in and planning for certain clinical trials relating to our COVID-19 product candidates, 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 product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating, as well as the COVID-19 pandemic. 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 product candidates 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.

In addition, certain of our clinical trials have been affected by and may continue to be affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment for our non-COVID-19 product candidates have been and may continue to be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. Some patients have not been and others may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, any inability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may adversely impact our clinical trial operations.

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, the eligibility criteria for the study and potential reduced enrollment due to the COVID-19 pandemic. 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, 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 a new drug application ("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 data obtained from studies in one jurisdiction, such as the United States, may not be accepted by regulatory authorities in other jurisdictions, and certain jurisdictions may require data from studies conducted in their country in order to obtain regulatory approval;
- 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 an NDA submitted by Scilex Pharmaceuticals Inc. ("Scilex Pharma") for Scilex Pharma's lead product candidate, ZTlido, 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. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our products or product candidates will be harmed. Further, the United Kingdom has withdrawn 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.

Inadequate funding for the FDA, the MHRA, the EMA and comparable foreign authorities and government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA, the MHRA, the EMA and comparable foreign authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes and the impact of crises that hinder its operations, such as COVID-19. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA, the MHRA, the EMA and comparable foreign authorities may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

ADCs and our antibody-drug-nanoparticle albumin-bound (“ADNAB”) platform 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 ADNABs, 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.

We may expend our limited resources to pursue a particular product, product candidate or indication and fail to capitalize on products, product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We are currently advancing multiple product candidates for a variety of indications. Simultaneously advancing so many product candidates creates a significant strain on our limited human and financial resources. As a result, we may not be able to provide sufficient resources to any single product candidate to permit the successful development and commercialization of such product candidate, causing material harm to our business. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products.

If, due to our limited resources and access to capital, we prioritize development of certain product candidates that ultimately prove to be unsuccessful, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

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. In addition, we may enter into collaboration and license agreements with certain collaborators, pursuant to which we may, among other things, agree to carry out manufacturing of our collaborators' material and product candidates. 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 or any potential collaborators' materials or 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 and our potential collaborators' 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 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 product candidates may not be available on commercially reasonable terms, or at all, which may delay the development and commercialization of product candidates.

There are a limited number of suppliers for raw materials that we use to manufacture our products and product candidates 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 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 or collaborators, which in turn could damage our reputation for quality and service. Any such incident could, among other things, lead to increased costs, lost revenue, reimbursement to customers for lost drug substance, damage to and possibly termination of existing customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other manufacturing runs. With respect to our commercial manufacturing, if problems are not discovered before the product is released to the market, we may be subject to regulatory actions, including product recalls, product seizures, injunctions to halt manufacture and distribution, restrictions on our operations, civil sanctions, including monetary sanctions, and criminal actions. In addition, such issues could subject us to litigation and/or liability for damages, the cost of which could be significant.

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

We face potential business disruptions and related risks resulting from the COVID-19 pandemic, which could have a material adverse effect on our business, financial condition and results of operations.

The COVID-19 pandemic continues to impact the global economy. Financial markets have experienced, and continue to experience, extreme fluctuations that may cause a contraction in available liquidity globally as important segments of the credit markets react to the development. The COVID-19 pandemic continues to rapidly evolve, and the extent to which COVID-19 may impact our business, clinical trials and sales of ZTlido will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the continued spread of the disease and variants thereof, including any future variants, the duration of the outbreak, vaccination rates, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

We are monitoring the continuing impact of the COVID-19 pandemic, and we may continue to experience disruptions that could severely impact the development of our product candidates, including:

- delays or difficulties in enrolling patients in our clinical trials as patients may be reluctant, or unable, to visit clinical sites;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators, clinical site staff and potential closure of clinical facilities;
- decreases in patients seeking treatment for chronic pain;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;

- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to the COVID-19 outbreak, which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others.

Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at third-party suppliers in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. Any manufacturing supply interruption of materials could adversely affect our ability to conduct ongoing and future research and testing activities. For example, we obtain our commercial supply of ZTlido and our clinical supply of SP-103 exclusively from Oishi Koseido Co., Ltd. and Itochu CHEMICAL FRONTIER Corporation in Japan. The COVID-19 pandemic may result in delays in the procurement and shipping of ZTlido, which may have an adverse impact on our operating results.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the continued duration of, the COVID-19 pandemic may be difficult to assess or predict, there could be significant disruption of the global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the COVID-19 pandemic and related factors could materially affect our business and the value of our common stock.

In addition, the continued spread of COVID-19 globally could materially and adversely impact our operations, including without limitation, our sales and marketing efforts, sales of ZTlido, travel, employee health and availability, which may have a material and adverse effect on our business, financial condition and results of operations.

Management is actively monitoring the global situation on our financial condition, liquidity, operations, suppliers, industry and workforce. Given the continued evolution of the COVID-19 outbreak and the global responses to curb its spread, we are not able to estimate the effects of the COVID-19 outbreak on our results of operations, financial condition or liquidity for fiscal year 2022.

Failure to comply with existing and future regulatory requirements as a contract manufacturing organization could adversely affect our business, results of operations and financial condition.

Operations as a contract manufacturing organization (“CMO”) are highly regulated. As a CMO, we are required to comply with the regulatory requirements of various local, state, provincial, national and international regulatory bodies having jurisdiction in the countries or localities in which we may manufacture products or product candidates or in which our collaborators’ products or product candidates are distributed. In particular, we are subject to laws and regulations concerning development, testing, manufacturing processes, equipment and facilities, including compliance with cGMPs, import and export regulations, and product registration and listing, among other things. As a result, our facilities are subject to regulation by the FDA, as well as regulatory bodies of other jurisdictions such as the EMA, depending on the countries in which our collaborators develop the products or product candidates we manufacture on their behalf. As we expand our operations and geographic scope, we may be exposed to more complex and new regulatory and administrative requirements and legal risks, any of which may require expertise in which we have little or no experience. It is possible that compliance with new regulatory requirements could impose significant compliance costs on us. Such costs could have a material adverse effect on our business, financial condition and results of operations.

These regulatory requirements impact many aspects of our operations, including manufacturing, developing, storage, distribution, import and export and record keeping related to collaborators’ products or product candidates. Noncompliance with any applicable regulatory requirements can result in government refusal to approve (i) facilities for testing or manufacturing product

candidates or (ii) potential products for commercialization. The FDA and other regulatory agencies can delay, limit or deny approval for many reasons, including:

- changes to the regulatory approval process, including new data requirements for products or product candidates in those jurisdictions, including the United States, in which our customers may be seeking approval;
- that a collaborator's product or product candidate may not be deemed to be safe or effective;
- the ability of the regulatory agency to provide timely responses as a result of its resource constraints; and
- that the manufacturing processes or facilities may not meet the applicable requirements.

In addition, if new legislation or regulations are enacted or existing legislation or regulations are amended or are interpreted or enforced differently, we may be required to obtain additional approvals or operate according to different manufacturing or operating standards. This may require a change in our development and manufacturing techniques or additional capital investments in our facilities. Any related costs may be significant. If we fail to comply with applicable regulatory requirements in the future, then we may be subject to warning letters and/or civil or criminal penalties and fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, restrictions on the import and export of products, debarment, exclusion, disgorgement of profits, operating restrictions and criminal prosecution and the loss of contracts and resulting revenue losses. Inspections by regulatory authorities that identify any deficiencies could result in remedial actions, production stoppages or facility closure, which would disrupt the manufacturing process and supply of product to our collaborators. In addition, such failure to comply could expose us to contractual and product liability claims, including claims by collaborators for reimbursement for lost or damaged active pharmaceutical ingredients or recall or other corrective actions, the costs of which could be significant.

In addition, certain product candidates we manufacture must undergo preclinical and clinical evaluations relating to product safety and efficacy before they are approved as commercial therapeutic products. The regulatory authorities having jurisdiction in the countries in which we or our collaborators intend to market their products may delay or put on hold clinical trials or delay approval of a product or determine that the product is not approvable. The FDA or other regulatory agencies can delay approval of a product candidate if our manufacturing facility, including any newly commissioned facility, is not able to demonstrate compliance with cGMPs, pass other aspects of pre-approval inspections or properly scale up to produce commercial supplies. The FDA and comparable government authorities having jurisdiction in the countries in which we or our collaborators may market approved products have the authority to withdraw product approval or suspend manufacture if there are significant problems with raw materials or supplies, quality control and assurance or the product we manufacture is adulterated or misbranded. If our manufacturing facilities and services are not in compliance with FDA and comparable government authorities, we may be unable to obtain or maintain the necessary approvals to continue manufacturing product candidates for our customers, which would materially adversely affect our results of operations and financial condition.

The consumers of any approved products we manufacture for our collaborators may significantly influence our business, results of operations and financial condition.

We will depend on, and have no control over, consumer demand for any approved products we manufacture for our collaborators. Consumer demand for our collaborators' products could be adversely affected by, among other things, delays in health regulatory approval, the inability of our collaborators to demonstrate the efficacy and safety of their products, the loss of patent and other intellectual property rights protection, the emergence of competing or alternative products, including generic drugs, the degree to which private and government payment subsidies for a particular product offset the cost to consumers and changes in the marketing strategies for such products. If the products we manufacture for our collaborators do not gain market acceptance, our revenues and profitability may be adversely affected.

Continued changes to the healthcare industry, including ongoing healthcare reform, adverse changes in government or private funding of healthcare products and services, legislation or regulations governing the privacy of patient information or patient access to care, or the delivery, pricing or reimbursement of pharmaceuticals and healthcare services or mandated benefits, may cause healthcare industry participants to purchase fewer services from us or influence the price that others are willing to pay for our services. Changes in the healthcare industry's pricing, selling, inventory, distribution or supply policies or practices could also significantly reduce our revenue and profitability.

If production volumes of key products that we manufacture for our collaborators decline, results of operations and financial condition may continue to be adversely affected.

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 Holding (which commercially launched, through Scilex Pharma, ZTlido 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.

Scilex Holding's commercialization efforts of ZTlido have been primarily focused in the United States. Commercialization of ZTlido 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 addition to the risks discussed elsewhere in this section, Scilex Holding's ability to successfully commercialize and generate revenues from ZTlido depends on a number of factors, including, but not limited to, Scilex Holding's ability to:

- develop and execute our sales and marketing strategies for Scilex Holding's products;
- achieve, maintain and grow market acceptance of, and demand for, Scilex Holding'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 Holding's products;
- maintain and extend intellectual property protection for Scilex Holding's products; and
- comply with applicable legal and regulatory requirements.

If Scilex Holding is unable to successfully achieve or perform these functions, Scilex Holding 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, COVISTIX 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 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 product candidate is approved;
- acceptance by physicians, major operators of cancer clinics and patients of the product candidate 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, MHRA, 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.

Price controls may be imposed, which may adversely affect our future profitability.

In some countries, including member states of the European Union (the “EU”), the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take a significant amount of time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices, and in certain instances render commercialization in certain markets infeasible or disadvantageous from a financial perspective. In some countries, we or our collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product and/or our product candidates to other available products in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third party payors or government authorities may lead to further pressure on the prices or reimbursement levels. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, the commercial launch of our product and/or product candidates could be delayed, possibly for lengthy periods of time, we or our collaborators may not launch at all in a particular country, we may not be able to recoup our investment in one or more product candidates, and there could be a material adverse effect on our business.

Recently, there has been considerable public and government scrutiny in the United States of pharmaceutical pricing and proposals to address the perceived high cost of pharmaceuticals. There have also been several recent state legislative efforts to address drug costs, which generally have focused on increasing transparency around drug costs or limiting drug prices or price increases. Adoption of new legislation at the federal or state level could affect demand for, or pricing of, our product candidates, if approved, and could diminish our ability to establish what we believe is a fair price for our products, ultimately diminishing our revenue for our products if they are approved.

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 public announcements by members of the U.S. Congress regarding their plans to repeal and replace the Healthcare Reform Law and Medicare, and the Biden administration has announced plans to amend and expand the scope of the Healthcare Reform Law. Although we cannot predict the ultimate content or timing of any healthcare reform legislation, potential changes resulting from any amendment, repeal, replacement or expansion 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 product candidates 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.

We may seek to establish collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

From time to time we may engage in efforts to enter into licensing, distribution and/or collaboration agreements with one or more pharmaceutical or biotechnology companies to assist us with development and/or commercialization of our other product candidates. If we are successful in entering into such agreements, we may not be able to negotiate agreements with economic terms similar to those negotiated by other companies. We may not, for example, obtain significant upfront payments, substantial royalty rates or milestones. If we fail to enter into any such agreements in a timely manner or at all, our efforts to develop and/or commercialize our product candidates may be undermined. In addition, if we do not raise funds through any such agreements, we will need to rely on other financing mechanisms, such as sales of debt or equity securities, to fund our operations. Such financing mechanisms, if available, may not be sufficient or timely enough to advance our programs forward in a meaningful way in the short-term.

We may not be successful in entering into additional collaborations as a result of many factors, including the following:

- competition in seeking appropriate collaborators;
- a reduced number of potential collaborators due to recent business combinations in the pharmaceutical industry;
- inability to negotiate collaborations on acceptable terms;
- inability to negotiate collaborations on a timely basis;
- a potential collaborator's evaluation of our product or product candidates;

- a potential collaborator's resources and expertise; and
- restrictions due to an existing collaboration agreement.

If we are unable to enter into collaborations, we may have to curtail the commercialization or the development of any product candidate on which we are seeking to collaborate, reduce or delay its development program or those for other of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to develop or commercialize our product candidates.

Even if we enter into collaboration agreements and strategic partnerships or license our intellectual property, we may not be able to maintain them or they may be unsuccessful, which could delay our timelines or otherwise adversely affect our business.

We, as well as any collaborators or licensees of our technologies and services, will not be able to commercialize our product candidates if preclinical studies do not produce successful results or clinical trials do not demonstrate safety and efficacy in humans.

Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and have an uncertain outcome. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. We, as well as any licensees and collaborators, may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent the commercialization of product candidates based on our technologies, including the following:

- Preclinical or clinical trials may produce negative or inconclusive results, which may require additional preclinical testing, additional clinical trials or the abandonment of projects that we, our licensees or our collaborators expect to be promising. For example, promising animal data may be obtained about the anticipated efficacy of a product candidate and then human tests may not result in such an effect. In addition, unexpected safety concerns may be encountered that would require further testing even if the product candidate produced an otherwise favorable response in human subjects.
- Initial clinical results may not be supported by further or more extensive clinical trials. For example, we or a licensee may obtain data that suggest a desirable response from a product candidate in a small human study, but when tests are conducted on larger numbers of people, the same extent of response may not occur. If the response generated by a product candidate is too low or occurs in too few treated individuals, then the product candidate will have no commercial value.
- Enrollment in any of our or any of our licensee's or collaborator's clinical trials may be slower than projected, resulting in significant delays. The cost of conducting a clinical trial increases as the time required to enroll adequate numbers of human subjects to obtain meaningful results increases. Enrollment in a clinical trial can be a slower-than-anticipated process because of competition from other clinical trials, because the study is not of interest to qualified subjects, or because the stringency of requirements for enrollment limits the number of people who are eligible to participate in the clinical trial.
- We, our licensees or our collaborators might have to suspend or terminate clinical trials if the participating subjects are being exposed to unacceptable health risks. Animal tests do not always adequately predict potential safety risks to human subjects. The risk of any product candidate is unknown until it is tested in human subjects, and if subjects experience adverse events during the clinical trial, the trial may have to be suspended and modified or terminated entirely.
- Regulators or institutional review boards may suspend or terminate clinical research for various reasons, including safety concerns or noncompliance with regulatory requirements.
- Any regulatory approval ultimately obtained may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable.
- The effects of our technology-derived or technology-enhanced product candidates may not be the desired effects or may include undesirable side effects.

Significant clinical trial delays could allow our competitors to bring products to market before we, any of our licensees or our collaborators do and impair our ability to commercialize our technologies and product candidates based on our technologies. Poor clinical trial results or delays may make it impossible to license a product candidate or so reduce its attractiveness to prospective licensees that we will be unable to successfully develop and commercialize such a product candidate.

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.

California enacted the California Consumer Privacy Act (“CCPA”), which creates new individual privacy rights for California consumers and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosure to consumers about such companies’ data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action. The CCPA went into effect on January 1, 2020, and beginning July 1, 2020, the California Attorney General may bring enforcement actions for violations. The CCPA, among other things, requires covered companies to provide disclosures to California consumers concerning the collection and sale of personal information, and will give such consumers the right to opt-out of certain sales of personal information. The CCPA may increase our company’s compliance costs and potential liability, and we cannot yet predict the impact of the CCPA on our business. In addition, a new California privacy law, the California Privacy Rights Act (the “CPRA”) was passed by California voters on November 3, 2020. The CPRA will create additional obligations with respect to processing and storing personal information that are scheduled to take effect on January 1, 2023 (with certain provisions having retroactive effect to January 1, 2022). Further, a new Virginia privacy law, Virginia Consumer Data Protection Act (“VCDPA”) was signed into law on March 2, 2021 and is also scheduled to take effect on January 1, 2023, and the Colorado Privacy Act (“CPA”) will take effect on July 1, 2023. The VCDPA and CPA will impose many similar obligations regarding the processing and storing of personal information as the CCPA and the CPRA.

International data protection laws, including Regulation 2016/679, known as the General Data Protection Regulation (“GDPR”), may also apply to health-related and other personal information obtained outside of the United States. The GDPR went into effect on May 25, 2018. The GDPR strengthened data protection requirements in the European Union, as well as potential fines for noncompliant companies of up to the greater of €20 million or 4% of annual global revenue. The regulation imposes numerous new requirements for the collection, use, storage and disclosure of personal information, including more stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to notify regulators and affected individuals of personal data breaches, extensive new internal privacy governance obligations and obligations to honor expanded rights of individuals in relation to their personal information, including the right to access, correct and delete their data. In addition, the GDPR includes restrictions on cross-border data transfers. The GDPR increased our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Further, the United Kingdom’s exit from the European Union, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated.

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 Eribitux, 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 Annual Report on 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. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

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. Although we maintain workers’ compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. Moreover, 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.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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. In addition, our CMO operations will depend, in part, on our ability to attract and retain an appropriately skilled and sufficient workforce to operate our development and manufacturing facilities. The facilities are located in a growing biotechnology hub and competition for skilled workers will continue to increase as the industry undergoes further growth in the area.

We are highly dependent on key members of our management and scientific staff, especially Henry Ji, Ph.D., Chairman of the Board, Chief Executive Officer, President and Interim 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. In addition, we may experience employee turnover as a result of the ongoing “great resignation” occurring throughout the U.S. economy, which has impacted job market dynamics. New hires require training and take time before they achieve full productivity. New employees may not become as productive as we expect, and we may be unable to hire or retain sufficient numbers of qualified individuals. 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 through Scilex Pharma, 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, which is marketed and sold through our subsidiary, Scilex Holding. 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.

In addition, through our contract manufacturing operations, we may manufacture product candidates intended for use in humans. These activities could expose us to risk of liability for personal injury or death to persons using such product candidates or approved products. We seek to reduce our potential liability through measures such as contractual indemnification provisions with collaborators (the scope of which may vary by collaborator, and the performances of which are not secured) and insurance maintained by us and our collaborators. Our business, financial condition and results of operations could be materially adversely affected if we are required to pay damages or incur defense costs in connection with a claim that is outside the scope of the indemnification agreements, if the indemnity, although applicable, is not performed in accordance with its terms or if our liabilities exceed the amount of applicable insurance or indemnity. In addition, we could be held liable for errors and omissions in connection with the services we perform.

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 currently carry product liability insurance and errors and omissions insurance that we believe is appropriate for our company. Although we maintain product liability insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have insufficient or no coverage. If we have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, we may not have, or be able to obtain, sufficient capital to pay such amounts. In addition, insurance coverage is becoming increasingly expensive, and we may not be able to maintain insurance coverage at a reasonable cost. We also may not be able to obtain additional insurance coverage that will be adequate to cover product liability risks that may arise. Consequently, a product liability claim may result in losses that could be material to our business, financial condition and results of operations.

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, the UK Bribery Act 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.

Federal regulation and enforcement may adversely affect the implementation of cannabis laws, and such regulations may negatively impact our business operations, revenues and profits.

As previously disclosed, we have formed a Chinese joint venture with LifeTech Scientific Co., Ltd. to commercialize our proprietary water soluble cannabidiol (“CBD”) formulation technologies for consumer and pharmaceutical applications in Asia (excluding Japan). We have also formed a new business unit, Scintilla Health, Inc., to explore commercial opportunities of our water-soluble CBD formulation technologies for both consumer and pharmaceutical applications in North America, Europe and other parts of the world.

Currently, there are over 30 states in the United States, plus the District of Columbia, that have laws and/or regulations that recognize, in one form or another, medical benefits or other uses for CBD infused or cannabis related products. These states have also passed laws governing the use and sale of cannabis products and others are considering similar legislation. Nonetheless, at least some provisions of these state laws are in direct conflict with the United States Federal Controlled Substances Act (21 U.S.C. § 811) (“CSA”), which places controlled substances, including cannabis, in a schedule. Cannabis is classified as a Schedule I drug, which is viewed as having a high potential for abuse, has no currently-accepted use for medical treatment in the U.S., and lacks acceptable safety for use under medical supervision. Under the CSA, the policies and regulations of the federal government and its agencies are that cannabis has no medical benefit and a range of activities including cultivation and the personal use of cannabis is prohibited.

Uncertainty remains the rule under the CSA. There is disagreement between the government and the courts regarding the precise scope of the CSA. Some courts have held that CBD is excluded from the CSA, which they believe, only covers the Tetrahydrocannabinol (“THC”) chemical. Others have held that CBD is covered by the CSA when it is derived from the cannabis plant. On December 20, 2018, the Agricultural Improvement Act of 2018 (the “2018 Farm Bill”) legalized the cultivation and production of hemp, a variation on the cannabis plant that contains CBD but less than 0.3% THC (the psychoactive chemical of the cannabis plant), providing at least some certainty about sources of legal CBD. Our water-soluble CBD formulation technologies are expected to utilize hemp.

Unless and until Congress amends the CSA to clarify precisely what is covered by the CSA, there is a risk that federal authorities may enforce current federal law against us despite our efforts to source our products from legal sources, and we may be deemed to be producing and/or dispensing marijuana-based products in violation of federal law. There is no assurance as to the timing or scope of any such potential amendment to the CSA. Active enforcement of the current federal regulatory position on cannabis may thus directly or indirectly, and adversely, affect our business, operations, revenues and any profits. The risk of strict enforcement of the CSA in light of Congressional activity, judicial holdings and stated federal policy remains uncertain.

The Department of Justice (“DOJ”) has not historically devoted resources to prosecuting individuals whose conduct is limited to possession of small amounts of marijuana for use on private property and has instead relied on state and local law enforcement to address marijuana activity. In the event the DOJ reverses its stated policy and begins strict enforcement of the CSA in states that have laws legalizing medical marijuana and recreational marijuana in small amounts, there may be a direct and adverse impact to our business and our revenue and profits. Furthermore, H.R. 83, enacted by Congress on December 16, 2014, provides that none of the funds made available to the DOJ pursuant to the 2015 Consolidated and Further Continuing Appropriations Act may be used to prevent certain states from implementing their own laws that authorized the use, distribution, possession or cultivation of medical marijuana.

Under the 2018 Farm Bill, the FDA has been given the authority to regulate CBD when incorporated into a food, drug or cosmetic substance. Immediately following the passage of the 2018 Farm Bill, the FDA signaled its intent to use this power. On May 31, 2019, the FDA held public hearings to obtain scientific data and information about the safety, manufacturing, product quality, marketing, labeling and sale of products containing cannabis or cannabis-derived compounds, including CBD. Currently, the FDA has not issued any guidance, rules or regulations regarding the use of CBD in foods, drugs or cosmetics. Because our water-soluble CBD formulation technologies may be used to produce CBD for inclusion in food or beverages, any FDA rules and regulations limiting our ability to source, manufacture and sell CBD products, or limiting the consumer’s ability to purchase and use the products, could have a material adverse effect on our business, financial condition and results of operations.

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 our 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.

A fast track product designation or other designation to facilitate product candidate development may not lead to faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

A product sponsor may apply for fast track designation from the FDA if a product is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition (“Fast Track Designation”). The FDA has broad discretion whether or not to grant this designation. We have received Fast Track Designation for SEMDEXA™, which is in development for the treatment of lumbosacral radicular pain. Even though SEMDEXA™ has received Fast Track Designation, we may not experience a faster process, review or approval compared to conventional FDA procedures. Fast Track Designation does not accelerate clinical trials, mean that regulatory requirements are less stringent or provide assurance of ultimate marketing approval by the FDA. Instead, Fast Track Designation provides opportunities for frequent interactions with FDA review staff, as well as eligibility for priority review, if relevant criteria are met, and rolling review. The FDA may rescind the fast track designation if it believes that the designation is no longer supported by data from our clinical development program. The FDA may also withdraw any fast track designation at any time.

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, we have not completed a corporate-sponsored clinical trial. Phase I trials are ongoing for RTX for knee osteoarthritis, RTX for cancer-related pain and anti-CD38 CAR-T for multiple myeloma a Phase III trial is ongoing for SEMDEXA™ for the treatment of lumbosacral radicular pain. Non-clinical studies are ongoing and a Phase II trial is planned to start in the first half of 2021 with higher strength SP-103. We are currently in a Phase II study of abivertinib for cytokine storm related to COVID-19 infection, a Phase I study of mesenchymal stem cells for the treatment of respiratory distress syndrome associated with COVID-19 infection and a Phase I study of COVI-GUARD in hospitalized patients with COVID-19. 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 SP-103, clinical trials of SEMDEXA™, clinical trials of CAR-T, including targeting CD38 using a CAR-T cell therapy, our biosimilar/biobetters antibodies, clinical trials of our COVID-19 related product candidates 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.

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, droughts or other extreme weather events and similar events, including those that may result from climate change generally. 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.

In addition, government-imposed travel restrictions, quarantines, shelter-in-place, shutdowns and similar government orders in response to the continuing COVID-19 pandemic have resulted, and may continue to result, in direct operational and administrative disruptions to our facilities. Our operations would be disrupted if any of our employees or employees of our business partners were suspected of having contracted COVID-19, which could require quarantine of some or all such employees or closure of our facilities for disinfection. If the operations in our principal executive offices or other facilities are disrupted by a surge of COVID-19 that results in new orders by the health officer of San Diego County, the Governor of California or the State Public Health and Director of the California Department of Public Health, we may not be able to operate for the duration of such order, which could negatively impact our business, operating results and financial condition.

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. In addition, as a result of the COVID-19 pandemic, we may face increased cybersecurity risks due to our reliance, and the reliance of our CROs, contractors and consultants reliance, on internet technology and the number of our employees, and employees of our CROs, contractors and consultants, who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. 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 debt 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 September 7, 2018, Scilex Pharma 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, as amended (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 Pharma. 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 Pharma 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 Pharma, or the holders of at least 25% in principal amount of the outstanding Scilex Notes by notice to Scilex Pharma 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 Pharma, the Scilex Notes will automatically become due and payable.

Pursuant to the Scilex Indenture, we and Scilex Pharma must also comply with certain covenants with respect to the commercialization of ZTlido, 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 by Scilex Pharma, 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 Pharma, engaging in certain transactions with affiliates; and the making of investments other than those permitted by the Scilex Indenture. In addition, if actual cumulative net sales of ZTlido 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. There can be no assurance that net sales of ZTlido for the period from October 1, 2022 through September 30, 2023 will meet the predetermined target sales threshold, and if the principal amount of the Scilex Notes is increased, we may need to obtain additional financing, and cannot be sure that any additional funding, if needed, will be available on terms favorable to us, or at all.

For purposes of the Scilex Indenture, an event of default includes, among other things, (i) a failure to pay any amounts when due under the Scilex Indenture, (ii) a breach or other failure to comply with the covenants (including financial, notice and reporting covenants) under the Scilex Indenture, (iii) a failure to make any payment on, or other event triggering an acceleration under, other material indebtedness of us, and (iv) the occurrence of certain insolvency or bankruptcy events (both voluntary and involuntary) involving us or certain of our subsidiaries.

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. Under the Tax Cut and Jobs Act of 2017 (the “TCJA”), as modified by the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”), U.S. federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such U.S. federal net operating losses is limited to 80 percent of taxable income beginning in 2021. It is uncertain if and to what extent various states will conform to the federal Tax Act or the CARES Act. The CARES Act also reinstated the net operating loss carryback provisions whereby net operating losses incurred in calendar tax years 2018, 2019 and 2020 may be carried back to offset taxable income of the five tax years preceding the year of the loss. We have undergone an ownership change for purposes of Section 382 in a prior year. For the year ended December 31, 2021, 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.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

Our effective income tax rate in the future could be adversely affected by a number of factors, including: changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities, changes in tax laws, and the outcome of income tax audits in various jurisdictions. We regularly assess all of these matters to determine the adequacy of its tax provision, which is subject to significant discretion.

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.

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 United Kingdom's withdrawal 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 the London Interbank Offered Rate (“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. Effective December 31, 2021, LIBOR will no longer be used to price new loans and one-week and two-month LIBOR will no longer be published. However, overnight, 1-month, 3-month, 6-month, and 12-month maturities will continue to be published through June 2023.

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.

We have significantly restructured our business and currently have a two segment reporting structure. Our two industry segments, designated as Sorrento Therapeutics and Scilex, have been in effect for a limited period of time and there are no assurances that we will be able to successfully operate as a restructured business.

We have traditionally focused on 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 our platform technologies.

With our previous acquisition of a majority stake in Scilex Pharma, a developer of specialty pharmaceutical products for the treatment of chronic pain, and the subsequent contribution of such stake to our majority-owned subsidiary, Scilex Holding, in connection with Scilex Holding’s acquisition of Semnur Pharmaceuticals, Inc. (“Semnur”), a pharmaceutical company developing an injectable product for the treatment of lower back pain, Scilex Holding will focus on non-opioid pain management.

Our strategy is based on a number of factors and assumptions, some of which are not within our control, such as the actions of third parties. There can be no assurance that we will be able to successfully execute all or any elements of our strategy, or that our ability to successfully execute our strategy will be unaffected by external factors. If we are unsuccessful in growing our business as planned, our financial performance could be adversely affected.

We are involved, and may become involved in the future, in disputes and other legal or regulatory proceedings that, if adversely decided or settled, could materially and adversely affect our business, financial condition and results of operations.

We are, and may in the future become, party to litigation, regulatory proceedings or other disputes. For example, on April 3, 2019, we filed two legal actions against, among others, Patrick Soon-Shiong and entities controlled by him, asserting claims for, among other things, fraud and breach of contract, arising out of Dr. Soon-Shiong’s purchase of the drug Cynviloq™ from our company in May 2015. The actions allege that Dr. Soon-Shiong and the other defendants, among other things, acquired the drug Cynviloq™ for the purpose of halting its progression to the market. As an additional example, on May 26, 2020, Wasa Medical Holdings filed a putative federal securities class action against us, our President, Chief Executive Officer and Chairman of the Board of Directors, Henry Ji, Ph.D., and our SVP of Regulatory Affairs, Mark R. Brunswick, Ph.D., alleging that we, Dr. Ji and Dr. Brunswick made materially false and/or misleading statements to the investing public regarding STI-1499 and its ability to inhibit the SARS-CoV-2 virus infection. A second putative federal securities class action was filed in the U.S. District Court for the Southern District of California against the same defendants alleging the same claims and seeking the same relief. In general, claims made by or against us in disputes and other legal or regulatory proceedings can be expensive and time consuming to bring or defend against, requiring us to expend significant resources and divert the efforts and attention of our management and other personnel from our business operations. While we intend to pursue any claims made by us, or defend against any claims brought against us, vigorously, we cannot predict the outcomes of such claims. Any failure to prevail in any claims made by us or any adverse determination against us in these proceedings, or even the allegations contained in the claims, regardless of whether they are ultimately found to be without

merit, may also result in settlements, injunctions or damages that could have a material adverse effect on our business, financial condition and results of operations.

Investors' expectations of our performance relating to environmental, social and governance factors may impose additional costs and expose us to new risks.

There is an increasing focus from certain investors, employees, regulators and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance ("ESG") factors. Some investors and investor advocacy groups may use these factors to guide investment strategies and, in some cases, investors may choose not to invest in our company if they believe our policies relating to corporate responsibility are inadequate. Third-party providers of corporate responsibility ratings and reports on companies have increased to meet growing investor demand for measurement of corporate responsibility performance, and a variety of organizations currently measure the performance of companies on such ESG topics, and the results of these assessments are widely publicized. Investors, particularly institutional investors, use these ratings to benchmark companies against their peers and if we are perceived as lagging with respect to ESG initiatives, certain investors may engage with us to improve ESG disclosures or performance and may also make voting decisions, or take other actions, to hold us and our board of directors accountable. In addition, the criteria by which our corporate responsibility practices are assessed may change, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. If we elect not to or are unable to satisfy such new criteria, investors may conclude that our policies with respect to corporate responsibility are inadequate. We may face reputational damage in the event that our corporate responsibility procedures or standards do not meet the standards set by various constituencies.

We may face reputational damage in the event our corporate responsibility initiatives or objectives do not meet the standards set by our investors, stockholders, lawmakers, listing exchanges or other constituencies, or if we are unable to achieve an acceptable ESG or sustainability rating from third-party rating services. A low ESG or sustainability rating by a third-party rating service could also result in the exclusion of our common stock from consideration by certain investors who may elect to invest with our competition instead. Ongoing focus on corporate responsibility matters by investors and other parties as described above may impose additional costs or expose us to new risks. Any failure or perceived failure by us in this regard could have a material adverse effect on our reputation and on our business, share price, financial condition, or results of operations, including the sustainability of our business over time.

We are subject to recently enacted state laws in California that require gender and diversity quotas for boards of directors of public companies headquartered in California.

In September 2018, California enacted Senator Bill 826 ("SB 826"), which generally requires public companies with principal executive offices in California to have at least two female directors on its board of directors if the company has at least five directors, and at least three female directors on its board of directors if the company has at least six directors.

Additionally, on September 30, 2020, California enacted Assembly Bill 979 ("AB 979"), which generally requires public companies with principal executive offices in California to include specified numbers of directors from "underrepresented communities". A director from an "underrepresented community" means a director who self-identifies as Black, African American, Hispanic, Latino, Asian, Pacific Islander, Native American, Native Hawaiian, Alaska Native, gay, lesbian, bisexual or transgender. By December 31, 2021, each public company with principal executive offices in California was required to have at least one director from an underrepresented community. By December 31, 2022, a public company with more than four but fewer than nine directors will be required to have a minimum of two directors from underrepresented communities, and a public company with nine or more directors will need to have a minimum of three directors from underrepresented communities.

We cannot assure that we can recruit, attract and/or retain qualified members of the board and meet gender and diversity quotas as required by SB 826 or AB 979, and our board of directors does not currently satisfy the quota required under SB 826. A failure to comply with either SB 826 or AB 979 could result in fines from the California Secretary of State, with a \$100,000 fine for the first violation and a \$300,000 fine for each subsequent violation of either law, and our reputation may be adversely affected.

Risks Related to Acquisitions

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

We have expanded, and plan to continue to expand, our assets, business and intellectual property portfolio through the acquisition of new assets, businesses and technologies.

For example, in November 2016, we acquired a majority of the outstanding capital stock of Scilex Pharma, which was contributed to our majority-owned subsidiary Scilex Holding in connection with the corporate reorganization of Scilex Holding and acquisition of Semnur by Scilex Holding in March 2019. These assets, together, constitute our Scilex segment. We also acquired Virttu Biologics Limited in 2017, SOFUSA assets, a revolutionary drug delivery technology, in July 2018 and SmartPharm Therapeutics, Inc. in September 2020. In June 2021, we acquired ACEA Therapeutics, Inc. and in February 2022, we acquired Virex Health, Inc., and are in the process of integrating these two companies and their technologies 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.

In addition, we may issue shares of our common stock or other equity-linked securities in connection with future acquisitions of businesses and technologies. Any such issuances of shares of our common stock could result in material dilution to our existing stockholders.

We may be required to make milestone payments to the former stockholders of Semnur in connection with our development and commercialization of SEMDEXA™, which could adversely affect the overall profitability of SEMDEXA™, if approved.

Under the terms of the Agreement and Plan of Merger Scilex Holding entered into with Semnur, Sigma Merger Sub, Inc., the prior wholly-owned subsidiary of Scilex Holding, Fortis Advisors LLC, solely as representative of the holders of Semnur equity (the "Semnur Equityholders"), and us, for limited purposes, Scilex Holding is obligated to pay the Semnur Equityholders up to an aggregate of \$280.0 million in contingent cash consideration based on the achievement of certain milestones. A \$40.0 million payment will be due upon obtaining the first approval of an NDA by the FDA of any Semnur product, which includes SEMDEXA. Additional payments of up to \$240 million will be due upon the achievement of certain cumulative net sales of Semnur products.

These milestone obligations could impose substantial additional costs on our Scilex operating segment, divert resources from other aspects of its business, and adversely affect the overall profitability of SEMDEXA, if approved. We may need to obtain additional financing to satisfy these milestone payments, and cannot be sure that any additional funding, if needed, will be available on terms favorable to us, or at all.

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.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the PTO and various foreign patent offices at various points over the lifetime of our patents and/or applications. We have systems in place to remind us to pay these fees, and we rely on our outside counsel or service providers to pay these fees when due. Additionally, the PTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business. In addition, we are responsible for the payment of patent fees for patent rights that we have licensed from other parties. If any licensor of these patents does not itself elect to make these payments, and we fail to do so, we may be liable to the licensor for any costs and consequences of any resulting loss of patent rights.

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 (which is held by our subsidiary, Scilex Holding), 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.

In addition, many of the formulations used and processes developed by us in manufacturing any of our collaborators' products are subject to trade secret protection, patents or other intellectual property protections owned or licensed by such collaborator. While we make significant efforts to protect our collaborators' proprietary and confidential information, including requiring our employees to enter into agreements protecting such information, if any of our employees breaches the non-disclosure provisions in such agreements, or if our collaborators make claims that their proprietary information has been disclosed, our reputation may suffer damage and we may become subject to legal proceedings that could require us to incur significant expenses and divert our management's time, attention and resources.

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.

In addition, our collaborators' products may be subject to claims of intellectual property infringement and such claims could materially affect our CMO business if their products cease to be manufactured and they have to discontinue the use of the infringing technology which we may provide. Any of the foregoing could affect our ability to compete or could have a material adverse effect on our business, financial condition and results of operations.

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 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 CynviloqTM 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 license 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 4, 2021 to December 31, 2021, our closing stock price ranged from \$4.65 to \$16.51

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;
- effects of public health crises, pandemics and epidemics, such as the COVID-19 pandemic; and
- other events or factors, many of which are beyond our control.

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

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

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

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

Our strategic investments may result in losses.

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

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

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

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

Our quarterly operating results may fluctuate significantly.

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

- variations in the level of expenses related to our development programs;
- the addition or termination of clinical trials;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting our product candidates; 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.

Our investors could experience substantial dilution of their investments as a result of subsequent exercises of our outstanding options, including the CEO Performance Award, or the grant of future equity awards by us.

As of December 31, 2021, 61.3 million shares of our common stock were reserved for issuance under our equity incentive plans, of which 22.5 million shares of our common stock were subject to options outstanding at such date at a weighted-average exercise price of \$6.19 per share, 3.4 million shares of our common stock were subject to outstanding restricted stock units, 3.2 million shares of our common stock were reserved for issuance pursuant to our 2019 Stock Incentive Plan and 7.2 million shares of our common stock were reserved for issuance pursuant to our 2020 Employee Stock Purchase Plan. In addition, 24,935,882 shares of our common stock are subject to the 10-year CEO performance award granted to Dr. Ji that is tied solely to achieving market capitalization milestones and has an exercise price of \$17.30 per share. To the extent outstanding options are exercised, our existing stockholders may incur dilution.

We rely on equity awards to motivate current employees and to attract new employees. The grant of future equity awards by us to our employees and other service providers may further dilute our stockholders.

Our directors and executive officers 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 February 28, 2022, our directors and executive officers beneficially owned, in the aggregate, approximately 3.0% 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 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.

Our Amended and Restated Bylaws provide that the Court of Chancery in the State of Delaware is the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our Amended and Restated Bylaws (our "Bylaws"), provide that, unless our Board of Directors consents to an alternative forum, the Court of Chancery in the State of Delaware will be the sole and exclusive forum for: (i) any derivative action or proceeding brought by or on our behalf; (ii) any direct action asserting a claim against us or any of our directors or officers pursuant to any of the provisions of the General Corporation Law of the State of Delaware, our Restated Certificate of Incorporation or our Bylaws; (iii) any action asserting a claim of breach of fiduciary duties owed by any of our directors, officers or other employees to our stockholders; or (iv) any action asserting a violation of Delaware decisional law relating to our internal affairs. This provision does not apply to (a) actions in which the Court of Chancery in the State of Delaware concludes that an indispensable party is not subject to the jurisdiction of Delaware courts, or (b) actions in which a federal court has assumed exclusive jurisdiction to a proceeding. This choice of forum provision is not intended to apply to any actions brought under the Securities Act of 1933, as amended, or the Securities Act, or the Securities Exchange Act of 1934, as amended, or the Exchange Act. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. However, our Bylaws do not relieve us of our duties to comply with federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations. Our Bylaws also provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and consented to this choice of forum provision.

