UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2020

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____to_____

Commission File No. 001-37590

Cerecor Inc.

(Exact name of registrant as specified in its charter)

Delaware	45-0705648
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

540 Gaither Road, Suite 400
Rockville, Maryland 20850
(Address of principal executive offices)
Telephone: (410) 522-8707
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 Par Value	CERC	Nasdaq Capital Market

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 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 (§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 Rule12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller reporting company ☒ Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant 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 the registrant's shares of common stock held by non-affiliates of the registrant as of June 30, 2020 (which is the last business day of the registrant's most recently completed second fiscal quarter) based upon the closing market price of such stock on the Nasdaq Capital Market on that date was approximately $112.1 million. Shares of common stock held by each officer and directors and by each person known to be the registrant who owned 10% or more of the outstanding common stock have been excluded in that such person may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 4, 2021, there were 89,104,816 outstanding shares of the registrant's common stock, par value $0.001 per share.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report and the information incorporated herein by reference contain forward-looking statements that involve a number of risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements.

Forward-looking statements can be identified by the use of forward-looking words such as “believes,” “expects,” “may,” “will,” “plans,” “intends,” “estimates,” “could,” “should,” “would,” “continue,” “seeks,” “aims,” “projects,” “predicts,” “pro forma,” “anticipates,” “potential” or other similar words (including their use in the negative), or by discussions of future matters such as: the development of product candidates or products; timing and success of trial results and regulatory review; potential attributes and benefits of product candidates; the expansion of Cerecor's drug portfolio; strategic alternatives for its neurological assets and its commercialized product, Millipred®; and other statements that are not historical. These statements include but are not limited to statements under the captions “Business,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” as well as other sections in this report. You should be aware that the occurrence of any of the events discussed under the caption “Risk Factors” and elsewhere in this report could substantially harm our business, results of operations and financial condition and cause our results to differ materially from those expressed or implied by our forward-looking statements. If any of these events occurs, the trading price of our common stock could decline and you could lose all or a part of the value of your shares of our common stock.

The cautionary statements made in this report are intended to be applicable to all related forward-looking statements wherever they may appear in this report. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

As used in this report, the terms “Cerecor,” “Company,” “we,” “us,” and “our” mean Cerecor Inc. and its subsidiaries unless the context indicates otherwise.

SUMMARY OF PRINCIPAL RISK FACTORS

This summary briefly states the principal risks and uncertainties facing our business that could affect our common stock, which are only a select portion of those risks. A more complete statement of those risks and uncertainties is set forth under Part I, Item 1A "Risk Factors" of this annual report. This summary is qualified in its entirety by that more complete statement. You should carefully read the entire "Risk Factors" section when considering the risks and uncertainties as part of your evaluation of our business.

- We will need substantial additional capital for the continued development of our product candidates and for our long-term operations, which might not be available to us on acceptable terms, or at all. Failure to obtain any necessary capital will force us to delay, limit or terminate our product development efforts or cease our operations.
- Our product candidates that we intend to commercialize are in early stages of development. If we do not successfully complete preclinical testing and clinical development of our product candidates or experience significant delays in doing so, our business may be materially harmed.
- If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- The marketing approval processes of the United States Food and Drug Administration (the "FDA") and comparable foreign regulatory authorities are lengthy, time-consuming, costly and inherently unpredictable. Our inability to obtain regulatory approval for our product candidates would substantially harm our business.
- There can be no assurance that we will apply for Emergency Use Authorization ("EUA") for the product we are developing for the treatment of COVID-19 induced acute respiratory distress syndrome ("ARDS") or, if we do apply, that it will be granted an EUA by the FDA. If no EUA is granted or, once granted, it is terminated, we will be unable to sell our product in the near future and will be required to pursue the drug approval process, which is lengthy and expensive.
- There can be no assurance of market acceptance for our product candidates.
- A pandemic, epidemic or outbreak of an infectious disease in the United States or elsewhere, including the COVID-19 pandemic, may materially adversely affect our business, including our clinical trial operations and our financial results.
- We rely on third parties to conduct, supervise and monitor our clinical trials. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we might not obtain marketing approval for or commercialize our product candidates in a timely manner or at all.
- Even if we were to obtain approval for our product candidates with the Rare Pediatric Disease Designation, the Rare Pediatric Disease Priority Review Voucher Program may no longer be in effect at the time of such approval or we might not be able to capture the value of the Rare Pediatric Disease Priority Review Voucher Program.
- We use third parties to manufacture all of our product candidates. This may increase the risk that we will not have sufficient quantities of our product candidates to conduct our clinical trials or such quantities at an acceptable cost, which could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates.
- We will continue to depend on Aytu to provide us with certain services to manage the operations of Millipred.
- If we are unable to obtain or maintain intellectual property rights, or if the scope of patent protection is not sufficiently broad, competitors could develop and commercialize products similar or identical to ours, and we might not be able to compete effectively in our market.
- If we breach the license and development agreements related to our product candidates, we could lose the ability to develop and commercialize our product candidates.