This choice of forum provision in our Bylaws may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. In addition, stockholders who do bring a claim in the Court of Chancery in the State of Delaware could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near Delaware. Furthermore, the enforceability of similar choice of forum provisions in other companies' governing documents has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provision in our Bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

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. 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 a material weakness 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, if not remediated, result in a material misstatement in our financial statements and could adversely affect our future results of operations, our stock price, and our ability to raise capital.

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 our annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

As previously disclosed on our Current Report on Form 8-K filed with the Securities and Exchange Commission on January 7, 2022, our former Chief Financial Officer passed away unexpectedly on January 6, 2022. Due in large part to the unexpected passing of our former Chief Financial Officer, our management has identified that we did not employ sufficient accounting resources with appropriate experience and technical expertise to effectively execute controls over certain judgmental accounting areas. As a result, certain of our control activities in the areas of revenue, business combinations, investments, debt, derivative liabilities and leases did not operate effectively and have been deemed deficient and the combination of the aforementioned deficiencies represented a material weakness in our internal control over financial reporting as of December 31, 2021. The material weakness did not result in a restatement of previously issued annual consolidated financial statements or condensed interim consolidated financial statements.

As a result of the material weakness, we are in the process of implementing remediation measures including, but not limited to, hiring a Chief Financial Officer and other personnel with appropriate experience and technical expertise to effectively execute controls over judgmental accounting areas. We believe that our remediation measures, if effectively implemented, will provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external purposes in accordance with generally accepted accounting principles (“GAAP”). We cannot assure you that the measures we have taken to date or any measures we may take in response to the material weakness in the future will be sufficient to remediate such material weakness or to avoid potential future material weaknesses. Any failure to implement these improvements to our internal control over financial reporting would result in a continued material weakness 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. 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. If we experience future material weaknesses or deficiencies in internal controls and we are unable to correct them in a timely manner, our ability to record, process, summarize and report financial information accurately and within the time periods specified in the rules and forms of the SEC, will be adversely affected. Any such failure could negatively affect the market price and trading liquidity of our common stock, lead to delisting, cause investors to lose confidence in our reported financial information, subject us to civil and criminal investigations and penalties, and generally materially and adversely impact our business and financial condition.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

The following table sets forth our principal properties as of December 31, 2021, all of which are leased:

Location	Lease term	Square footage	Primary use
Sorrento Therapeutics segment			
San Diego, CA ⁽¹⁾	2038 - option to extend for one additional 5-year period	77,000	Research and development
San Diego, CA	2034 - option to extend for one additional 10-year period	69,000	Research and development
San Diego, CA ⁽¹⁾	2038 - option to extend for one additional 5-year period	61,000	Administrative, research and development
San Diego, CA ⁽¹⁾	2038 - option to extend for one additional 5-year period	43,000	Research and development
San Diego, CA ⁽¹⁾⁽²⁾	2038 - option to extend for one additional 5-year period	30,000	Principal executive offices and Administrative
San Diego, CA	2029 - option to extend for one additional 5-year period	36,000	Contract manufacturing
San Diego, CA	2025	11,000	Research and development
San Diego, CA	2025 - option to extend for one additional 5-year period	9,000	Research and development
Suzhou, China	2022	50,000	Contract manufacturing, research and development
Scilex segment			
Palo Alto, CA	2024 - option to extend for one additional 3-year period	6,000	Administrative

- (1) These facilities are leased on coterminous terms that are based on a 188 month lease that is estimated to commence in the first half of 2023 when such necessary construction has been completed.
- (2) This facility is utilized by both the Sorrento Therapeutics and Scilex segments.

Item 3. Legal Proceedings.

In the normal course of business, we may be named as a defendant in one or more lawsuits. Other than as set forth below, 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.

Information regarding reportable legal proceedings is contained in [Note 11](#) of the accompanying notes to consolidated financial statements in this Annual Report on Form 10-K under the heading “Litigation”.

Item 4. Mine Safety Disclosures.

None.

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

Market Information

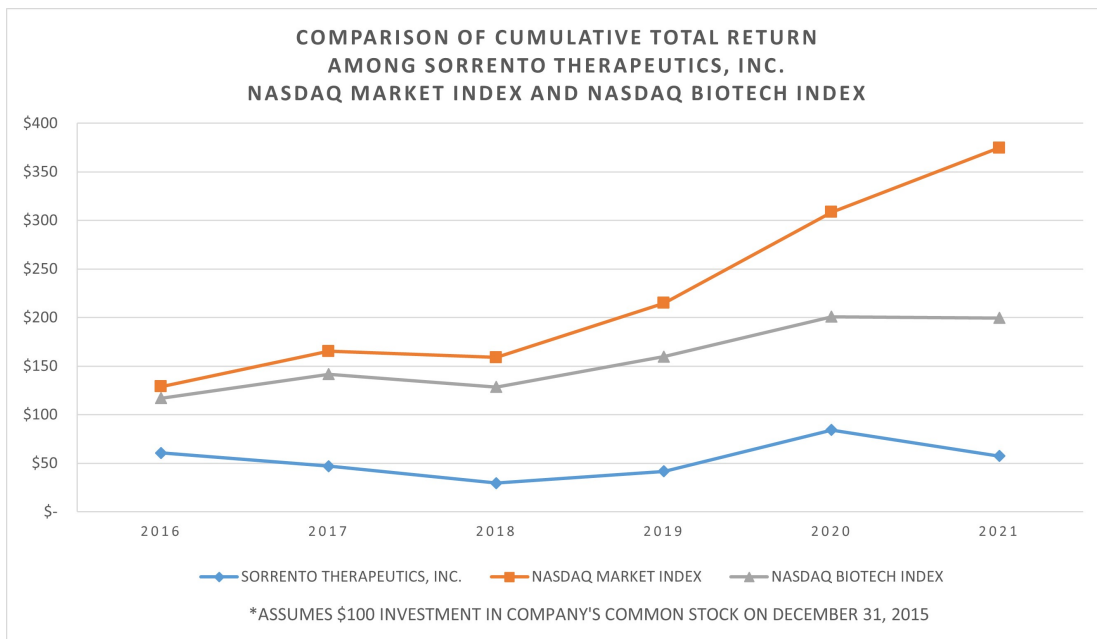
Our common stock is listed on the Nasdaq Capital Market under the symbol “SRNE”.

Holders of Record

As of February 28, 2022, there were 207 holders of record of our common stock.

Performance Graph

The following graph compares the cumulative total stockholder return on our common stock from December 31, 2016 to December 31, 2021 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, 2015 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. [Reserved]

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 Annual Report on 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 Annual Report on Form 10-K. Additionally, you should read the “Risk Factors” section of this Annual Report on 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 biopharmaceutical company focused on delivering innovative and clinically meaningful therapies to address unmet medical needs.

At our core, we are antibody-centric 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, CD47, BCMA, CTLA-4, CD123, CD47, LAG3, ROR1, VEGFR2, CCR2 and CD137 and SARS-CoV-2 neutralizing antibodies, among others. We also have programs assessing the use of our technologies and products in autoimmune, inflammatory, viral and neurodegenerative diseases.

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”), lymphatic drug targeting (SOFUSA®), as well as bispecific antibody approaches. We acquired SOFUSA, a revolutionary drug delivery technology, in July 2018, which delivers biologics directly into the lymphatic system to potentially achieve improved efficacy and reduce adverse effects compared to standard parenteral immunotherapy. Additionally, our majority-owned subsidiary, Scilex Holding Company (“Scilex Holding”), acquired the assets of Semnur Pharmaceuticals, Inc. (“Semnur”) in March 2019. Semnur’s SEMDEXA™ (“SP-102”) compound has the potential to become the first U.S. Food and Drug Administration (“FDA”)–approved epidural steroid product for the treatment of sciatica. In response to the global SARS-CoV-2 (“COVID-19”) pandemic, we are utilizing the Bruton’s tyrosine kinase (“BTK”) inhibitor (Abivertinib, acquired from ACEA Therapeutics, Inc.) to treat the cytokine storm associated with a COVID-19 infection. We are also internally developing and conducting clinical studies for potential coronavirus antiviral therapies and vaccines, including COVI-MSC™, COVI-AMG™, COVIDROPS™, and COVISHIELD™, and diagnostic test solutions, such as COVISTIX™ and COVITRACK™.

With each of our clinical and preclinical programs, we aim to tailor our therapies to treat specific stages in the evolution of a disease, from elimination to equilibrium and escape. In addition, our objective in our immuno-oncology programs 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, oncolytic viruses (Seprehvec™) and a palliative care program targeted to treat intractable pain in advanced cancer (resiniferatoxin, or “RTX”). Our cellular therapy programs focus on our allogeneic DAR-T platform for adoptive cellular immunotherapy to treat both solid and liquid tumors.

From the start of the COVID-19 pandemic, our mission has been to leverage our deep expertise in developing targeted antibodies for cancer immunotherapy to create best-in-category treatments and diagnostics to ease suffering and assist in the global response to COVID-19. We have leveraged, and continue to leverage, our G-MAB library and antibody development engineering capabilities to advance promising diagnostics and neutralizing antibody candidates to test for and treat COVID-19 and the immune reactions associated with SARS-CoV-2 infection.

STI-2020, or plutavimab, is a highly potent neutralizing antibody (“nAb”) to COVID-19 that is currently being developed for intranasal (“IN”) instillation as STI-2099, or COVIDROPS. In preclinical studies, STI-2020/2099 was highly effective against the original Washington strain and early variants of concern (“VoCs”), including the delta VoC. STI-2020, the intravenous (“IV”) formulation and COVIDROPS were both cleared by the FDA for Phase I healthy volunteer studies which were completed and demonstrated that the nAbs were well-tolerated (IV up to 200 mg and intranasal up to 60 mg) without dose limiting toxicity or severe or serious adverse events (“AEs”). Most AEs were mild and unrelated. Phase II studies of COVIDROPS in outpatients with COVID-19 have begun enrollment in Mexico, the United Kingdom and the U.S. The United Kingdom study reached the planned interim analysis threshold in the first half of January 2022. The study in Mexico began pediatric enrollment in early 2022. We are also

developing a broad-spectrum neutralizing antibody, STI-9167 (COVISHIELD), to be formulated both for IV and IN administration. STI-9167 (IV formulation) and STI-9199 (IN formulation using STI-9167 drug substance) have not only been broadly effective in preclinical studies for prior VoCs but are highly potent against the Omicron VoC. A healthy subject study for STI-9167/9199 is expected to begin in the first quarter of 2022 with Phase II studies of COVISHIELD to follow.

We have also developed two promising potential rescue treatments with Abivertinib (STI-5656), an oral next generation dual epidermal growth factor receptor (“EGFR”) (including mutant forms)/BTK inhibitor, or epidermal growth factor receptor/BTK inhibitor to treat hospitalized COVID-19 patients and COVI-MSC™ (samtonadstrocel or STI-8282), human allogeneic adipose-derived mesenchymal stromal cells for patients suffering from COVID-19-induced acute respiratory distress (“ARD”). Both have been cleared by the FDA and Abivertinib has completed Phase II clinical studies in the U.S. and Brazil of Abivertinib to treat COVID-19-induced acute respiratory distress syndrome (“ARDS”). While all patient groups improved with treatment, the U.S. study identified an At-Risk population who were the best responders: those who required oxygen supplementation with non-invasive ventilation or high flow oxygen at baseline. Although the Brazil study did not enroll a population as sick as those in the U.S. study, the results were similarly supportive. In the U.S. study, the At-Risk patients were discharged on average two days sooner from the intensive care unit. In both studies, there was nearly a 50% reduction of death and/or mechanical ventilation or extracorporeal membrane oxygenation by day 29. This data was used to power a pivotal Phase III Abivertinib study which is expected to begin enrollment in the second quarter of 2022. Two separate Phase II COVI-MSC studies are currently enrolling in Brazil and the U.S. in patients with COVID-19-induced ARDS. We are also working with Brazilian regulators (ANVISA) to conduct a COVID-19 study with COVI-MSCs in pulmonary long-haul patients post-recovery from the acute infection.

In furtherance of our goal to enable early detection and treatment across the entire continuum of COVID-19 solutions, we are further developing a number of highly sensitive and rapid diagnostic tests. COVISTIX™ is a lateral flow antigen test that uses a proprietary platinum-based colloid and antibody combination, resulting in high sensitivity and accuracy. This is a simple and rapid (15-minute) test with a shallow nasal swab and is designed for point-of-care and at-home use. This product has been approved under emergency use authorization for use in Mexico and Brazil as a point-of-care test and has also received its Conformité Européenne (“CE”) mark.

We previously have reported early data from Phase I trials of our carcinoembryonic antigen (“CEA”)-directed CAR-T program. We treated five patients with stage 4, unresectable adenocarcinoma (four with pancreatic cancer and one with colorectal cancer) and CEA-positive liver metastases with anti-CEA CAR-T. During 2021, we decided to pivot away from an autologous CAR-T platform to allogeneic DAR-T and successfully submitted an Investigational New Drug application (“IND”) for our CD38 DAR-T candidate for relapsed or refractory multiple myeloma (“RRMM”). We anticipate the first patient enrollment in the first quarter of 2022.

With respect to Abivertinib for the treatment of non-small cell lung cancer (NSCLC), our oral small molecule combined EGFR/BTK inhibitor, a final imaging read of Phase III data is pending with additional follow-up from patients who continued on treatment in the years since the last update presented at the American Society of Clinical Oncology (ASCO) 2019 Annual Meeting. It is anticipated that a pre-new drug application (“NDA”) meeting will be requested to discuss the pathway to a planned NDA filing. Finally, we intend to start studies in castrate resistant prostate cancer with Abivertinib in the U.S. in the first quarter of 2022 and in Brazil in the second quarter of 2022.

With respect to our anti-CD38 ADC program, we began enrolling patients in the first quarter of 2021 in a Phase Ib ascending dose study for systemic Amyloid light-chain (“AL”) amyloidosis. We intend to start a new study to target RRMM in a partnership with Columbia University in the first quarter of 2022 and are planning collaborations with Columbia to target metastatic esophageal and lung cancer and with MD Anderson to treat T-cell acute lymphoblastic leukemia (“T-ALL”).

Additionally, based upon our exclusive licensing arrangement with Mayo Clinic for its antibody-drug-nanoparticle albumin-bound (“ADNAB™”) platform, the next generation in ADC technology, we intend to file several INDs in 2022 to treat various cancer targets. We also have an ongoing partnership with Mayo Clinic, directed to the use of lymphatic delivery using a hollow core microneedle array device manufactured by our SOFUSA unit, to explore whether lymphatic delivery of products traditionally delivered by IV administration can improve the pharmacokinetic profile and efficacy while reducing their AE profile. We also have an active program using the SOFUSA delivery system to treat rheumatoid arthritis patients resistant to etanercept and expect to announce preliminary results from an ongoing study in the first quarter of 2022.

Broadly speaking, we believe we are among the world’s leading cellular therapy 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 DAR-T solutions. DAR-T therapy can become a versatile drug product platform capable of delivering multiple targeted therapeutic approaches.

Outside of immuno-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 RTX, a non-opioid naturally-occurring product that specifically targets transient receptor potential vanilloid-1 (“TRPV1”). Depending on the site of injection, RTX can ablate or destroy targeted nerves (e.g., an epidural injection) or temporarily defunctionalize them (peripheral injections such as intra-articular). TRPV1 largely is responsible for the noxious chronic and inflammatory pain signaling that can occur post trauma but leaves other nerve functions intact. RTX has been granted orphan drug status for the treatment of intractable pain with end-stage or advanced cancer and two Phase Ib first-in-human trials (intrathecal and epidural routes) were completed. A Phase Ib trial studying the safety and efficacy of RTX to treat moderate to severe osteoarthritis (“OA”) knee pain was completed in early 2021 with one year follow-up data and preliminary results showed the potential for long-term efficacy with no dose-limiting toxicity. We have received clearance to proceed with Phase II clinical trials of RTX to treat severe cancer pain (epidural) and moderate-to-severe OA of the knee pain (intra-articular). The knee OA study began enrolling in the fourth quarter of 2021 and the epidural cancer pain study is expected to start enrolling in the first quarter of 2022.

Also, in this area, we have developed in-house and acquired proprietary technologies to responsibly develop next generation, branded pharmaceutical products to better manage patients’ medical conditions, maximize the quality of life of patients and assist healthcare providers. The flagship product of our subsidiary, Scilex Pharmaceuticals Inc. (“Scilex Pharma”), ZTlido® (lidocaine topical system 1.8%) (“ZTlido”) 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 October 2018. Scilex Pharma has now built a full commercial organization, which includes sales, marketing, market access and medical affairs.

Impact of COVID-19 on Our Business

We are closely monitoring the COVID-19 pandemic and its potential impact on our business. In an effort to protect the health and safety of our employees, we took proactive action from the earliest signs of the outbreak, including implementing social distancing policies at our facilities, facilitating remote working arrangements and imposing employee travel restrictions.

The extent to which COVID-19 may impact our business, clinical trials and sales of ZTlido will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

Recent Developments

On February 1, 2022, we completed the acquisition of Virex Health, Inc. (“Virex”) pursuant to that certain Agreement and Plan of Merger (the “Virex Merger Agreement”), dated as of January 14, 2022, among us, Virex, VH Merger Sub I, Inc., our wholly owned subsidiary (“Merger Sub”), VH Merger Sub II, LLC, our wholly owned subsidiary (“Merger LLC”), and Fortis Advisors LLC, as representative of the equityholders of Virex (the “Stockholders’ Representative”). Pursuant to the terms of the Merger Agreement, Merger Sub was merged with and into Virex (the “Initial Merger”), with Virex continuing as the surviving corporation in such merger, and subsequent to the Initial Merger, Virex was merged with and into Merger LLC (the “Subsequent Merger”), with Merger LLC surviving as our wholly owned subsidiary. At the effective time of the Subsequent Merger, the name of Merger LLC as the surviving company in the Subsequent Merger was changed to Virex Health, LLC.

Upon completion of the Initial Merger, the equityholders of Virex (the “Virex Equityholders”) became entitled to receive the following amounts (to be paid in cash and stock as further described below): (i) \$12,000,000, as such amount was adjusted to \$11,566,275 (and may be further adjusted post-closing) pursuant to the terms of the Virex Merger Agreement for indebtedness, transaction expenses and cash (the “Closing Consideration”) and (ii) subject to achievement of certain regulatory milestones, up to \$10,000,000 in additional consideration (the “Milestone Payment” and together with the Closing Consideration, the “Merger Consideration”).

Pursuant to the Merger Agreement, the Merger Consideration shall be paid as follows: (i) 59% in cash; and (ii) 41% in shares of our common stock. Upon completion of the Initial Merger, the Virex Equityholders became entitled to receive an aggregate of \$6,824,126 in cash and an aggregate of 1,281,662 shares of our common stock based on a price per share equal to \$3.70 (representing the volume weighted average closing price per share of our common stock for the eleven consecutive trading days ending on the date that was three trading days prior to the closing date). Ten percent of the Closing Consideration was deposited into an escrow account (in the form of cash and stock) as partial security for the indemnification obligations of the Virex Equityholders under the Merger Agreement and \$150,000 was set aside for expenses that may be incurred by the Stockholders’ Representative.

At any time shares of our common stock are issued in respect of a Milestone Payment, the number of shares to be issued will be based on a price per share equal to the volume weighted average closing price per share of our common stock for the eleven

consecutive trading days ending on the date that is three trading days prior to the applicable issuance date. The aggregate number of shares of our common stock issuable pursuant to the Virex Merger Agreement as Merger Consideration shall not exceed 19.99% of the total number of shares of our common stock issued and outstanding at the closing date.

Results of Operations

The following discussion of our operating results explains material changes in our results of operations for the years ended December 31, 2021 and 2020. The discussion should be read in conjunction with the consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. We operate in two operating and reportable segments, Sorrento Therapeutics and Scilex.

Comparison of the Years Ended December 31, 2021 and 2020

Revenues. Revenues were \$52.9 million for the year ended December 31, 2021, as compared to \$40.0 million for the year ended December 31, 2020.

Revenues in our Sorrento Therapeutics segment increased from \$13.7 million to \$24.4 million for the year ended December 31, 2021 compared to the prior year and were primarily attributed to higher contract manufacturing service revenues.

Revenues in our Scilex segment increased from \$26.3 million to \$28.5 million for the year ended December 31, 2021 compared to the prior year due to increased product sales of ZTlido.

Cost of revenues. Cost of revenues for the years ended December 31, 2021 and 2020 were \$13.0 million and \$9.9 million, respectively, and relate to product sales, the sale of customized reagents and providing contract manufacturing services. The costs generally include employee-related expenses, including salary and benefits, direct materials and overhead costs including rent, depreciation, utilities, facility maintenance and insurance.

Cost of revenues for our Sorrento Therapeutics segment increased by \$1.6 million and was driven by the increase in revenues.

Cost of revenues for our Scilex segment increased by \$1.5 million as compared to the prior year and was attributable to higher sales volumes of ZTlido.

Research and development expenses. Research and development expenses for the years ended December 31, 2021 and 2020 were \$206.9 million and \$111.3 million, respectively. Research and development expenses primarily include expenses associated with isolating and advancing human antibody drug candidates derived from our libraries, as well as advancing our RTX, COVID-19, SP-102, Oncolytic Virus, antibody drug conjugate (“ADC”) and oncology programs. 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.

Research and development expenses for our Sorrento Therapeutics segment increased by \$96.3 million as compared to the prior fiscal year and were primarily driven by higher headcount and increased clinical development costs spent on advancing our various research and development programs.

Research and development expenses for our Scilex segment decreased by \$0.8 million as compared to the prior fiscal year and were primarily driven by lower clinical development costs.

We expect research and development expenses for both segments to increase as we: (i) advance various 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 year ended December 31, 2021 was \$24.2 million. These expenses related to the Aardvark Asset Purchase Agreement for \$5.0 million and the entry into the Mount Sinai License Agreement for \$7.5 million during the period as further described in [Note 7](#) of the accompanying notes to the consolidated financial statements in this Annual Report on Form 10-K. These expenses also related to \$10.2 million related to our investment in Deverra Therapeutics, Inc. during the period as further described in [Note 5](#) of the

accompanying notes to the consolidated financial statements in this Annual Report on Form 10-K. The remainder related to our investments in various licensing arrangements entered into during the period. We recognized \$43.0 million of acquired in-process research and development expenses for the year ended December 31, 2020, which were primarily related to various licensing arrangements entered into during the year, as well as other investments in new technologies and preclinical programs.

Selling, general and administrative expenses. General and administrative expenses for the years ended December 31, 2021 and 2020 were \$196.9 million and \$116.2 million, respectively and consisted primarily of salaries and personnel-related expenses, stock-based compensation expense, professional fees, infrastructure expenses, legal and other general corporate expenses.

Selling, general and administrative expenses for our Sorrento Therapeutics segment increased by approximately \$73.1 million as compared to the prior fiscal year and were primarily attributed to higher headcount, professional fees and stock-based compensation expense as compared to the same period of the prior year.

Selling, general and administrative expenses for our Scilex segment increased by approximately \$7.6 million as compared to the prior fiscal year and were primarily attributed to higher professional fees.

Loss on derivative liabilities. Loss on derivative liabilities for the year ended December 31, 2021 was \$0.3 million compared to a loss of \$6.6 million for the year ended December 31, 2020.

Loss on contingent consideration. During the year ended December 31, 2021, we recorded a loss on contingent consideration and acquisition consideration payable of approximately \$9.2 million resulting from the change in fair value of the Earn-Out Consideration associated with the acquisition of ACEA Therapeutics, Inc. (“ACEA”). (See [Note 3](#) and [Note 7](#) of the accompanying notes to consolidated financial statements in this Annual Report on Form 10-K). During the year ended December 31, 2020, we did not record any loss or gain on contingent consideration.

There was no gain or loss on derivative liabilities for our Sorrento Therapeutics segment during the year ended December 31, 2021. Gain on derivative liabilities for our Sorrento Therapeutics segment for the year ended December 31, 2020 totaled \$5.8 million and was primarily attributed to the full repayment of the term loans provided by certain funds and accounts managed by Oaktree Capital Management, L.P. (the “Term Loans”) during 2020 as further described in [Note 8](#) of the accompanying notes to the consolidated financial statements in this Annual Report on Form 10-K

Loss on derivative liabilities for our Scilex segment for the year ended December 31, 2021 totaled \$0.3 million and was primarily attributed to revised probabilities and revised sales forecasts as further described in [Note 3](#) of the accompanying notes to the consolidated financial statements in this Annual Report on Form 10-K. Gain on derivative liabilities for our Scilex segment for the year ended December 31, 2020 totaled \$0.8 million and was primarily attributed to revised probabilities and revised sales forecasts as further described in [Note 3](#) of the accompanying notes to the consolidated financial statements in this Annual Report on Form 10-K

Loss on Marketable Investments. Loss on marketable investments reflects \$39.8 million in unrealized losses related to the change in fair value of our shares of Celularity Inc. and \$24.1 million of realized gains from the sale of our shares of ImmunityBio, Inc. during the year ended December 31, 2021. We recorded approximately \$0.7 million in realized gains related to other investments during the year ended December 31, 2021. During the year ended December 31, 2020, we did not have any marketable investments.

Scilex Notes principal increase. Actual cumulative net sales of ZTlido from the issue date of the Scilex Notes through December 31, 2021 did not equal or exceed 95% of a predetermined target sales threshold for such period, which resulted in a \$28.0 million increase in the principal amount of the Scilex Notes, effective February 15, 2022. As a result, we recorded the increase of \$28.0 million in principal and non-operating expense at December 31, 2021.

Interest expense. Interest expense for the years ended December 31, 2021 and 2020 was \$10.2 million and \$20.2 million, respectively. The decrease resulted primarily from a decrease in interest expense associated with the term loans with Oaktree Capital Management L.P. and affiliates, which were fully repaid in the year ended December 31, 2020. Interest income was immaterial for both periods.

Loss on debt extinguishment. Loss on debt extinguishment for the year ended December 31, 2021 was \$6.7 million and was attributable to the repurchases of the outstanding principal on the Scilex Notes, and was partially offset by short-term debt forgiveness. Loss on debt extinguishment for the year ended December 31, 2020 was \$51.9 million and was attributed to the repayments of outstanding principal on the Term Loans.

Income tax benefit. Income tax benefit for the year ended December 31, 2021 and 2020 was \$33.5 million and \$2.0 million, respectively. The increase in the year ended December 31, 2021 was primarily due to deferred tax liabilities recognized from the ACEA acquisition resulting in a release of valuation allowance in 2021 compared to 2020.

Loss on equity method investments. Loss on equity investments for the year ended December 31, 2021 was \$0.1 million compared to a loss on equity investments of \$5.8 million for the year ended December 31, 2020. The loss was attributed to the recognition of our portion of the net loss or net income from our equity method investments. During the year ended December 31, 2020, we also recorded an impairment loss of approximately \$3.8 million related to an equity method investment for which we determined the investment's value was no longer supportable. (See [Note 5](#) of the accompanying notes to consolidated financial statements in this Annual Report on Form 10-K).

Net loss. Net loss for the year ended December 31, 2021 was \$429.1 million as compared to a net loss of \$314.4 million for 2020.

Comparison of the Years Ended December 31, 2020 and 2019

For a discussion regarding our financial condition and results of operations for the year ended December 31, 2020 as compared to the year ended December 31, 2019, please refer to the discussion under the heading “Results of Operations— Comparison of the Years Ended December 31, 2020 and 2019” in Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, filed with the Securities and Exchange Commission (the “SEC”) on February 19, 2021.

Liquidity and Capital Resources

As of December 31, 2021, we had \$36.7 million in cash and cash equivalents attributable in part to proceeds from the following debt and equity financing arrangements:

Debt Financings

ACEA Significant Debt Arrangements

At the closing of the transactions contemplated by the Agreement and Plan of Merger, dated as of April 2, 2021, by and among us, AT Merger Sub, Inc., an exempted company incorporated with limited liability in the Cayman Islands and our now wholly owned subsidiary, ACEA, and Fortis Advisors LLC, as representative of the shareholders of ACEA and as a result thereof, on June 1, 2021, we, as the indirect parent to Hangzhou ACEA Pharmaceutical Research Co., Ltd. (“ACEA Hangzhou”) and Zhejiang ACEA Pharmaceutical Co., Ltd. (“ACEA Zhejiang”), each of which are indirect subsidiaries of ACEA, succeeded to the financial obligations of ACEA Hangzhou and ACEA Zhejiang, each of whom are parties to agreements with ACEA Bio (Hangzhou) Co., Ltd. (“ACEA Bio”) (an entity unrelated to ACEA Hangzhou and ACEA Zhejiang) as set forth below.

Pursuant to that certain contract, dated as of August 15, 2018, between ACEA Hangzhou and ACEA Bio, ACEA Hangzhou borrowed an aggregate of approximately \$29.1 million (184,600,000 RMB) from ACEA Bio in a series of loans thereunder (the “Contract”). Each loan under the Contract is for a period of 10 years and the maturity dates thereof range from August 15, 2023 to August 15, 2028. Each loan is interest free for the first five years, after which time the interest rate is 5.39% per annum.

The outstanding principal amount under the Contract as of December 31, 2021 is \$29.1 million. As a part of the preliminary purchase price allocation, we estimated the fair value of the Contract to be approximately \$17.1 million.

2018 Oaktree Term Loan Agreement

In November 2018, we 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”). In May 2019, we entered into an amendment to the Loan Agreement, under which terms the Lenders agreed to make available to us \$20.0 million (collectively, with the Initial Loan, the “Term Loans”). During the year ended December 31, 2020, we repaid \$120.0 million of the outstanding principal under the Term Loans plus approximately \$9.4 million of related prepayment premium, exit fees and accrued interest thereon.

Scilex Notes

Scilex Pharma entered into purchase agreements (the “2018 Purchase Agreements”) with certain investors (collectively, the “Scilex Note Purchasers”) and us. Pursuant to the 2018 Purchase Agreements, on September 7, 2018, Scilex Pharma issued and sold to

the Scilex Note Purchasers senior secured notes due 2026 in an aggregate principal amount of \$224.0 million (the “Scilex Notes”) for an aggregate purchase price of \$140.0 million (the “Scilex Notes Offering”). In connection with the Scilex Notes Offering, Scilex Pharma also entered into an Indenture (the “Indenture”) governing the Scilex Notes with U.S. Bank National Association, a national banking association, as trustee and collateral agent, and us. 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 Pharma under the Indenture.

We identified a number of embedded derivatives that require bifurcation from the Scilex Notes and were separately accounted for in the consolidated financial statements as derivative liabilities. Certain of these embedded features include default interest provisions, contingent rate increases, contingent put options, optional and automatic acceleration provisions and tax indemnification obligations. The fair value of the derivative liabilities associated with the Scilex Notes was estimated using the discounted cash flow method under the income approach combined with a Monte Carlo simulation model. This involves significant Level 3 inputs and assumptions, including a risk adjusted net sales forecast, an effective debt yield, estimated marketing approval probabilities for SP-103 and an estimated probability of an initial public offering by Scilex Holding that satisfies certain valuation thresholds and timing considerations. We re-evaluate this assessment each reporting period.

The 2018 Purchase Agreements and Indenture provide that, upon the occurrence of an event of default, the lenders thereunder may, by written notice to us, declare all of the outstanding principal and interest under the Indenture immediately due and payable. For purposes of the Indenture, an event of default includes, among other things, (i) a failure to pay any amounts when due under the Indenture, (ii) a breach or other failure to comply with the covenants (including financial, notice and reporting covenants) under the Indenture, (iii) a failure to make any payment on, or other event triggering an acceleration under, other material indebtedness of us, and (iv) the occurrence of certain insolvency or bankruptcy events (both voluntary and involuntary) involving us or certain of our subsidiaries. We are subject to certain customary default clauses under the Indenture and are in compliance with the event of default clauses under the Indenture.

On December 14, 2020, we, Scilex Pharma, U.S. Bank National Association, a national banking association, as trustee (the “Trustee”) and collateral agent, and the beneficial owners of the Scilex Notes and the Scilex Note Purchasers entered into a Consent Under and Amendment No. 3 to Indenture and Letter of Credit (the “Amendment”), which amended: (i) the Indenture, and (ii) the Letter of Credit.

On December 14, 2020, and in connection with the Amendment, the aggregate \$45.0 million in restricted funds held in previously established reserve and collateral accounts were released and Scilex Pharma utilized such funds to repurchase an aggregate of \$45.0 million in principal amount of the Scilex Notes. Scilex Pharma also repurchased \$20.0 million in principal amount of the Scilex Notes in each of December 2020, February 2021 and April 2021.

Actual cumulative net sales of ZTlido from the issue date of the Scilex Notes through December 31, 2021 did not equal or exceed 95% of a predetermined target sales threshold for such period, which resulted in a \$28.0 million increase in the principal amount of the Scilex Notes, effective February 15, 2022. As a result, we recorded the increase of \$28.0 million in principal and non-operating expense at December 31, 2021.

Effective February 14, 2022, Scilex Pharma issued a draw notice to us under the Letter of Credit as required under the terms of the Indenture because actual cumulative net sales of ZTlido from the issue date of the Scilex Notes through December 31, 2021 were less than a specified sales threshold for such period, and we paid to Scilex Pharma \$35,000,000 in a single lump-sum amount as a subordinated loan. Per the terms of the Amendment, in February 2022, Scilex Pharma repurchased Scilex Notes from the holders thereof on a pro rata basis in an aggregate amount equal to the lesser of \$20.0 million at a purchase price in cash equal to 100% of the principal amount thereof.

Bridge Loan Agreement

On February 16, 2022, we entered into a Bridge Loan Agreement between us, as borrower, and B. Riley Commercial Capital, LLC, as lender (the “Lender”), pursuant to which we borrowed \$45.0 million from the Lender (the “Bridge Loan”). For services rendered in connection with originating and arranging the Bridge Loan, we agreed to pay to B. Riley Securities, Inc., an affiliate of the Lender, an upfront fee equal to four percent of the principal amount of the Bridge Loan. The Bridge Loan bears no interest and will mature on June 16, 2022. Upon the occurrence and during the continuance of an “Event of Default” under the Loan Agreement, the Bridge Loan shall bear interest at the rate of 15% per annum.

Marketable Investments

On March 9, 2021, NantKwest, Inc. and ImmunityBio completed their previously announced 100% stock-for-stock merger (the “ImmunityBio Merger”). The combined company operates under the name ImmunityBio, Inc. and its shares of common stock commenced trading on the Nasdaq Global Select Market on March 10, 2021 under the new ticker, “IBRX”. The former stockholders of ImmunityBio were entitled to receive 0.8190 shares of common stock of the combined company for each outstanding share of ImmunityBio common stock held immediately prior to the ImmunityBio Merger. Prior to the closing of the ImmunityBio Merger, we owned 10,000,000 shares of common stock of ImmunityBio, and we therefore received 8,190,000 shares of common stock of the post-merger company.

Prior to the ImmunityBio Merger, our investment in ImmunityBio was historically included as an equity investment in our consolidated balance sheets and accounted for as an equity security without a readily determinable fair value. As of the completion of the ImmunityBio Merger, we accounted for our investment in ImmunityBio as an equity investment with a readily determinable fair value and reclassified our investment in ImmunityBio to marketable investments within our consolidated balance sheets. The investment in ImmunityBio was classified as a current asset because the investment was liquidated to finance our current operations. In connection with the change in fair value of our investment in ImmunityBio, we recorded a realized gain on marketable investments of \$24.1 million during the year ended December 31, 2021. We sold 8,190,000 shares of ImmunityBio common stock during the year ended December 31, 2021 for net proceeds to us of \$124.0 million. We had no remaining shares of ImmunityBio common stock as of December 31, 2021.

On July 16, 2021, Celularity Inc. (“Pre-Merger Celularity”), a company of which we held an equity interest, completed its previously announced merger with GX Acquisition Corp. (the “Celularity Merger”). Following the completion of the Celularity Merger, the combined, publicly traded company formerly known as GX Acquisition Corp. was renamed Celularity Inc. (“Celularity”) and its Class A common stock commenced trading on the Nasdaq Capital Market on July 19, 2021 under the ticker “CELU”. In connection with the Celularity Merger, all outstanding shares of Series A Preferred Stock of Pre-Merger Celularity were converted into shares of Pre-Merger Celularity common stock and then each share of Pre-Merger Celularity common stock was converted into the right to receive shares of Class A common stock of the post-merger company. We received 19,922,124 shares of Class A common stock of the post-merger company in the Celularity Merger. We also purchased an aggregate of 500,000 shares of Class A common stock of Celularity for an aggregate purchase price of \$5,000,000 in a private placement transaction that closed on July 16, 2021 concurrently with the closing of the Celularity Merger. Our investment in Celularity has historically been accounted for as an equity security without a readily determinable fair value. As of the trading commencement date, we account for our investment in Celularity as an equity security with a readily determinable fair value. As of December 31, 2021, we owned 20,422,124 shares of Class A common stock of Celularity. 19,922,124 shares of the Class A Common Stock of Celularity held by us are subject to transfer restrictions until the earliest to occur of (i) 365 days after July 16, 2021; (ii) the first day after the date on which the closing price of the Class A Common Stock equals or exceeds \$12.00 per share (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like) for any 20 trading days within any 30-trading day period commencing at least 150 days after July 16, 2021; or (iii) the date on which Celularity completes a liquidation, merger, capital stock exchange, reorganization or other similar transaction that results in all of Celularity’s public shareholders having the right to exchange their Class A Common Stock for cash, securities or other property, subject to certain exceptions.

Equity Financings

At-the-Market Sales Agreement

On April 27, 2020, we entered into a Sales Agreement (the “Sales Agreement”) with A.G.P./Alliance Global Partners, as sales agent (the “Agent”), pursuant to which we could offer and sell through or to the Agent up to \$250.0 million in shares of its common stock (the “Shares”). On December 4, 2020, we entered into Amendment No. 1 (the “December 2020 Amendment”) to the Sales Agreement, which amended the Sales Agreement to provide that we could offer and sell, from time to time, through or to the Agent, up to an additional \$450.0 million in shares of our common stock, such that we could offer and sell up to an aggregate of \$700.0 million in shares of our common stock pursuant to the Sales Agreement, as amended by the December 2020 Amendment (the “Original Amended Sales Agreement”).

On December 3, 2021, we amended and restated the Original Amended Sales Agreement to include Cantor Fitzgerald & Co., B. Riley Securities, Inc. and H.C. Wainwright & Co., LLC as additional sales agents for our “at the market offering” program (the “Amended and Restated Sales Agreement”).

On December 23, 2021, we entered into Amendment No. 1 (the “December 2021 Amendment”) to the Amended and Restated Sales Agreement, with Cantor Fitzgerald & Co., B. Riley Securities, Inc. and H.C. Wainwright & Co., LLC (the “Sales Agents”).

The December 2021 Amendment amended the Amended and Restated Sales Agreement to provide that we may offer and sell, from time to time, through or to the Sales Agents, as sales agents and/or principals, up to an additional \$5,000,000,000 in shares of our common stock (the “Additional Shares”), such that we may offer and sell up to an aggregate of \$5,442,943,290 in shares of our common stock (the “Offering”) pursuant to the Amended and Restated Sales Agreement, as amended by the December 2021 Amendment (the “Amended Sales Agreement”), inclusive of \$442,943,290 in shares sold pursuant to the Original Amended Sales Agreement and the Amended and Restated Sales Agreement through December 22, 2021. Any Additional Shares offered and sold in the Offering will be issued pursuant to our shelf registration statement on Form S-3ASR (the “Registration Statement”), which became automatically effective upon filing with the SEC on December 23, 2021. The Additional Shares may be offered only by means of a prospectus forming a part of the Registration Statement.

Subject to the terms and conditions of the Amended Sales Agreement, each Sales Agent will use its commercially reasonable efforts to sell the shares of our common stock from time to time, based upon our instructions. Under the Amended Sales Agreement, the Sales Agents may sell the shares of our common stock by any method permitted by law deemed to be an “at the market offering” as defined in Rule 415 promulgated under the Securities Act of 1933, as amended.

We have no obligation to sell any shares of our common stock pursuant to the Amended Sales Agreement, and may at any time suspend offers under the Amended Sales Agreement. The Offering will terminate upon (i) the election of the Sales Agents upon the occurrence of certain adverse events, (ii) three business days’ advance notice from us to the Sales Agents or a Sales Agent (with respect to itself) to us, or (iii) the sale of all \$5,442,943,290.81 of shares of our common stock pursuant thereto.

Under the terms of the Amended Sales Agreement, the Sales Agents will be entitled to a commission at an initial fixed rate of 3.0% of the gross proceeds from each sale of shares of our common stock under the Amended Sales Agreement, which percentage may be adjusted (but not above 3.0%) based on the aggregate amount of securities sold by the Sales Agents pursuant to the Amended Sales Agreement.

We currently intend to use any additional net proceeds from the Offering for working capital and general corporate purposes, which may include capital expenditures, research and development expenditures, regulatory affairs expenditures, clinical trial expenditures, acquisitions of new technologies and investments, business combinations and the repayment, refinancing, redemption or repurchase of indebtedness or capital stock. We also may use a portion of the net proceeds to repurchase or redeem a portion or all of the Scilex Notes.

During the year ended December 31, 2021, we sold an aggregate of 21,085,014 shares of our common stock pursuant to the Original Amended Sales Agreement and the Amended Sales Agreement for aggregate net proceeds to us of approximately \$175.6 million.

Universal Shelf Registration Statement

On December 23, 2021, we filed an automatic universal shelf registration statement on Form S-3 (the “WKSI Shelf Registration Statement”) with the SEC as a well-known seasoned issuer as defined in Rule 405 under the Securities Act. The WKSI Shelf Registration Statement provides us with the ability to offer an indeterminate amount of securities, including equity and other securities as described in the WKSI Shelf Registration Statement. Pursuant to the WKSI 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. In connection with the WKSI Shelf Registration Statement, we entered into the Amended Sales Agreement (discussed above) and included in the WKSI Shelf Registration Statement a prospectus covering \$5,000,000,000 of shares of our common stock issuable pursuant to the Amended Sales agreement.

Contingent Consideration

We have contingent consideration obligations in connection with certain acquisition and licensing transactions that are contingent upon achieving certain specified milestones or the occurrence of certain events, including those described within the accompanying notes to the consolidated financial statements of this Form 10-K. Upon the achievement of such milestones or the occurrence of such events, we will be obligated to make certain cash or stock payments in accordance with the terms of such acquisition and license agreements.

Use of Cash

Cash Flows from Operating Activities. Net cash used for operating activities was \$281.8 million for 2021 as compared to \$159.5 million for 2020. Net cash used reflects the cash spent on our research activities and cash spent to support the commercial launch of our products.

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 preclinical development and research activities, support the commercial launch of our products and fund our joint ventures, collaborations and other third-party agreements.

Cash Flows from Investing Activities. Net cash provided by investing activities was \$79.8 million for the year ended December 31, 2021 and was attributed to proceeds received of \$124.8 million from sales of marketable investments. We also spent approximately \$35.3 million related to various investments in new technologies and preclinical programs, \$0.8 million in connection with the acquisition of ACEA, net of cash acquired, and approximately \$8.9 million primarily attributed to expenditures on laboratory equipment. During the year ended December 31, 2020, net cash used by investing activities was \$39.9 million. We invested approximately \$31.1 million in licensing arrangements, invested approximately \$2.3 million in new technologies and preclinical programs and spent approximately \$6.5 million on equipment and building improvements.

Cash Flows from Financing Activities. Net cash provided by financing activities was \$181.3 million for 2021 as compared to \$174.2 million for 2020. During the year ended December 31, 2021, we received \$201.8 million from equity offerings, proceeds from short-term debt of \$49.7 million and proceeds of \$15.4 million from common stock issuances and warrant exercises. During the year ended December 31, 2021, we repaid \$45.9 million in principal amount of the Scilex Notes, of which \$32.7 million was attributed to principal included within financing activities and \$13.1 million was attributed to principal included in operating activities. We also repaid \$53.0 million in other short-term debt. During the year ended December 31, 2020, we received \$317.9 million from equity offerings, proceeds from short-term debt of \$18.6 million and proceeds of \$98.4 million from common stock issuances and warrant exercises. During the year ended December 31, 2020, we repaid \$120.0 million of outstanding principal under the Term Loans, paid \$6.3 million of related exit and prepayment fees thereon, made payments of \$69.8 million on the Scilex Notes and repaid \$9.4 million in short-term debt. We also paid \$55.0 million related to the Semnur Share Exchange as further described in [Note 7](#) of the accompanying notes to the consolidated financial statements in this Annual Report on Form 10-K.

Future Liquidity Needs. We have principally financed our operations through underwritten public offerings and private debt and equity financings, as we have not generated any significant product related revenue from our principal operations to date. 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. We will seek to raise additional funds through various potential sources, such as equity and debt financings or through corporate collaboration, grant agreements 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 these uncertainties.

We anticipate that we will continue to incur net losses into the foreseeable future as we: (i) advance our product pipeline and other product candidates into clinical trials, (ii) continue our development of, and seek regulatory approvals for, our product candidates in clinical trials, (iii) expand our corporate infrastructure, and (iv) incur our share of joint venture and collaboration costs for our products and technologies.

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.

Material Cash Requirements

As of December 31, 2021, our material contractual obligations are as follows:

- Short-term operating lease liabilities as disclosed in [Note 11](#) in the accompanying notes to the consolidated financial statements in this Annual Report on Form 10-K;
- Future minimum payments under the Scilex Notes, based on a percentage of projected net sales of ZTlido, as disclosed in [Note 8](#) in the accompanying notes to the consolidated financial statements in this Annual Report on Form 10-K; and
- Approximately \$8.8 million of indebtedness in connection with the Scilex Holding accounts receivable revolving loan facility, as disclosed in [Note 8](#) in the accompanying notes to the consolidated financial statements in this Annual Report on Form 10-K.
- In connection with the acquisition of ACEA as further discussed in [Note 7](#), we recorded short term contingent consideration of \$7.5 million as of December 31, 2021.

Our material long-term contractual obligations include:

- Long-term operating lease liabilities as disclosed in [Note 11](#) in the accompanying notes to the consolidated financial statements in this Annual Report on Form 10-K; and
- Future minimum payments under the Scilex Notes, based on a percentage of projected net sales of ZTlido, as disclosed in [Note 8](#) in the accompanying notes to the consolidated financial statements in this Annual Report on Form 10-K.
- In connection with the acquisition of ACEA as further discussed in [Note 7](#), we recorded long term contingent consideration of \$123.8 million as of December 31, 2021.

Critical Accounting Estimates

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.

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

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 no significant reversals are expected. (See [Note 1](#) of the accompanying notes to the consolidated financial statements in this Annual Report on Form 10-K).

Investments in Other Entities. We hold a portfolio of investments in equity securities. 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. Our other equity investments are carried at cost, less impairment, plus or minus changes resulting from observable price changes in orderly transactions for identical or similar 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 readily determinable.

Debt, Including Debt With Detachable Warrants. Debt with detachable warrants is 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 Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 815, *Derivatives and Hedging*. Embedded features that require bifurcation are initially and subsequently measured at fair value. See [Note 3](#) of the accompanying notes to the consolidated financial statements in this Annual Report on Form 10-K for additional discussion on the derivative liabilities associated with embedded features in our debt instruments.

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. 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.

Intangible assets. In order to estimate the fair value of our identifiable intangible assets and other long-lived assets, we primarily use an income approach, using the present value of estimated future cash flows from those assets. The key assumptions that we use in our discounted cash flow model are the amount and timing of estimated future cash flows to be generated by the asset over an extended period of time and a rate of return that considers the relative risk of achieving the cash flows, the time value of money, and other factors that a willing market participant would consider. Significant judgment is required to estimate the amount and timing of future cash flows and the relative risk of achieving those cash flows.

Contingent consideration. The fair value of contingent consideration liabilities assumed in business combinations is recorded as part of the purchase price consideration of the acquisition and is determined using a discounted cash flow model or Monte Carlo simulation model. The significant inputs of such models are not observable in the market, such as certain financial metric growth rates, volatility rates, projections associated with applicable milestones, discount rates and the related probabilities and payment structure in the contingent consideration arrangement. Fair value adjustments to contingent consideration liabilities are recorded through operating expenses in the consolidated statement of operations. Contingent consideration arrangements assumed by an asset acquisition will be measured and accrued when such contingency is resolved.

Recent Accounting Pronouncements

Refer to [Note 1](#) of the accompanying notes to the consolidated financial statements in this Annual Report on 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. 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 and we do not use derivative financial instruments to hedge against interest rate risk.

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 8](#) of the accompanying notes to the consolidated financial statements in this Annual Report on Form 10-K. For the 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.

Beginning in 2021, we held investments in marketable investments with readily determinable fair values, which are included as current marketable investments within our consolidated balance sheets. Our investment in these publicly traded equity securities is recorded at fair value and is subject to market price volatility. Changes in the fair value of such investments are recorded in our consolidated statement of operations within loss on marketable investments. A portion of our marketable investments is subject to certain transfer restrictions and is adjusted for a discount for lack of marketability as further discussed in [Note 3](#) and in [Note 5](#) of the accompanying notes to consolidated financial statements in this Annual Report on Form 10-K. As of December 31, 2021, a price change of 10 percent would increase or decrease the fair value of our current marketable investments by approximately \$9.0 million in the aggregate.

Concentration Risk. During the fiscal years ended December 31, 2021, 2020 and 2019, sales to the sole customer and third-party logistics distribution provider of Scilex Pharma, Cardinal Health, represented 100% of the net revenue of Scilex Pharma. This exposes us to concentration of customer risk. We monitor the financial condition of the sole customer of Scilex Pharma, limit our credit exposure by setting credit limits, and did not experience any credit losses for the years ended December 31, 2021, 2020 and 2019. As we continue to expand the commercialization of ZTlido, we are not limited to the current customer and have the option of expanding our distribution network with additional distributors through establishing our own affiliates, by acquiring existing third-party business or product rights or by partnering with additional third parties. We obtain our commercial supply of ZTlido and our clinical supply of SP-103 exclusively from Oishi Koseido Co., Ltd. and ITOCHU CHEMICAL FRONTIER Corporation in Japan.

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 Annual Report on 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 principal officers, as appropriate, to allow for timely decisions regarding required disclosure.

In designing and evaluating our 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 Principal Executive Officer and Principal 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 Annual Report on Form 10-K. Based on the foregoing, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were not effective as of the end of the period covered by this Annual Report on Form 10-K as a result of the material weakness described below.

Management’s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) and 15d-15(f) promulgated under the Exchange Act. Internal control over financial reporting is a process designed by, or under the supervision of, our Principal Executive Officer and Principal 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 our financial statements for external purposes in accordance with U.S. GAAP. Internal control over financial reporting includes policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of an issuer’s assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that an issuer’s receipts and expenditures are being made only in accordance with authorizations of its management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of an issuer’s assets that could have a material effect on the consolidated financial statements. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, the application of any evaluation of effectiveness to future periods is subject to the risk that controls may become inadequate because of changes in conditions, or that compliance with the policies or procedures may deteriorate.

As required by Rule 13a-15(c) promulgated under the Exchange Act, our management, with the participation of our Principal Executive Officer and Principal Financial Officer, evaluated the effectiveness of our internal control over financial reporting as of December 31, 2021. Management’s assessment was based on criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control - Integrated Framework (2013 Framework) (“COSO”). Based on management’s assessment, management has concluded that our internal control over financial reporting was not effective as of December 31, 2021 due to the material weakness in our internal control over financial reporting, as follows: As previously disclosed on our Current Report on Form 8-K filed with the Securities and Exchange Commission on January 7, 2022, our former Chief Financial Officer passed away unexpectedly on January 6, 2022. As a result of our former Chief Financial Officer’s passing as well as other considerations, management concluded that we did not employ sufficient accounting resources with appropriate experience and technical expertise to effectively execute controls over certain judgmental accounting areas. As a result, certain of our control activities in the areas of revenue, business combinations, investments, debt, derivative liabilities and leases did not operate effectively and have been deemed deficient and the combination of the aforementioned deficiencies represents a material weakness in our internal control over financial reporting.

Ernst & Young, LLP, our independent registered public accounting firm, has issued a report on our internal control over financial reporting as of December 31, 2021. See “Report of Independent Registered Public Accounting Firm – Opinion on Internal Control over Financial Reporting” beginning on Page F-2 of this Annual Report on Form 10-K.

Planned Remediation of Material Weaknesses

As a result of the material weakness described above, we are in the process of implementing remediation measures, including, but not limited to, hiring a Chief Financial Officer and other personnel with appropriate experience and technical expertise to effectively execute controls over judgmental accounting areas. We believe that our remediation measures, if effectively implemented, will provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external purposes in accordance with U.S. GAAP. Any failure to implement these improvements to our internal control over financial reporting would result in a continued material weakness 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

There were no changes in our internal control over financial reporting (as defined by Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. As identified above under “Management’s Report on Internal Control Over Financial

Reporting”, a material weakness was identified in our internal control over financial reporting as of December 31, 2021. Our plans for remediating such material weakness, enumerated above, will constitute changes in our internal control over financial reporting, prospectively, when such remediation plans are effectively implemented.

Inherent Limitations over Internal Controls

Our management, including our Principal Executive Officer and Principal Financial Officer, intends that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost effective control system, misstatements due to error or fraud may occur and not be detected.

Item 9B. Other Information.

Not applicable.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

Item 10. Directors, Executive Officers and Corporate Governance.**Board of Directors**

The following table sets forth the names, ages as of March 11, 2022, and certain other information for each member of our board of directors (our “Board”):

Name	Age	Position
Henry Ji, Ph.D.	57	Chairman of the Board, President, Chief Executive Officer and Interim Chief Financial Officer
Dorman Followwill	58	Lead Independent Director
Elizabeth A. Czerepak	66	Director
Kim D. Janda, Ph.D.	64	Director
David Lemus	59	Director
Jaisim Shah	61	Director
Yue Alexander Wu, Ph.D.	58	Director

Henry Ji, Ph.D., co-founded and has served as a director of Sorrento Therapeutics, Inc. since January 2006, served as its Chief Scientific Officer from November 2008 to September 2012, as its Interim Chief Executive Officer from April 2011 to September 2012, as its President and Chief Executive Officer since September 2012, as Chairman of the Board since August 2017 and as Interim Chief Financial Officer since January 2022. Dr. Ji also served as our Secretary from September 2009 to June 2011. In 2002, Dr. Ji founded BioVintage, Inc., a research and development company focusing on innovative life science technology and product development, and has served as its President since 2002. From 2001 to 2002, Dr. Ji served as Vice President of CombiMatrix Corporation, a publicly traded biotechnology company that develops proprietary technologies, including products and services in the areas of drug development, genetic analysis, molecular diagnostics and nanotechnology. During his tenure at CombiMatrix, Dr. Ji was responsible for strategic technology alliances with biopharmaceutical companies. From 1999 to 2001, Dr. Ji served as Director of Business Development, and in 2001 as Vice President, of Stratagene Corporation (later acquired by Agilent Technologies, Inc.) where he was responsible for novel technology and product licensing and development. In 1997, Dr. Ji co-founded Stratagene Genomics, Inc., a wholly owned subsidiary of Stratagene Corporation, and served as its President and Chief Executive Officer from its founding until 1999. Dr. Ji previously served as a director of Celularity Inc. from June 2017 to July 2021. Dr. Ji is the holder of several issued and pending patents in the life science research field and is the sole inventor of Sorrento Therapeutics Inc.’s intellectual property. Dr. Ji has a Ph.D. in Animal Physiology from the University of Minnesota and a B.S. in Biochemistry from Fudan University.

Dr. Ji has demonstrated significant leadership skills as President and Chief Executive Officer of Stratagene Genomics, Inc. and Vice President of CombiMatrix Corporation and Stratagene Corporation and brings more than 18 years of biotechnology and biopharmaceutical experience to his position on our Board. Dr. Ji’s extensive knowledge of the industry in which we operate, as well as his unique role in our day-to-day operations as our President and Chief Executive Officer, allows him to bring to our Board a broad understanding of the operational and strategic issues we face.

Dorman Followwill has served as a director of our Company since October 2017 and as our lead independent director since August 2020. Mr. Followwill was Senior Partner, Transformational Health at Frost & Sullivan, a business consulting firm involved in market research and analysis, growth strategy consulting and corporate training across multiple industries, from 2016 to September 2020. Prior to that time, he served in various roles at Frost & Sullivan, including Partner on the Executive Committee managing the P&L of the business in Europe, Israel and Africa, and Partner overseeing the Healthcare and Life Sciences business in North America, since initially joining Frost & Sullivan to help found the Consulting practice in January 1988. Mr. Followwill has more than 30 years of organizational leadership and management consulting experience, having worked on hundreds of consulting projects across all major regions and across multiple industry sectors, each project focused around the strategic imperative of growth. He obtained his BA from Stanford University in The Management of Organizations in 1985.

We believe that Mr. Followwill’s extensive knowledge and understanding of the healthcare and life sciences industries qualify him to serve on our Board.

Elizabeth A. Czerepak has served as a director of our Company since November 2021 has over 35 years of experience in big pharma, biotechnology and venture capital and has served as the Chief Financial Officer of BeyondSpring Inc. (Nasdaq: BYSI), a global biopharmaceutical company focused on developing innovative immuno-oncology cancer therapies, since September 2020. Prior to that, from May 2018 to January 2020, she served as the Chief Financial Officer and the Chief Business Officer of Genevant Sciences, Inc., a technology-focused lipid nanoparticle delivery company; as the Chief Financial Officer and Executive Vice

President, Corporate Development of Altimmune, Inc., a clinical stage vaccines company, from 2015 to 2018; and the Chief Financial Officer and the Chief Business Officer of Isarna Therapeutics Inc., which develops selective transforming growth factor beta inhibitors for cancer, ophthalmic and fibrotic diseases, from 2014 to 2015. Ms. Czerepak previously served as the Chief Financial Officer, Secretary, Principal Accounting Officer and Head of Human Resources at Cancer Genetics, Inc., a company that develops and commercializes molecular diagnostics, from 2011 to 2014; and a Managing Director at JPMorgan Chase & Co. and Bear, Stearns & Co., and a General Partner at Bear Stearns Health Innoventures L.P., a venture capital fund, from 2000 to 2009. Ms. Czerepak was a NASD (now FINRA) Registered Representative (Series 7 and Series 63) from 2001 to 2008. She has served as a director and chair of the audit committee of Delcath Systems, Inc. (Nasdaq: DCTH), an interventional oncology company focused on the treatment of liver cancer, since February 2020. Ms. Czerepak served on the boards of directors of Spectrum Pharmaceuticals, Inc. (Nasdaq: SPPI) from June 2019 to December 2020, and Scilex Holding Company from September 2019 to October 2020. She received a B.A. magna cum laude in Spanish and Mathematics Education from Marshall University in 1976 and an MBA from Rutgers University in 1982. In 2020, Ms. Czerepak earned a Corporate Director Certificate from Harvard Business School.

We believe that Ms. Czerepak is qualified to serve on our Board because of her significant leadership experience in the biopharmaceutical sector and her substantial finance, venture capital and business expertise.

Kim D. Janda, Ph.D., has served as a director of our Company since April 2012. Dr. Janda has served as Ely R. Callaway, Jr. Chaired Professor in the Departments of Chemistry, Immunology and Microbial Science at The Scripps Research Institute since 1996 and as the Director of the Worm Institute of Research and Medicine (WIRM) at The Scripps Research Institute since 2005. Furthermore, Dr. Janda has served as a Skaggs Scholar within the Skaggs Institute of Chemical Biology, also at The Scripps Research Institute, since 1996. Dr. Janda holds a B.S. degree from the University of South Florida in Clinical Chemistry and a doctoral degree from the University of Arizona with Robert B. Bates in natural product total synthesis. A hallmark of his research is that Dr. Janda has been able to uniquely combine principles of medicinal chemistry together with modern molecular biology, immunology and neuropharmacology, allowing the creation of both synthetic/natural molecules and processes with biological, chemical and physical properties. Dr. Janda has published over 425 original publications in refereed journals and founded the biotechnological companies CombiChem, Drug Abuse Sciences and AIPartia. Dr. Janda is associate editor of Bioorg & Med. Chem., PloS ONE and serves, or has served, on numerous journals including J. Comb. Chem., Chem. Reviews, J. Med. Chem., The Botulinum Journal, Bioorg. & Med. Chem. Lett., and Bioorg. & Med. Chem. Over a career of almost 25 years, Dr. Janda has provided numerous seminal contributions and is considered one of the first scientists to merge chemical and biological approaches into a cohesive research program. Dr. Janda serves on the Scientific Advisory Boards of Materia, Inc. and Singapore Ministry of Education (MOE), EP1 Physical Sciences.

Dr. Janda has almost 25 years of experience in life sciences and very strong technical expertise relating to the discovery and development of antibody therapeutics, which gives him a unique understanding of the research challenges and opportunities facing our company. As an experienced scientist and inventor on multiple patents in the life sciences industry, Dr. Janda brings critical insights into the operational requirements of a discovery and development company as well as to our overall business and strategies relating to our ongoing development efforts, and serves as the chair of our Scientific Advisory Board.

David Lemus has served as a director of our Company since October 2017. Mr. Lemus has served as Chief Executive Officer of IronShore Pharmaceuticals Inc. since January 2020. He also currently serves as a non-executive board member of Silence Therapeutics, plc (Nasdaq: SLN) and BioHealth Innovation, Inc., and served previously on several other boards of public and private companies as a non-executive director. He served from November 2017, to September 2018 as the Interim Chief Operating Officer and Chief Financial Officer of Proteros biosciences GmbH. Previously, from January 2016 to May 2017, he served as Interim Chief Financial Officer and Chief Operating Officer of Medigene AG. From 2011-2015, he was employed by Sigma Tau Pharmaceuticals, Inc., and served as the company's Chief Executive Officer. Previous to this role, Mr. Lemus served as Chief Financial Officer and Executive V.P. of MorphoSys AG for more than 13 years. Prior to MorphoSys AG, Mr. Lemus held various management positions at Hoffman La Roche, and was the Group Treasurer of Lindt & Spruengli AG. Mr. Lemus received an M.S. from the Massachusetts Institute of Technology Sloan School of Management in 1988 and a B.S. in Accounting from the University of Maryland in 1984. Mr. Lemus is also a certified public accountant licensed in the State of Maryland.

We believe that Mr. Lemus' extensive accounting and financial background and business experience in the life sciences industry qualify him to serve on our Board.

Jaisim Shah has served as a director of our Company since September 2013. He has more than 25 years of global biopharma experience including over 15 years in senior management leading business development, commercial operations, investor relations, marketing and medical affairs. Mr. Shah has served as the President and Chief Executive Officer and board member of Scilex Holding Company since its inception in March 2019. He has also served as the Chief Executive Officer and board member of Semnur Pharmaceuticals, Inc. since its inception in 2013. Prior to Semnur, Mr. Shah was a consultant to several businesses, including Sorrento Therapeutics, Inc., and was the Chief Business Officer of Elevation Pharmaceuticals, where Mr. Shah led a successful sale of Elevation to Sunovion in September 2012. Prior to Elevation, Mr. Shah was president of Zelos Therapeutics, where Mr. Shah focused

on financing and business development. Prior to Zelos, Mr. Shah was the Senior Vice President and Chief Business Officer at CytRx, a biopharmaceutical company. Previously, Mr. Shah was Chief Business Officer at Facet Biotech and PDL BioPharma where he completed numerous licensing/partnering and strategic transactions with pharmaceutical and biotech companies. Prior to PDL, Mr. Shah was at Bristol-Myers Squibb, most recently as Vice President of Global Marketing where he received the “President’s Award” for completing one of the most significant collaborations in the company’s history. Previously, Mr. Shah was at F. Hoffman-La Roche in international marketing and was global business leader for corporate alliances with Genentech and Idec. Mr. Shah previously served as a director of Celularity Inc. from June 2017 to July 2021. Mr. Shah holds an M.A. in Economics from the University of Akron and an M.B.A. from Oklahoma University.

We believe that Mr. Shah’s extensive operational, executive and business development experience qualifies him to serve on our Board.

Yue Alexander Wu, Ph.D., has served as a director of our Company since August 2016. He is co-founder and CEO of Cothra Bioscience, Inc., a translation medicine and precision therapeutics company. He was previously President, Chief Executive Officer and Chief Strategy Officer of Crown Bioscience International, a leading global drug discovery and development solutions company, which he co-founded in 2006, until 2017. From 2004 to 2006, Dr. Wu was Chief Business Officer of Starvax International Inc. in Beijing, China, a biotechnology company focusing on oncology and infectious diseases. From 2001 to 2004, Dr. Wu was a banker with Burrill & Company where he was head of Asian Activities. Dr. Wu has served as a director of CASI Pharmaceuticals, Inc. (Nasdaq: CASI) since June 2013. Dr. Wu received his Ph.D. in Molecular Cell Biology and his MBA from University of California at Berkeley. He earned an M.S. in Biochemistry from University of Illinois, Urbana-Champaign and his B.S. in Biochemistry from Fudan University in Shanghai, China.

We believe that Dr. Wu’s scientific background and business experience qualify him to serve on our Board.

Agreements with Directors

None of our directors was selected pursuant to any arrangement or understanding, other than compensation arrangements in the ordinary course of business.

Audit Committee

We have a separately designated standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Exchange Act. Our Audit Committee is currently comprised of Ms. Czerepak, Messrs. Followwill and Lemus and Dr. Wu. Mr. Lemus serves as the Chairperson of the Audit Committee.

Our Board has determined that each of Ms. Czerepak and Mr. Lemus is an audit committee financial expert, as defined under applicable SEC rules, and that Ms. Czerepak, Messrs. Followwill and Lemus and Dr. Wu meet the background and financial sophistication requirements under the rules of The Nasdaq Stock Market LLC. In making these determinations, the Board made a qualitative assessment of each of Ms. Czerepak’s, Messrs. Followwill’s and Lemus’ and Dr. Wu’s level of knowledge and experience based on a number of factors, including each individual’s formal education and experience. Both our independent registered public accounting firm and internal financial personnel regularly meet privately with our Audit Committee and have unrestricted access to the Audit Committee. The information under the heading “Board Independence” in Item 13 below is incorporated herein by reference.

Director Nominations

No material changes have been made to the procedures by which security holders may recommend nominees to our Board from those that were described in our Definitive Proxy Statement for our 2021 Annual Meeting of Stockholders that was filed with the SEC on October 5, 2021.

Executive Officers

Our only executive officer as of March 11, 2022 is Dr. Ji. Dr. Ji’s age, positions and biography is discussed under the section “Board of Directors” above.

Family Relationships

There are no family relationships between or among any of our executive officers or directors.

Legal Proceedings with Directors or Executive Officers

There are no legal proceedings related to any of our directors or executive officers that require disclosure pursuant to Items 103 or 401(f) of Regulation S-K.

Code of Ethics

We have adopted the Sorrento Therapeutics, Inc. Code of Business Conduct and Ethics that applies to all of our employees, executive officers and directors. The Code of Business Conduct and Ethics is available to stockholders on our Internet website at www.sorrentotherapeutics.com/investors/corporate-governance. If we make any substantive amendments to our Code of Business Conduct and Ethics or grant any waiver from a provision of our Code of Business Conduct and Ethics to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our Internet website at investors.sorrentotherapeutics.com/corporate-governance/governance-overview and/or in our public filings with the SEC.

Delinquent Section 16(a) Reports

During the year ended December 31, 2021, Kim D. Janda, Ph.D., a member of our board of directors, filed one Form 4 late with respect to an option exercise and sale of shares effected on April 12, 2021 by Dr. Janda pursuant to a Rule 10b5-1 trading plan.

Item 11. Executive Compensation.

Compensation Discussion and Analysis

Compensation Philosophy

The primary goals of our Board with respect to executive compensation are to attract and retain talented and dedicated executives, to tie annual and long-term cash and stock incentives to achievement of specified performance objectives, and to create incentives resulting in increased stockholder value. To achieve these goals, our Compensation Committee recommends to our Board executive compensation packages, generally comprising a mix of salary, discretionary bonus and equity awards. Although we have not adopted any formal guidelines for allocating total compensation between equity compensation and cash compensation, we have implemented and maintain compensation plans that tie a substantial portion of our executives' overall compensation to achievement of corporate goals.

Role of Compensation Consultant

The Compensation Committee has the power to engage independent advisors to assist it in carrying out its responsibilities. For 2021, through August 2021, the Compensation Committee re-engaged Compensia, Inc. ("Compensia"), a national compensation consulting firm, as its compensation consultant to review and advise on our compensation practices. The Compensation Committee assessed the independence of Compensia pursuant to SEC rules and concluded that the work of Compensia has not raised any conflict of interest. In 2021, Compensia undertook the following projects for the Compensation Committee:

- June 2021—Evaluated the compensation arrangements for the Company's chief executive officer against a comparable group of similar life sciences companies and its own proprietary data; and
- June 2021—Evaluated the compensation arrangements for the members of the Company's Board of Directors against a comparable group of similar life sciences companies and its own proprietary data.

With respect to the salary increase for our chief executive officer to \$1,000,000 that was retroactive to January 1, 2021 and the increase in his target bonus to 100%, each of which was approved by the Compensation Committee in June 2021, the comparable group of life sciences companies consisted of the following companies, determined to: (i) generally have similar revenues as us;

(ii) generally have similar market capitalization as us, (iii) generally have similar operating income as us, and (iv) generally have the same number of employees as us:

AbCellera Biologics Inc.	MacroGenics, Inc.
Accelaron Pharma Inc.	Mersana Therapeutics, Inc.
Allogene Therapeutics, Inc.	Mirati Therapeutics, Inc.
Arcus Biosciences, Inc.	Nektar Therapeutics
Arrowhead Pharmaceuticals, Inc.	Quidel Corporation
Dicerna Pharmaceuticals, Inc.	SpringWorks Therapeutics, Inc.
Fate Therapeutics, Inc.	Turning Point Therapeutics, Inc.
Heron Therapeutics, Inc.	Twist BioScience Corporation
ImmunityBio, Inc.	Vir Biotechnology, Inc.
ImmunoGen, Inc.	Xencor, Inc.
Inovio Pharmaceuticals, Inc.	

In August 2021, the Compensation Committee engaged Prescient Healthcare Group (“Prescient”) as its compensation consultant. In August 2021, Prescient conducted a competitive landscapes and compensation structures analysis for the Compensation Committee, which included an executive compensation structure analysis for the Company’s chief executive officer, chief financial officer and non-employee directors.

With respect to the grant of an option to purchase 2,500,000 shares of our common stock to our chief executive officer in August 2021 and the salary increase for our chief executive officer to \$1,500,000 that was retroactive to January 1, 2021 and approved by the Compensation Committee in December 2021, the comparable group of life sciences companies consisted of the following companies that have approved products or product candidates that are competitive with the Company’s products and product candidates:

Abbott Laboratories	Johnson & Johnson
AbbVie Inc.	Merck KGaA
Alexion Pharmaceuticals, Inc.	Merck Sharp & Dohme Corp.
Amgen Inc.	Moderna, Inc.
Arrowhead Pharmaceuticals, Inc.	Novartis AG
AstraZeneca PLC	Pfizer Inc.
Bayer AG	PTC Therapeutics, Inc.
BioHaven Pharmaceutical Holding Company Ltd.	Regeneron Pharmaceuticals, Inc.
Bristol-Myers Squibb Company	Roche Holding AG
Eli Lilly and Company	Sanofi
Gilead Sciences, Inc.	Takeda Pharmaceutical Company Limited
GlaxoSmithKline plc	Teva Pharmaceutical Industries Limited
Incyte Corporation	

In 2021, Compensia and Prescient reviewed and advised the Compensation Committee on the matters described above.

In setting 2021 compensation, the Compensation Committee reviewed the competitive market analyses provided by Compensia in June 2021 and Prescient in August 2021 and compared each named executive officer’s base salary, target annual performance bonus and equity compensation value, separately and in the aggregate, to amounts paid to similarly-situated executives at our peer companies. The Compensation Committee believes that targeting compensation towards similarly situated executives at our peer companies helps achieve the compensation objectives described above. However, compensation for each named executive officer may vary from this range depending on other factors the Compensation Committee considers relevant, such as internal pay equity among

our named executive officers or levels of authority, responsibility and experience of our named executive officers that exceed the norms for individuals holding comparably-titled positions at other companies.

Elements of Compensation

We evaluate individual executive performance with a goal of setting compensation at levels our Board or any applicable committee thereof believes are comparable with executives in other companies of similar size and stage of development while taking into account our relative performance and our own strategic goals. The compensation received by our named executive officers consists of the following elements:

Base Salary

Base salaries for our executives are established based on the scope of their responsibilities and individual experience, taking into account competitive market compensation paid by other companies for similar positions within our industry.

The Compensation Committee considers compensation data from the peer companies to the extent the executive positions at these companies are considered comparable to our positions and informative of the competitive environment. Compensation data for our peer group were collected from available proxy-disclosed data. This information was gathered and analyzed for the 25th, 50th and 75th percentiles for annual base salary, short-term incentive pay elements and long-term incentive pay elements.

The amended and restated employment agreement between us and Dr. Ji, dated May 9, 2017, provided for an annual base salary for Dr. Ji of \$600,000, as may be adjusted from time to time. In May 2018, the Compensation Committee increased Dr. Ji's annual base salary from \$600,000 to \$670,000 with retroactive effect to January 1, 2018. Dr. Ji's salary was not adjusted, and remained \$670,000, during 2019. In June 2020, after considering a competitive market analysis provided by Compensia in June 2020, the Compensation Committee increased Dr. Ji's annual base salary to \$700,000, with retroactive effect to January 1, 2020. In June 2021, after considering the competitive market analysis provided by Compensia in June 2021, the Compensation Committee increased Dr. Ji's annual base salary to \$1,000,000, with retroactive effect to January 1, 2021. Following discussions with Dr. Ji regarding his compensation in the second half of 2021, culminating in a process rooted in the findings of the Prescient competitive analysis of two key factors: (1) a detailed analysis of each member of the peer group's pipeline of products in clinical trials (as defined from IND filing, Ph. I, Ph. II, Ph. III, up to and including an NDA filing), and (2) a detailed competitive compensation analysis of a peer group with similar pipeline dynamics, and after considering both the June 2021 competitive analysis from Compensia as well as the more expansive Prescient competitive analysis, in December 2021, the Compensation Committee increased Dr. Ji's annual base salary to \$1,500,000, with retroactive effect to January 1, 2021.

The offer letter between us and Najjam Asghar, our former Senior Vice President and Chief Financial Officer, dated April 24, 2019, provided for an annual base salary of \$300,000, as could be adjusted from time to time. In October 2020, the Compensation Committee considered the competitive market analysis provided by Compensia in June 2020 and increased Mr. Asghar's annual base salary to \$400,000, retroactive to August 18, 2020, the effective date of his promotion to Senior Vice President and Chief Financial Officer. In March 2021, the Compensation Committee increased Mr. Asghar's salary to \$450,000, with retroactive effect to January 1, 2021. The main drivers that the Compensation Committee considered in setting Mr. Asghar's salary increase were as follows: (1) the increase still fit comfortably within a reasonable range within the peer group in the June 2020 Compensia competitive analysis, and (2) the Compensation Committee considered the increase important for both motivational and retention purposes. Mr. Asghar passed away on January 6, 2022.

Variable Pay

We design our variable pay programs to be both affordable and competitive in relation to the market. We monitor the market and adjust our variable pay programs as needed. Our variable pay programs, such as our bonus program, are designed to motivate employees to achieve overall goals. Our programs are designed to avoid entitlements, to align actual payouts with the actual results achieved, and to be easy to understand and administer.

Bonuses

For 2021, Dr. Ji's target annual bonus was equal to 100% of his annual salary, which the Compensation Committee set in June 2021 after considering the competitive market analysis provided by Compensia in June 2021. Our offer letter with Mr. Asghar provided that Mr. Asghar's annual target bonus was equal to 30% of his annual salary, which the Compensation Committee increased to 40% in October 2020 after considering the competitive market analysis provided by Compensia in 2020 and Mr. Asghar's promotion in August 2020. Mr. Asghar passed away on January 6, 2022.

As of the date of the filing of this Annual Report on Form 10-K, the Compensation Committee has not yet determined the annual bonus amount, if any, that will be awarded Dr. Ji for 2021. We expect the Compensation Committee to assess 2021 performance and determine the 2021 annual bonus awards for Dr. Ji in the second half of 2022. Once such annual bonus amount, if any, has been determined, we will, in accordance with Securities and Exchange Commission rules and regulations, file a Current Report on Form 8-K or otherwise disclose the 2021 annual bonus amount within four business days after the Compensation Committee has assessed 2021 performance and determined the 2021 annual bonus awards for Dr. Ji.

Equity-Based Incentives

Salaries and bonuses are intended to compensate our executive officers for short-term performance. We also have adopted an equity incentive program intended to reward longer-term performance and to help align the interests of our named executive officers with those of our stockholders. We believe that long-term performance is achieved through an ownership culture that rewards performance by our named executive officers through the use of equity incentives. Our equity incentive plan has been established to provide our employees, including our named executive officers, with incentives to help align those employees' interests with the interests of our stockholders.

When making equity-award decisions, the Compensation Committee considers market data, the grant size, the forms of long-term equity compensation available to it under our existing plans and the status of previously granted awards. The amount of equity incentive compensation granted reflects the executives' expected contributions to our future success. Existing ownership levels are not a factor in award determination, as the Compensation Committee does not want to discourage executives from holding significant amounts of our stock.

Future equity awards that we make to our named executive officers will be driven by our sustained performance over time, our named executive officers' ability to impact our results that drive stockholder value, their level of responsibility, their potential to fill roles of increasing responsibility, and competitive equity award levels for similar positions in comparable companies. Equity forms a key part of the overall compensation for each executive officer and is evaluated each year as part of the annual performance review process and incentive payout calculation.

The amounts awarded to the named executive officers are based on the Compensation Committee's subjective determination of what is appropriate to incentivize the executives. Generally, the grants to named executive officers vest over: (i) a four-year period with 25% vesting on each anniversary of the grant date, or (ii) a four-year period with 1/4 of the shares vesting on the first anniversary of the applicable vesting commencement date, and 1/48 of the shares vesting thereafter on a monthly basis. All equity awards to our employees, including named executive officers, and to directors have been granted and reflected in our financial statements, based upon the applicable accounting guidance, with the exercise price equal to the fair market value of one share of common stock on the grant date.

In order to encourage a long-term perspective and to encourage key employees to remain with us, our stock options typically have annual vesting over a four-year period and a term of ten years. Generally, vesting ends upon termination of services and exercise rights of vested options cease three months after termination of services. Prior to the exercise of an option, the holder has no rights as a stockholder with respect to the shares subject to such option, including voting rights and the right to receive dividends or dividend equivalents.

In August 2021, the Compensation Committee determined to grant to Dr. Ji a long-term equity based incentive in the form of an option to purchase 2,500,000 shares of our common stock, 25% of which shares shall vest on August 30, 2022 and 1/48th of which shall vest monthly thereafter. The Compensation Committee considered the competitive market analysis provided by Prescient in August 2021 and other data in determining the number of options granted to Dr. Ji, and also considered the following: Dr. Ji, having taken on the additional role as the head of research and development, had driven a remarkable pipeline increase from five products in the clinic to 23 products in the clinic over the previous 18 month period, a major leap forward for the company, especially in light of our lean company size of roughly 500 employees. This significant increase in pipeline productivity was the main driver for this grant.

In March 2021, Mr. Asghar was granted long-term equity based incentives in the form of an option to purchase 100,000 shares of our common stock, 25% of which shares were to vest on March 16, 2022 and 1/48th of which were to vest monthly thereafter, and a restricted stock award with respect to 56,974 shares of our common stock that were to vest 1/4 annually from the date of grant. These grants were well within the Chief Financial Officer peer group analysis provided by Compensia and the Compensation Committee believed that they were important for ongoing motivational purposes, and for retention in an incredibly tight labor market. Mr. Asghar passed away on January 6, 2022, on which date the stock option and the restricted stock award terminated unvested.

CEO Performance Award

On August 7, 2020, the Compensation Committee approved a grant to Dr. Ji of a 10-year CEO performance award tied solely to achieving market capitalization milestones (the “CEO Performance Award”) which was approved by our stockholders at the 2020 Annual Meeting of Stockholders held on October 16, 2020. The CEO Performance Award consists of a 10-year option to purchase an aggregate of 24,935,882 shares of our common stock, which was equal to 10% of our outstanding shares of common stock on the day prior to the date of grant, and vests in ten tranches. Each of the ten tranches vests only if a market capitalization milestone is achieved, which requires two market capitalization prongs to be met to achieve each milestone: (1) a six calendar month trailing average (based on trading days); and (2) a 30-calendar day trailing average (based on trading days). To meet the first market capitalization milestone, our current market capitalization must increase to \$5.0 billion. For the next two milestones, our market capitalization must continue to increase in additional \$2.0 billion increments. For the three milestones thereafter, our market capitalization must increase in additional \$3.0 billion increments. For the next three milestones thereafter, our market capitalization must increase in additional \$4.0 billion increments. For the final milestone, our market capitalization must increase by an additional \$5.0 billion. Thus, for Dr. Ji to fully vest in the award, our market capitalization must increase to \$35.0 billion. The exercise price per share subject to the CEO Performance Award is \$17.30, which is a 20% premium to the closing sales price of our common stock on August 7, 2020, the date the CEO Performance Award was approved by the Compensation Committee. As of December 31, 2021, none of the CEO Performance Award was vested.