- Our Chief Executive Officer and our Chief Scientific Officer have interests in the development of CERC-006 that may conflict with interests of stockholders.
- We have incurred significant net losses in most periods since our inception and we might continue to incur net losses in the future.
- Armistice Capital Master Fund Ltd. (“Armistice”) has significant influence over us, and its interests may be different from or conflict with those of our other stockholders.

PART I

Item 1. Business.

Overview

Cerecor Inc. (the “Company”, “Cerecor” or “we”) is a biopharmaceutical company focused on becoming a leader in development and commercialization of treatments for rare and orphan diseases. The Company is advancing its clinical-stage pipeline of innovative therapies that address unmet patient needs within rare and orphan diseases.

The Company's rare disease pipeline includes CERC-801, CERC-802 and CERC-803 (“CERC-800 compounds”), which are in development for therapies for congenital disorders of glycosylation and CERC-006, an oral mTORC1/2 inhibitor in development for the treatment of complex lymphatic malformations. The Company is also developing two monoclonal antibodies, CERC-002 and CERC-007. CERC-002 targets the cytokine LIGHT (TNFSF14) and is in clinical development for the treatment of severe pediatric-onset Crohn's disease and COVID-19 acute respiratory distress syndrome (“ARDS”). CERC-007 targets the cytokine IL-18 and is in clinical development for the treatment of Still’s disease (adult-onset Still’s disease (“AOSD”) and systemic juvenile idiopathic arthritis (“sJIA”)) and multiple myeloma (“MM”). CERC-006, 801, 802 and 803 have all received Orphan Drug Designation (“ODD”) and Rare Pediatric Disease Designation (“RPDD”), which makes all four eligible for a priority review voucher (“PRV”) upon approval from the U.S. Food and Drug Administration (“FDA”).

On February 3, 2020, the Company consummated its merger with Aevi Genomic Medicine, Inc. (“Aevi”), in which Cerecor acquired the rights to CERC-002, CERC-006 and CERC-007 (the “Aevi Merger”). Cerecor also entered into an employment agreement with Aevi's Chief Executive Officer, Mike Cola, for him to serve as Cerecor's Chief Executive Officer and an employment agreement with Aevi's Chief Scientific Officer, Dr. Garry Neil, for him to serve as Cerecor's Chief Medical Officer (shortly thereafter promoted to Chief Scientific Officer). Additionally, Mr. Cola and Dr. Sol Barer, the former Chairman of the Board of Aevi, were appointed to the Company's Board of Directors. Dr. Barer serves as the Chairman of the Company’s Board.

The Company continues to explore strategic alternatives for its non-core assets, including its commercialized product, Millipred®, an oral prednisolone indicated across a wide variety of inflammatory conditions, and its neurology pipeline assets.

Recent Developments

Research and Development

In February 2021, we announced that the FDA granted Fast Track designation (“FTD”) to CERC-803 for the treatment of Leukocyte Adhesion Deficiency Type II (“LAD-II”, also known as SLC35C1-CDG). FTD is granted to drugs being developed for the treatment of serious or life-threatening diseases or conditions where there is an unmet medical need. The purpose of the provision is to help facilitate development and expedite the review of drugs to treat serious or life-threatening conditions so that an approved product can reach the market expeditiously. Specifically, FTD features actions to expedite the development and review, including the eligibility of a rolling review by the FDA.

On March 1, 2021, we announced final efficacy data including 60 day mortality from our exploratory Phase 2 U.S.-based, multi-center (10 sites), placebo-controlled proof of concept trial (NCT04412057) of the human anti-LIGHT (TNFSF14) monoclonal antibody CERC-002 in patients with COVID-19 ARDS. All patients in this trial were hospitalized with COVID-19-associated pneumonia and mild-to-moderate ARDS. A total of 83 patients (82 treated) were randomized 1:1 to receive the standard of care at the sites plus either a single dose of 1,200 mg of CERC-002 or placebo subcutaneously. Due to the protocol allowing patients to receive high flow oxygen prior to randomization, 62 patients were included in the intention-to-treat (“ITT”) analysis of the primary endpoint. The final analysis demonstrated the trial met its primary efficacy endpoint (proportion of patients alive and free of respiratory failure over the 28-day study period) compared to placebo in COVID-19 patients with ARDS treated with a single dose of the anti-LIGHT monoclonal antibody CERC-002 (n=62, p=0.044). Efficacy was highest in a prespecified subpopulation of patients over the age of 60 (n=34, OR = 3.38, p=0.042). CERC-002 showed statistically significant efficacy on top of corticosteroids and standard of care treatments in COVID-19 ARDS: over 90% of patients received concomitant systemic corticosteroids and >60% received remdesivir. CERC-002 was well-tolerated. No drug-related serious adverse effects (“SAEs”) were reported in the trial, and there was no increase in infections in CERC-002 treated patients.