Benefits Programs

We design our benefits programs to be both affordable and competitive in relation to the market while conforming with local laws and practices. We monitor the market and local laws and practices and adjust our benefits programs as needed. We design our benefits programs to provide an element of core benefits and, to the extent possible, offer options for additional benefits, be tax-effective for employees in each country and balance costs and cost sharing between us and our employees.

Timing of Equity Awards

Only the Compensation Committee may approve stock option grants to our executive officers. Stock options are generally granted at meetings of the Compensation Committee or pursuant to a unanimous written consent of the Compensation Committee. The exercise price of a newly granted option is the closing price of our common stock on the date of grant.

Executive Equity Ownership

We encourage our executives to hold a significant equity interest in our company. However, we do not have specific share retention and ownership guidelines for our executives.

Hedging Policy

Our Insider Trading and Window Period Policy prohibits our directors, officers and employees, and their family members, from engaging in hedging transactions involving our securities.

Consideration of Advisory Votes to Approve the Compensation of our Named Executive Officers

We value the opinions of our stockholders, including as expressed through advisory votes to approve the compensation of our named executive officers (“Say-on-Pay Votes”). In our most recent Say-On-Pay Vote, conducted at our 2021 annual meeting of stockholders, held on November 15, 2021, our stockholders approved the compensation of our named executive officers on an advisory basis, with approximately 63.3% of the votes cast in favor of the fiscal 2020 compensation of our named executive officers. In setting fiscal 2022 compensation, we will consider the outcome of the Say-on-Pay Vote during our 2021 annual meeting of stockholders and will continue to consider the outcome of future Say-on-Pay Votes, as well as stockholder feedback received throughout the year, when making compensation decisions for our executive officers.

Effect of Accounting and Tax Treatment on Compensation Decisions

In the review and establishment of our compensation programs, we consider the anticipated accounting and tax implications to us and our executives.

Generally, Section 162(m) of the Code disallows public companies a tax deduction for federal income tax purposes of compensation in excess of \$1 million paid to their chief executive officer and certain other specified officers in any taxable year. For tax years ending prior to December 31, 2017, compensation in excess of \$1 million could only be deducted if it was

“performance-based compensation” within the meaning of Section 162(m) of the Code or qualified for one of the other exemptions from the deduction limit. The exemption from Section 162(m) of the Code’s deduction limit for performance-based compensation has been repealed, effective for taxable years beginning after December 31, 2017, such that compensation paid to our covered officers (which now also includes our Chief Financial Officer) in excess of \$1 million will generally not be deductible unless it qualifies for transition relief applicable to certain arrangements in place as of November 2, 2017. We seek to maintain flexibility in compensating our executives in a manner designed to promote our corporate goals and, therefore, while we are mindful of the benefit of the full deductibility of compensation, our Compensation Committee has not adopted a policy requiring that any or all compensation to be deductible. Our Compensation Committee may authorize compensation payments that are not fully tax deductible if we believe that such payments are appropriate to attract and retain executive talent or meet other business objectives.

Role of Executives in Executive Compensation Decisions

The Board and our Compensation Committee generally seek input from our Chief Executive Officer, Dr. Ji, when discussing the performance of, and compensation levels for, executives other than himself. The Compensation Committee also works with Dr. Ji and our Chief Financial Officer to evaluate the financial, accounting, tax and retention implications of our various compensation programs. Neither Dr. Ji nor any of our other executives participate in deliberations relating to his compensation.

Compensation Risk Management

We have considered the risk associated with our compensation policies and practices for all employees, and we believe we have designed our compensation policies and practices in a manner that does not create incentives that could lead to excessive risk taking that would have a material adverse effect on us for the following reasons:

- We structure our compensation to consist of base salary, variable pay, equity-based pay and benefits. The base portion of compensation is designed to provide a steady income regardless of our stock price performance so that executives do not feel pressured to focus exclusively on stock price performance to the detriment of other important business measures. Our variable pay and equity-based pay programs are designed to reward both short- and long-term corporate performance. For short-term performance, our variable pay programs are designed to motivate employees to achieve overall goals. For long-term performance, our stock option awards generally vest over four years and are only valuable if our stock price increases over time. We believe that these variable elements of compensation are a sufficient percentage of overall compensation to motivate executives to produce superior short- and long-term corporate results, while the fixed element is also sufficiently high that the executives are not encouraged to take unnecessary or excessive risks in doing so.
- Our bonus program has been structured around attainment of overall corporate goals for the past several years and we have seen no evidence that it encourages unnecessary or excessive risk taking.

SUMMARY COMPENSATION TABLE

The following table provides certain summary information concerning compensation awarded to, earned by or paid to each person who served as our principal executive officer at any time during fiscal year 2021 and each person who served as our principal financial officer at any time during fiscal year 2021 (collectively, the “named executive officers”). We did not have any other executive officers during fiscal year 2021.

Name and Principal Position	Year	Salary(\$)	Bonus (\$)	Stock Awards (\$) ⁽¹⁾	Option Awards (\$) ⁽²⁾	All Other Compensation (\$) ⁽³⁾	Total(\$)
Henry Ji, Ph.D.	2021	1,639,250 ⁽⁴⁾	* ⁽⁵⁾	—	18,085,250	52,829	19,777,329
Chairman of the Board, Chief Executive Officer and President	2020	839,250 ⁽⁶⁾	560,000	—	156,087,048 ⁽⁷⁾	51,406	157,537,704
Najjam Asghar	2021	450,000	—	579,995	832,650	37,342	1,899,987
Former Senior Vice President and Chief Financial Officer ⁽⁸⁾	2020	318,371	160,000	—	1,520,628	33,321	2,032,320

- (1) These amounts represent the aggregate grant date fair value of restricted stock unit awards to the applicable named executive officer in the relevant fiscal year, computed in accordance with FASB ASC Topic 718. The dollar amounts listed do not necessarily reflect the dollar amounts of compensation actually realized or that may be realized by the applicable named executive officer. For a detailed description of the assumptions used for purposes of determining grant date fair value, see [Note 10](#) of the accompanying notes to the consolidated financial statements in this Annual Report on Form 10-K.
- (2) These amounts represent the aggregate grant date fair value of awards for grants of options to purchase shares of our common stock and, for 2020, options to purchase shares of Scilex Holding Company, to the applicable named executive officer in the relevant fiscal year, computed in accordance with FASB ASC Topic 718. The dollar amounts listed do not necessarily reflect the dollar amounts of compensation actually realized or that may be realized by the applicable named executive officer. For a detailed description of the assumptions used for purposes of determining grant date fair value, see [Note 10](#) of the accompanying notes to the consolidated financial statements in this Annual Report on Form 10-K.
- (3) Comprised of payments for executive disability benefits.
- (4) Comprised of \$1,500,000 of salary paid by us and \$139,250 of salary payable by Scilex Holding Company for Dr. Ji’s role as its Executive Chairperson, which Scilex Holding Company salary was approved by our stockholders at the annual meeting of our stockholders held on October 16, 2020.
- (5) Does not include for 2022 the amount of any annual bonus that may be awarded to Dr. Ji as the Compensation Committee has not, as of the date of the filing of this Annual Report on Form 10-K, yet determined the annual bonus amounts, if any, that will be awarded Dr. Ji for 2021. See “Elements of Compensation-Variable Pay-2021 Bonuses” above for a discussion of the target bonus amount for Dr. Ji for fiscal year 2021. We expect the Compensation Committee to assess 2021 performance and determine the 2021 annual bonus award for Dr. Ji in the second half of 2022. Dr. Ji may also be entitled to receive a bonus from Scilex Holding Company in connection with his role as its Executive Chairperson; however, the amount of any such bonus has not yet been determined. Once such annual bonus amounts, if any, have been determined, we will, in accordance with Securities and Exchange Commission rules and regulations, file a Current Report on Form 8-K or otherwise disclose the 2021 annual bonus amounts within four business days after the Compensation Committee has assessed 2021 performance and determined the 2021 annual bonus awards for Dr. Ji.
- (6) Comprised of \$700,000 of salary paid by us and \$139,250 of salary payable by Scilex Holding Company for Dr. Ji’s role as its Executive Chairperson, which Scilex Holding Company salary was approved by our stockholders at the annual meeting of stockholders held on October 16, 2020. Excludes \$301,750 of salary that would have been payable by Scilex Holding Company for Dr. Ji’s role as its Executive Chairperson, which amount was foregone by Dr. Ji as it was not approved by our stockholders at our 2021 annual meeting of stockholders held on November 15, 2021.
- (7) Includes \$150,317,148 of grant date fair value attributable to the CEO Performance Award, which was approved by our stockholders at our 2020 Annual Meeting of Stockholders held on October 16, 2020. Excludes \$6,510,980 of grant date fair value attributable to the option to purchase 7,844,554 shares of common stock of Scilex Holding Company that was foregone and relinquished by Dr. Ji as it was not approved by our stockholders at our 2021 annual meeting of our stockholders held on November 15, 2021.
- (8) Mr. Asghar was promoted to the role of Senior Vice President and Chief Financial Officer for the Company in August 2020. Mr. Asghar passed away on January 6, 2022.

GRANTS OF PLAN-BASED AWARDS DURING FISCAL YEAR 2021

The following table shows for fiscal year 2021, certain information regarding grants of plan-based awards to our named executive officers:

Named Executive Officer	Grant Date	Date of Board/Compensation Committee Approval	All Other Stock Awards: Number of shares of stock or units (#)	All Other Option Awards: Number of Securities Underlying Options (#)	Exercise Price Per Share (\$ / Share)	Grant Date Fair Value of Stock and Option Awards (\$)⁽¹⁾
Henry Ji, Ph.D.	8/30/2021	8/29/2021	—	2,500,000	8.86	18,085,250
Najjam Asghar ⁽²⁾	3/16/2021	3/16/2021	—	100,000	10.18	832,650
	3/16/2021	3/16/2021	56,974	—	—	579,995

- (1) The amounts shown in this column do not reflect dollar amounts actually received by our named executive officers. Instead, these amounts represent the aggregate grant date fair value of the stock option and restricted stock unit awards determined in accordance with FASB ASC Topic 718. The valuation assumptions used in determining the amounts are described in [Note 10](#) of the accompanying notes to the consolidated financial statements in this Annual Report on Form 10-K. With respect to options, our named executive officers will only realize compensation to the extent the trading price of our common stock is greater than the exercise price of such stock options on the date the options are exercised.
- (2) Mr. Asghar passed away on January 6, 2022, on which date the stock option and the restricted stock award terminated unvested.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

The following table sets forth information for the named executive officers regarding the number of shares subject to both exercisable and unexercisable stock options, as well as the exercise prices and expiration dates thereof, as of December 31, 2021. Except for the options set forth in the table below, no other equity awards were held by any our named executive officers as of December 31, 2021:

Name	Option Awards							Stock Awards	
	Option Grant Date	Date of Board/Compensation Committee Approval	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Earned Options(%) Unexercisable	Option Exercise Price (\$) ⁽¹⁾	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares of Stock That Have Not Vested (\$)
Henry Ji, Ph.D.	10/29/2013 ⁽²⁾	10/29/2013	10/1/2013	101,000	—	8.40	10/29/2023	—	—
	10/7/2014 ⁽²⁾	10/7/2014	10/7/2014	100,000	—	4.32	10/7/2024	—	—
	2/24/2015 ⁽³⁾	2/24/2015	2/24/2015	80,000	—	12.78	2/24/2025	—	—
	2/24/2015 ⁽²⁾	2/24/2015	2/24/2015	80,000	—	12.78	2/24/2025	—	—
	3/11/2016 ⁽²⁾	3/11/2016	3/11/2016	100,000	—	5.79	3/11/2026	—	—
	8/12/2016 ⁽²⁾	8/12/2016	8/12/2016	300,000	—	6.52	8/12/2026	—	—
	9/14/2017 ⁽²⁾	9/14/2017	9/14/2017	750,000	—	1.80	9/14/2027	—	—
	5/17/2018 ⁽²⁾	5/17/2018	5/17/2018	671,875	78,125	7.20	5/17/2028	—	—
	4/14/2019 ⁽²⁾	4/19/2019	4/14/2019	1,000,000	500,000	3.78	4/14/2029	—	—
	8/14/2019 ⁽²⁾⁽⁴⁾	6/6/2019	3/18/2019	2,073,948	942,704	1.16	6/6/2029	—	—
	6/15/2020 ⁽²⁾	6/14/2020	6/15/2020	562,500	937,500	4.89	6/15/2030	—	—
	10/16/2020 ⁽⁵⁾	8/7/2020	8/7/2020	—	24,935,882	17.30	8/7/2030	—	—
	8/30/2021 ⁽²⁾	8/29/2021	8/30/2021	—	2,500,000	8.86	8/30/2031	—	—
	Najjam Asghar ⁽⁶⁾	11/29/2019 ⁽²⁾	11/29/2019	11/29/2019	26,042	23,958	2.92	11/29/2029	—
12/6/2019 ⁽²⁾		12/6/2019	12/6/2019	25,000	25,000	3.52	12/6/2029	—	—
6/15/2020 ⁽²⁾		6/14/2020	6/15/2020	30,000	50,000	4.89	6/15/2020	—	—
11/12/2020 ⁽²⁾		10/23/2020	8/18/2020	40,000	80,000	6.10	11/12/2030	—	—
12/21/2020 ⁽²⁾⁽⁴⁾		12/21/2020	12/21/2020	187,500	562,500	1.16	12/21/2030	—	—
3/16/2021 ⁽²⁾		3/16/2021	3/16/2021	—	100,000	10.18	3/16/2031	—	—
3/16/2021 ⁽⁷⁾		3/16/2021	3/16/2021	—	—	—	—	56,974	264,929

- (1) Represents the fair market value of a share of our common stock, as determined by the Board, on the option's grant date.
- (2) Shares subject to the option vest and become exercisable over a four-year period, with 1/4 of the shares vesting on the first anniversary of the Vesting Commencement Date, and 1/48 of the shares vesting following each one-month period of the participant's continued employment or service with the Company thereafter.
- (3) 62.5% of the shares subject to the option vested over a four-year period, with 1/4 of the shares vesting on the first anniversary of the Vesting Commencement Date, and 1/48 of the shares vesting following each one-month period of the participant's continued employment or service with the Company thereafter. The remaining 37.5% of the shares subject to the option vested upon the consummation of a certain strategic transaction.
- (4) Represents options granted by our subsidiary, Scilex Holding Company.
- (5) Reflects the CEO Performance Award, which is intended to compensate Dr. Ji over its 10-year maximum term and will vest only if certain pre-established market capitalization milestones are achieved, which requires two market capitalization prongs to be met to achieve each milestone: (1) a six-calendar month trailing average (based on trading days); and (2) a 30-calendar day trailing average (based on trading days). For the first tranche to vest, Sorrento's market capitalization has to increase to \$5 billion. For the next two tranches to vest, Sorrento must increase its market capitalization in additional \$2 billion increments, then by increments of \$3 billion for the three tranches after that, then by increments of \$4 billion for the next three tranches and a final increment of \$5 billion for the final tranche—up to a total market capitalization of \$35 billion. For each tranche that is achieved, Dr. Ji will vest and earn the right to exercise the option for that number of shares of Sorrento common stock that corresponds to approximately 1% of Sorrento's total outstanding shares, calculated as of August 6, 2020. The option, to the extent vested, will be exercisable until August 7, 2030 (ten years from the date of

grant). The CEO Performance Award was approved by our stockholders at the 2020 Annual Meeting of Stockholders held on October 16, 2020. As of December 31, 2021, none of the CEO Performance Award was vested.

- (6) Mr. Asghar passed away on January 6, 2022.
- (7) 1/4th of the shares subject to the restricted stock unit award were to vest on each one year anniversary of the grant date.

OPTION EXERCISES AND STOCK VESTED

The following table presents the number of shares of our common stock acquired upon the exercise of stock options by our named executive officers during 2021 and the aggregate value realized upon the exercise of stock options (calculated based on the difference between the closing price of our common stock on the date of exercise and the exercise price of the exercised stock option). No restricted stock unit awards held by any of our named executive officers vested during 2021.

Name	Option Awards	
	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise (\$)
Henry Ji, Ph.D.	1,000	\$ 34,100

PENSION BENEFITS, NONQUALIFIED DEFINED CONTRIBUTION AND OTHER

NONQUALIFIED DEFERRED COMPENSATION

No pension benefits were paid to any of our named executive officers during fiscal 2021. We do not currently sponsor any non-qualified defined contribution plans or non-qualified deferred compensation plans.

Employment, Severance, Separation and Change in Control Agreements

Chief Executive Officer Amended and Restated Employment Agreement

On May 9, 2017, we entered into an Amended and Restated Employment Agreement (the “Restated Agreement”) with Dr. Ji. Pursuant to the Restated Agreement, Dr. Henry Ji will continue to serve as our President and Chief Executive Officer for an initial term of three years commencing on May 9, 2017. Following this initial three year term, the Restated Agreement shall renew automatically for additional 12 month terms unless either we or Dr. Ji provide written notice of non-renewal at least three months in advance of the expiration of the then-current term. The Restated Agreement supersedes and replaces a prior employment agreement with Dr. Ji, dated September 21, 2012, as amended on October 18, 2012.

Pursuant to the Restated Agreement, Dr. Ji shall (i) receive an annual base salary (the “Annual Base Salary”) of \$600,000, as may be adjusted from time to time; (ii) be eligible to participate in an annual incentive program, with a target annual bonus incentive equal to 55% of his then-current Annual Base Salary (the “Annual Bonus”); and (iii) receive employee benefits, paid personal leave and expense reimbursement in accordance with our policies. In addition, Dr. Ji’s performance will be reviewed by the Board at least annually, and his Annual Base Salary, target Annual Bonus and any other compensation will be subject to adjustment by the Board, provided that Dr. Ji’s Annual Base Salary and target Annual Bonus may not be adjusted downward.

Pursuant to the Restated Agreement, we have the right to terminate Dr. Ji’s employment at any time with or without “cause” (as defined in the Restated Agreement). In addition, Dr. Ji may resign with or without “good reason” (as defined in the Restated Agreement) upon 30 days’ written notice to us. Under each such circumstance, Dr. Ji will be entitled to receive any accrued but unpaid base salary as of the date of termination or resignation, any expenses owed to him and any amount accrued and arising from his participation in, or vested benefits accrued under, any employee benefit plans, programs or arrangements, including any 401(k), profit sharing or pension plan (collectively, the “Termination Payments”).

In the event that Dr. Ji’s employment is terminated by us without “cause” or by our non-renewal of the term of the Restated Agreement, or by Dr. Ji for “good reason,” in either case outside of a Change of Control Window (as defined below), then, subject to Dr. Ji’s timely execution and non-revocation of a release in favor of us, Dr. Ji will be entitled to receive the following: (i) the Termination Payments; (ii) an amount equal to his then-current Annual Base Salary, payable in a lump sum; (iii) an amount equal to his pro-rata then-current target Annual Bonus, payable in a lump sum; (iv) 12 months of health insurance benefits for Dr. Ji and for his eligible dependents who were covered under our health insurance plans as of the date his employment was terminated; and (v) one year of accelerated vesting of Dr. Ji’s then-outstanding awards of equity compensation, with performance-criteria deemed satisfied at target.

If Dr. Ji’s employment is terminated without “cause” or by our non-renewal of the term of the Restated Agreement, or by Dr. Ji for “good reason,” in either case during the period commencing three months prior to a Change of Control and ending 12 months after a Change of Control (as defined in the Restated Agreement) (the “Change of Control Window”), then, subject to Dr. Ji’s timely execution and non-revocation of a release in favor of us, Dr. Ji will be entitled to receive the following: (i) the Termination Payments; (ii) an amount equal to twice his then-current Annual Base Salary, payable in a lump sum; (iii) an amount equal to twice his pro-rata then-current target Annual Bonus, payable in a lump sum; (iv) 24 months of health insurance benefits for Dr. Ji and for his eligible

dependents who were covered under our health insurance plans as of the date his employment was terminated; and (v) accelerated vesting of Dr. Ji's then-outstanding awards of equity compensation, with performance-criteria deemed satisfied target.

The CEO Performance Award does not provide for automatic acceleration of vesting upon a change in control event; however, in the event of a change of control, the achievement of the market capitalization milestones will be based on our market capitalization determined by the product of the total number of outstanding shares of our common stock immediately before the change of control multiplied by the per share price (plus the per share value of any other consideration) received by our stockholders in the change of control. Any portion of the CEO Performance Award that does not vest in accordance with the above will be forfeited automatically as of immediately prior to the effective time of the change of control and never shall become vested.

Former Chief Financial Officer Change of Control Severance Agreement

On November 5, 2020, we entered into a Change of Control and Severance Agreement (the "Severance Agreement") with Mr. Asghar. Pursuant to the Severance Agreement, if Mr. Asghar's employment was terminated without "cause" or by Mr. Asghar for "good reason," in either case during the period commencing three months prior to a Change of Control (as defined in the Severance Agreement) and ending 12 months after a Change of Control, then, subject to Mr. Asghar's timely execution and non-revocation of a release in favor of us, Mr. Asghar would have been entitled to receive the following: (i) an amount equal to his then-current annual base salary, payable in a lump sum; (ii) an amount equal to his then-current target annual bonus, payable in a lump sum; (iii) 12 months of health insurance benefits for Mr. Asghar and for his eligible dependents who were covered under the Company's health insurance plans as of the date his employment was terminated; and (iv) accelerated vesting of Mr. Asghar's then-outstanding awards of equity compensation, with performance-criteria, if any, deemed satisfied at target. Mr. Asghar passed away on January 6, 2022 and this agreement is therefore no longer in effect.

POTENTIAL PAYMENTS UPON TERMINATION OR CHANGE IN CONTROL

Other than the provisions of the executive severance benefits to which our named executive officers would be entitled to at December 31, 2021 (the last trading day of the year) as set forth above, we have no liabilities under termination or change in control conditions. We do not have a formal policy to determine executive severance benefits. Each executive severance arrangement is negotiated on an individual basis.

The tables below estimate the current value of amounts payable to our named executive officers that were serving as such as of the end of December 31, 2021 in the event that a termination of employment occurred on December 31, 2021 (the last trading day of the year). The closing price of our common stock, as reported on the Nasdaq Capital Market, was \$4.65 on December 31, 2021. The following tables exclude certain benefits, such as accrued vacation, that are available to all employees generally. The actual amount of payments and benefits that would be provided can only be determined at the time of a change in control and/or the named executive officer's qualifying separation from the Company.

Henry Ji, Ph.D.

	By Sorrento Without Cause or by Dr. Ji for Good Reason or Sorrento's Non- Renewal Outside of Change of Control Window	By Sorrento Without Cause or by Dr. Ji for Good Reason or Sorrento's Non- Renewal During Change of Control Window
Cash Payments	\$ 1,639,250	\$ 3,278,500
Continuation of Benefits	26,939	53,878
Value of Option Shares Accelerated	326,250 ⁽¹⁾	435,000 ⁽²⁾
Total Cash Benefits and Payments	<u>\$ 1,992,439</u>	<u>\$ 3,767,378</u>

(1) Consists of the value of one year of vesting of the in-the-money stock options held by Dr. Ji as of December 31, 2021, the vesting of which would be accelerated. The CEO Performance Award was not in-the-money as of December 31, 2021.

(2) Consists of the value of 100% of the in-the-money stock options held by Dr. Ji as of December 31, 2021, the vesting of which would be accelerated. The CEO Performance Award was not in-the-money as of December 31, 2021.

	By Sorrento Without Cause or by Mr. Asghar for Good Reason During Change of Control Window	
Cash Payments	\$	450,000
Continuation of Benefits		38,391
Value of Option Shares Accelerated		334,626 ^{(1) (2)}
Total Cash Benefits and Payments	\$	823,017

- (1) Mr. Asghar passed away on January 6, 2022 and therefore neither of the scenarios in this table can occur after that date.
- (2) Consists of the value of 100% of the in-the-money stock options held by Mr. Asghar as of December 31, 2021, the vesting of which would be accelerated.

DIRECTOR COMPENSATION

The following table sets forth summary information concerning the total compensation paid to our non-employee directors in 2021 for services to our company:

Name	Fees Earned or Paid in Cash (\$)	Option Awards (\$) ⁽¹⁾	All Other Compensation (\$)	Total (\$)
Dorman Followwill	123,000	1,808,525	—	1,931,525
Elizabeth A. Czerepak ⁽²⁾	8,125	488,610	—	496,735
Kim D. Janda, Ph.D.	55,000	1,808,525	187,500 ⁽³⁾	2,051,025
David Lemus	80,000	1,808,525	—	1,888,525
Jaisim Shah	55,000	1,808,525	579,280 ⁽⁴⁾	2,442,805
Dr. Robin L. Smith ⁽⁵⁾	48,125	1,808,525	—	1,856,650
Yue Alexander Wu, Ph.D.	100,000	1,808,525	—	1,908,525

- (1) These amounts represent the aggregate grant date fair value of awards for grants of options to each listed director for the fiscal year ended December 31, 2021, computed in accordance with FASB ASC Topic 718. These amounts do not represent the actual amounts paid to or realized by the directors during the fiscal year ended December 31, 2021. The value as of the grant date for stock options is recognized over the number of months of service required for the stock option to vest in full. For a detailed description of the assumptions used for purposes of determining grant date fair value, see [Note 10](#) of the accompanying notes to the consolidated financial statements in this Annual Report on Form 10-K. As of December 31, 2021, our non-employee directors held options to purchase the following number of shares of our common stock: Mr. Followwill—490,000; Ms. Czerepak—100,000; Dr. Janda—772,400; Mr. Lemus—490,000; Mr. Shah—795,000; and Dr. Wu—525,000.
- (2) Ms. Czerepak was elected to the Board effective November 15, 2021.
- (3) Consists of fees earned by Dr. Janda for non-employee consulting services provided to the Company.
- (4) Comprised solely of salary paid by Scilex Holding Company to Mr. Shah in connection with his service as President and Chief Executive Officer of Scilex Holding Company.
- (5) Dr. Smith's service on the Board ceased when her term expired on November 15, 2021.

Outside Director Compensation Policy

Our outside director compensation policy in effect during 2021 provided that each non-executive director received a \$55,000 annual cash retainer, with the amount being increased to \$78,000 for any Lead Director and \$100,000 for any Board chairman. Further, the chairperson of each of our Audit, Compensation and Corporate Governance and Nominating Committees received an additional annual cash retainer of \$25,000. Other members of our Audit, Compensation and Corporate Governance and Nominating Committees received an additional cash retainer of \$10,000. In addition, each non-executive director was entitled to receive an annual grant of a stock option to purchase 250,000 shares of common stock, which vests monthly over a period of 48 months from the date of grant, subject to continued service through each vesting date. As a new director, Ms. Czerepak was granted an option to purchase

100,000 shares of common stock, which vests monthly over a period of 12 months from the date of grant, subject to continued service through each vesting date. Additionally, we reimbursed each outside director for reasonable travel expenses related to such director's attendance at Board and committee meetings.

Effective January 1, 2022, our Compensation Committee approved an amendment and restatement of our outside director compensation policy (the "Amended Outside Director Compensation Policy"). Pursuant to the Amended Outside Director Compensation Policy, each non-executive director is entitled to receive a \$82,500 annual cash retainer, with the amount being increased to \$117,000 for any Lead Independent Director or any Board chairperson. Further, the chairperson of each of our Audit, Compensation and Corporate Governance and Nominating Committees is entitled to receive an additional annual cash retainer of \$37,500. Other members of our Audit, Compensation and Corporate Governance and Nominating Committees are entitled to receive an additional cash retainer of \$15,000. In addition, each non-executive director will be entitled to receive an annual grant of a stock option to purchase 250,000 shares of common stock, which vests monthly over a period of 48 months from the date of grant, subject to continued service through each vesting date. Additionally, we will reimburse each outside director for reasonable travel expenses related to such director's attendance at Board and committee meetings.

Other Compensation

We intend to provide benefits and perquisites for our named executive officers at levels comparable to those provided to other executive officers in our industry. Our Board or any applicable committee thereof, in its discretion, may revise, amend or add to the benefits and perquisites of any named executive officer as it deems it advisable and in the best interest of the Company and our stockholders.

Compensation Committee Interlocks and Insider Participation

Our Compensation Committee consists of two directors, each of whom is a non-employee director: Mr. Followwill and Dr. Wu. Dr. Wu serves as the Chairperson of the Compensation Committee. During 2021, neither Mr. Followwill nor Dr. Wu was an officer or employee of ours, was formerly an officer of ours or had any relationship requiring disclosure by us under Item 404 of Regulation S-K. No interlocking relationship as described in Item 407(e)(4) of Regulation S-K exists between any of our executive officers or Compensation Committee members, on the one hand, and the executive officers or compensation committee members of any other entity, on the other hand, nor has any such interlocking relationship existed in the past.

Compensation Committee Report

The Compensation Committee has reviewed and discussed the Compensation Discussion and Analysis required by Item 402(b) of Regulation S-K of the SEC's rules and regulations with management and, based on such review and discussions, the Compensation Committee recommended to the Board of Directors that the Compensation Discussion and Analysis be included in this Annual Report on Form 10-K.

Compensation Committee

Dr. Yue Alexander Wu

Mr. Dorman Followwill

The foregoing Compensation Committee Report shall not be deemed to be "soliciting material," deemed "filed" with the SEC or subject to the liabilities of Section 18 of the Exchange Act. Notwithstanding anything to the contrary set forth in any of the Company's previous filings under the Securities Act of 1933, as amended, or the Exchange Act that might incorporate by reference future filings, including this Annual Report on Form 10-K, in whole or in part, the foregoing Compensation Committee Report shall not be incorporated by reference into any such filings.

Pay Ratio Disclosure

As of the date of the filing of this Annual Report on Form 10-K, the pay ratio for Dr. Ji, our Chief Executive Officer, is not calculable. The pay ratio is not calculable as the Compensation Committee has not, as of the date of the filing of this Annual Report on Form 10-K, yet determined the annual bonus amounts, if any, that will be awarded our Chief Executive Officer for 2021. We expect the Compensation Committee to assess 2021 performance and determine the 2021 annual bonus award and actual total compensation for our Chief Executive Officer in the second half of 2022. Once such annual bonus amount, if any, has been determined, we will, in accordance with Securities and Exchange Commission rules and regulations, file a Current Report on Form 8-K or otherwise disclose the pay ratio within four business days after the Compensation Committee has assessed 2021 performance and determined the 2021 annual bonus awards and actual total compensation for our Chief Executive Officer.

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

The following table sets forth information as of February 28, 2022, with respect to the beneficial ownership of shares of our common stock by:

- each person or group known to us to be the beneficial owner of more than five percent of our common stock;
- each of our directors;
- each of our named executive officers; and
- all of our current directors and executive officers as a group.

This table is based upon information supplied by officers, directors, and principal stockholders and a review of Schedules 13D and 13G, if any, filed with the SEC. Other than as set forth below, we are not aware of any other beneficial owner of more than five percent of our common stock as of February 28, 2022. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons and entities named in the table below have sole voting and investment power with respect to all shares of common stock that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership is based on 342,335,102 shares of common stock outstanding as of February 28, 2022, adjusted as required by rules promulgated by the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options and warrants that are either immediately exercisable or exercisable on or before April 29, 2022, which is 60 days after February 28, 2022. These shares are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise noted below, the address of each beneficial owner listed in the table is c/o Sorrento Therapeutics, Inc., 4955 Directors Place, San Diego, California 92121.

Name of Beneficial Owner	Beneficial Ownership of Common Stock	
	Number of Shares	Percentage of Class
Named Executive Officers and Directors:		
Dr. Henry Ji, Chairman of the Board, President and Chief Executive Officer	8,425,375 ⁽¹⁾	2.4 %
Dorman Followwill, Lead Independent Director	278,588 ⁽²⁾	*
Elizabeth A. Czerepak, Director	41,666 ⁽³⁾	*
Dr. Kim Janda, Director	414,226 ⁽⁴⁾	*
David Lemus, Director	276,458 ⁽³⁾	*
Jaisim Shah, Director	694,091 ⁽⁵⁾	*
Dr. Yue Alexander Wu, Director	316,458 ⁽⁶⁾	*
All Current Officers and Directors as a Group (7 persons)	10,446,862 ⁽⁷⁾	3.0 %
5% Stockholders:		
BlackRock, Inc.	21,775,865 ⁽⁸⁾	6.4 %

* Less than 1%.

- (1) Comprised of (i) 2,055,807 shares of common stock held directly, (ii) 2,271,693 shares of common stock held in family trusts, of which Dr. Ji is a co-trustee with his wife Vivian Q. Zhang, (iii) 40,000 shares of common stock held directly by Dr. Ji's wife, and (iv) 4,057,875 shares of common stock issuable pursuant to stock options exercisable within 60 days after February 28, 2022. Each of Dr. Ji and Vivian Q. Zhang, while acting as co-trustees, have the power to act alone and have those actions binding on both trustees' and the trusts' assets, including voting and dispositive power over the shares of common stock held by the family trusts.
- (2) Comprised of (i) 2,130 shares of common stock held directly, and (ii) 276,458 shares of common stock issuable pursuant to stock options exercisable within 60 days after February 28, 2022.
- (3) Comprised solely of shares of common stock issuable pursuant to stock options exercisable within 60 days after February 28, 2022.

- (4) Comprised of (i) 3,000 shares of common stock held directly, and (ii) 411,226 shares of common stock issuable pursuant to stock options exercisable within 60 days after February 28, 2022.
- (5) Comprised of (i) 112,633 shares of common stock held directly, and (ii) 581,458 shares of common stock issuable pursuant to stock options exercisable within 60 days after February 28, 2022.
- (6) Comprised of (i) 5,000 shares of common stock held directly, and (ii) 311,458 shares of common stock issuable pursuant to stock options exercisable within 60 days after February 28, 2022.
- (7) Comprised of shares included under “Named Executive Officers and Directors.”
- (8) BlackRock, Inc. (“BlackRock”) filed a Schedule 13G/A on February 7, 2022 reporting that it had sole voting power with respect to 21,089,575 shares of common stock and sole dispositive power with respect to 21,775,865 shares of common stock in its capacity as a parent holding company or control person in accordance with Rule 13d-1(b)(1)(ii)(G) under the Exchange Act. BlackRock’s address is 55 East 52nd Street, New York, New York 10055.

SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS

The following table sets forth additional information with respect to the shares of common stock that may be issued upon the exercise of options and other rights under our existing equity compensation plans and arrangements in effect as of December 31, 2021. The information includes the number of shares covered by, and the weighted average exercise price of, outstanding options and the number of shares remaining available for future grant, excluding the shares to be issued upon exercise of outstanding options.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	25,949,409 ⁽¹⁾	\$ 6.19	35,375,026 ⁽²⁾
Equity compensation plans not approved by security holders	—	—	—
Total	25,949,409	\$ 6.19	35,375,026

(1) Includes 3,443,896 RSUs granted under our 2019 Plan for which there is no exercise price reflected in column (b).

(2) Comprised of shares available for future issuance under the 2019 Stock Incentive Plan (the “2019 Plan”), the Amended and Restated 2009 Stock Incentive Plan, the 2020 Employee Stock Purchase Plan and the CEO Performance Award.

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

Review, Approval or Ratification of Transactions with Related Persons

The Board conducts an appropriate review of and oversees all related party transactions on a continuing basis and reviews potential conflict of interest situations where appropriate. The Board has not adopted formal standards to apply when it reviews, approves or ratifies any related party transaction. However, the Board has followed the following standards: (i) all related party transactions must be fair and reasonable and on terms comparable to those reasonably expected to be agreed to with independent third parties for the same goods and/or services at the time they are authorized by the Board and (ii) all related party transactions should be authorized, approved or ratified by the affirmative vote of a majority of the directors who have no interest, either directly or indirectly, in any such related party transaction.

Transactions with Related Persons

The following is a description of transactions or series of transactions since January 1, 2021, or any currently proposed transaction, to which we have been a party, in which the amount involved in the transaction or series of transactions exceeds \$120,000 and in which any of our directors, executive officers or persons who we know held more than five percent of any class of our capital stock, including their immediate family members, had or will have a direct or indirect material interest, other than compensation arrangements that are described under Item 11 of this Annual Report on Form 10-K.

Dr. Janda Consulting Agreement

On July 15, 2020, we entered into a consulting agreement with Kim Janda, Ph.D., a member of our Board, pursuant to which Dr. Janda will provide consulting and advisory services in exchange for (i) a one-time fee of \$250,000, which is payable at a rate of 1/12th per month over twelve months, and (ii) an option to purchase up to 150,000 shares of our common stock, which was granted on August 7, 2020 and vests at a rate of 1/48th per month commencing on July 15, 2020. On October 8, 2021, we entered into an amendment to the consulting agreement with Dr. Kim whereby the one-time fee was increased to \$301,091, payable through September 30, 2022.

ITOCHU Product Development Agreement

As of January 1, 2021, approximately 14.7% of the outstanding capital stock of our subsidiary, Scilex Holding Company, represented a noncontrolling interest that was held by ITOCHU CHEMICAL FRONTIER Corporation. Scilex Pharmaceuticals Inc., a wholly-owned subsidiary of Scilex Holding Company, has entered into a product development agreement with ITOCHU CHEMICAL FRONTIER Corporation, which serves as the sole manufacturer and supplier to Scilex Pharmaceuticals Inc. for ZTlido® (lidocaine topical system 1.8%). Effective January 19, 2021, ITOCHU CHEMICAL FRONTIER Corporation no longer held any shares of outstanding capital stock of Scilex Holding Company. During the year ended December 31, 2021, Scilex Pharmaceuticals Inc. purchased approximately \$5.7 million of inventory from ITOCHU CHEMICAL FRONTIER Corporation.

Pulsar Therapeutics, Inc. License Agreement

On May 13, 2020, we entered into a license agreement with Pulsar Therapeutics, Inc. (“Pulsar”), pursuant to which we licensed Pulsar’s nanoparticle technology for vaccine and antibody uses in exchange for a cash payment, certain royalties of net sales, a sublicense fee and an investment by us in Pulsar through the transfer of 1.0 million shares of our common stock in exchange for a 5.0% equity interest in Pulsar. As of the date of the investment, Henry Ji, Ph.D., a member of our Board and our Chief Executive Officer and President, was a director and chairperson of the board of directors of Pulsar and owned approximately 45.0% of Pulsar’s outstanding shares, and Jaisim Shah, a member of our Board, owned approximately 5.0% of Pulsar’s outstanding shares.

Cytimm Therapeutics, Inc. Equity Interest

On May 15, 2020, we acquired a 50% equity interest in Cytimm Therapeutics, Inc. (“Cytimm”) in exchange for an investment of \$2.5 million by us. As of the date of the acquisition, Henry Ji, Ph.D., a member of our Board and our Chief Executive Officer and President, was a director, the chairperson of the board of directors and a stockholder of Cytimm.

Transactions with Deverra Therapeutics, Inc.

On December 7, 2021, we loaned Deverra Therapeutics, Inc. (“Deverra”) \$1.0 million in consideration for the issuance of a promissory note by Deverra to us. The note accrues interest at a rate of 10% per year and matures on the date that is six months from the date of issuance. As of the date of the loan, Henry Ji, Ph.D., a member of our Board and our Chief Executive Officer and President, was a director and the chairperson of the board of directors of Deverra, and Jaisim Shah, a member of our Board, was a director of Deverra.

Transactions with Aardvark Therapeutics, Inc.

In April 2021, we entered into an asset purchase agreement (the “Aardvark Asset Purchase Agreement”) with Aardvark Therapeutics, Inc. to acquire Aardvark’s Delayed Burst Release Low Dose Naltrexone (DBR-LDN), or ARD-301, asset and intellectual property rights, for the treatment of chronic pain, fibromyalgia and chronic post-COVID syndrome. As consideration for the purchase of the assets, we paid Aardvark an upfront license fee of \$5.0 million comprised of 616,655 shares of our common stock. We also agreed to pay Aardvark (i) milestone payments upon the receipt of certain regulatory approvals, and (ii) milestone payments upon our achievement of certain commercial sales milestones. We will also pay certain royalties in the mid-single digit to low-double digit percentages of annual net sales by us. In May 2021, we paid \$5.0 million in cash for 3,888,932 shares of Series B Preferred Stock of Aardvark. In July 2021, we paid consideration of \$5.0 million in cash for an additional 3,888,932 shares of Series B Preferred Stock of Aardvark, resulting in an increase in our ownership interest in Aardvark to approximately 8%. Tien Lee, MD, a member of the board of directors of Scilex Holding Company, our majority owned subsidiary, is the founder and chief executive officer of Aardvark. Kim D. Janda, Ph.D., a member of our Board, is a member of the advisory board of Aardvark.

Indemnification Agreements with Directors and Executive Officers

We have entered into indemnity agreements with certain directors, officers and other key employees of ours under which we agreed to indemnify those individuals under the circumstances and to the extent provided for in the agreements, for expenses, damages, judgments, fines, settlements and any other amounts they may be required to pay in actions, suits or proceedings which they are or may be made a party or threatened to be made a party by reason of their position as a director, officer or other agent of ours, and otherwise to the fullest extent permitted under Delaware law and our Bylaws. We also have an insurance policy covering our directors and executive officers with respect to certain liabilities, including liabilities arising under the Securities Act of 1933, as amended, or otherwise. We believe that these provisions and insurance coverage are necessary to attract and retain qualified directors, officers and other key employees.

Board Independence

Our Board is responsible for establishing corporate policies and for our overall performance, although it is not involved in our day-to-day operations. Our Board consults with our counsel to ensure that our Board's determinations are consistent with all relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in the rules of The Nasdaq Stock Market LLC, as in effect from time to time. Consistent with these considerations, after review of all relevant transactions or relationships between each director, or any of his or her family members, us, our senior management and our independent registered public accounting firm, our Board has determined that all of our directors, other than Dr. Ji, Dr. Janda and Mr. Shah, are independent.

Item 14. Principal Accounting Fees and Services.

The following table represents aggregate fees billed to us for the fiscal years ended December 31, 2021 and December 31, 2020 by Ernst & Young LLP, our independent registered public accounting firm for each period. All fees described below were pre-approved by the Audit Committee.

	Year Ended December 31	
	2021	2020
Audit Fees (1)	\$ 2,011,222	\$ 1,628,120
Audit-Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
Total Fees	\$ 2,011,222	\$ 1,628,120

- (1) Audit fees consisted of fees for services rendered in connection with the annual audit of our consolidated financial statements, quarterly reviews of financial statements included in our quarterly reports on Form 10-Q, and the audit of internal control over financial reporting. Audit fees also consisted of services provided in connection with issuances of consents included in registration statements, standalone audits, consultation on accounting matters, and SEC registration statement services.

Audit Committee's Pre-Approval Policies and Procedures

The Audit Committee has adopted a policy for the pre-approval of audit and non-audit services rendered by our independent registered public accounting firm. The policy generally pre-approves specified services in the defined categories of audit services, audit-related services and tax services up to specified amounts. Pre-approval may also be given as part of the Audit Committee's approval of the scope of the engagement of the independent auditors or on an individual explicit case-by-case basis before the independent registered public accounting firm are engaged to provide each service. The pre-approval of services may be delegated to one or more of the Audit Committee members, but the decision must be reported to the full Audit Committee at its next scheduled meeting. By the adoption of this policy, the Audit Committee has delegated the authority to pre-approve services to the Chairperson of the Audit Committee, subject to certain limitations.

The Audit Committee has determined that the rendering of services by Ernst & Young LLP other than audit services is compatible with maintaining the principal accounting firm's independence.

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 Annual Report on Form 10-K.

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*	<u>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).</u>
2.2*	<u>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).</u>
2.3	<u>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).</u>
2.4*	<u>Agreement and Plan of Merger, dated as of March 18, 2019, by and among Sorrento Therapeutics, Inc., Semnur Pharmaceuticals, Inc., Scilex Holding Company, Sigma Merger Sub, Inc. and Fortis Advisors LLC, solely as the Equityholders' Representative (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed with the SEC on March 22, 2019).</u>
2.5	<u>Amendment No. 1 to Agreement and Plan of Merger, dated as of August 7, 2019, by and between Scilex Holding Company and Fortis Advisors LLC, solely as the Equityholders' Representative (incorporated by reference to Exhibit 2.2 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 12, 2019).</u>
2.6*	<u>Agreement and Plan of Merger, dated August 20, 2020, by and among Sorrento Therapeutics, Inc., SP Merger Sub, Inc., SmartPharm Therapeutics, Inc. and John C. Thomas, Jr., as representative of the stockholders of SmartPharm Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed with the SEC on August 20, 2020).</u>
2.7*	<u>Agreement and Plan of Merger, dated April 2, 2021, by and among Sorrento Therapeutics, Inc., AT Merger Sub, Inc., ACEA Therapeutics, Inc. and Fortis Advisors, LLC, as representative of the shareholders of ACEA Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed with the SEC on April 5, 2021).</u>
2.8*^	<u>Agreement and Plan of Merger, dated January 14, 2022, by and among Sorrento Therapeutics, Inc., VH Merger Sub I, Inc., VH Merger Sub II, LLC, Virex Health, Inc. and Fortis Advisors LLC, as representative of the stockholders of Virex Health, Inc. (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed with the SEC on February 1, 2022).</u>
3.1	<u>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).</u>
3.2	<u>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).</u>
3.3	<u>Amended and Restated Bylaws of Sorrento Therapeutics, Inc. (incorporated by reference to Exhibit 3.3 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 15, 2019).</u>

- 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 [Voting Agreement, dated as of April 29, 2016, by and between Sorrento Therapeutics, Inc. and Yuhan Corporation \(incorporated by reference to Exhibit 4.12 to the Registrant's Registration Statement on Form S-3 filed with the SEC on June 29, 2016\).](#)
- 4.3 [Registration Rights Agreement, dated November 8, 2016, by and among Sorrento Therapeutics, Inc. and the persons party thereto \(incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on November 8, 2016\).](#)
- 4.4 [Registration Rights Agreement, dated April 27, 2017, by and among Sorrento Therapeutics, Inc. and the persons party thereto \(incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on April 28, 2017\).](#)
- 4.5 [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 \(incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the SEC on December 21, 2017\).](#)
- 4.6 [Registration Rights Agreement, dated December 21, 2017, by and among Sorrento Therapeutics, Inc. and the purchasers identified on Schedule A thereto \(incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K filed with the SEC on December 21, 2017\).](#)
- 4.7 [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 \(incorporated by reference to Exhibit 4.2 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2018\).](#)
- 4.8 [Registration Rights Agreement, dated June 13, 2018, by and among Sorrento Therapeutics, Inc. and the purchasers identified on Schedule A thereto \(incorporated by reference to Exhibit 4.3 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2018\).](#)
- 4.9 [Form of Warrant, dated November 7, 2018, issued by Sorrento Therapeutics, Inc. \(incorporated by reference to Exhibit 4.1 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2018\).](#)
- 4.10 [Registration Rights Agreement, dated November 7, 2018, by and among Sorrento Therapeutics, Inc. and the parties identified on Schedule A thereto \(incorporated by reference to Exhibit 4.2 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2018\).](#)
- 4.11 [Agreement and Consent, dated November 7, 2018, by and among Sorrento Therapeutics, Inc. and the Warrant Holders party thereto \(incorporated by reference to Exhibit 10.6 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2018\).](#)
- 4.12 [Form of Warrant, dated May 3, 2019, issued by Sorrento Therapeutics, Inc. \(incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on May 3, 2019\).](#)
- 4.13 [Amendment No. 1 to the Registration Rights Agreement, dated as of May 3, 2019, by and among Sorrento Therapeutics, Inc. and the persons party thereto \(incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the SEC on May 3, 2019\).](#)
- 4.14 [Form of Series A Warrant \(incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on June 28, 2019\).](#)
- 4.15 [Form of Series C Warrant \(incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K filed with the SEC on June 28, 2019\).](#)
- 4.16 [Form of Warrant \(incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on October 8, 2019\).](#)
- 4.17 [Amendment No. 2 to the Registration Rights Agreement, dated as of December 6, 2019, by and among Sorrento Therapeutics, Inc. and the persons party thereto \(incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the SEC on December 9, 2019\).](#)

- 4.18 [Registration Rights Agreement, dated as of March 4, 2021, by and between Sorrento Therapeutics, Inc. and the Icahn School of Medicine at Mount Sinai \(incorporated by reference to Exhibit 4.19 to the Registrant's Registration Statement on Form S-3 filed with the SEC on April 9, 2021\).](#)
- 4.19 [Description of Securities of Sorrento Therapeutics, Inc.](#)
- 10.1± [Form of Indemnification Agreement \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on September 7, 2012\).](#)
- 10.2 [Lease Agreement, dated September 12, 2016, between Sorrento Therapeutics, Inc. and HCP Life Science REIT, Inc. \(incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2016\).](#)
- 10.3 [First Amendment to Office Lease, dated October 19, 2018, between Sorrento Therapeutics, Inc. and HCP Life Science REIT, Inc. \(incorporated by reference to Exhibit 10.15 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 15, 2019\).](#)
- 10.4± [Amended and Restated Employment Agreement between Sorrento Therapeutics, Inc. and Henry Ji, Ph.D. dated May 9, 2017 \(incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 15, 2017\).](#)
- 10.5+ [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 \(incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2018\).](#)
- 10.6 [Form of Purchase Agreement, dated as of September 7, 2018, by and among Scilex Pharmaceuticals Inc., Sorrento Therapeutics, Inc. and the purchasers party thereto \(incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2018\).](#)
- 10.7 [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 \(incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2018\).](#)
- 10.8 [Lease Agreement, dated November 13, 2018, between Sorrento Therapeutics, Inc. and HCP Life Science Estates, Inc. \(incorporated by reference to Exhibit 10.30 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 15, 2019\).](#)
- 10.9± [Sorrento Therapeutics, Inc. 2019 Stock Incentive Plan \(incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on October 20, 2020\).](#)
- 10.10^ [Omnibus Amendment No. 1 to Indenture and Letter of Credit, dated as of October 1, 2019, by and among Scilex Pharmaceuticals, Inc., Sorrento Therapeutics, Inc., U.S. Bank National Association, as trustee and collateral agent, and the beneficial owners of the senior secured notes due 2026 and the holders of such securities listed on the signature pages \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on October 1, 2019\).](#)
- 10.11^† [Omnibus Amendment No. 2 to Indenture and Letter of Credit, dated as of March 30, 2020, by and among Scilex Pharmaceuticals, Inc., Sorrento Therapeutics, Inc., U.S. Bank National Association, as trustee and collateral agent, and the beneficial owners of the senior secured notes due 2026 and the holders of such securities listed on the signature pages \(incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 11, 2020\).](#)
- 10.12± [Outside Director Compensation Policy.](#)
- 10.13± [Performance Stock Option Award Agreement, dated as of August 7, 2020, by and between Sorrento Therapeutics, Inc. and Henry Ji, Ph.D. \(incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed with the SEC on October 20, 2020\).](#)
- 10.14± [Sorrento Therapeutics, Inc. 2020 Employee Stock Purchase Plan \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on October 20, 2020\).](#)

- 10.15† [Consent Under and Amendment No. 3 to Indenture and Letter of Credit, dated December 14, 2020, by and among Scilex Pharmaceuticals Inc., Sorrento Therapeutics, Inc., U.S. Bank National Association, as trustee and collateral agent, and the beneficial owners of the senior secured notes due 2026 and the holders of such securities listed on the signature pages thereto \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on December 15, 2020\).](#)
- 10.16 [Stock Purchase Agreement, dated as of March 4, 2021, by and between Sorrento Therapeutics, Inc. and the Icahn School of Medicine at Mount Sinai \(incorporated by reference to Exhibit 4.18 to the Registrant's Registration Statement on Form S-3 filed with the SEC on April 9, 2021\).](#)
- 10.17†^ [Exclusive License Agreement, dated as of March 4, 2021, by and between Sorrento Therapeutics, Inc. and the Icahn School of Medicine at Mount Sinai \(incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 5, 2021\).](#)
- 10.18± [Sorrento Therapeutics, Inc. 2021 Cash-Settled Stock Appreciation Plan \(incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 5, 2021\).](#)
- 10.19± [Sorrento Therapeutics, Inc. Stock Appreciation Rights Award Agreement \(incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 5, 2021\).](#)
- 10.20^ [Earn-Out Agreement, dated June 1, 2021, by and between Sorrento Therapeutics, Inc. and Fortis Advisors LLC \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on June 4, 2021\).](#)
- 10.21 [Contract, dated August 15, 2018, by and between Hangzhou ACEA Pharmaceutical Research Co., Ltd. and ACEA Bio \(Hangzhou\) Co., Ltd. \(translated into English from its original text in Chinese\) \(incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on June 4, 2021\).](#)
- 10.22 [Loan Agreement, dated January 6, 2018, by and between Zhejiang ACEA Pharmaceutical Co., Ltd. and ACEA Bio \(Hangzhou\) Co., Ltd. \(translated into English from its original text in Chinese\) \(incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed with the SEC on June 4, 2021\).](#)
- 10.23 [Sorrento Gateway Lease, dated September 1, 2021, by and between Sorrento Therapeutics, Inc. and HCP Life Science REIT, Inc. \(4930 Directors Place\) \(incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 5, 2021\).](#)
- 10.24 [First Amendment to Office Lease, dated September 14, 2021, by and between Sorrento Therapeutics, Inc. and HCP Life Science REIT, Inc. \(4930 Directors Place\) \(incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 5, 2021\).](#)
- 10.25 [Second Amendment to Office Lease, dated September 1, 2021, by and between Sorrento Therapeutics, Inc. and HCP Life Science REIT, Inc. \(4955 Directors Place\) \(incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 5, 2021\).](#)
- 10.26 [First Amendment to Office Lease, dated October 10, 2020, by and between Sorrento Therapeutics, Inc. and HCP Life Science Estates, Inc. \(4939 Directors Place\) \(incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 5, 2021\).](#)
- 10.27 [Second Amendment to Office Lease, dated September 1, 2021, by and between Sorrento Therapeutics, Inc. and HCP Life Science REIT, Inc. \(4939 Directors Place\) \(incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 5, 2021\).](#)
- 10.28† [Amended and Restated Sales Agreement, dated as of December 3, 2021, by and among Sorrento Therapeutics, Inc., Cantor Fitzgerald & Co., B. Riley Securities, Inc., H.C. Wainwright & Co., LLC and A.G.P/Alliance Global Partners \(incorporated by reference to Exhibit 1.1 to the Current Report on Form 8-K filed with the SEC on December 3, 2021\).](#)
- 10.29 [Amendment No. 1 to Amended and Restated Sales Agreement, dated as of December 23, 2021, by and among Sorrento Therapeutics, Inc., Cantor Fitzgerald & Co., B. Riley Securities, Inc. and H.C. Wainwright & Co., LLC \(incorporated by reference to Exhibit 1.1 to the Current Report on Form 8-K filed with the SEC on December 23, 2021\).](#)
- 21.1 [List of Subsidiaries](#)
- 23.1 [Consent of Ernst & Young LLP](#)
- 23.2 [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 and 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 Principal Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, as amended.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL 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 supplemental 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.

^ Certain identified information has been omitted pursuant to Item 601(b)(10) of Regulation S-K because such information is both (i) not material and (ii) of the type that the Registrant treats as private or confidential. The Registrant hereby undertakes to furnish supplemental copies of the unredacted exhibit upon request by the SEC.

† Non-material schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant hereby undertakes to furnish supplemental copies of any of the omitted schedules and exhibits upon request by the SEC.

Item 16. Form 10-K Summary.

None.

Sorrento Therapeutics, Inc.
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Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control over Financial Reporting

We have audited Sorrento Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, because of the effect of the material weakness described below on the achievement of the objectives of the control criteria, Sorrento Therapeutics, Inc. (the Company) has not maintained effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

A material weakness is a deficiency, or 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 weakness has been identified and included in management's assessment in the section, "Management's Annual Report on Internal Control over Financial Reporting". Management has identified that the Company did not employ sufficient accounting resources with appropriate experience and technical expertise to effectively execute controls over certain judgmental and technical accounting areas. As a result, certain of the Company's control activities in the areas of revenue, business combinations, investments, debt, derivative liabilities and leases did not operate effectively and have been deemed deficient and the combination of the aforementioned deficiencies represents a material weakness in the Company's internal control over financial reporting.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2021 and 2020, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for the years then ended, and the related notes. This material weakness was considered in determining the nature, timing and extent of audit tests applied in our audit of the 2021 consolidated financial statements, and this report does not affect our report dated March 11, 2022, which expressed an unqualified opinion thereon that included an explanatory paragraph regarding 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 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.

/s/ Ernst & Young LLP

San Diego, California
March 11, 2022

Report 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. (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

We also have 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, 2021, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 11, 2022 expressed an adverse opinion thereon.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in [Note 2](#) to the consolidated financial statements, the Company has suffered recurring losses from operations, has recurring negative cash flows from operations, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in [Note 2](#). The consolidated 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.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Valuation of acquired intangible assets and contingent consideration liabilities recorded in connection with the ACEA Therapeutics, Inc. business combination

Description of the Matter As disclosed in [Note 7](#) of the consolidated financial statements, the Company completed the acquisition of ACEA Therapeutics, Inc. (“ACEA”) on June 1, 2021 for net consideration of approximately \$166.2 million. The transaction was accounted for as a business combination. In connection with the acquisition, the Company recorded intangible assets consisting of in-process research and development of \$190.8 million. The Company recognized a liability of \$122.1 million on the acquisition date for consideration payable that is contingent upon achieving certain regulatory and sales-based milestones. The Company determines the fair value of these contingent consideration arrangements, both as part of the initial purchase price allocation and on an ongoing basis each reporting period, until the arrangements are settled. As of December 31, 2021, the amount recorded for future estimated contingent consideration related to the ACEA acquisition is \$131.3 million.

Auditing the Company’s accounting for its acquisition of ACEA was complex due to the significant estimation uncertainty in determining the fair value of identified intangible assets and the recorded contingent consideration liabilities. The significant estimation uncertainty was primarily due to the sensitivity of the respective fair values to underlying assumptions including discount rates, revenue projections and estimated probabilities of successful commercialization. These significant assumptions are forward-looking and could be affected by future economic and market conditions.

How We Addressed the Matter in Our Audit Our substantive audit procedures included, among others, involving our internal valuation specialists to assist us in evaluating and testing the valuation methodologies and significant assumptions stated above. For example, we compared the significant assumptions to current industry, market and economic trends, to historical results of the Company’s business and other guideline companies in the same industry and to other sources. Furthermore, we performed, among other procedures, independent comparative calculations to estimate certain significant assumptions and compared our estimates with those of the Company. We also performed a sensitivity analysis of the significant assumptions to evaluate the change in the fair value of the acquired in-process research and development assets and contingent consideration liabilities recorded that would result from changes in the assumptions.

Scilex notes and valuation of embedded derivative liabilities

Description of the Matter The carrying value of the Company’s Scilex notes was \$101.2 million as of December 31, 2021. As discussed in [Note 1](#) to the consolidated financial statements, the Company accounts for debt, such as the Scilex notes, 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’s derivative liabilities were valued at \$35.7 million as of December 31, 2021. The derivative liabilities consist of various embedded features in the Scilex notes. As discussed in [Note 3](#) to the consolidated financial statements, the fair value of the embedded derivative liabilities was estimated using the discounted cash flow method under the income approach, combined with a Monte Carlo simulation model.

Auditing the carrying value of the Scilex notes was challenging because of the subjective auditor judgment necessary in evaluating the propriety of the Company’s accounting for certain embedded features within the Scilex notes that are not derivative liabilities. Such embedded features include contractual increases in outstanding principal, contingent on the achievement of certain predetermined target sales thresholds over certain periods. Auditing the Company’s valuation of its embedded derivative liabilities was challenging because of the subjective auditor judgment necessary in evaluating the propriety of the complex valuation methodologies and significant assumptions used in estimating the fair value of such embedded derivative liabilities as of the balance sheet date. Such significant assumptions include a risk adjusted net sales forecast and an effective debt yield.

How We Addressed the Matter in Our Audit Our substantive audit procedures included, among others, assessing the impact on the carrying value of embedded features within the Scilex notes that are not derivative liabilities and independently recalculating the carrying value of the Scilex notes in accordance with the terms of the arrangement. As it relates to the embedded derivative liabilities, we involved our internal valuation specialists to assist us in evaluating and testing the valuation methodologies and significant assumptions stated above. For example, we performed independent comparative calculations to estimate a risk adjusted net sales forecast and effective debt yield and compared our estimates with the Company’s assumptions. Additionally, we searched for contrary evidence, including, for example, comparing the Company’s revenue projections within the valuation models to the historical financial results of the Company.

/s/ Ernst & Young LLP
We have served as the Company's auditor since 2020.

San Diego, California
March 11, 2022

Report 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 statements of operations, comprehensive income (loss), stockholders' equity, and cash flows of Sorrento Therapeutics, Inc. and subsidiaries (the "Company") for the year ended December 31, 2019, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the results of the Company's operations and cash flows for the year ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

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 negative working capital, 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 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 the financial statements are free of material misstatement, whether due to error or fraud. Our audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ DELOITTE & TOUCHE LLP

San Diego, California
March 2, 2020

We began serving as the Company's auditor in 2016. In 2020 we became the predecessor auditor.

SORRENTO THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except for share amounts)

ASSETS	December 31,	
	2021	2020
Current assets:		
Cash and cash equivalents	\$ 36,665	\$ 56,464
Marketable investments	90,217	—
Accounts receivables, net	18,715	15,506
Inventory	8,106	1,831
Prepaid expenses	11,804	8,712
Other current assets	7,482	3,721
Total current assets	172,989	86,234
Property and equipment, net	41,325	31,861
Operating lease right-of-use assets	85,173	42,052
Intangibles, net	259,705	73,675
Goodwill	79,525	43,554
Equity investments	51,271	256,397
Other assets, net	4,830	2,049
Total assets	\$ 694,818	\$ 535,822
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 27,414	\$ 24,706
Accrued payroll and related benefits	21,503	20,859
Accrued expenses	37,975	19,198
Current portion of deferred revenue	1,108	4,485
Current portion of operating lease liabilities	11,539	3,626
Current portion of contingent consideration	7,934	398
Current portion of debt	31,980	23,208
Total current liabilities	139,453	96,480
Long-term debt, net of discount	110,627	92,258
Deferred tax liabilities, net	2,426	6,918
Deferred revenue	118,942	113,185
Derivative liabilities	35,700	35,400
Operating lease liabilities	83,431	50,301
Contingent consideration	124,349	549
Other long-term liabilities	1,761	—
Total liabilities	\$ 616,689	\$ 395,091
Commitments and contingencies (Note 11)		
Equity:		
Sorrento Therapeutics, Inc. equity		
Common stock, \$0.0001 par value; 750,000,000 shares authorized and 314,573,225 and 275,285,582 shares issued and outstanding at December 31, 2021 and 2020, respectively	32	28
Additional paid-in capital	1,513,758	1,172,346
Accumulated other comprehensive income	1,026	520
Accumulated deficit	(1,386,604)	(958,279)
Treasury stock, 7,568,182 shares at cost at December 31, 2021 and 2020	(49,464)	(49,464)
Total Sorrento Therapeutics, Inc. stockholders' equity	78,748	165,151
Noncontrolling interests	(619)	(24,420)
Total equity	78,129	140,731
Total liabilities and equity	\$ 694,818	\$ 535,822

See accompanying notes

SORRENTO THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
For the Years Ended December 31, 2021, 2020 and 2019
(In thousands, except for per share amounts)

	2021	2020	2019
Revenue:			
Net product revenues	\$ 28,735	\$ 26,628	\$ 21,974
Service revenues	24,169	13,358	9,458
Total revenues	52,904	39,986	31,432
Operating costs and expenses:			
Cost of product sold	3,851	2,149	5,933
Cost of services	9,180	7,791	6,304
Research and development	206,922	111,340	106,879
Acquired in-process research and development	24,208	42,992	75,301
Selling, general and administrative	196,856	116,179	103,557
Intangible amortization	4,140	4,053	3,941
Loss (gain) on contingent consideration	9,198	—	(11,090)
Total operating costs and expenses	454,355	284,504	290,825
Loss from operations	(401,451)	(244,518)	(259,393)
(Loss) gain on derivative liabilities	(300)	6,600	(36,792)
Loss on marketable investments	(15,013)	—	—
Loss on debt extinguishment	(6,695)	(51,939)	(27,810)
(Loss) gain on foreign currency exchange	(973)	812	(330)
Scilex Notes principal increase	(28,000)	—	—
Interest expense, net	(10,224)	(20,157)	(35,048)
Other income gain (loss)	128	(1,378)	(203)
Loss before income tax	(462,528)	(310,580)	(359,576)
Income tax benefit	(33,516)	(2,014)	(473)
Loss on equity method investments	(126)	(5,844)	(3,909)
Net loss	(429,138)	(314,410)	(363,012)
Net loss attributable to noncontrolling interests	(813)	(15,949)	(70,944)
Net loss attributable to Sorrento	\$ (428,325)	\$ (298,461)	\$ (292,068)
Net loss per share - basic per share attributable to Sorrento	\$ (1.45)	\$ (1.30)	\$ (2.20)
Net loss per share - diluted per share attributable to Sorrento	\$ (1.45)	\$ (1.30)	\$ (2.35)
Weighted-average shares outstanding during period - basic shares attributable to Sorrento	294,774	229,823	132,732
Weighted-average shares outstanding during period - diluted shares attributable to Sorrento	294,774	229,823	140,514

See accompanying notes

SORRENTO THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
For the Years Ended December 31, 2021, 2020 and 2019
(In thousands)

	2021	2020	2019
Net loss	\$ (429,138)	\$ (314,410)	\$ (363,012)
Other comprehensive income (loss):			
Foreign currency translation adjustments	506	790	(285)
Total other comprehensive income (loss)	506	790	(285)
Comprehensive loss	(428,632)	(313,620)	(363,297)
Comprehensive loss attributable to noncontrolling interests	(813)	(15,949)	(70,944)
Comprehensive loss attributable to Sorrento	<u>\$ (427,819)</u>	<u>\$ (297,671)</u>	<u>\$ (292,353)</u>

See accompanying notes

SORRENTO THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the Years Ended December 31, 2021, 2020 and 2019
(In thousands)

	Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Noncontrolling Interest	Total
	Shares	Amount	Shares	Amount					
Balance, December 31, 2018	122,281	13	7,568	(49,464)	626,658	15	(367,750)	(1,972)	207,500
Issuance of common stock upon exercise of stock options	268	—	—	—	492	—	—	—	492
Issuance of common stock upon exercise of warrants	3,128	—	—	—	8,359	—	—	—	8,359
Issuance of common stock for public placement, net	259	—	—	—	990	—	—	—	990
Equity contribution related to Semnur acquisition	—	—	—	—	27,991	—	—	26,600	54,591
Stock-based compensation	—	—	—	—	12,648	—	—	—	12,648
Issuance of 2019 Warrants	—	—	—	—	4,288	—	—	—	4,288
Issuance of December 2019 Warrants	—	—	—	—	6,010	—	—	—	6,010
2019 Public Offering of common stock and warrants, net of issuance costs	8,333	1	—	—	23,322	—	—	—	23,323
2019 Registered Direct Offering, net of issuance costs	10,870	1	—	—	23,384	—	—	—	23,385
Issuance of common stock through conversion of convertible notes	22,660	3	—	—	53,980	—	—	—	53,983
Adjustment to noncontrolling interests	—	—	—	—	—	—	—	484	484
Foreign currency translation adjustment	—	—	—	—	—	(285)	—	—	(285)
Net loss	—	—	—	—	—	—	(292,068)	(70,944)	(363,012)
Balance, December 31, 2019	167,799	18	7,568	(49,464)	788,122	(270)	(659,818)	(45,832)	32,756
Issuance of common stock upon exercise of stock options	1,339	—	—	—	5,578	—	—	—	5,578
Issuance of common stock upon exercise of warrants	33,091	3	—	—	92,770	—	—	—	92,773
Issuance of common stock for equity offerings	69,228	7	—	—	317,858	—	—	—	317,865
Equity issued for SmartPharm acquisition	1,832	—	—	—	19,421	—	—	—	19,421
Other acquisitions, license agreements and investments paid in equity	1,997	—	—	—	9,544	—	—	—	9,544
Changes to noncontrolling interests	—	—	—	—	(92,366)	—	—	37,361	(55,005)
Stock-based compensation	—	—	—	—	31,419	—	—	—	31,419
Foreign currency translation adjustment	—	—	—	—	—	790	—	—	790
Net loss	—	—	—	—	—	—	(298,461)	(15,949)	(314,410)
Balance, December 31, 2020	275,286	28	7,568	(49,464)	1,172,346	520	(958,279)	(24,420)	140,731
Issuance of common stock under equity compensation plans	1,603	—	—	—	10,218	—	—	—	10,218
Issuance of common stock upon exercise of warrants	2,550	1	—	—	9,049	—	—	—	9,050
Issuance of common stock for equity offerings	25,483	2	—	—	201,824	—	—	—	201,826
Equity issued for the acquisition of ACEA Therapeutics, Inc.	5,519	—	—	—	42,168	—	—	—	42,168
Other acquisitions, license agreements and investments paid in equity	1,565	1	—	—	13,689	—	—	—	13,690
Changes to noncontrolling interests from increased ownership in Scilex Holding	2,567	—	—	—	(23,963)	—	—	23,963	—
Other changes to noncontrolling interests	—	—	—	—	—	—	—	651	651
Stock-based compensation	—	—	—	—	88,427	—	—	—	88,427
Foreign currency translation adjustment	—	—	—	—	—	506	—	—	506
Net loss	—	—	—	—	—	—	(428,325)	(813)	(429,138)
Balance, December 31, 2021	314,573	32	7,568	(49,464)	1,513,758	1,026	(1,386,604)	(619)	78,129

See accompanying notes

SORRENTO THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
For the Years Ended December 31, 2021, 2020 and 2019
(In thousands, except for share amounts)

	2021	2020	2019
Operating activities:			
Net loss	\$ (429,138)	\$ (314,410)	\$ (363,012)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	12,462	11,007	10,989
Non-cash interest expense and amortization of debt issuance costs	9,162	12,897	22,526
Scilex Notes principal increase	28,000	—	—
Payment on Scilex Notes attributed to accreted interest related to the debt discount	(13,172)	—	—
Non-cash operating lease cost	3,855	3,702	4,053
Stock-based compensation	90,188	31,419	12,648
Acquired in-process research and development	24,208	42,992	75,301
Loss on debt extinguishment, net	6,695	51,939	27,810
Loss (gain) loss on derivative liability	300	(6,600)	36,792
Loss on marketable investments	15,013	—	—
Loss on equity method investments	126	5,844	3,909
Loss (gain) on contingent liabilities and acquisition consideration payable	9,198	—	(11,090)
Deferred income taxes	(35,927)	(2,125)	(373)
Changes in operating assets and liabilities, excluding effect of acquisitions:			
Accounts receivable	(2,957)	(1,051)	(10,622)
Accrued payroll	(111)	4,945	5,678
Prepaid expenses and other current assets	(12,019)	6,445	(314)
Accounts payable	(3,878)	(3,677)	10,221
Accrued expenses and other liabilities	20,747	(1,188)	4,061
Deferred revenue	(1,024)	(362)	(945)
Other	(3,549)	(1,313)	(628)
Net cash used for operating activities	(281,821)	(159,536)	(172,996)
Investing activities:			
Proceeds from sale of marketable investments	124,767	—	—
Purchases of property and equipment	(8,871)	(6,528)	(11,442)
Purchase of assets related to Semnur, net of cash acquired	—	—	(17,040)
ACEA acquisition consideration paid in cash, net of cash acquired	(754)	—	—
Other acquisitions and investments consideration paid in cash	(35,295)	(33,395)	(9,691)
Net cash provided by (used for) investing activities	79,847	(39,923)	(38,173)
Financing activities:			
Proceeds from equity offerings, net of issuance costs	201,825	317,865	47,697
Proceeds from exercises of stock options and warrants	15,420	98,351	8,851
Proceeds from Oaktree Term Loans, net of issuance costs	—	—	17,411
Proceeds from short-term debt and working capital funding arrangements, net of issuance costs	49,743	18,587	8,000
Payments of debt and other obligations	(85,656)	(205,564)	(3,074)
Payments related to Semnur Share Exchange	—	(55,000)	—
Net cash provided by financing activities	181,332	174,239	78,885
Net change in cash, cash equivalents and restricted cash	(20,642)	(25,220)	(132,284)
Net effect of exchange rate changes on cash	843	915	(277)
Cash, cash equivalents and restricted cash at beginning of period	56,464	80,769	213,330
Cash, cash equivalents and restricted cash at end of period	\$ 36,665	\$ 56,464	\$ 80,769
Supplemental disclosures:			
Cash paid during the period for:			
Income taxes	1,200	0	13
Interest	1,060	3,419	12,738
Supplemental disclosures of non-cash investing and financing activities:			
SmartPharm acquisition consideration paid in equity	—	19,421	—
Semnur acquisition consideration paid in equity	—	—	54,591
Semnur acquisition costs incurred but not paid	—	—	601
Scilex Notes principal increase	28,000	—	—
ACEA acquisition consideration paid in equity	42,168	—	—
Right-of-use assets obtained in exchange for new and amended operating lease liabilities	49,459	1,878	6,777
Other acquisitions, license agreements and investments consideration paid in equity	13,689	9,544	—
Changes to noncontrolling interests from increased ownership in Scilex Holding	23,963	—	—
Conversion of convertible notes	—	—	53,983
Other loan forgiveness	7,304	—	—
Property and equipment costs incurred but not paid	1,253	600	849
Reconciliation of cash, cash equivalents and restricted cash within the Company's consolidated balance sheets:			
Cash and cash equivalents	36,665	56,464	22,521
Restricted cash	—	—	58,248
Cash, cash equivalents, and restricted cash	\$ 36,665	\$ 56,464	\$ 80,769

See accompanying notes

SORRENTO THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Significant Accounting Policies

Description of Business

Sorrento Therapeutics, Inc. (the “Company”) is a clinical and commercial stage biopharmaceutical company developing new therapies to treat cancer, pain (non-opioid treatments), autoimmune disease and COVID-19. The Company’s multimodal, multipronged approach to fighting cancer is made possible by its extensive immuno-oncology platforms, including key assets such as fully human antibodies (“G-MAB™ library”), immuno-cellular therapies (“DAR-T™”), antibody-drug conjugates (“ADCs”), and oncolytic virus (“Seprehvec™”). The Company is also developing potential antiviral therapies and vaccines against coronaviruses, including Abivertinib, COVI-AMG™, COVISHIELD™, COVI-MSC™ and COVIDROPS™; and diagnostic test solutions, including COVITRACK™ and COVISTIX™.

The Company’s commitment to life-enhancing therapies for patients is also demonstrated by its effort to advance a first-in-class (TRPV1 agonist) non-opioid pain management small molecule, resiniferatoxin (“RTX”), and SP-102 (10 mg, dexamethasone sodium phosphate viscous gel) (SEMDEXA™), a novel, viscous gel formulation of a widely used corticosteroid for epidural injections to treat lumbosacral radicular pain, or sciatica, and to commercialize ZTlido® (lidocaine topical system) 1.8% for the treatment of post-herpetic neuralgia (PHN). RTX has been cleared for a Phase II trial for intractable pain associated with cancer and a Phase II trial in osteoarthritis patients. SEMDEXA announced highly statistically significant positive top-line results from its Phase III Pivotal Trial C.L.E.A.R Program for its novel, non-opioid product for the treatment of lumbosacral radicular pain (sciatica). ZTlido® was approved by the FDA on February 28, 2018.

Basis of Presentation and Principles of Consolidation

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. The Company operates in two operating and reportable segments, Sorrento Therapeutics and Scilex. The Sorrento Therapeutics segment is organized around the Company’s immuno-oncology therapeutic area, leveraging its proprietary G-MAB™ antibody library and targeted delivery modalities to generate the next generation of cancer therapeutics. The Scilex segment is largely organized around the Company’s non-opioid pain management operations. See [Note 14](#).

Use of Estimates

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 at the date of the financial statements and the reported amounts of revenues and 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. Cash and cash equivalents consist of money market accounts and bank deposits, which are highly liquid and readily tradable.

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 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 accounts receivable and payable, and other financial instruments in current assets or current liabilities.

Accounts Receivable, Net

Accounts receivable are presented net of allowances for expected credit losses and consist of trade receivables from sales and services provided to certain customers, which are generally unsecured. 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. The allowance for doubtful accounts is not material.

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 net realizable value for those items that are potentially excess, obsolete or slow-moving. The Company considers the need for allowances for excess and obsolete inventory based upon historical experience, sales trends, and specific categories of inventory and expiration dates for inventory on hand. As of December 31, 2021, net inventory was \$8.1 million, comprised of \$4.7 million of finished goods and \$3.3 million of raw materials and supplies. Net inventory as of December 31, 2020 was \$1.8 million, primarily comprised of finished goods.

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

The Company accounts for business combinations using the acquisition method of accounting, which requires that assets acquired, including in-process research and development ("IPR&D") projects and liabilities assumed be recorded at their fair values as of the acquisition date on the Company's consolidated balance sheets. Any excess of purchase price over the fair value of net assets acquired is recorded as goodwill. The determination of estimated fair value requires the Company to make significant estimates and assumptions. As a result, the Company may record adjustments to the fair values of assets acquired and liabilities assumed within the measurement period (up to one year from the acquisition date) with the corresponding offset to goodwill. Transaction costs associated with business combinations are expensed as they are incurred.

When the Company determines net assets acquired do not meet the definition of a business combination under the acquisition method of accounting, the transaction is accounted for as an acquisition of assets and, therefore, no goodwill is recorded and contingent consideration such as payments upon achievement of various developmental, regulatory and commercial milestones generally is not recognized at the acquisition date. In an asset acquisition, up-front payments allocated to IPR&D projects at the acquisition date and subsequent milestone payments are charged to expense in the Company's consolidated statements of operations unless there is an alternative future use.

Contingent Consideration

The fair value of contingent consideration liabilities assumed in business combinations is recorded as part of the purchase price consideration of the acquisition, and is determined using a discounted cash flow model or Monte Carlo simulation model. The significant inputs of such models are not observable in the market, such as certain financial metric growth rates, volatility rates, projections associated with applicable milestones, discount rates and the related probabilities and payment structure in the contingent consideration arrangement. Fair value adjustments to contingent consideration liabilities are recorded through operating expenses in the consolidated statement of operations. Contingent consideration arrangements assumed in an asset acquisition will be measured and accrued when such contingency is resolved.

Acquired In-Process Research and Development

The Company has acquired, and may continue to acquire, the rights to develop and commercialize new drug candidates. The up-front payments to acquire new drug compounds or drug delivery devices, as well as future milestone payments associated with assets that do not meet the definition of a derivative and that are deemed probable to achieve, are immediately expensed as acquired IPR&D, provided that the drug candidates have not achieved regulatory approval for marketing and, absent obtaining such approval, have no alternative future use. Intangible assets acquired in a business combination that are used for IPR&D activities are considered indefinite lived until the completion or abandonment of the associated research and development efforts. Upon commercialization of the relevant research and development project, the Company amortizes the acquired IPR&D over its estimated useful life. Capitalized IPR&D 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.

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 at the reporting unit level 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 assesses 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 performs a quantitative goodwill impairment test. The Company may also elect to bypass the qualitative assessment in a period and elect to proceed to perform the quantitative goodwill impairment test. The Company performed its annual assessment for goodwill impairment at the Sorrento Therapeutics and Scilex reporting unit levels in the fourth quarter of 2021, noting no indication of impairment. There were no triggering events indicating the potential for impairment through December 31, 2021.

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 the expected use of the assets and the effects of obsolescence, demand, anticipated technological advances, market influences and other economic 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' net book value to future net undiscounted cash flows that the assets are expected to generate.

Debt, Including Debt With Detachable Warrants

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 debt are first allocated to the debt and the warrants at their relative estimated fair values. The portion of the proceeds 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 Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 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. Consequently, the Company imputes interest on the carrying value of the debt and records interest expense using an imputed effective interest rate. The Company reassesses the expected payments each reporting period and accounts 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.

Derivative Liabilities

Derivative liabilities are recorded on the Company's consolidated balance sheets at their fair value on the date of issuance and are revalued on each balance sheet date until such instruments are settled or expire, with changes in the fair value between reporting periods recorded as other income or expense.

Investments in Other Entities

The Company holds a portfolio of investments in equity securities. 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. The Company's other equity investments non-marketable securities are carried at cost, less impairment, plus or minus changes resulting from observable price changes in orderly transactions for identical or similar investments. The Company's investments in marketable equity securities are measured at fair value.

Research and Development Costs

The Company expenses the cost of research and development as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including clinical trial costs, manufacturing costs for both clinical and preclinical materials as well as other contracted services, license fees and other external costs. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity is performed or when the goods have been received, rather than when payment is made, in accordance with FASB ASC Topic 730, *Research and Development*.

Income Taxes

The provisions of the FASB 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, 2021, the Company maintained a full valuation allowance against its deferred tax assets, with the exception of an amount equal to its deferred tax liabilities that are scheduled to reverse against the Company's deferred tax assets.

Leases

The Company determines if an arrangement is a lease at inception. Operating lease right-of-use ("ROU") assets and lease liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. As the Company's leases do not provide an implicit rate, it uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. The Company calculates the associated lease liability and corresponding ROU asset upon lease commencement using a discount rate based on a credit-adjusted secured borrowing rate commensurate with the term of the lease. The operating lease ROU asset also includes any lease payments made and is reduced by

lease incentives. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Revenue Recognition

The Company's revenues are generated from product sales, the sale of customized reagents and other materials, contract manufacturing services, and other service revenues.

The following table shows revenue disaggregated by product and service type for the years ended December 31, 2021, 2020 and 2019 (in thousands):

	Years Ended December 31,		
	2021	2020	2019
Scilex Pharmaceuticals Inc. product sales	\$ 28,546	\$ 26,331	\$ 21,033
Other product revenue	189	297	941
Net product revenue	\$ 28,735	\$ 26,628	\$ 21,974
Concortis Biosystems Corporation	15,599	7,730	6,520
Bioserv Corporation	4,672	4,976	2,450
Other service revenue	3,898	652	488
Service revenue	\$ 24,169	\$ 13,358	\$ 9,458

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 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.

Scilex Product Sales

Revenues from product sales is fully comprised of sales of ZTlido. The Company's performance obligation with respect to sales of ZTlido 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, 2021 was not material. Sales of ZTlido are generated within the United States. Substantially all of the Company's product revenue and accounts receivable result from a sole customer.

For product sales, the Company records gross-to-net sales adjustments for government and managed care rebates, chargebacks, wholesaler and distributor fees, sales returns and prompt payment discounts. Such variable consideration is estimated in the period of the sale and is 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.

Concortis Biosystems Corporation ("Concortis")

Contract manufacturing revenue associated with sales of customized reagents related to delivering proprietary cytotoxins, linkers and linker-toxins is recognized at a point in time upon the transfer of control, which is generally upon shipment given the short contract terms of two months or less generally. Revenue associated with contract development and manufacturing of highly customized ADC services related to providing synthetic expertise to antibodies provided by customers is recognized over time as the service and related deliverables are highly customized and unique to each customer's needs, which does not have alternative use to the Company. The Company also has an enforceable right to the payment for the ADC services completed to date. In recognizing the revenue over time, the Company measures its progress using an input method based on the effort it expends toward the satisfaction of its performance obligations. The Company estimates the amount of effort it expends including the time it will take the Company to complete the activities relative to the estimated total effort to satisfy each performance obligation. This approach requires the Company to make estimates and use judgement. If the Company's estimates or judgements change over the course of the contract, they may affect the timing and amount of revenue that the Company recognizes in the current and future periods.

As of December 31, 2021, the estimated revenue expected to be recognized for future performance obligations associated with contract development and manufacturing services was approximately \$0.2 million.

Bioserv Corporation (“Bioserv”)

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, 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, 2021 and 2020, the estimated revenue expected to be recognized for future performance obligations associated with contract manufacturing services was approximately \$0.1 million and \$3.4 million, respectively.

Other Service Revenue

If the license to the Company’s intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. If the license to the Company’s intellectual property is bundled with other promises that are not distinct, the Company assesses the nature of the combined performance obligation to determine whether it is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company recorded the non-refundable, up-front license fee under current license agreements as deferred revenue upon receipt of the payment as it is determined not distinct from the ongoing performance obligation. License revenue is recognized over the term when the ongoing performance obligation is satisfied.

As of December 31, 2021, future performance obligations for 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, 2021, was approximately \$7.0 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, 2021 and 2020, the NantCell license agreement, effective April 21, 2015, represented \$110.0 million of contract liabilities reflected in long-term deferred revenue. See [Note 7](#) for additional information regarding the remaining performance obligation for the agreement.

In November 2020, the Company was awarded a contract with the Defense Advanced Research Projects Agency (“DARPA Contract”) and co-funded by the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense, to develop a rapid countermeasure to COVID-19 using gene-encoded neutralizing antibodies. The contract provides funding of up to \$34.0 million for the development through Phase II clinical studies of a gene-encoded antibody that could enable rapid protection from and/or treatment of SARS-CoV-2 infection and COVID-19. The Company recognized \$2.8 million and \$0.2 million in grant revenue associated with the DARPA Contract during the years ended December 31, 2021 and 2020, respectively, which is included within other service revenue.

Stock-Based Compensation

The Company estimates the fair value of stock option awards and its Employee Stock Purchase Plan (“ESPP”) on the grant or offering date using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires inputs such as the risk-free interest rate, expected term and expected volatility. Stock-based compensation expense is recognized on a straight-line basis, net of actual forfeitures in the period. The Company estimated the CEO Performance Award (as defined in [Note 10](#)) on the grant date using Monte Carlo simulations. Key assumptions for estimating the performance-based awards fair value at the date of grant included, volatility of the Company’s common stock price, post-vesting exercise behavior, and the derived service period. Recognition of stock-based compensation expense of all the tranches commenced on the date of grant, as the probability of meeting the ten market capitalization milestones is not considered in determining the timing of expense recognition. The expense will be recognized ratably over the expected vesting period of each respective tranche.

Comprehensive Loss

Comprehensive loss is primarily comprised of net income (loss) and foreign currency translation adjustments. The Company displays comprehensive loss and its components in its consolidated statements of comprehensive loss.

Net Loss per Share

Basic net loss per share is computed by dividing net loss for the period by the weighted average number of shares of common stock outstanding. 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 the 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.

Recent Accounting Pronouncements

In October 2021, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2021-08, *Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers*, which requires an acquirer in a business combination to recognize and measure contract assets and contract liabilities in accordance with Accounting Standards Codification (“ASC”) Topic 606. ASU 2021-08 is effective for fiscal years beginning after December 15, 2022 and early adoption is permitted. The Company is evaluating the impact the standard will have on its consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. The amendments in this update simplify the accounting for income taxes by removing certain exceptions to the general principles in ASC Topic 740. The amendments also improve consistent application of and simplify U.S. GAAP for other areas of ASC Topic 740 by clarifying and amending existing guidance. The amendments in this update are effective for interim and annual periods for the Company beginning after December 15, 2020. The Company adopted the standard on January 1, 2021. The adoption of the standard had no impact on its consolidated financial statements.

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 negative working capital and 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.

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.

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. Fair Value Measurements

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, 2021				
	Balance	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	\$ 36,665	\$ 36,665	\$ —	\$ —
Marketable investments	90,217	2,560		87,657
Total assets	\$ 126,882	\$ 39,225	\$ —	\$ 87,657
Liabilities:				
Derivative liabilities - non-current	\$ 35,700	\$ —	\$ —	\$ 35,700
Contingent consideration	7,934	—	—	\$ 7,934
Contingent consideration - non-current	124,349	—	—	124,349
Total liabilities	\$ 167,983	\$ —	\$ —	\$ 167,983

Fair Value Measurements at December 31, 2020				
	Balance	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	\$ 56,464	\$ 56,464	\$ —	\$ —
Total assets	\$ 56,464	\$ 56,464	\$ —	\$ —
Liabilities:				
Derivative liabilities - non-current	\$ 35,400	\$ —	\$ —	\$ 35,400
Contingent consideration	398	—	—	398
Contingent consideration, non-current	549	—	—	549
Total liabilities	\$ 36,347	\$ —	\$ —	\$ 36,347

Marketable Investments

As further discussed in [Note 5](#), the Company holds 20,422,124 shares of Celularity Inc. ("Celularity") Class A Common Stock of which 19,922,124 shares with a value of approximately \$87.7 million as of December 31, 2021 are subject to certain transfer restrictions. The shares held by the Company are measured at fair value at each reporting period based on the closing price of Celularity's common stock on the last trading day of each reporting period, and the shares subject to transfer restriction are adjusted for a discount for lack of marketability. As of December 31, 2021, the discount for lack of marketability was determined using a Monte Carlo simulation model resulting in an implied discount for lack of marketability of 14.0%.

Contingent Consideration

In connection with the acquisition of ACEA Therapeutics, Inc. ("ACEA") as further discussed in [Note 7](#), the Company preliminarily recorded estimated contingent consideration of \$122.1 million as of the acquisition date of June 1, 2021. The Company

assessed the fair value of contingent consideration using a discounted cash flow method combined with a Monte Carlo simulation model. Significant Level 3 assumptions used in the measurement include revenue projections, estimated probabilities of successful commercialization and a discount rate of 14.4% and 15.0% as of June 1, 2021 and December 31, 2021, respectively. As further discussed in [Note 7](#), the Indebtedness Shares (as defined in [Note 7](#)) were subject to a true-up, as set forth in the ACEA Merger Agreement (as defined in [Note 7](#)), if the price at which such shares were issued was greater than the closing price of the Company's common stock on the date that was six months after June 1, 2021 ("Put Option"). The Company assessed the fair value of the Put Option using a Black-Scholes model and Level 3 assumptions. The Company recorded a total fair value of \$8.9 million and \$7.5 million associated with the Put Option as of June 1, 2021 and December 31, 2021, respectively. The Put Option is included within the current portion of the contingent consideration and acquisition consideration payable. During the year ended December 31, 2021, the Company recorded a loss of \$9.2 million related to the change in fair value of the contingent consideration.

There were no changes to the fair value of contingent consideration during the year ended December 31, 2020.

During the year ended December 31, 2019, the fair value remeasurement adjustments related to the Company's acquisitions resulted in a decrease to the contingent consideration liabilities by \$0.7 million. The Company also recorded a \$10.4 million gain related to the settlement of the acquisition consideration payable associated with the acquisition of Virttu Biologics Limited in 2017.

The following table includes a summary of the changes to contingent consideration liabilities during the years ended December 31, 2021, 2020 and 2019:

(in thousands)	Fair Value
Balance at December 31, 2018	\$ 12,037
Re-measurement of Fair Value	(736)
Settlements of contingent consideration	<u>(10,354)</u>
Balance at December 31, 2019	\$ 947
Re-measurement of Fair Value	—
Settlements of contingent consideration	—
Balance at December 31, 2020	\$ 947
Re-measurement of Fair Value	9,198
Contingent consideration related to the acquisition of ACEA Therapeutics, Inc.	<u>122,139</u>
Balance at December 31, 2021	<u>\$ 132,284</u>

Derivative liabilities

The Company recorded a loss on derivative liabilities of \$0.3 million during the year ended December 31, 2021, which related to the compound derivative liabilities associated with the Scilex Notes (as defined in [Note 8](#)). The Company recorded a gain on derivative liabilities of \$6.6 million and a loss on derivative liabilities of \$36.8 million for the years ended December 31, 2020 and 2019, respectively, which related to the compound derivative liabilities associated with the Term Loans (as defined in [Note 8](#)) and the Scilex Notes. The compound derivative liabilities consist of the fair value of various embedded features as further described in [Note 8](#). The fair value of the derivative liabilities associated with the Scilex Notes was estimated using the discounted cash flow method under the income approach combined with a Monte Carlo simulation model. This involves significant Level 3 inputs and assumptions.

The key assumptions for the Scilex Notes for the year ended December 31, 2021 included a 6.2% risk-adjusted net sales forecast and an effective debt yield of 15.0%. The key assumptions for the Scilex Notes for the year ended December 31, 2020 included a 7% risk-adjusted net sales forecast, an effective debt yield of 15% and an estimated probability of 100% of not obtaining marketing approval before March 31, 2021. The key assumptions for the Scilex Notes for the year ended December 31, 2019 included an 8% risk adjusted net sales forecast, an effective debt yield of 19.7% and estimated probabilities of 55% and 100% of not obtaining marketing approval before July 1, 2023 and March 31, 2021, respectively, and an estimated high probability of a Scilex Holding IPO that satisfies certain valuation thresholds.

As further discussed in [Note 8](#), the Term Loans, which include the Early Conditional Loan, were paid in full as of December 31, 2020 and the associated derivative liabilities were relieved. Significant Level 3 inputs and assumptions for derivative liabilities associated with the Term Loans primarily included the estimated probabilities of satisfying certain commercial and financial milestones estimated using a with and without discounted cash flow approach.

During the year ended December 31, 2019, the Company recorded a derivative liability and corresponding debt discount of approximately \$7.0 million, which was attributed to a contingent acceleration feature related to the Early Conditional Loan. The debt discount was amortized over the remaining term of the Term Loans and was recorded as interest expense in the consolidated statement

of operations. Additionally, the Company recorded a mark-to-market loss on derivative liabilities related to the contingent acceleration feature of the Early Conditional Loan of \$1.8 million for the year ended December 31, 2019. The Company also recorded a loss on derivative liabilities of \$4.3 million during 2019 associated with the 2019 Warrants (as defined in [Note 8](#)) for the year ended December 31, 2019.

The following table includes a summary of the derivative liabilities measured at fair value using significant unobservable inputs (Level 3) during the years ended December 31, 2021, 2020 and 2019:

(in thousands)	Fair Value	
Balance at December 31, 2018	\$	—
Additions		6,996
Re-measurement of Fair Value		36,804
Balance at December 31, 2019	\$	43,800
Additions		8,800
Re-measurement of Fair Value		(17,200)
Balance at December 31, 2020	\$	35,400
Re-measurement of Fair Value		300
Balance at December 31, 2021	\$	35,700

4. Property and Equipment

Property and equipment consisted of the following as of December 31, 2021 and 2020 (in thousands):

	December 31,	
	2021	2020
Furniture and fixtures	\$ 1,709	\$ 1,349
Office equipment	3,525	280
Capitalized software	98	0
Machinery and lab equipment	56,076	41,919
Leasehold improvements	15,529	14,295
Construction in progress	7,878	4,031
	84,815	61,874
Less accumulated depreciation	(43,490)	(30,013)
	\$ 41,325	\$ 31,861

Depreciation expense for the years ended December 31, 2021, 2020 and 2019 was \$8.3 million, \$7.0 million and \$7.0 million, respectively.

5. Investments

The Company's investments include investments accounted for as equity method investments, equity investments without readily determinable fair value and equity investments with readily determinable fair value. As of December 31, 2021, the Company's equity method investments include an ownership interest in Immunotherapy NANTibody, LLC ("NANTibody"), NantCancerStemCell, LLC ("NantStem"), Deverra Therapeutics, Inc. ("Deverra") and ImmuneOncia Therapeutics, LLC, among others. The Company's equity investments without readily determinable fair value include an ownership interest in NantBioScience, Inc. ("NantBioScience"), Aardvark Therapeutics, Inc. ("Aardvark") and Elsie Biotechnologies, Inc. ("Elsie"), among others. The Company's equity investments with readily determinable fair value include an ownership interest in Celularity.

The Company recorded no impairment loss for the year ended December 31, 2021. During the year ended December 31, 2020, the Company recorded an impairment loss of approximately \$3.8 million related to an equity method investment for which the Company determined the investment's value is no longer supportable. The loss is included within loss on equity method investments in the Company's consolidated statement of operations.

Celularity

On July 16, 2021, Celularity ("Pre-Merger Celularity"), a company of which the Company held an equity interest, completed its previously announced merger with GX Acquisition Corp. (the "Celularity Merger"). Following the completion of the Celularity Merger, the combined, publicly traded company formerly known as GX Acquisition Corp. was renamed Celularity Inc. and its Class

A common stock commenced trading on the Nasdaq Capital Market on July 19, 2021 under the ticker “CELU”. In connection with the Celularity Merger, all outstanding shares of Series A Preferred Stock of Pre-Merger Celularity were converted into shares of Pre-Merger Celularity common stock and then each share of Pre-Merger Celularity common stock was converted into the right to receive shares of Class A common stock of the post-merger company. The Company received 19,922,124 shares of Class A common stock of the post-merger company in the Celularity Merger. The Company also purchased an aggregate of 500,000 shares of Class A common stock of Celularity for an aggregate purchase price of \$5,000,000 in a private placement transaction that closed on July 16, 2021 concurrently with the closing of the Celularity Merger (the “Private Placement Shares”). Dr. Henry Ji, the Company’s Chief Executive Officer and Chairperson, and Jaisim Shah, a member of the Company’s Board of Directors, each served on the board of directors of Pre-Merger Celularity from June 2017 until the closing of the Celularity Merger in July 2021. Dr. Robin L. Smith, who served as a member of the Company’s Board of Directors from December 2019 through November 15, 2021, served on the board of directors of Pre-Merger Celularity from August 2019 until the closing of the Celularity Merger in July 2021 and has served on the board of directors of Celularity since the closing of the Celularity Merger in July 2021.

The Company’s investment in Celularity has historically been included as an equity investment in its consolidated balance sheets and accounted for as an equity security without a readily determinable fair value of \$125.0 million before the trading commencement date. As of the trading commencement date, the Company accounts for its investment in Celularity as an equity security with a readily determinable fair value. As of December 31, 2021, the Company owned 20,422,124 shares of Class A common stock of Celularity. 19,922,124 shares of the Class A Common Stock of Celularity held by the Company are subject to transfer restrictions until the earliest to occur of (i) 365 days after July 16, 2021; (ii) the first day after the date on which the closing price of the Class A Common Stock equals or exceeds \$12.00 per share (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like) for any 20 trading days within any 30-trading day period commencing at least 150 days after July 16, 2021; or (iii) the date on which Celularity completes a liquidation, merger, capital stock exchange, reorganization or other similar transaction that results in all of Celularity’s public shareholders having the right to exchange their Class A Common Stock for cash, securities or other property, subject to certain exceptions (the “Restricted Shares”).

In connection with the change in fair value of the Restricted Shares, the Company recorded an unrealized loss on equity investment of \$37.3 million during the year ended December 31, 2021. The Company has reclassified its investment in Celularity associated with the Restricted Shares to marketable investments under current assets within its consolidated balance sheets. The investment in Celularity associated with the Restricted Shares is classified as a current asset because the investment can be liquidated to finance the Company’s current operations once the transfer restrictions are lifted, which will occur before December 31, 2022. In connection with the change in fair value of the Private Placement Shares, the Company recorded an unrealized loss of \$2.4 million on marketable investments during the year ended December 31, 2021. The Company classifies its investment in Celularity associated with the Private Placement Shares as marketable investments within its consolidated balance sheets. The investment in Celularity associated with the Private Placement Shares is classified as a current asset because the investment can be liquidated to finance the Company’s current operations.

ImmunityBio

On March 9, 2021, NantKwest, Inc. and ImmunityBio (formerly known as NantCell, Inc.) completed their previously announced 100% stock-for-stock merger (the “ImmunityBio Merger”). The combined company operates under the name ImmunityBio, Inc. and its shares of common stock commenced trading on the Nasdaq Global Select Market on March 10, 2021 under the new ticker, “IBRX”. The former stockholders of ImmunityBio were entitled to receive 0.8190 shares of common stock of the combined company for each outstanding share of ImmunityBio common stock held immediately prior to the ImmunityBio Merger. Prior to the closing of the ImmunityBio Merger, the Company owned 10,000,000 shares of common stock of ImmunityBio, and the Company therefore received 8,190,000 shares of common stock of the post-merger company.

Prior to the ImmunityBio Merger, the Company’s investment in ImmunityBio was historically included as an equity investment in its consolidated balance sheets and accounted for as an equity security without a readily determinable fair value. As of the completion of the ImmunityBio Merger, the Company accounted for its investment in ImmunityBio as an equity investment with a readily determinable fair value and reclassified its investment in ImmunityBio to marketable investments within its consolidated balance sheets. The investment in ImmunityBio was classified as a current asset because the investment was liquidated to finance the Company’s current operations. In connection with the disposal of its investment in ImmunityBio, the Company recorded a realized gain on marketable investments of \$24.1 million during the year ended December 31, 2021. The Company sold 8,190,000 shares of ImmunityBio common stock during the year ended December 31, 2021 for net proceeds to the Company of \$124.0 million. The Company had no remaining shares of ImmunityBio common stock as of December 31, 2021.

Aardvark

During the year ended December 31, 2021, the Company paid \$10.0 million in cash for an aggregate of 7,777,864 shares of Series B Preferred Stock of Aardvark. The Company accounts for its investment in Aardvark as an equity investment without a readily determinable fair value and carries its investment in Aardvark at cost, less impairment, plus or minus changes resulting from observable price changes in orderly transactions for identical or similar investments. Tien Lee, MD, a member of the board of directors of Scilex Holding Company (“Scilex Holding”), a majority owned subsidiary of the Company, is the founder and chief executive officer of Aardvark. Kim D. Janda, Ph.D., a member of the Board of Directors of the Company, is a member of the advisory board of Aardvark.

Deverra

During the year ended December 31, 2021, the Company paid approximately \$10.2 million in consideration for an aggregate of 5,622,703 shares of common stock of Deverra, a development-stage, biotechnology company focused on developing cellular immunotherapy programs. The Company’s payment consisted of (i) the cancellation of certain promissory notes issued by Deverra to the Company with an aggregate principal amount of \$6.0 million and unpaid accrued interest of approximately \$0.1 million and (ii) a cash payment of \$4.1 million. In addition, on December 7, 2021, the Company loaned Deverra an aggregate of \$1.0 million in consideration of a promissory note, which matures six months from the date of issuance. The Company initially agreed to make additional investments in Deverra, but the Company and Deverra subsequently terminated the Company’s obligation to make such additional investments. The Company has determined that its investment in Deverra’s common stock represents an equity method investment and that substantially all of the fair value of the underlying assets of Deverra relates to a single IPR&D asset. The Company immediately expensed all costs associated with the investment and the total consideration paid was expensed as acquired in-process research and development during the year ended December 31, 2021. The Company has a variable interest in Deverra and Deverra is deemed to be a variable interest entity (“VIE”). The Company is not, however, the primary beneficiary of the VIE as it does not have the power to direct the activities of Deverra. In connection with the Company’s purchase of Deverra common stock, Dr. Henry Ji, the Company’s Chief Executive Officer and Chairperson, and Jaisim Shah, a member of the Company’s Board of Directors, were appointed to the board of directors of Deverra.

Elsie

During the year ended December 31, 2021, the Company paid \$10.0 million in cash for 10,000,000 shares of Series A Preferred Stock of Elsie. The Company accounts for its investment in Elsie as an equity investment without a readily determinable fair value and carries its investment in Elsie at cost, less impairment, plus or minus changes resulting from observable price changes in orderly transactions for identical or similar investments. In connection with the Company’s purchase of Elsie Series A Preferred Stock, Dr. Henry Ji was appointed to the board of directors of Elsie.

NANTibody

The Company’s investment in NANTibody is reported in equity method investments on its consolidated balance sheets and its share of NANTibody’s income or loss is recorded in loss on equity method investments on its consolidated statement of operations. The Company continues to hold 40% of the outstanding equity of NANTibody and NantCell holds the remaining 60%. The Company’s investment in NANTibody had a carrying value of zero as of December 31, 2021 due to the Company’s share of cumulative losses. The carrying value of the Company’s investment in NANTibody was approximately \$0.5 million as of December 31, 2020.

NANTibody recorded net loss of \$0.7 million, \$0.1 million and \$2.4 million for the twelve months ended September 30, 2021, 2020 and 2019, respectively. As of September 30, 2021, NANTibody had \$2.4 million in current assets, \$9.6 million in current liabilities, \$0.1 million in noncurrent assets and no noncurrent liabilities. As of September 30, 2020, NANTibody had \$4.9 million in current assets, \$3.5 million in current liabilities, \$0.2 in noncurrent assets and no noncurrent liabilities.

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 one quarter lag.

NantCancerStemCell (“NantStem”)

The Company’s investment in NantStem is reported in equity method investments on its consolidated balance sheets and its share of NantStem’s income or loss is recorded in loss on equity method investments on its consolidated statement of operations. 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 carrying value of the Company’s investment in NantStem was approximately \$18.5 million and \$18.1 million as of December 31, 2021 and 2020, respectively.

NantStem recorded a net gain of \$0.1 million for the twelve months ended September 30, 2021 and 2020, respectively, and a net loss of \$0.9 million for the twelve months ended September 30, 2019. As of September 30, 2021, NantStem had \$83.1 million in current assets, no current liabilities, \$0.5 million in noncurrent assets and no noncurrent liabilities. As of September 30, 2020, NantStem had \$80.0 million in current assets, no current liabilities, \$1.7 million in noncurrent assets and no noncurrent liabilities.

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 one quarter lag.

6. Goodwill and Intangible Assets

Goodwill totaled \$79.5 million as of December 31, 2021. Goodwill for the Sorrento Therapeutics segment and Scilex segment was \$72.8 million and \$6.7 million, respectively, as of December 31, 2021. Goodwill increased by \$35.9 million during the year ended December 31, 2021 as compared to \$43.6 million as of December 31, 2020 as a result of the Company's acquisition of ACEA. The Company performed an annual assessment for goodwill impairment in the fourth quarter of 2021, noting no impairment.

Amortization for the intangible assets that have finite useful lives is generally recorded on a straight-line basis over their useful lives. Intangible assets with indefinite useful lives totaling \$218.4 million are included in acquired in-process research and development in the table below. A summary of the Company's identifiable intangible assets as of December 31, 2021 and 2020 is as follows (in thousands):

	Weighted Average Amortization Period (Years)	December 31, 2021		
		Gross Carrying Amount	Accumulated Amortization	Intangibles, net
Customer relationships	2	\$ 1,585	\$ 1,453	\$ 132
Acquired technology	19	3,410	1,412	1,998
Acquired in-process research and development	—	218,430	—	218,430
Technology placed in service	15	21,940	4,754	17,186
Patent rights	15	32,720	11,283	21,437
Assembled workforce	5	605	343	262
Internally developed software	2	520	260	260
Total intangible assets		\$ 279,210	\$ 19,505	\$ 259,705

	Weighted Average Amortization Period (Years)	December 31, 2020		
		Gross Carrying Amount	Accumulated Amortization	Intangibles, net
Customer relationships	6	\$ 1,585	\$ 1,426	\$ 159
Acquired technology	19	3,410	1,236	2,174
Acquired in-process research and development	—	28,260	—	28,260
Technology placed in service	15	21,940	3,291	18,649
Patent rights	15	32,720	9,103	23,617
Assembled workforce	5	605	222	383
Internally developed software	1	520	87	433
Total intangible assets		\$ 89,040	\$ 15,365	\$ 73,675

As of December 31, 2021, the remaining weighted average life for identifiable intangible assets subject to amortization is 14.7 years. Aggregate amortization expense was \$4.1 million for each of the years ended December 31, 2021 and 2020.

Estimated future amortization expense related to intangible assets, excluding indefinite-lived intangible assets, at December 31, 2021 is as follows (in thousands):

Years Ending December 31,	Amount
2022	\$ 3,968
2023	4,134
2024	3,957
2025	3,845
2026	3,845
Thereafter	21,527
Total	<u>\$ 41,276</u>

7. Significant Agreements and Contracts

2021 Acquisitions

Acquisition of ACEA Therapeutics, Inc.

On June 1, 2021 (the “Closing Date”), the Company completed the acquisition of ACEA pursuant to the terms of the Agreement and Plan of Merger (the “ACEA Merger Agreement”), dated as of April 2, 2021, by and among the Company, AT Merger Sub, Inc., an exempted company incorporated with limited liability in the Cayman Islands and wholly owned subsidiary of the Company, ACEA and Fortis Advisors LLC, as representative of the shareholders of ACEA, whereby ACEA became a wholly owned subsidiary of the Company. With operations in both China and the United States, ACEA is developing multiple clinical and preclinical-stage new chemical entity compounds, including the late clinical drug candidate, Abivertinib.

The total value of the consideration paid by the Company for the acquisition of ACEA was equal to \$38.0 million plus approximately \$1.9 million (which amount represented the Company’s agreed upon share of certain interest, fees and other expenses) resulting in an aggregate payment of approximately \$39.9 million (which amount was subject to further adjustment for indebtedness, transaction expenses and cash, in each case pursuant to the terms of the ACEA Merger Agreement) (the “Closing Consideration”). Pursuant to the terms of the ACEA Merger Agreement, a portion of the Closing Consideration equal to (i) \$38,059,326 was used to repay certain existing indebtedness of ACEA, which amount was paid to the holders thereof in the form of shares of common stock of the Company and an aggregate of 5,519,469 shares (“Indebtedness Shares”) of the Company’s common stock were issued in respect thereof based on a price per share equal to \$6.8955 (representing the volume weighted average closing price per share of Common Stock, as reported on The Nasdaq Stock Market LLC, for the 10 consecutive trading days ending on the date that was three trading days prior to the Closing Date) and (ii) \$100,000 was set aside for expenses incurred by the shareholders’ representative thereunder. The Indebtedness Shares were subject to a true-up, as set forth in the ACEA Merger Agreement, if the price at which such shares were issued is greater than the closing price of the Company’s common stock on the date that is six months after June 1, 2021.

In addition to the Closing Consideration, the Company will pay the ACEA equityholders (i) up to \$450.0 million in additional payments, subject to the receipt of certain regulatory approvals and achievement of certain net sales targets with respect to the assets acquired from ACEA and (ii) five to ten percent of the annual net sales on specified royalty-bearing products (the “Earn-Out Consideration”). The fair value of the Earn-Out Consideration on the acquisition date was preliminarily estimated to be \$122.1 million. The fair value of the Earn-Out Consideration as of December 31, 2021 was \$131.3 million. The amount referenced in clause (i) of the preceding sentence includes the amounts that would have otherwise been due to ACEA under that certain License Agreement, dated July 13, 2020, between the Company and ACEA, which agreement was terminated in its entirety upon completion of the acquisition of ACEA.

The preliminary purchase price allocation was calculated based on an upfront consideration of \$44.1 million, which was based on the Company’s closing share price on June 1, 2021. The ACEA Merger Agreement resulted in net identifiable assets of approximately \$166.2 million, which includes separate and distinct intangible assets comprised of acquired in-process research and development of \$190.8 million, goodwill of \$36.0 million, fair value of debt assumed of approximately \$32.1 million, deferred tax liabilities of \$31.4 million and other net assets of approximately \$2.9 million. The purchase price allocation is preliminary as the Company is still completing the valuation of the intangible assets, contingent consideration, taxes, the fair value of debt assumed and other net assets, changes to which may also increase or decrease the amount of goodwill recognized. Goodwill largely reflects the broad-spectrum and synergistic infrastructures and expertise in pharmaceutical and biological drug discovery, development and manufacturing, and expanded geographic coverage in China and North America and is not deductible for tax purposes. Acquisition costs related to the acquisition of ACEA were not material. Results of operations prior to and since the date of acquisition were not material. Customary tax related matters such as the filing of pre-acquisition tax returns are subject to finalization as of December 31, 2021, and such matters may result in adjustments to the purchase price allocation.

The Company is still in the process of finalizing the working capital adjustments and the purchase price allocation, given the size and scope of the assets and liabilities subject to valuation. While the Company does not expect material changes in the valuation

outcome, certain assumptions and findings that were in place at the date of acquisition could result in changes in the purchase price allocation.

Asset Purchase Agreement with Aardvark Therapeutics, Inc.

In April 2021, the Company entered into an asset purchase agreement (the “Aardvark Asset Purchase Agreement”) with Aardvark to acquire Aardvark’s Delayed Burst Release Low Dose Naltrexone (DBR-LDN), or ARD-301, asset and intellectual property rights, for the treatment of chronic pain, fibromyalgia and chronic post-COVID syndrome. As consideration for the purchase of the assets, the Company paid Aardvark an upfront license fee of \$5.0 million comprised of 616,655 shares of the Company’s common stock, and which was expensed as acquired in-process research and development during the year ended December 31, 2021. The Company also agreed to pay Aardvark (i) milestone payments upon the receipt of certain regulatory approvals, and (ii) milestone payments upon the Company’s achievement of certain commercial sales milestones. The Company will also pay certain royalties in the mid-single digit to low-double digit percentages of annual net sales by the Company. Tien Lee, MD, a member of the board of directors of Scilex Holding, a majority owned subsidiary of the Company, is the founder and chief executive officer of Aardvark. Kim D. Janda, Ph.D., a member of the board of directors of the Company, is a member of the advisory board of Aardvark. As discussed in [Note 5](#), the Company holds an investment interest in Aardvark.

2020 Acquisition

Acquisition of SmartPharm Therapeutics, Inc.

On September 1, 2020, the Company completed the acquisition of SmartPharm, a gene-encoded protein therapeutics company developing non-viral DNA and RNA gene delivery platforms for COVID-19, Influenza and rare diseases with broad potential for application in enhancing antibody-centric therapeutics. The total base consideration paid to the holders of capital stock of SmartPharm in the acquisition was \$19.5 million, which was comprised of approximately 1.8 million shares of the Company’s common stock.

The purchase price allocation resulted in net identifiable assets of \$19.5 million, which includes separate and distinct indefinite lived intangible assets comprised of acquired in-process research and development of \$13.9 million, goodwill of \$5.3 million and other net assets of \$0.3 million. Goodwill largely reflects the synergies expected to be achieved with SmartPharm’s gene delivery platforms and the assembled workforce. Goodwill is not deductible for tax purposes. Results of operations since the date of acquisition were not material.

2019 Acquisition

Acquisition of Semnur Pharmaceuticals, Inc. (“Semnur”)

On March 18, 2019, the Company entered into an Agreement and Plan of Merger (the “Merger Agreement”) with Semnur Pharmaceuticals, Inc. (“Semnur”) and Scilex Holding, whereby Semnur became a wholly-owned subsidiary of Scilex Holding (the “Merger”), and thereby Scilex Holding acquired Semnur’s SEMDEXA™ (SP-102) technology for consideration valued at approximately \$70.0 million, excluding contingent consideration, transaction costs of \$3.1 million and liabilities assumed of \$4.2 million, which was allocated based on the relative fair value of the assets acquired. The \$70.0 million of consideration consisted of approximately \$15.0 million in cash and shares of Scilex Holding valued at approximately \$55.0 million (the “Stock Consideration”). Following the issuance of the Stock Consideration, the Company’s ownership in Scilex Holding was diluted to approximately 58% of Scilex Holding’s issued and outstanding capital stock.

Pursuant to the Merger Agreement, Scilex Holding also agreed to pay the holders of Semnur’s capital stock and options (the “Semnur Equityholders”) up to \$280.0 million in aggregate contingent cash consideration based on the achievement of certain milestones, which is comprised of a \$40.0 million payment that will be due upon obtaining the first approval of a New Drug Application of a Semnur product by the U.S. Food and Drug Administration (the “FDA”) and additional payments that will be due upon the achievement of certain amounts of net sales of Semnur products as follows: (a) a \$20.0 million payment upon the achievement of \$100.0 million in cumulative net sales of a Semnur product, (b) a \$20.0 million payment upon the achievement of \$250.0 million in cumulative net sales of a Semnur product, (c) a \$50.0 million payment upon the achievement of \$500.0 million in cumulative net sales of a Semnur product, and (d) a \$150.0 million payment upon the achievement of \$750.0 million in cumulative net sales of a Semnur product.

In March 2019, the Company also entered into an Exchange and Registration Rights Agreement (the “Exchange Agreement”) with the Semnur Equityholders. Pursuant to the Exchange Agreement, if within 18 months of the closing of the Merger, 100% of the outstanding equity of Scilex Holding had not been acquired by a third party or Scilex Holding had not entered into a definitive agreement with respect to, or otherwise consummated, a firmly underwritten offering of Scilex Holding’s capital stock that meets certain requirements and includes the Stock Consideration, then the Semnur Equityholders could collectively elect to exchange, during

the 60-day period commencing the date that is the 18 month anniversary of the closing of the Merger, the Stock Consideration for shares of the Company's common stock with a value of \$55.0 million (the "Semnur Share Exchange") based on a price per share of the Company's common stock equal to the greater of (a) the 30-day trailing volume weighted average price of one share of the Company's common stock as reported on the Nasdaq Capital Market as of the consummation of the Semnur Share Exchange and (b) \$5.55 (subject to adjustment for any stock dividend, stock split, stock combination, reclassification or similar transaction) (the "Exchange Price"). On September 28, 2020, the Company entered into an amendment to the Exchange Agreement to, among other things, provide that if the Company received notice from the Semnur Equityholders that they will proceed with the Semnur Share Exchange (the "Exchange Notice"), the Company could, in its sole discretion, elect, within seven days of receipt of the Exchange Notice, to exchange all the Stock Consideration and the rights to receive cash from Scilex Holding held by the Semnur Equityholders for an amount in cash equal to \$55.0 million, in lieu of issuing \$55.0 million of shares of the Company's common stock at the Exchange Price. On September 28, 2020, the Semnur Equityholders delivered the Exchange Notice to the Company. On October 5, 2020, the Company notified the Semnur Equityholders of its election to pay cash, and paid \$55.0 million in cash to the Semnur Equityholders and effectuated the Semnur Share Exchange on October 9, 2020. Following the completion of the Semnur Share Exchange and as of December 31, 2020, the Company held approximately 82.3% of the outstanding common stock of Scilex Holding. On January 29, 2021, the Company acquired additional shares of Scilex Holding in exchange for 2,567,456 shares of the Company's stock, resulting in the Company holding approximately 99.9% of the outstanding common stock of Scilex Holding. As of December 31, 2021, the Company held approximately 99.9% of the outstanding common stock of Scilex Holding.

The transaction was accounted for as an asset acquisition since substantially all the value of the gross assets was concentrated in a single asset. No contingent consideration was recorded as of December 31, 2019 and 2020 since the related regulatory approval milestones are not deemed probable until they actually occur. Approximately \$75.3 million was expensed as acquired in-process research and development during the year ended December 31, 2019.

License Agreements

License Agreement with Icahn School of Medicine at Mount Sinai

In March 2021, the Company entered into an exclusive license agreement (the "Mount Sinai License Agreement") with Icahn School of Medicine at Mount Sinai ("Mount Sinai") to acquire a worldwide, exclusive, sublicensable license to certain of Mount Sinai's patents and monoclonal antibodies as well as certain related technical information ("Licensed Products") to develop, manufacture, commercialize, and exploit related products and services for all fields, uses, and applications, including for the diagnosis, prevention, treatment and cure of coronavirus.

As consideration for the Mount Sinai License Agreement, the Company paid Mount Sinai an upfront license fee of \$7.5 million, comprised of 851,305 shares of the Company's common stock, which was expensed as acquired in-process research and development during the year ended December 31, 2021. The Company also agreed to pay Mount Sinai (i) certain milestone payments upon the achievement of certain clinical trial and regulatory milestones, and (ii) certain royalties in the low-single digit to mid-single digit percentages of annual net sales of Licensed Products by the Company and a share of any sublicense revenue received by the Company from sublicensees.

License Agreement with ACEA Therapeutics, Inc.

In July 2020, the Company entered into a License Agreement (the "ACEA License Agreement") with ACEA Therapeutics, Inc. ("ACEA"). Pursuant to the ACEA License Agreement, ACEA granted the Company an exclusive license and right under certain patents and certain know-how and other intellectual property ("Licensed Know-How") to fully utilize, exploit and commercialize (i) the Licensed Know-How, (ii) Abivertinib (AC0010), a selective, orally available irreversible small molecule tyrosine kinase inhibitor to Bruton's tyrosine kinase and mutant epidermal growth factor receptor, including any improvements thereto, and (iii) (a) any composition, product, or component part thereof, and (b) any and all services offered in connection or associated therewith, in all fields of use, including the diagnosis, treatment and/or cure of any human disease or disorder worldwide, other than the People's Republic of China.

As consideration for the license under the ACEA License Agreement, the Company paid ACEA an up-front license fee of \$15.0 million in cash, which was expensed as acquired in-process research and development during the year ended December 31, 2020. The Company also agreed to pay ACEA certain milestone payments under the ACEA License Agreement; however, upon completion of the acquisition of ACEA, the ACEA License Agreement was terminated in its entirety and no further payments will be due under the ACEA License Agreement.

License Agreement with The Trustees of Columbia University in the City of New York

In July 2020, the Company entered into an Exclusive License Agreement (the “Columbia License Agreement”) with The Trustees of Columbia University in the City of New York (“Columbia”). Pursuant to the Columbia License Agreement, Columbia granted the Company (i) an exclusive license under certain patents, other intellectual property and materials to discover, develop, commercialize and exploit certain products and services (“Products”) in all diagnostic applications of high-performance loop-mediated isothermal amplification (“HP-LAMP”) for coronaviruses and influenza viruses (the “Field”) worldwide, subject to certain limitations. Pursuant to the Columbia License Agreement, Columbia also granted to the Company an option, exercisable for twelve months from the effective date of the Columbia License Agreement and subject to the satisfaction of certain conditions, to acquire an exclusive worldwide license to such patents, other intellectual property and materials for additional diagnostic application(s) of HP-LAMP (other than for coronaviruses and influenza viruses), subject to certain limitations.

As consideration for the license under the Columbia License Agreement, the Company paid Columbia an up-front license fee of \$5.0 million in cash, which was expensed as acquired in-process research and development during the year ended December 31, 2020. The Company also agreed to pay Columbia (i) an earned royalty on the net sales of Products in the Field worldwide, and (ii) minimum annual royalty payments of \$1.0 million no later than ten days following the first bona fide commercial sale of a Product to a third-party customer and on an annual basis thereafter. In addition, the Company agreed to pay Columbia a percentage of certain non-royalty sublicense revenue and other payments received by the Company from its sublicensees as consideration for the grant of any sublicense, option or similar rights. Pursuant to the Columbia License Agreement, the Company also agreed to pay certain one-time, development milestone payments to Columbia upon the receipt of certain regulatory approvals or the first commercial sale of certain Products for diagnostic applications within the Field.

License Agreement with Mayo Foundation

In September 2020, the Company entered into a patent and know-how license agreement (the “Mayo License Agreement”) with Mayo Foundation for Medical Education and Research (“Mayo”). Pursuant to the Mayo License Agreement, Mayo granted the Company a sublicensable license under certain of Mayo’s patents, know-how, and materials relating to targeted nanoparticle therapies (“Patent Rights”, “Know-How”, and “Materials”, respectively) to reproduce, use, commercialize, and exploit related products, processes and services (“Licensed Products”) for the prevention, diagnosis and/or treatment of human diseases and conditions worldwide.

As consideration for the license under the Mayo License Agreement, the Company paid Mayo an upfront license fee of \$9.3 million comprised of approximately \$2.3 million in cash and 996,803 shares of the Company’s common stock, which was expensed as acquired in-process research and development during the year ended December 31, 2020. The Company also agreed to (i) reimburse Mayo up to \$3.4 million for preclinical and clinical research expenses associated with the Know-How, Patent Rights and Materials arising prior to the entry into the Mayo License Agreement, and (ii) reimburse Mayo approximately \$2.0 million for expenses related to the development and manufacturing of the Materials arising prior to the entry into the Mayo License Agreement. Such reimbursements were paid and expensed as acquired in-process research and development during the year ended December 31, 2020.

The Company also agreed to pay Mayo (i) certain milestone payments upon the initiation of certain clinical trials, (ii) certain milestone payments upon the receipt of certain regulatory approvals, and (iii) certain milestone payments upon the achievement of certain commercial sales milestones. The Company will also pay certain royalties in the low-single digit to mid-single digit percentages of annual net sales of Licensed Products by the Company and a share of any sublicense revenue received by the Company from sublicensees.

License Agreement with Personalized Stem Cells, Inc.

In October 2020, the Company entered into a license agreement (the “License Agreement”) with Personalized Stem Cells, Inc. (“PSC”). Pursuant to the License Agreement, PSC granted the Company an exclusive license and right under certain patents, certain know-how and other intellectual property to fully utilize, exploit and commercialize certain products and services using allogeneic adipose-derived stem cells for or in respect of human health, including the diagnosis and treatment and/or cure of any human disease or disorder (excluding commercial sales for the diagnosis, treatment and/or cure of SARS-CoV-2 or other respiratory diseases in the People’s Republic of China) worldwide (excluding the People’s Republic of China for products directed at COVID-19 or other respiratory diseases). PSC also agreed to transfer certain cell lines composed of stromal vascular cells, master cell banks and finished final drug lots (the “Product Materials”) to the Company. The Company agreed to grant PSC rights to use data derived by the Company from a certain Phase I COVID-19 study for PSC’s own programs that are not competitive with the businesses or activities of the Company, and for PSC to sublicense such data to third parties for research, development and regulatory purposes.

As consideration for the license under the License Agreement, the Company paid PSC an upfront license fee of \$3.5 million in cash, which was expensed as acquired in-process research and development during the year ended December 31, 2020. The Company also agreed to pay PSC (i) a milestone payment upon the issuance of a regulatory approval, and (ii) certain milestone payments upon PSC’s manufacture and delivery of the Product Materials to the Company. The Company will also pay royalties in the low-single digit

percentages of annual net sales of licensed products and services by the Company and a share of any sublicense revenue received by the Company from sublicensees.

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 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 an equity sale of NantCell common stock to a third party. The Company terminated the agreement, effective January 29, 2020, due to NantCell's material breach of the agreement. The termination and remedies related to such termination are currently pending in an arbitration before the American Arbitration Association (See the information under the heading "Litigation" in Note 11 for additional information). The Company has therefore deferred recognition of the upfront payment and the value of the equity interest received until the arbitration is concluded or resolved. On March 9, 2021, NantKwest, Inc. and ImmunityBio (formerly known as NantCell, Inc.) completed their previously announced 100% stock-for-stock merger (See [Note 5](#)).

8. Debt

2018 Purchase Agreements and Indenture for Scilex

On September 7, 2018, Scilex Pharma 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 Pharma, 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 million (the "Scilex Notes Offering"). In connection with the Scilex Notes Offering, Scilex Pharma also entered into an Indenture (the "Indenture") governing the Scilex Notes with U.S. Bank National Association, a national banking association, as trustee (the "Trustee") and collateral agent (the "Collateral Agent"), and the Company. Pursuant to the Indenture, the Company agreed to irrevocably and unconditionally guarantee, on a senior unsecured basis, the punctual performance and payment when due of all obligations of Scilex Pharma under the Indenture (the "Guarantee").

The net proceeds of the Offering were approximately \$89.3 million, after deducting the Offering expenses payable by Scilex Pharma and funding a segregated reserve account (\$20.0 million) (the "Reserve Account") and a segregated collateral account (\$25.0 million) (the "Collateral Account") pursuant to the terms of the Indenture. Funds in the Reserve Account were to be released to Scilex Pharma upon receipt by the Trustee of an officer's certificate under the Indenture from Scilex Pharma confirming receipt of a marketing approval letter from the FDA with respect to SP-103 (the "Marketing Approval Letter") on or prior to July 1, 2023. Funds in the Collateral Account were to 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 were initially 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 for the prior fiscal quarter, beginning on February 15, 2019. However, because Scilex Pharma did not receive the Marketing Approval Letter by March 31, 2021, the percentage of net sales payable was increased to be in the range of 15% to 25%. If actual cumulative net sales of ZTlido from October 1, 2022 through September 30, 2023 are less than 60% of a predetermined target sales threshold for such period, then Scilex Pharma 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 was to be increased by \$28,000,000 on February 15, 2022 if actual cumulative net sales of ZTlido 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 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 Pharma'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 Pharma (as defined in the Indenture),

each holder of a Scilex Note shall have the right to require Scilex Pharma 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 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 Pharma, or the holders of at least 25% in principal amount of the outstanding Scilex Notes by notice to Scilex Pharma 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 Pharma, the Scilex Notes will automatically become due and payable.

Pursuant to the Indenture, the Company and Scilex Pharma must also comply with certain covenants with respect to the commercialization of ZTlido, 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 Pharma; engaging in certain transactions with affiliates; and the making of investments other than those permitted by the Indenture.

Pursuant to a Collateral Agreement by and among Scilex Pharma, the Trustee and the Collateral Agent (the "Collateral Agreement"), the Scilex Notes will be secured by ZTlido and all of the existing and future property and assets of Scilex Pharma necessary for, or otherwise relevant to, now or in the future, the manufacture and sale of ZTlido, on a worldwide basis (exclusive of Japan), including, but not limited to, the intellectual property related to ZTlido, the marketing or similar regulatory approvals related to ZTlido, any licenses, agreements and other contracts related to ZTlido, and the current assets related to ZTlido 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 Pharma or any of its affiliates or licensees (or sub-licensees) (including SP-103).

Pursuant to the terms of the Indenture, the Company issued an irrevocable standby letter of credit to Scilex Pharma (the "Letter of Credit"), which provides that, in the event that (1) Scilex Pharma does not hold at least \$35,000,000 in unrestricted cash (which is inclusive of the amount in the Collateral Account) as of the end of any calendar month during the term of the Scilex Notes, (2) actual cumulative net sales of ZTlido 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 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 Pharma as beneficiary of the Letter of Credit, will draw, and the Company will pay to Scilex Pharma, \$35,000,000 in a single lump-sum amount as a subordinated loan. In the event that Scilex Pharma draws on, and the Company pays to Scilex Pharma, \$35,000,000 in a single lump-sum amount as a subordinated loan, each holder of the Scilex Notes had the right to require the Company to purchase all or any part of such holder's outstanding Scilex Notes in the principal amount of, and at a purchase price in cash equal to, \$25,000,000 multiplied by such holder's pro rata portion of the then-outstanding Scilex Notes. 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 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 Pharma 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.

On December 14, 2020, Scilex Pharma, the Company, the Trustee and the Agent, and the beneficial owners of the Scilex Notes and the Scilex Note Purchasers entered into a Consent Under and Amendment No. 3 to Indenture and Letter of Credit (the "Amendment"), which amended: (i) the Indenture, and (ii) the Letter of Credit.

Pursuant to the Amendment, the Scilex Note Purchasers agreed to release all of the aggregate \$45.0 million in restricted funds held in the Reserve Account and the Collateral Account for the purpose of consummating the repurchase of an aggregate of \$45.0 million of principal amount of the Scilex Notes from the Holders on a pro rata basis at a purchase price equal to 100% of the principal amount thereof (such repurchase, the "Effective Date Repurchase"). In connection with the Effective Date Repurchase, the parties also agreed to remove Scilex Pharma's obligations under the Indenture to (i) repurchase \$25.0 million of Scilex Notes from the holders if the Letter of Credit is drawn on, and (ii) repurchase \$20.0 million of the Scilex Notes from the holders if Scilex Pharma does not receive the Marketing Approval Letter on or prior to July 1, 2023.

The Amendment also revised the minimum cash covenant in the Indenture to provide that the amount of cash equivalents in bank accounts that Scilex Pharma is required to have as of the end of any calendar month shall, commencing with the month ending December 31, 2020, be equal to at least \$4.0 million in the aggregate, provided that if Scilex Pharma did not effectuate (i) the

December Optional Repurchase (as defined below) and (ii) at least one of either (x) the February Optional Repurchase (as defined below) or (y) the April Optional Repurchase (as defined below), then, commencing with the month ending April 30, 2021, and for each month thereafter, such amount would be at least \$10.0 million in the aggregate. If Scilex Pharma fails to meet the foregoing minimum cash requirements, then Scilex Pharma will be required to draw on the Letter of Credit.

The Amendment also provided Scilex Pharma with the option, in its sole and absolute discretion, to repurchase Scilex Notes from the holders thereof on a pro rata basis on each of December 16, 2020 (the “December Optional Repurchase”), February 12, 2021 (the “February Optional Repurchase”) and April 13, 2021 (the “April Optional Repurchase” and, together with the December Optional Repurchase and the February Optional Repurchase, the “Optional Repurchases”), in each case in an aggregate amount equal to the lesser of \$20.0 million or the then-outstanding principal amount of Scilex Notes, at a purchase price in cash equal to 100% of the principal amount thereof.

The Amendment further provides that in the event that the Letter of Credit is drawn upon by Scilex Pharma, then Scilex Pharma shall, within five business days of such draw, repurchase Scilex Notes from the holders thereof on a pro rata basis in an aggregate amount equal to the lesser of \$20.0 million or the then-outstanding principal amount of the Scilex Notes, at a purchase price in cash equal to 100% of the principal amount thereof. In addition, upon the Letter of Credit being drawn on, Scilex Pharma will be required to have minimum cash of \$10.0 million at all times thereafter.

Pursuant to the Amendment, the Holders also consented to Scilex Pharma incurring up to \$10.0 million of indebtedness in connection with an accounts receivable revolving loan facility with another lender and the incurrence of liens and the pledge of collateral to such lender in connection therewith.

On December 14, 2020, the restricted funds in the Reserve Account and the Collateral Account were released and the Effective Date Repurchase was effected. Scilex Pharma also effectuated the December Optional Repurchase on December 16, 2020. Following the Effective Date Repurchase and the December Optional Repurchase, the aggregate principal amount of the Scilex Notes was reduced by an aggregate of \$65.0 million. The Company accounted for the Amendment as a debt modification under ASC Topic 470-50 as the modified terms were not substantially different than the pre-modified terms.

Scilex Pharma effectuated the February Optional Repurchase and the April Optional Repurchase, which reduced the aggregate principal by \$40.0 million during the year ended December 31, 2021. In connection with the repurchases, the Company recorded a loss on partial debt extinguishment of \$14.0 million during the year ended December 31, 2021.

Actual cumulative net sales of ZTlido from the issue date of the Scilex Notes through December 31, 2021 did not equal or exceed 95% of a predetermined target sales threshold for such period, which resulted in a \$28.0 million increase in the principal amount of the Scilex Notes, effective February 15, 2022. As a result, the Company recorded the increase of \$28.0 million in principal and non-operating expense at December 31, 2021.

Effective February 14, 2022, Scilex Pharma issued to the Company a draw notice under the Letter of Credit as required under the terms of the Indenture because actual cumulative net sales of ZTlido from the issue date of the Scilex Notes through December 31, 2021 were less than a specified sales threshold for such period. As a result of the draw notice being issued, the Company paid to Scilex Pharma \$35,000,000 in a single lump-sum amount as a subordinated loan. Per the terms of the Amendment, in February 2022, Scilex Pharma repurchased Scilex Notes from the holders thereof on a pro rata basis in an aggregate amount equal to \$20.0 million at a purchase price in cash equal to 100% of the principal amount thereof.

To estimate the fair value of the Scilex Notes, 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 principal payments and the discounted rate of return reflective of the Company’s credit risk.

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

	December 31,	
	2021	2020
Principal	\$ 133,998	\$ 151,872
Unamortized debt discount	(30,601)	(51,022)
Unamortized debt issuance costs	(2,235)	(3,698)
Carrying value	<u>\$ 101,162</u>	<u>\$ 97,152</u>
Estimated fair value	<u>\$ 115,400</u>	<u>\$ 122,300</u>

Future minimum payments under the Scilex Notes, based on a percentage of projected net sales of ZTlido are estimated as follows (in thousands):

Year Ending December 31,	
2022	\$ 9,135
2023	12,005
2024	13,637
2025	14,746
2026	84,475
Total future minimum payments	133,998
Unamortized debt discount	(30,601)
Unamortized capitalized debt issuance costs	(2,235)
Total Scilex Notes	101,162
Current portion	(9,135)
Long-term portion of Scilex Notes	\$ 92,027

The Company made principal payments of \$45.9 million and \$69.8 million during the fiscal years ended December 31, 2021 and 2020, respectively. 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 and SP-103, if the 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 imputed effective interest rate at December 31, 2021 was 7.7 %. The amount of debt discount and debt issuance costs included in interest expense for the fiscal years ended December 31, 2021, 2020 and 2019 was approximately \$7.9 million, \$10.6 million and \$15.0 million, respectively.

The Company identified a number of embedded derivatives that require bifurcation from the Scilex Notes and that were separately accounted for in the consolidated financial statements as derivative liabilities. Certain of these embedded features include default interest provisions, contingent rate increases, contingent put options, optional and automatic acceleration provisions and tax indemnification obligations. The fair value of the derivative liabilities associated with the Scilex Notes was estimated using the discounted cash flow method under the income approach combined with a Monte Carlo simulation model. This involves significant Level 3 inputs and assumptions, including a risk adjusted net sales forecast, an effective debt yield, estimated marketing approval probabilities for SP-103 and an estimated probability of an initial public offering by Scilex Holding that satisfies certain valuation thresholds and timing considerations. The Company re-evaluates this assessment each reporting period.

The 2018 Purchase Agreements and Indenture, as amended, provide that, upon the occurrence of an event of default, the lenders thereunder may, by written notice to the Company, declare all of the outstanding principal and interest under the Indenture immediately due and payable. For purposes of the Indenture, an event of default includes, among other things, (i) a failure to pay any amounts when due under the Indenture, (ii) a breach or other failure to comply with the covenants (including financial, notice and reporting covenants) under the Indenture, (iii) a failure to make any payment on, or other event triggering an acceleration under, other material indebtedness of the Company, and (iv) the occurrence of certain insolvency or bankruptcy events (both voluntary and involuntary) involving the Company or certain of its subsidiaries. The Company is subject to certain customary default clauses under the Indenture and is in compliance with event of default clauses under the Indenture.

Effective February 14, 2022, Scilex Pharma issued to the Company a draw notice under the Letter of Credit as required under the terms of the Indenture because actual cumulative net sales of ZTlido from the issue date of the Scilex Notes through December 31, 2021 were less than a specified sales threshold for such period. As a result of the draw notice being issued, the Company paid to Scilex Pharma \$35,000,000 in a single lump-sum amount as a subordinated loan. Per the terms of the Amendment, in February 2022, Scilex Pharma repurchased Scilex Notes from the holders thereof on a pro rata basis in an aggregate amount equal to \$20.0 million at a purchase price in cash equal to 100% of the principal amount thereof.

Effective February 15, 2022, in accordance with the Indenture, the principal amount of the Scilex Notes was increased by \$28.0 million because actual cumulative net sales of ZTlido from the issue date of the Scilex Notes through December 31, 2021 did not equal or exceed 95% of a predetermined target sales threshold for such period.

2018 Oaktree Term Loan Agreement

In November 2018, the Company 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”). In May 2019, the Company entered into an amendment to the Loan Agreement, under which terms the Lenders agreed to make available to the Company \$20.0 million (the “Early Conditional Loan”, and collectively, with the Initial Loan, the “Term Loans”). The Initial Loan matured on November 7, 2023 and bore interest at a rate equal to the London Interbank Offered Rate plus the applicable margin, or 7%. 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 and will be exercisable from May 7, 2019 through May 7, 2029.

In connection with the May 2019 amendment, the Company issued to the Lenders warrants to purchase an aggregate of 1,333,304 shares of the Company’s common stock (the “2019 Warrants”). The 2019 Warrants have an exercise price per share of \$3.94, subject to adjustment for stock splits, reverse stock splits, stock dividends and similar transactions, and are exercisable from November 3, 2019 through November 3, 2029. The Company recorded a loss on derivative liabilities associated with the 2019 Warrants of \$4.3 million on the issuance date.

During the year ended December 31, 2020, the Company repaid \$120.0 million of outstanding principal under the Term Loans plus approximately \$9.4 million of related prepayment premium, exit fees and accrued interest thereon. In connection with the repayment of outstanding principal, the Company recorded a loss on debt settlement of \$51.9 million.

Interest expense recognized for stated interest on the Term Loans totaled \$3.0 million and \$10.7 million and for the years ended December 31, 2020 and 2019, respectively. Debt discount and debt issuance costs were amortized as interest expense using the effective interest method. The amount of debt discount and debt issuance costs included in interest expense on the Term Loans for the years ended December 31, 2020 and 2019 was approximately \$2.2 million and \$5.5 million, respectively.

2018 Securities Purchase Agreement for Private Placement

In March 2018, the Company entered into a Securities Purchase Agreement (the “March 2018 Securities Purchase Agreement”) with certain investors (the “March 2018 Purchasers”), in which the Company issued and sold to the March 2018 Purchasers, (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 Company’s common stock (the “Warrants”). In June 2018, the Company entered into an amendment (the “June 2018 Amendment”), in which the Company issued and sold to the March 2018 Purchasers, (1) Notes in an aggregate principal amount of \$37,848,750, and (2) Warrants to purchase an aggregate of 2,698,662 shares of the Company’s common stock.

In November 2019, the March 2018 Purchasers agreed to convert the full principal amount, plus all accrued interest into shares of the Company’s common stock. The Company accounted for the conversion as an induced conversion of debt and recorded a loss on settlement of debt of \$27.8 million.

2020 Revolving Credit Facility

On December 14, 2020, Scilex Pharma entered into the Credit and Security Agreement (the “Credit Agreement”) with CNH Finance Fund I, L.P. (“CNH”) which provides Scilex Pharma with the ability to incur indebtedness under an accounts receivable revolving loan facility in an aggregate amount of up to \$10.0 million and the incurrence of liens and the pledge of collateral to CNH in connection with the revolving loan facility. Under the terms of the Credit Agreement, interest accrues daily on the principal amount outstanding at a rate per annum equal to the Wall Street Journal Prime Rate plus 1.75%. All indebtedness incurred and outstanding will be due and payable in full on January 1, 2024, unless the Credit Agreement is earlier terminated. As of December 31, 2021, the outstanding balance was \$8.8 million. On February 16, 2022, the Company notified CNH that it was terminating the Credit Agreement, effective March 18, 2022. The balance of the indebtedness, including principal, interest, fees and charges, will be settled by the Company on the termination date.

ACEA Significant Debt Arrangements

At the closing of the transactions contemplated by the ACEA Merger Agreement and as a result thereof, on June 1, 2021, the Company, as the indirect parent to Hangzhou ACEA Pharmaceutical Research Co., Ltd. (“ACEA Hangzhou”) and Zhejiang ACEA Pharmaceutical Co., Ltd. (“ACEA Zhejiang”), each of which are indirect subsidiaries of ACEA, succeeded to the financial obligations of ACEA Hangzhou and ACEA Zhejiang, each of whom are parties to agreements with ACEA Bio (Hangzhou) Co., Ltd. (“ACEA Bio”) (an entity unrelated to ACEA Hangzhou and ACEA Zhejiang) as set forth below.

Pursuant to that certain Contract, dated as of August 15, 2018, between ACEA Hangzhou and ACEA Bio, ACEA Hangzhou borrowed an aggregate of approximately \$29.1 million (184,600,000 RMB) from ACEA Bio in a series of loans thereunder (the

“Contract”). Each loan under the Contract is for a period of 10 years and the maturity dates thereof range from August 15, 2023 to August 15, 2028. Each loan is interest free for the first five years, after which time the interest rate is 5.39% per annum.

The outstanding principal amount under the Contract as of December 31, 2021 is \$29.1 million. As part of the preliminary purchase price allocation, the Company estimated the fair value of the Contract to be approximately \$17.1 million.

9. Stockholders' Equity

At-the-Market Sales Agreement

On April 27, 2020, the Company entered into a Sales Agreement (the “Sales Agreement”) with A.G.P./Alliance Global Partners, as sales agent (the “Agent”), pursuant to which the Company could offer and sell through or to the Agent up to \$250.0 million in shares of its common stock (the “Shares”). On December 4, 2020, the Company entered into Amendment No. 1 (the “December 2020 Amendment”) to the Sales Agreement, which amended the Sales Agreement to provide that the Company could offer and sell, from time to time, through or to the Agent, up to an additional \$450.0 million in shares of the Company’s common stock, such that the Company could offer and sell up to an aggregate of \$700.0 million in shares of its common stock pursuant to the Sales Agreement, as amended by the December 2020 Amendment (the “Original Amended Sales Agreement”).

On December 3, 2021, the Company amended and restated the Original Amended Sales Agreement to include Cantor Fitzgerald & Co., B. Riley Securities, Inc. and H.C. Wainwright & Co., LLC as additional sales agents for the Company’s “at the market offering” program (the “Amended and Restated Sales Agreement”).

On December 23, 2021, the Company entered into Amendment No. 1 (the “December 2021 Amendment”) to the Amended and Restated Sales Agreement with Cantor Fitzgerald & Co., B. Riley Securities, Inc. and H.C. Wainwright & Co., LLC (the “Sales Agents”). The December 2021 Amendment amended the Amended and Restated Sales Agreement to provide that the Company may offer and sell, from time to time, through or to the Sales Agents, as sales agents and/or principals, up to an additional \$5,000,000,000 in shares of the Company’s common stock (the “Additional Shares”), such that the Company may offer and sell up to an aggregate of \$5,442,943,290 in shares of its common stock (the “Offering”) pursuant to the Amended and Restated Sales Agreement, as amended by the December 2021 Amendment (the “Amended Sales Agreement”), inclusive of \$442,943,290 in shares sold pursuant to the Original Amended Sales Agreement and the Amended and Restated Sales Agreement through December 22, 2021.

Subject to the terms and conditions of the Amended Sales Agreement, each Sales Agent will use its commercially reasonable efforts to sell the shares of the Company’s common stock from time to time, based upon the Company’s instructions. Under the Amended Sales Agreement, the Sales Agents may sell the shares of the Company’s common stock by any method permitted by law deemed to be an “at the market offering” as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the “Securities Act”).

The Company has no obligation to sell any shares of its common stock pursuant to the Amended Sales Agreement, and may at any time suspend offers under it. The Offering will terminate upon (i) the election of the Sales Agents upon the occurrence of certain adverse events, (ii) three business days’ advance notice from the Company to the Sales Agents or a Sales Agent (with respect to itself) to the Company, or (iii) the sale of all \$5,442,943,290 of shares of the Company’s common stock pursuant thereto.

Under the terms of the Amended Sales Agreement, the Sales Agents will be entitled to a commission at an initial fixed rate of 3.0% of the gross proceeds from each sale of shares of the Company’s common stock under the Amended Sales Agreement, which percentage may be adjusted (but not above 3.0%) based on the aggregate amount of securities sold by the Sales Agents pursuant to the Amended Sales Agreement.

During the years ended December 31, 2021 and 2020, the Company sold an aggregate of 21,085,014 and 30,991,918 shares of its common stock, respectively, pursuant to the Original Amended Sales Agreement and the Amended and Restated Sales Agreement for aggregate net proceeds to the Company of approximately \$175.6 million and \$227.7 million, respectively.

Common Stock Purchase Agreement

In April 2020, the Company entered into a Common Stock Purchase Agreement (the “Purchase Agreement”) with Arnaki Ltd. (the “Purchaser”), pursuant to which the Purchaser was committed to purchase up to an aggregate of \$250.0 million of shares of the Company’s common stock over the 36-month term of the Purchase Agreement. During the year ended December 31, 2020, the Company sold an aggregate of 1,423,077 shares of its common stock pursuant to the Purchase Agreement for aggregate net proceeds of \$8.0 million. Effective October 27, 2020, the Company voluntarily terminated the Purchase Agreement. The Purchase Agreement was terminable at will by the Company with no penalty.

Aspire Transaction

In February 2020, the Company entered into a Common Stock Purchase Agreement (the “Aspire Purchase Agreement”) with Aspire Capital Fund, LLC, (“Aspire Capital”), pursuant to which Aspire Capital was committed to purchase up to an aggregate of \$75.0 million of shares of the Company’s common stock over a 24-month term. Upon execution of the Aspire Purchase Agreement, the Company issued to Aspire Capital 897,308 shares of the Company’s common stock as a commitment fee. The Company used and is using proceeds it received under the Aspire Purchase Agreement for working capital and general corporate purposes and for the repayment of the Term Loans. On April 24, 2020, the Aspire Purchase Agreement terminated effective immediately in accordance with its terms as the Company issued and sold, as of such date, an aggregate of 33,825,010 shares of the Company’s common stock for the full \$75.0 million of shares available for issuance thereunder.

Equity Distribution Agreement

In April 2020, the Company voluntarily terminated the Equity Distribution Agreement, dated October 1, 2019 (the “Distribution Agreement”), that the Company entered into with JMP Securities LLC (“JMP Sales Agent”), effective immediately. Pursuant to the Distribution Agreement, the Company could offer and sell, from time to time, through the JMP Sales Agent, shares of the Company’s common stock having an aggregate offering price of up to \$75,000,000. During the term of the Distribution Agreement, the Company sold an aggregate of 2,120,149 shares of its common stock thereunder for aggregate gross proceeds to the Company of approximately \$7.4 million. The Distribution Agreement was terminable at will by the Company with no penalty.

2019 Public Offering of Common Stock and Warrants

In June 2019, the Company entered into an underwriting agreement (the “Underwriting Agreement”) with JMP Securities LLC (the “Representative”), as representative of the several underwriters named therein (the “Underwriters”), relating to a firm commitment underwritten public offering. The net proceeds from the June 2019 Offering were approximately \$23.3 million, after deducting underwriting discounts and commissions and other estimated offering expenses, and were received in July 2019.

2019 Registered Direct Offering

In October 2019, the Company announced the closing of its previously announced registered direct offering of 10,869,566 shares of its common stock and warrants to purchase up to 10,869,566 shares of its common stock, at a combined purchase price of \$2.30 per share and related warrant. The net proceeds from this offering were approximately \$23.4 million, after deducting the placement agent’s fees and other estimated offering expenses, and were received in October 2019.

10. Stock Incentive and Employee Benefit Plans

2019 Stock Incentive Plan

In September 2019, the Company’s stockholders approved the Sorrento Therapeutics, Inc. 2019 Stock Incentive Plan (the “2019 Plan”). The 2019 Plan replaced and superseded the Company’s Amended and Restated 2009 Stock Incentive Plan (the “2009 Plan”) and no further awards will be granted under the 2009 Plan. The 2019 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 following table summarizes stock option activity as of December 31, 2021 under the 2019 Plan and the 2009 Plan, and the changes for the period then ended (dollar values in thousands, other than weighted-average exercise price):

	Options Outstanding	Weighted- Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2020	18,762,920	\$ 4.97	—
Options Granted	6,621,685	9.18	
Options Canceled	(1,692,981)	5.91	
Options Exercised	(1,176,111)	3.97	
Outstanding at December 31, 2021	22,515,513	\$ 6.19	\$ 9,952

The aggregate intrinsic value of options exercised during the years ended December 31, 2021, 2020 and 2019 was \$5.2 million, \$4.1 million and \$0.5 million, respectively. The fair value of employee stock options was estimated at the grant date using the following assumptions:

	Years Ended December 31,		
	2021	2020	2019
Weighted-average grant date fair value	\$ 7.49	\$ 4.54	\$ 3.40
Dividend yield	—	—	—
Volatility	110 %	105 %	96 %
Risk-free interest rate	0.96 %	0.46 %	2.02 %
Expected life of options (years)	5.7	5.7	6.0

The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. The expected volatility is based on the historical volatility of the Company's stock. The risk-free interest rate is based on the U.S. Treasury yield curve over the expected term of the option. 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.

Under the 2019 Plan and the Company's prior equity award and option plans, total stock-based compensation recorded as operating expense was \$29.7 million, \$15.0 million and \$8.3 million for the years ended December 31, 2021, 2020 and 2019, respectively. The total unrecognized compensation cost related to unvested employee and director stock option grants as of December 31, 2021 was \$86.7 million and the weighted average period over which these grants are expected to vest is 2.8 years.

The following table summarizes restricted stock unit ("RSU") activity as of December 31, 2021 under the 2019 Plan and the changes for the period then ended:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Outstanding at December 31, 2020	—	\$ —
RSUs Granted	3,829,618	9.68
RSUs Released	(132,540)	13.96
RSUs Cancelled	(263,182)	9.84
Outstanding at December 31, 2021	3,433,896	\$ 9.50

Scilex Holding Company

In June 2019, the stockholders of Scilex Holding approved the Scilex Holding Company 2019 Stock Option Plan (the "2019 Stock Option Plan"). Under Scilex Holding, total stock-based compensation recorded as operating expenses was \$5.8 million, \$5.4 million and \$4.3 million for the years ended December 31, 2021, 2020 and 2019, respectively. The total unrecognized compensation cost related to unvested employee and director stock option grants as of December 31, 2021 was \$8.8 million and the weighted average period over which these grants are expected to vest is 1.8 years.

As of December 31, 2021, options to purchase 26,743,510 shares of the common stock of Scilex Holding were outstanding and 18,256,490 shares were reserved for awards available for future issuance under the 2019 Stock Option Plan.

Employee Stock Purchase Plan

On October 16, 2020 at the Company's 2020 Annual Meeting of Stockholders (the "Annual Meeting"), the Company's stockholders approved the Company's 2020 Employee Stock Purchase Plan ("ESPP"). Under the terms of the ESPP, the Company's employees can elect to have up to 15% of their annual compensation, up to a maximum of \$25,000 per year, withheld to purchase shares of the Company's common stock for a purchase price equal to 85% of the lesser of the fair market value per share (at closing) of the Company's common stock on (i) the commencement date of the six-month offering period, or (ii) the respective purchase date. The initial offering period commenced on November 6, 2020 and ended on May 5, 2021, with subsequent offering periods commencing on May 6th of each year and ending on November 5th of the following year. Total stock-based compensation recorded as operating expense for the ESPP was \$1.1 million and \$0.2 million for the years ended December 31, 2021 and 2020, respectively.

CEO Performance Award

On August 7, 2020, the Compensation Committee of the Company's Board of Directors (the "Compensation Committee") approved a grant to Henry Ji, Ph.D., the Company's Chairman of the Board, Chief Executive Officer and President, of a 10-year CEO performance award tied solely to achieving market capitalization milestones (the "CEO Performance Award"), subject to approval of the Company's stockholders at the Annual Meeting. The CEO Performance Award consists of a 10-year option to purchase an aggregate of 24,935,882 shares of the Company's common stock, which was equal to 10% of the Company's outstanding shares of common stock on the day prior to the date of grant, and vests in ten tranches. Each of the ten tranches vests only if a market capitalization milestone is achieved, which requires two market capitalization prongs to be met to achieve each milestone: (1) a six calendar month trailing average (based on trading days); and (2) a 30 calendar day trailing average (based on trading days). To meet the first market capitalization milestone, the Company's current market capitalization must increase to \$5.0 billion. For the next two milestones, the Company's market capitalization must continue to increase in additional \$2.0 billion increments. For the three milestones thereafter, the Company's market capitalization must increase in additional \$3.0 billion increments. For the next three milestones thereafter, the Company's market capitalization must increase in additional \$4.0 billion increments. For the final milestone, the Company's market capitalization must increase by an additional \$5.0 billion. Thus, for Dr. Ji to fully vest in the award, the Company's market capitalization must increase to \$35.0 billion. The exercise price per share subject to the CEO Performance Award is \$17.30, which is a 20% premium to the closing sales price of the Company's common stock on August 7, 2020, the date the CEO Performance Award was approved by the Compensation Committee. The CEO Performance Award was approved by the Company's stockholders at the Annual Meeting held on October 16, 2020, which represents the date of grant for accounting purposes.

Recognition of stock-based compensation expense of all the tranches commenced on the date of grant, as the probability of meeting the ten market capitalization milestones is not considered in determining the timing of expense recognition. The expense will be recognized ratably over the expected vesting period of each respective tranche. If the related market capitalization milestone is achieved earlier than its expected achievement period, then the stock-based compensation expense for that vesting tranche will be accelerated and recorded in the period in which the associated milestone is achieved. The market capitalization requirement is considered a market condition under FASB ASC Topic 718 *Compensation – Stock Compensation* and is estimated on the grant date using Monte Carlo simulations. Key assumptions for estimating the performance-based awards fair value at the date of grant included, volatility of the Company's common stock price, post-vesting exercise behavior, and the derived service period.

Total stock-based compensation recorded as operating expense for the CEO Performance Award was \$51.8 million and \$10.8 million for the year ended December 31, 2021 and 2020, respectively. As of December 31, 2021, the Company had approximately \$87.7 million of total unrecognized stock-based compensation expense remaining under the CEO Performance Award if all market capitalization milestones are achieved. The assumptions used in determining this valuation included an expected volatility of 91.0%, a dividend yield of zero, a risk-free interest rate of 0.75%, and an expected remaining term of 9.8 years. As of December 31, 2021, the expected remaining term is 8.8 years.

Common Stock Reserved for Future Issuance

As of December 31, 2021, approximately 77.3 million shares of common stock were reserved for future issuance, comprised of 16.0 million shares for common stock warrants, 24.9 million for the CEO Performance Award, 7.2 million reserved for issuance under the ESPP plan and approximately 25.9 million shares under stock incentive plans. As of December 31, 2021, approximately 3.2 million shares of common stock remained available for grant under the 2019 Plan.

Employee Benefit 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 \$1.7 million, \$1.4 million and \$1.3 million, for the years ended December 31, 2021, 2020 and 2019, respectively.

11. Commitments and Contingencies

Litigation

In the normal course of business, the Company may be named as a defendant in one or more lawsuits. Other than as set forth below, 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.

On April 3, 2019, the Company filed two legal actions against, among others, Patrick Soon-Shiong and entities controlled by him, asserting claims for, among other things, fraud and breach of contract, arising out of Dr. Soon-Shiong's purchase of the drug Cynviloq™ from the Company in May 2015. The actions allege that Dr. Soon-Shiong and the other defendants, among other things, acquired the drug Cynviloq™ for the purpose of halting its progression to the market. Specifically, the Company has filed:

- An arbitration demand with the American Arbitration Association in Los Angeles, California against NantPharma, LLC (“NantPharma”) and Chief Executive Officer Patrick Soon-Shiong, related to alleged fraud and breaches of the Stock Sale and Purchase Agreement, dated May 14, 2015, entered into between NantPharma and the Company, filed as Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 7, 2015. On May 24, 2019, NantCell, Inc., Dr. Soon-Shiong and Immunotherapy NANTibody LLC (“NANTibody”) General Counsel Charles Kim filed a motion in the Los Angeles Superior Court to stay or dismiss the Company's arbitration demand. On October 9, 2019, the Los Angeles Superior Court denied the motion to stay or dismiss the arbitration demand, and the arbitration is ongoing against NantPharma. On March 5, 2020, the Company filed a legal action against Dr. Soon-Shiong in Los Angeles Superior Court, asserting claims for fraudulent inducement and common law fraud, arising out of Dr. Soon-Shiong's purchase of the drug Cynviloq™ from the Company in May 2015. The action alleges that, among other things, Dr. Soon-Shiong acquired the drug Cynviloq™ for the purpose of halting its progression to the market. In connection with filing this civil action in the Los Angeles Superior Court, where the Company will have the right to a jury trial against Dr. Soon-Shiong, the Company has dismissed Dr. Soon-Shiong from the related, ongoing arbitration against NantPharma; and
- An action in the Los Angeles Superior Court derivatively on behalf of NANTibody against NantCell, Inc., NANTibody Board Member and NantCell, Inc. Chief Executive Officer Patrick Soon-Shiong, and NANTibody officer Charles Kim, related to several breaches of the June 11, 2015 Limited Liability Company Agreement for NANTibody entered into between the Company and NantCell, Inc. The suit also alleges breaches of fiduciary duties and seeks, inter alia, a declaration that the Assignment Agreement entered into on July 2, 2017, between NantPharma and NANTibody is void and an equitable unwinding of the Assignment Agreement. The suit calls for the restoration of \$90.05 million to the NANTibody capital account, thereby restoring the Company's equity method investment in NANTibody to its invested amount as of June 30, 2017 of \$40.0 million. On May 24, 2019, NantCell, Inc. and Dr. Soon-Shiong filed a cross-complaint against the Company and Dr. Henry Ji, seeking unspecified damages, as well as additional punitive damages and specific performance, related to alleged fraud, alleged breaches of the Exclusive License Agreement for certain antibodies (dated June 11, 2015 and entered into between NANTibody, LLC and the Company), and alleged tortious interference with contract. On May 24, 2019, NANTibody and NantPharma filed a new complaint in the action against the Company and Dr. Henry Ji, seeking unspecified damages, as well as additional punitive damages and specific performance, related to alleged fraud, alleged breaches of the Stock Sale and Purchase Agreement, alleged breaches of the Exclusive License Agreement for certain antibodies (dated April 21, 2015 and entered into between NantCell, Inc. and the Company), and alleged tortious interference with contract. On July 8, 2019, the Company and Dr. Henry Ji filed motions to compel the cross-complaint and new action to arbitration. On October 9, 2019, the Los Angeles Superior Court granted the motions to compel to arbitration all of the claims brought by NANTibody, NantCell, Inc. and NantPharma, and denied the motions to compel as to the claims brought by Dr. Soon-Shiong. Subsequently, NANTibody, NantCell, Inc., and NantPharma have re-filed their claims in arbitration with the American Arbitration Association. On May 4, 2020, the Company filed counterclaims against NANTibody and NantPharma related to breaches of the April 21, 2015 and June 11, 2015 Exclusive License Agreements. The claims against Dr. Soon-Shiong have been stayed pending resolution of the claims filed in arbitration. The original derivative action is no longer stayed, and the parties are currently engaged in discovery in the suit.

On May 26, 2020, Wasa Medical Holdings filed a putative federal securities class action in the U.S. District Court for the Southern District of California, Case No. 3:20-cv-00966-AJB-DEB, against the Company, its President, Chief Executive Officer and Chairman of the Board of Directors, Henry Ji, Ph.D., and its SVP of Regulatory Affairs, Mark R. Brunswick, Ph.D. The action alleges that the Company, Dr. Ji and Dr. Brunswick made materially false and/or misleading statements to the investing public by publicly issuing false and/or misleading statements regarding STI-1499 and its ability to inhibit the SARS-CoV-2 virus infection and that such statements violated Section 10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder. The suit seeks to recover damages caused by the alleged violations of federal securities laws, along with the plaintiffs' reasonable costs and expenses incurred in the lawsuit, including counsel fees and expert fees. On June 11, 2020, Jeannette Calvo filed a second putative federal securities class action in the U.S. District Court for the Southern District of California, Case No. 3:20-cv-01066-JAH-WVG, against the same defendants alleging the same claims and seeking the same relief. On February 12, 2021, the U.S. District Court for the Southern District of California issued an order consolidating the cases and appointing a lead plaintiff, Andrew Zenoff ("Plaintiff"), and lead counsel. On April 5, 2021, Plaintiff filed a consolidated amended complaint in accordance with the U.S. District Court for the Southern District of California's scheduling order. Pursuant to that scheduling order, the defendants filed a motion to dismiss on May 20, 2021 and Plaintiff filed its opposition to the motion on July 2, 2021. The defendants' reply was filed on August 4, 2021. On or about November 18, 2021, the U.S. District Court for the Southern District of California issued an order granting the motion to dismiss with leave to amend. On November 30, 2021, Plaintiff filed a first amended consolidated complaint. On December 30, 2021, the defendants filed a motion to dismiss the first amended consolidated complaint. Pursuant to a stipulated scheduling order, the defendants filed their opposition to the motion on February 7, 2022, and the defendants filed their reply on February 28, 2022. A hearing is scheduled for the motion on May 19, 2022. The Company is defending these matters vigorously.

On July 26, 2021, Sachin Chaudhari filed a verified stockholder derivative complaint in the U.S. District Court for the Southern District of California, Case No. 0723211, against Dr. Ji, Mr. Brunswick, and the Company's Board of Directors as defendants, and against the Company, as a nominal defendant. The action alleges, among other things, that defendants breached their fiduciary duties, violated Section 20(a) of the Securities Exchange Act of 1934, as amended, engaged in waste and were unjustly enriched in connection with the alleged false and misleading statements to the investing public by publicly issuing false and/or misleading statements regarding STI-1499 and its ability to inhibit the SARS-CoV-2 virus infection. The suit seeks to recover on behalf of the Company those damages caused by the alleged breaches of duty and related claims, along with the plaintiffs' reasonable costs and expenses incurred in the lawsuit, including counsel fees and expert fees. On July 27, 2021, Michael Sabatina filed a verified stockholder derivative complaint in the Delaware Chancery Court, Case No. 2021-0654 against Dr. Ji and Mr. Brunswick, as defendants, and against the Company as a nominal defendant, alleging the same general claims and seeking the same general relief. Both of these derivative cases have been stayed by their respective courts pending resolution of the motion to dismiss the federal securities class action described above. The Company is defending these matters vigorously.

Operating Leases

The Company leases administrative, research and development, sales and marketing and manufacturing facilities under various non-cancelable lease agreements. Facility leases generally provide for periodic rent increases, and many contain escalation clauses and renewal options. As of December 31, 2021, the Company's leases have remaining lease terms of approximately 0.5 to 16.8 years, some of which include options to extend the lease terms for up to five years, and some of which allow for early termination. Many of the Company's leases are subject to variable lease payments. Variable lease payments are recognized in the period in which the obligation for those payments are incurred, are not included in the measurement of the ROU assets or lease liabilities and are immaterial. As of December 31, 2021, the Company has no finance leases.

Operating lease costs were approximately \$12.5 million, \$10.1 million and \$10.0 million for the years ended December 31, 2021, 2020 and 2019, respectively, and were primarily comprised of long-term operating lease costs. Short-term operating lease costs were immaterial. Supplemental quantitative information related to leases includes the following (in thousands):

	Year ended December 31,	
	2021	2020
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash outflows from operating leases	\$ 11,225	\$ 9,880
ROU assets obtained in exchange for new and amended operating lease liabilities	\$ 49,459	\$ 1,878
Weighted average remaining lease term in years	15.1	8.4
Weighted average discount rate	12.4%	12.2%

Maturities of lease liabilities are as follows (in thousands):

Years ending December 31,	Operating leases
2022	\$ 12,929
2023	14,090
2024	14,196
2025	13,538
2026	13,280
Thereafter	166,183
Total lease payments	234,216
Less imputed interest	(139,246)
Total lease liabilities as of December 31, 2021	<u>\$ 94,970</u>

On September 23, 2021, the Company entered into a lease agreement with LLJ Sorrento Industrial LLC (the "9151 Rehco Road Lease"), pursuant to which the Company leases the premises located at 9151 Rehco Road, San Diego, California. The 9151 Rehco Road Lease has an initial term of 148-months. The 9151 Rehco Road Lease commenced in September 2021.

On August 1, 2021, the Company entered into a lease agreement with HCP Life Science REIT, Inc. (the "Landlord"), pursuant to which the Company leases the premises located at 4921 Directors Place, San Diego, California (the "4921 Directors Place Lease"). The 4921 Directors Place Lease has an initial term of 188-months. The 4921 Directors Place Lease commenced in August 2021.

On September 1, 2021, the Company entered into a lease agreement with the Landlord (the "4930 Directors Place Lease"), pursuant to which the Company will lease the premises located at 4930 Directors Place, San Diego, California. The 4930 Directors Place Lease has an initial term of 188-months and includes approximately 163,205 rentable square feet with total lease future payments of \$201.0 million. The 4930 Directors Place Lease provides for periodic rent increases, and renewal and termination options. The 4930 Directors Place Lease is expected to commence in 2023.

In connection with entry into the lease agreement for the 4930 Directors Place Lease, the Company's existing lease agreements with the Landlord for 9380 Judicial Drive, 4921 Directors Place, 4955 Directors Place and 4939 Directors Place (the "Other Leases") were extended to be coterminous with the term of the 4930 Directors Place Lease and the initial rent for the extension period of each of the Other Leases will be at the current market rates.

12. Income Taxes

Total loss before income taxes summarized by region for the years ended December 31, 2021, 2020 and 2019 is as follows (in thousands):

	2021	2020	2019
United States	\$ (466,562)	\$ (315,516)	\$ (362,776)
Foreign	3,908	(908)	(709)
Total	<u>\$ (462,654)</u>	<u>\$ (316,424)</u>	<u>\$ (363,485)</u>

The components of the provision expense (benefit) were as follows for the years ended December 31, 2021, 2020 and 2019 (in thousands):

	2021	2020	2019
Current income tax expense (benefit):			
Federal	\$ —	\$ (19)	\$ (68)
State	38	72	27
Foreign	2,375	58	(37)
Total current	2,413	111	(78)
Deferred income tax expense (benefit):			
Federal	(80,858)	(55,321)	(53,080)
State	(11,999)	(2,730)	(12,173)
Foreign	178	(288)	(154)
Total deferred	(92,679)	(58,339)	(65,407)
Changes in tax rate	(223)	507	(94)
Changes in valuation allowance	56,973	55,707	65,106
Total income tax benefit from continuing operations	\$ (33,516)	\$ (2,014)	\$ (473)

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, 2021 and 2020 (in thousands):

	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	\$ 181,428	\$ 134,072
Deferred revenue	25,626	25,456
Tax credit carryforwards	33,126	22,209
Intangible assets	27,810	31,140
Operating lease liabilities	19,734	11,726
Debt related interest	26,002	22,448
Stock based compensation	10,516	5,359
Accrued expenses and other	15,076	14,033
Total deferred tax assets	339,318	266,443
Less valuation allowance	(261,238)	(203,512)
Total deferred tax assets	78,080	62,931
Deferred tax liabilities:		
Investment in common stock	(16,372)	(45,507)
Operating lease right-of-use assets	(17,592)	(9,146)
Intangible assets	(44,640)	(13,274)
Other	(1,902)	(1,925)
Total deferred tax liabilities	(80,506)	(69,852)
Net deferred tax liabilities	\$ (2,426)	\$ (6,921)

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, 2021, 2020 and 2019 (in thousands):

	2021	2020	2019
Income tax benefit at federal statutory rate	\$ (97,157)	\$ (66,449)	\$ (76,332)
Valuation allowance	56,973	55,707	65,106
State, net of federal tax benefit	(5,826)	(3,339)	(8,904)
Debt discount and interest limitation	8,954	896	7,013
Income tax credits and incentives	(9,549)	(3,685)	(3,018)
Compensation expense	14,472	4,446	764
Acquisition related charges	2,711	583	18,811
Prior year true-up and carryback	(3,209)	7,790	(187)
Other	(885)	2,037	(3,726)
Income tax benefit	<u>\$ (33,516)</u>	<u>\$ (2,014)</u>	<u>\$ (473)</u>

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 \$261.2 million against its deferred tax assets as of December 31, 2021. 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. The change in valuation allowance also included approximately \$41.6 million in 2021 and \$8.1 million in 2019 attributable to the ACEA Therapeutics, Inc. and Semnur Pharmaceuticals, Inc. acquisitions, respectively.

As of December 31, 2021, the Company had \$788.5 million, \$246.4 million and \$3.6 million of federal, state and foreign net operating loss carryforwards, respectively. The net operating loss carryforwards begin to expire in 2035, 2029 and 2024 for federal, state and foreign, respectively.

The Company also had research and development and orphan drug income tax credits of \$27.3 million and \$17.9 million for federal and state, respectively. The federal income tax credits begin to expire in 2030, while the state income tax 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, 2021, there was no impact of such limitations on the Company's income tax provision.

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 on January 1, 2007 through December 31, 2021 are open and subject to examination by the U.S. and state taxing authorities due to the carryforward of net operating losses and research and development credits. There are no active audits as of December 31, 2021.

A reconciliation of the beginning and ending amount of unrecognized tax expense (benefits) is as follows for the years ended December 31, 2021, 2020 and 2019 (in thousands):

	2021	2020	2019
Beginning balance	\$ 6,397	\$ 5,336	\$ 4,352
Increase related to prior year tax positions	258	133	257
Decrease related to prior year tax positions	—	—	(7)
Increase related to current year tax positions	2,442	928	734
Increase related to acquisitions	36	—	—
Ending balance	<u>\$ 9,133</u>	<u>\$ 6,397</u>	<u>\$ 5,336</u>

At December 31, 2021, 2020 and 2019, \$8.3 million, \$5.6 million and \$4.4 million, respectively, of the Company's total unrecognized tax benefits, if recognized, would impact the effective tax rate, however given the full valuation allowance in the jurisdiction in which the unrecognized tax benefits relate to, the impact on the effective tax rate would be nil.

The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. No interest or penalties have been recognized as of and for the periods ended December 31, 2021, 2020 or 2019.

The Company believes that no material amount of the liabilities for uncertain tax positions will expire within 12 months of December 31, 2021.

13. Related Party Agreements and Other

Jaisim Shah, a member of the Company's Board of Directors, was Semnur's Chief Executive Officer, a member of its Board of Directors and a stockholder of Semnur prior to the acquisition transaction.

Semnur is party to an Assignment Agreement with Shah Investor LP, pursuant to which Shah Investor LP assigned certain intellectual property to Semnur and Semnur agreed to pay Shah Investor LP a contingent quarterly royalty in the low-single digits based on quarterly net sales of any pharmaceutical formulations for local delivery of steroids by injection developed using such intellectual property, which would include SEMDEXA. Mahendra Shah, Ph.D., who served on the board of directors of Scilex Holding from March 2019 to October 2020, is the managing partner of Shah Investor LP.

As of December 31, 2020, approximately 14.7% of the outstanding capital stock of Scilex Holding represented a noncontrolling interest and was held by ITOCHU CHEMICAL FRONTIER Corporation. Scilex Pharma has entered into a product development agreement (the "Product Development Agreement") with ITOCHU CHEMICAL FRONTIER Corporation and another party (together, the "Developers"), which together serve as the sole manufacturer and supplier to Scilex Pharma for lidocaine tape products, including ZTlido and SP-103 (each, a "Product"). Effective January 19, 2021, ITOCHU CHEMICAL FRONTIER Corporation no longer held any shares of outstanding capital stock of Scilex Holding Company. During the years ended December 31, 2021 and December 31, 2020, Scilex Pharma purchased approximately \$5.7 million and \$1.0 million of inventory from the Developers pursuant to the Product Development Agreement, respectively. Pursuant to the Product Development Agreement, Scilex Pharma is required to make aggregate royalty payments between 25% and 35% to the Developers based on net profits. Net profits are defined as net sales, less cost of goods and marketing expenses. Net sales are defined as total gross sales of any Product, less all applicable deductions, to the extent accrued, paid or allowed in the ordinary course of business with respect to the sale of such Product, and to the extent that they are in accordance with U.S. GAAP. If Scilex Pharma were to sublicense the licensed technologies, the Developers will receive the same proportion of any sub-licensing fees received therefrom. The Product Development Agreement will continue in full force and effect until October 2, 2028, the date that is ten years from the date of the first commercial sale of ZTlido. The Product Development Agreement will renew automatically for subsequent successive one-year renewal periods unless Scilex Pharma or the Developers terminate it upon 6-month written notice.

On July 15, 2020, the Company entered into a consulting agreement with Kim Janda, Ph.D., a member of the Company's Board of Directors, pursuant to which Dr. Janda will provide consulting and advisory services in exchange for (i) a one-time fee of \$250,000, which is payable at a rate of 1/12th per month over twelve months, and (ii) an option to purchase up to 150,000 shares of the Company's common stock, which was granted on August 7, 2020 and vests at a rate of 1/48th per month commencing on July 15, 2020. On October 8, 2021, the Company entered into an amendment to the consulting agreement with Dr. Kim whereby the one-time fee was increased to \$301,091, payable through September 30, 2022.

On May 13, 2020, the Company entered into a license agreement with Pulsar Therapeutics, Inc. ("Pulsar"), pursuant to which it licensed Pulsar's nanoparticle technology for vaccine and antibody uses in exchange for a cash payment, certain royalties of net sales, a sublicense fee and an investment by the Company in Pulsar through the transfer of 1.0 million shares of the Company's common stock in exchange for a 5.0% equity interest in Pulsar. As of the date of the investment, Henry Ji, Ph.D., a member of the Company's Board of Directors and the Company's Chief Executive Officer and President, was a director and chairperson of the board of directors of Pulsar and owned approximately 45.0% of Pulsar's outstanding shares, and Jaisim Shah, a member the Company's Board of Directors, owned approximately 5.0% of Pulsar's outstanding shares.

On May 15, 2020, the Company acquired a 50% equity interest in Cytimm Therapeutics, Inc. ("Cytimm") in exchange for an investment of \$2.5 million by the Company. As of the date of the acquisition, Henry Ji, Ph.D., a member of the Company's Board of Directors and the Company's Chief Executive Officer and President, was a director, the chairperson of the board of directors and a stockholder of Cytimm.

In April 2021, the Company entered into the Aardvark Asset Purchase Agreement with Aardvark, as further described in [Note 7](#). As discussed in [Note 5](#), the Company holds an investment interest in Aardvark. In May 2021, the Company paid \$5.0 million in cash for 3,888,932 shares of Series B Preferred Stock of Aardvark. In July 2021, the Company paid consideration of \$5.0 million in cash for an additional 3,888,932 shares of Series B Preferred Stock of Aardvark, resulting in an increase in the Company's ownership interest in Aardvark to approximately 8%. Tien Lee, MD, a member of the board of directors of Scilex Holding, a majority owned

subsidiary of the Company, is the founder and chief executive officer of Aardvark. Kim D. Janda, Ph.D., a member of the board of directors of the Company, is a member of the advisory board of Aardvark.

During the year December 31, 2021, the Company paid approximately \$10.2 million in consideration for 5,622,703 shares of common stock of Deverra, as further described in [Note 5](#). In connection with the Company's purchase of Deverra common stock, Dr. Henry Ji, Ph.D., a member of the Company's Board of Directors and the Company's Chief Executive Officer and Chairperson, and Jaisim Shah, a member of the Company's Board of Directors, were appointed to the board of directors of Deverra. In addition, on December 7, 2021, the Company loaned Deverra an aggregate of \$1.0 million in consideration of a promissory note, which matures six months from the date of issuance.

During the year ended December 31, 2021, the Company paid \$10.0 million in cash for 10,000,000 shares of Series A Preferred Stock of Elsie, as further described in [Note 5](#). In connection with the Company's purchase of Elsie Series A Preferred Stock, Dr. Henry Ji, Ph.D., a member of the Company's Board of Directors and the Company's Chief Executive Officer and President, was appointed to the board of directors of Elsie.

14. Segment Information

As of January 1, 2019, the Company realigned its businesses into two operating and reportable segments, Sorrento Therapeutics and Scilex. The Company reports segment information based on the management approach. The management approach designates the internal reporting used by the Chief Operating Decision Maker ("CODM"), which is the Company's Chief Executive Officer, for making decisions and assessing performance as the source of the Company's reportable segments. The CODM allocates resources and assesses the performance of each operating segment based on licensing, product sales and services revenue, operating expenses, and operating income (loss) before interest and taxes. The Company has determined its reportable segments to be Sorrento Therapeutics and Scilex based on the information used by the CODM.

Sorrento Therapeutics. The Sorrento Therapeutics segment is organized around the Company's immuno-oncology therapeutic area, leveraging its proprietary G-MAB™ antibody library and targeted delivery modalities to generate the next generation of cancer therapeutics. These modalities include proprietary CAR-T, DAR-T, and ADCs as well as bispecific antibody approaches. Additionally, this segment also includes SOFUSA®, a drug delivery technology that delivers biologics directly into the lymphatic system to potentially achieve improved efficacy and fewer adverse effects than standard parenteral immunotherapy, and RTX, which is a non-opioid-based neurotoxin and is currently in clinical trials for late stage cancer pain and osteoarthritis.

Scilex. The Scilex segment is largely organized around the Company's non-opioid pain management operations. Revenues from the Scilex segment are exclusively derived from the sale of ZTlido.

- In October 2018, Scilex Pharma commercially launched ZTlido and began recognizing revenue.
- Semnur's SEMDEXA™ (SP-102) compound could become the first FDA-approved epidural steroid product for the treatment of sciatica. SEMDEXA™ has been awarded fast track status by the FDA.
- Product candidates also include SP-104, 4.5 mg Delayed Burst Release Low Dose Naltrexone Hydrochloride (DBR-LDN) Capsule, for the treatment of chronic pain, fibromyalgia.

The Company manages its assets on a company basis, not by segments, as many of its assets are shared or commingled. With the exception of unrestricted cash balances, the Company's CODM does not regularly review asset information by reportable segment. The majority of long-lived assets for both segments are located in the United States.

The following table presents information about the Company's reportable segments for the years ended December 31, 2021, 2020 and 2019 (in thousands):

(in thousands)	Years Ended December 31,								
	2021			2020			2019		
	Sorrento Therapeutics	Scilex	Total	Sorrento Therapeutics	Scilex	Total	Sorrento Therapeutics	Scilex	Total
External revenues	\$ 24,358	\$ 28,546	\$ 52,904	\$ 13,655	\$ 26,331	\$ 39,986	\$ 10,399	\$ 21,033	\$ 31,432
Operating expenses	387,200	67,155	454,355	225,687	58,817	284,504	130,529	160,296	290,825
Operating (loss) income	(362,842)	(38,609)	(401,451)	(212,032)	(32,486)	(244,518)	(120,130)	(139,263)	(259,393)
Unrestricted cash	32,178	4,487	36,665	51,475	4,989	56,464	12,176	10,345	22,521

15. Quarterly Financial Data (Unaudited)

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

	Quarter Ended	Quarter Ended	Quarter Ended	Quarter Ended	Year Ended
	December 31,	September 30,	June 30,	March 31,	December 31,
2021					
Revenues	\$ 13,076	\$ 12,062	\$ 13,511	\$ 14,255	\$ 52,904
Operating costs and expenses	\$ 127,685	\$ 113,449	\$ 114,061	\$ 99,160	\$ 454,355
Net loss (income) attributable to Sorrento	\$ (144,417)	\$ (119,803)	\$ (166,615)	\$ 2,510	\$ (428,325)
Net loss per share - basic	\$ (0.47)	\$ (0.40)	\$ (0.57)	\$ 0.01	\$ (1.45)
Net loss per share - diluted	\$ (0.47)	\$ (0.40)	\$ (0.57)	\$ 0.01	\$ (1.45)
Weighted-average shares - basic	308,853	299,276	290,003	280,604	294,774
Weighted-average shares - diluted	308,853	299,276	290,003	297,909	294,774
2020					
Revenues	\$ 11,505	\$ 11,753	\$ 9,007	\$ 7,721	\$ 39,986
Operating costs and expenses	\$ 82,028	\$ 94,857	\$ 56,735	\$ 50,884	\$ 284,504
Net loss attributable to Sorrento	\$ (71,503)	\$ (84,023)	\$ (77,740)	\$ (65,195)	\$ (298,461)
Net loss per share - basic	\$ (0.27)	\$ (0.33)	\$ (0.36)	\$ (0.36)	\$ (1.30)
Net loss per share - diluted	\$ (0.27)	\$ (0.33)	\$ (0.36)	\$ (0.36)	\$ (1.30)
Weighted-average shares - basic	267,863	251,211	216,956	182,609	229,823
Weighted-average shares - diluted	267,863	257,670	216,956	182,609	229,823

16. Loss Per Share

For the years ended December 31, 2021, 2020, and 2019, 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 and the if-converted method for potentially dilutive shares of common stock issuable upon the Semnur Share Exchange, which is described in [Note 7](#).

The following table sets forth the reconciliation of basic and diluted earnings per share for the years ended December 31, 2021, 2020 and 2019 (in thousands, except per share):

	Years Ended December 31,		
	2021	2020	2019
Numerator			
Net loss attributable to Sorrento	\$ (428,325)	\$ (298,461)	\$ (292,068)
Net loss attributable to Semnur holders of Scilex Holding	—	—	(38,669)
Net loss used for diluted earnings per share	(428,325)	(298,461)	(330,737)
Denominator for basic loss per share	294,774	229,823	132,732
Potentially dilutive shares of Sorrento common stock issuable upon Semnur Share Exchange	—	—	7,782
Denominator for loss earnings per share	294,774	229,823	140,514
Basic loss per share	\$ (1.45)	\$ (1.30)	\$ (2.20)
Diluted loss per share	\$ (1.45)	\$ (1.30)	\$ (2.35)

The potentially dilutive stock options and warrants that have been excluded because the effect would have been anti-dilutive consisted of the following (in thousands):

	Years Ended December 31,		
	2021	2020	2019
Outstanding options	22,516	18,763	14,587
Outstanding RSUs	3,434	—	—
Outstanding warrants	16,020	18,605	57,556

17. Subsequent Events

Acquisition of Virex

On February 1, 2022 the Company completed the acquisition of Virex Health, Inc., a Delaware corporation (“Virex”) based in Boston, Massachusetts that has developed an at-home diagnostic platform pursuant to that certain Agreement and Plan of Merger (the “Virex Merger Agreement”), dated as of January 14, 2022. Upon completion of the merger of a subsidiary of the Company and Virex, the equity holders of Virex (the “Virex Equityholders”) became entitled to receive the following amounts (to be paid in cash and stock as further described below): (i) \$12,000,000, as such amount was adjusted to \$11,566,275 (and may be further adjusted post-closing) pursuant to the terms of the Virex Merger Agreement for indebtedness, transaction expenses and cash (the “Closing Consideration”) and (ii) subject to achievement of certain regulatory milestones, up to \$10,000,000 in additional consideration (the “Milestone Payment” and together with the Closing Consideration, the “Merger Consideration”).

Pursuant to the Virex Merger Agreement, the Merger Consideration shall be paid as follows: (i) 59% in cash; and (ii) 41% in shares of common stock of the Company. Upon completion of the merger, Virex Equityholders became entitled to receive an aggregate of \$6,824,126 in cash and an aggregate of 1,281,662 shares of common stock based on a price per share equal to \$3.70.

The aggregate number of shares of common stock issuable pursuant to the Virex Merger Agreement as Merger Consideration shall not exceed 19.99% of the total number of shares of common stock issued and outstanding at the closing date.

Due to the close proximity of the acquisition date and the Company’s filing of the Company’s Annual Report on Form 10-K for the year ended December 31, 2021, the Company is unable to disclose the information required by ASC Topic 805, Business Combinations.

Bridge Loan Agreement

On February 16, 2022, the Company entered into a Bridge Loan Agreement between the Company, as borrower, and B. Riley Commercial Capital, LLC, as lender (the "Lender"), pursuant to which the Company borrowed \$45.0 million from the Lender (the "Bridge Loan"). For services rendered in connection with originating and arranging the Bridge Loan, the Company agreed to pay to B. Riley Securities, Inc., an affiliate of the Lender, an upfront fee equal to four percent of the principal amount of the Bridge Loan. The Bridge Loan bears no interest and will mature on June 16, 2022. Upon the occurrence and during the continuance of an "Event of Default" under the Loan Agreement, the Bridge Loan shall bear interest at the rate of 15% per annum. An "Event of Default" under the Loan Agreement includes, among other things, the Company's failure to pay any principal of, or interest on, the Bridge Loan when such principal or interest becomes due and payable or to otherwise perform or observe the terms of the Loan Agreement (subject to cure periods), a material inaccuracy of the Company's representation and warranties under the Loan Agreement, a failure by the Company to generally pay its debts as they become due or a bankruptcy, insolvency or similar event involving the Company.

DESCRIPTION OF SECURITIES OF SORRENTO THERAPEUTICS, INC.

The authorized capital stock of Sorrento Therapeutics, Inc., a Delaware corporation (the “**Company**”), consists of:

- 750,000,000 shares of common stock, \$0.0001 par value per share (“**Common Stock**”); and
- 100,000,000 shares of preferred stock, \$0.0001 par value per share (“**Preferred Stock**”).

Common Stock

Except as otherwise expressly provided in the Company’s Restated Certificate of Incorporation, as amended (the “**Certificate of Incorporation**”) or as required by applicable law, all shares of Common Stock have the same rights and privileges and rank equally, share ratably and are identical in all respects as to all matters, including, without limitation, those described below:

- **Voting rights.** Each holder of Common Stock is entitled to one vote per share on each matter that requires stockholder approval. Holders of Common Stock do not have any cumulative voting rights. There is no provision for cumulative voting for the election of directors, which means that more than one-half of the shares voted can elect all of the directors then standing for election. The Company’s Amended and Restated Bylaws (the “**Bylaws**”) provide that all elections shall be determined by a plurality of votes cast, and except as otherwise required by law or the rules and regulations of any stock exchange applicable to the Company, all other matters shall be determined by a majority of votes cast affirmatively or negatively.
- **Dividend rights.** The holders of outstanding shares of Common Stock are entitled to receive ratably such dividends, if any, as may be declared by the Company’s board of directors (the “**Board**”) out of legally available funds. However, the current policy of the Board is to retain earnings, if any, for the operations and potential expansion of the business.
- **Liquidation rights.** Upon liquidation, dissolution or winding-up, the holders of Common Stock are entitled to share ratably in all of the Company’s assets which are legally available for distribution, after payment of or provision for all liabilities.
- **No preemptive or similar rights.** The holders of Common Stock have no preemptive, subscription, redemption or conversion rights.
- **Anti-Takeover Provisions.** See the below section titled “Anti-Takeover Effects of Provisions of the Company’s Certificate of Incorporation, Bylaws and the DGCL”.

Listing

The Common Stock is listed on the Nasdaq Capital Market under the symbol “SRNE.”

Preferred Stock

The Certificate of Incorporation provides that the Board may by resolution, without further vote or action by the stockholders, establish one or more classes or series of Preferred Stock having the number of shares and relative voting rights, designation, dividend rates, liquidation, and other rights, preferences and limitations as may be fixed by them without further stockholder approval. Once designated by the Board, each series of Preferred Stock will have specific financial and other terms that will be set forth in the applicable certificate of designation for the series. Prior to the issuance of shares of each series of Preferred Stock, the Board is required by the General Corporation Law of the State of Delaware (the “*DGCL*”) and the Certificate of Incorporation to adopt resolutions and file a certificate of designation with the Secretary of State of the State of Delaware. The certificate of designation fixes for each class or series the designations, powers, preferences, rights, qualifications, limitations and restrictions, including, but not limited to, some or all of the following:

- The distinctive designation of such series and the number of shares which shall constitute such series, which number may be increased (except where otherwise provided by the Board in creating such series) or decreased (but not below the number of shares thereof then outstanding) from time to time by resolution of the Board;
- The rate and manner of payment of dividends payable on shares of such series, including the dividend rate, date of declaration and payment, whether dividends shall be cumulative and the conditions upon which and the date from which such dividends shall be cumulative;
- Whether shares of such series shall be redeemable, the time or times when, and the price or prices at which, shares of such series shall be redeemable, the redemption price, the terms and conditions of redemption and the sinking fund provisions, if any, for the purchase or redemption of such shares;
- The amount payable on shares of such series and the rights of holders of such shares in the event of any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Company;
- The rights, if any, of the holders of shares of such series to convert such shares into, or exchange such shares for, shares of Common Stock, other securities or shares of any other class or series of Preferred Stock and the terms and conditions of such conversion or exchange;
- The voting rights, if any, and whether full or limited, of the shares of such series, which may include no voting rights, one vote per share or such higher or lower number of votes per share as may be designated by the Board; and
- The preemptive or preferential rights, if any, of the holders of shares of such series to subscribe for, purchase, receive or otherwise acquire any part of any new or additional issue of stock of any class, whether now or hereafter authorized, or of any bonds,

debentures, notes or any of the Company's other securities, whether or not convertible into shares of Common Stock.

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

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

Warrants

As of December 31, 2021, the Company had outstanding warrants to purchase an aggregate of 16,020,254 shares of Common Stock as follows:

- warrants to purchase an aggregate of 2,424,242 shares with an exercise price of \$2.61 per share, all of which are currently exercisable and expire on June 21, 2023;
- warrants to purchase an aggregate of 2,663,012 shares with an exercise price of \$3.28 per share, all of which are currently exercisable (subject to certain beneficial ownership limitations) and expire on December 13, 2023;
- warrants to purchase an aggregate of 500,000 shares with an exercise price of \$3.28 per share, all of which are currently exercisable and expire on May 7, 2029;
- warrants to purchase an aggregate of 750,000 shares with an exercise price of \$3.94 per share, all of which are currently exercisable and expire on November 3, 2029;
- Series A warrants to purchase an aggregate of 6,033,000 shares with an exercise price of \$3.75 per share, all of which are currently exercisable (subject to certain beneficial ownership limitations) and expire on July 2, 2029, all of which shall be automatically exercised on a "cashless" basis upon expiration in accordance with the terms of the Series A warrants; and
- Series C warrants to purchase an aggregate of 3,650,000 shares with an exercise price of \$3.75 per share, all of which are currently exercisable (subject to certain beneficial ownership limitations) and expire on July 2, 2029, all of which may be automatically exercised on a "cashless" basis upon expiration in accordance with the terms of the Series C warrants.

All of the outstanding warrants contain provisions for the adjustment of the exercise price in the event of stock dividends, stock splits or similar transactions. In addition, certain of the warrants contain a "cashless exercise" feature that allows the holders thereof to exercise the warrants without a cash payment to the Company under certain circumstances. Certain of the warrants also contain provisions that provide certain rights to warrant holders in the event of a fundamental transaction, including a merger or consolidation with or into another entity, such as:

- the right to receive the same amount and kind of consideration paid to the holders of Common Stock in the fundamental transaction;
- the right to require the Company to repurchase the unexercised portion of certain warrants at the warrant's respective fair value using the Black Scholes option pricing formula; or
- the right to require the Company or a successor entity to redeem the unexercised portion of certain warrants for the same consideration paid to holders of Common Stock in the fundamental transaction at the warrant's respective fair value using the Black Scholes option pricing formula.

Anti-Takeover Effects of Certain Provisions of the Company's Certificate of Incorporation, Bylaws and General Corporation Law of the State of Delaware

Certain provisions of the Certificate of Incorporation, the Bylaws and the DGCL may have the effect of discouraging potential acquisition proposals or tender offers or delaying or preventing a change in control. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in the Company's best interests, including attempts by stockholders to replace or remove the Company's management.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of the Company to first negotiate with the Board. These provisions may delay or prevent someone from acquiring or merging with the Company, which may cause the market price of the Common Stock to decline.

Blank Check Preferred Stock

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

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

Advance Notice Bylaws

The Bylaws contain an advance notice procedure for stockholder proposals to be brought before any meeting of stockholders, including proposed nominations of persons for election to the Board. Stockholders at any meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the Board or by a stockholder who was a stockholder of record on the record date for the meeting,

who is entitled to vote at the meeting and who has given the Company's corporate secretary timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. Although the Bylaws do not give the Board the power to approve or disapprove of stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, the Bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of the Company.

Choice of Forum

The Bylaws provide that, unless the Board consents to an alternative forum, the Court of Chancery in the State of Delaware will be the sole and exclusive forum for: (i) any derivative action or proceeding brought by or on behalf of the Company; (ii) any direct action asserting a claim against the Company or any of its directors or officers pursuant to any of the provisions of the DGCL, the Certificate of Incorporation or the Bylaws; (iii) any action asserting a claim of breach of fiduciary duties owed by any of its directors, officers or other employees to its stockholders; or (iv) any action asserting a violation of Delaware decisional law relating to its internal affairs. This provision does not apply to (a) actions in which the Court of Chancery in the State of Delaware concludes that an indispensable party is not subject to the jurisdiction of Delaware courts, or (b) actions in which a federal court has assumed exclusive jurisdiction to a proceeding. This choice of forum provision is not intended to apply to any actions brought under the Securities Act or the Exchange Act. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. However, the Bylaws do not relieve the Company of its duties to comply with federal securities laws and the rules and regulations thereunder, and its stockholders will not be deemed to have waived the Company's compliance with these laws, rules and regulations. The Bylaws also provide that any person or entity purchasing or otherwise acquiring any interest in shares of capital stock of the Company will be deemed to have notice of and consented to this choice of forum provision.

This choice of forum provision in the Bylaws may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with the Company or its directors, officers or other employees, which may discourage such lawsuits against the Company and its directors, officers and other employees. In addition, stockholders who do bring a claim in the Court of Chancery in the State of Delaware could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near Delaware. Furthermore, the enforceability of similar choice of forum provisions in other companies' governing documents has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable.

Interested Stockholder Transactions

The Company is subject to Section 203 of the DGCL, which prohibits "business combinations" between a publicly-held Delaware corporation and an "interested stockholder," which is

generally defined as a stockholder who is a beneficial owner of 15% or more of a Delaware corporation's voting stock for a three-year period following the date that such stockholder became an interested stockholder, unless: (i) the transaction is approved by the board of directors before the date the interested stockholder attained that status; (ii) upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced; or (iii) on or after the date of the transaction, the transaction is approved by the board of directors and authorized at a meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder. In general, the DGCL defines a business combination to include the following: (a) any merger or consolidation involving the corporation and the interested stockholder; (b) any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder; (c) subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; (d) any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or (e) the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

Filling Vacancies

The Certificate of Incorporation provides that the number of directors shall be fixed from time to time exclusively by the Board pursuant to a resolution adopted by a majority of the total number of authorized directors whether or not there exist any vacancies in previously authorized directorships. As of December 31, 2021, the Board consists of seven directors.

In the event of a vacancy on the Board, however occurring, including a vacancy resulting from an increase in the size of the Board, unless otherwise required by law or by resolution of the Board, such vacancy shall be filled only by a majority vote of the directors then in office, though less than a quorum (and not by stockholders), and directors so chosen shall serve for the remainder of the full term of the director for which the vacancy was created or occurred or until such director's successor shall have been duly elected and qualified. This system of electing and filling vacancies may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of the Company, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Removal of Directors

The Certificate of Incorporation provides for the removal of any of the Company's directors only for cause and only by the affirmative vote of the holders of at least 67% of the voting power of all of the then outstanding shares of the Company's capital stock then entitled to vote at an election of directors, voting together as a single class. However, in December 2015, the Delaware Chancery Court issued a decision, *In Re VAALCO Energy, Inc.*, in which the court interpreted Section 141(k) of the DGCL and held that if a company does not have (i) a classified board of directors or (ii) cumulative voting in election of directors, then such company may not provide in its certificate of incorporation or bylaws that its directors may be removed only for

cause. Prior to the *VAALCO* decision, it was not clear whether Section 141(k) prohibits this type of provision when the company does not have classified board or cumulative vote. The *VAALCO* decision made it clear that the removal provision in the Certificate of Incorporation is now invalid. As previously disclosed in a Current Report on Form 8-K filed by the Company on April 18, 2018, the Board resolved that, until such time as an amendment to the Certificate of Incorporation is approved by the Company's stockholders to permit stockholders to remove the Company's directors with or without cause by a majority of stockholders, the Company will not enforce the director removal provision of the Certificate of Incorporation to the extent it purports to limit removal of directors by stockholders only for cause or only by a supermajority of the voting power of all of the then-outstanding shares of capital stock of the Company.

No Stockholder Action by Written Consent; Special Meetings

The Certificate of Incorporation eliminates the right of stockholders to act by written consent without a meeting and the right to call a special meeting of stockholders or to require that the Board call a special meeting, except as may be required by statute.

Amendment of Charter Provisions

The amendment of any of the above provisions in the Certificate of Incorporation, except for the provision making it possible for the Company's board of directors to issue undesignated Preferred Stock, would require approval by a stockholder vote by the holders of at least 67% of the voting power of the then outstanding shares of capital stock entitled to vote generally in the election of directors.

The provisions of the DGCL and the Certificate of Incorporation could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of the Common Stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the Company's management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Subsidiaries of Sorrento Therapeutics, Inc.

Name	State or Jurisdiction of Incorporation or Organization
Concortis Biosystems, Corp.	Delaware
Ark Animal Health, Inc.	Delaware
TNK Therapeutics, Inc.	Delaware
BioServ Corporation	Delaware
Adnab, Inc.	Delaware
ACEA Therapeutics, Inc.	Cayman Islands
Scilex Holding Company	Delaware
Semnur Pharmaceuticals, Inc.	Delaware
Scilex Pharmaceuticals Inc.	Delaware
Levena Biopharma US, Inc.	Delaware
Levena Suzhou Biopharma Co., Ltd.	People's Republic of China
Sorrento Therapeutics (Shanghai) Co., Ltd.	People's Republic of China
Nanjing Levena Biopharma Co. Ltd.	People's Republic of China
Sorrento Therapeutics, S. de R.L. de C.V.	Mexico
SmartPharm Therapeutics, Inc.	Delaware

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statements (Form S-3 Nos. 333-223856, 333-223857, 333-228770, 333-229609, 333-232163, 333-234869, 333-235970, 333-237142, 333-249178, 333-249386, 333-253646, 333-255165, 333-256304, 333-257412 and 333-261888) of Sorrento Therapeutics, Inc., and

(2) Registration Statements (Form S-8 Nos. 333-163670, 333-198307, 333-213130, 333-227305, 333-234622, 333-249616 and 333-249617) of Sorrento Therapeutics, Inc.;

of our reports dated March 11, 2022, with respect to the consolidated financial statements of Sorrento Therapeutics, Inc. and the effectiveness of internal control over financial reporting of Sorrento Therapeutics, Inc. included in this Annual Report (Form 10-K) of Sorrento Therapeutics, Inc. for the year ended December 31, 2021.

/s/ Ernst & Young LLP

San Diego, California
March 11, 2022

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-163670, 333-198307, 333-213130, 333-227305, 333-234622, 333-249616 and 333-249617 on Form S-8 and Registration Statement Nos. 333-223856, 333-223857, 333-228770, 333-229609, 333-232163, 333-234869, 333-235970, 333-237142, 333-249178, 333-249386, 333-253646, 333-255165, 333-256304, 333-257412 and 333-261888 on Form S-3 of our report dated March 2, 2020, relating to the financial statements of Sorrento Therapeutics, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2021.

/s/ Deloitte & Touche LLP

San Diego, California

March 11, 2022

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
Pursuant to Rule 13a-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Henry Ji, Ph.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of Sorrento Therapeutics, Inc.;
 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
 4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries is made known to me by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, 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;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
 5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.
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/s/ Henry Ji, Ph.D.

Henry Ji, Ph.D.

*Chairman of the Board of Directors, Chief Executive Officer,
President and Interim Chief Financial Officer
(Principal Executive Officer and Principal Financial Officer)*

Dated: March 11, 2022

CERTIFICATION

The undersigned, in his capacity as the principal executive officer and principal financial officer of Sorrento Therapeutics, Inc. (the “Company”), hereby certifies, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), that, to the best of his knowledge:

1. This Annual Report on Form 10-K for the period ended December 31, 2021 fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
2. The information contained in this Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the period covered by this Annual Report.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission (“SEC”) or its staff upon request.

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of this Annual Report), irrespective of any general incorporation language contained in such filing.

IN WITNESS WHEREOF, the undersigned has set his hands hereto as of the 11th day of March 2022.

/S/ HENRY JI, PH.D.

Henry Ji, Ph.D.
*Chairman of the Board of Directors, Chief Executive Officer,
President and Interim Chief Financial Officer*
(Principal Executive Officer and Principal Financial Officer)