In December 2020, we announced that the Company dosed its first patient in a Phase 1b clinical trial of CERC-007 to treat relapsed or refractory MM. We also announced that the FDA accepted the Company’s Investigational New Drug

Applications as active to study the uses of: CERC-007 to treat relapsed or refractory MM; CERC-007 to treat Still's disease (including AOSD and sJIA); and CERC-803 to treat LAD-II.

In November 2020, we announced a collaboration with The Frontiers in Congenital Disorders of Glycosylation Consortium on a prospective pivotal trial evaluating the safety, tolerability and efficacy of CERC-801 in patients suffering from Phosphoglucomutase-1 deficiency related congenital disorders of glycosylation ("PGM1-CDG").

New Leadership Appointment

On March 1, 2021, the Company appointed Schond L. Greenway as Chief Financial Officer. Mr. Greenway brings over 20 years of investment banking, finance and corporate advisory experience in the biopharmaceutical and healthcare sectors. The Company believes Mr. Greenway will provide valuable insights and guidance as the Company anticipates several significant near-term milestones and continues to transform into a leader in development and commercialization of treatments for rare and orphan diseases.

Our Strategy

Our strategy for increasing stockholder value includes:

- Advancing our pipeline of compounds through development and to regulatory approval;
- Acquiring or licensing rights to targeted, complementary differentiated preclinical and clinical stage compounds;
- Developing the go-to-market strategy to quickly and effectively market, launch, and distribute each of our compounds that receive regulatory approval; and
- Opportunistically out-licensing rights to indications or geographies.

Pipeline Assets— Overview, Competition and Intellectual Property

Clinical-Stage Pipeline

The following chart summarizes key information about our clinical-stage pipeline and is followed by further detail for each program, including an overview, competition, licenses (if applicable), and intellectual property:

* The anticipated milestones are forward-looking statements that are subject to significant risks and uncertainties and therefore subject to change based on various factors (many of which are beyond the Company's control). Refer to the Company's Risk Factors disclosed in Item 1A in this Annual Report on Form 10-K.

+ Orphan Drug Designation, Rare Pediatric Disease Designation; Eligibility for Priority Review Voucher upon approval

‡ Fast Track Designation

CERC-002: ***Anti-LIGHT monoclonal antibody for treatment of COVID-19 ARDS and Severe Pediatric-onset Crohn's Disease*****.**

- **Overview:** CERC-002 is a fully human anti-LIGHT or tumor necrosis factor superfamily member 14 ("TNFSF14") monoclonal antibody. It is the only clinical stage anti-LIGHT therapy and has the potential to treat a number of LIGHT-associated immune diseases. It is currently in development for cytokine storm induced COVID-19 ARDS and pediatric onset Crohn's disease.

- **Role of LIGHT in Acute Inflammatory Response:** LIGHT (homologous to **L**ymphotoxin, exhibits **i**nducible expression and competes with HSV **g**lycoprotein D for binding to **h**erpesvirus entry mediator, a receptor expressed on **T** lymphocytes) is a cytokine with inflammatory actions encoded by the TNFSF14 gene. LIGHT plays an important role in regulating immune responses in the lung, gut and skin. It stimulates T Cell and B Cell response as well as induces the release of other cytokines such as IL-1, IL-6, IL-8, IL-10, TNF and GM-CSF. It thus plays a key role in immune responses to viral pneumonia and other diseases.

- **About COVID-19 ARDS:** ARDS is a severe inflammatory disease of the lungs caused by a build up of excess fluid in the alveoli of the lungs. ARDS is a condition most commonly associated with illnesses such as sepsis, trauma, viral and bacterial pneumonia. Current literature suggests that COVID-19 usually begins as an upper respiratory tract infection; however, for some patients, the COVID-19 virus enters the lower respiratory tract and causes direct injury to the lungs by filling the alveoli with excess fluid. Often times, as decrease in oxygenation occurs in the blood, breathing becomes distressed and organs become oxygen-deficient. The lungs attempt to heal, but the resulting inflammatory response often ends up damaging the lungs further. When a patient presents with symptoms associated with ARDS—shortness of breath, chest pain, rapid heart rate and reduced blood oxygen levels—they may be transported to the intensive care unit to be monitored and possibly treated with artificial or mechanical ventilation.

- **About Pediatric-onset Crohn's Disease:** Pediatric-onset Crohn's disease is a rare, inflammatory bowel disease characterized by severe, chronic inflammation of the intestinal wall or any portion of the gastrointestinal tract. In pediatric Crohn's disease, the immune system responds to a stimulus, often an infection, but the response is abnormal. The immune system mistakenly targets the gastrointestinal system. This sustained and abnormal immune system

activity causes chronic inflammation and irritation of the tissues of the gastrointestinal tract, resulting in the signs and symptoms of pediatric Crohn's disease. Pediatric-onset Crohn's disease has a more aggressive phenotype than the adult-onset disease.

- **Competition:**
  - **COVID-19 ARDS:** While there have been anti-viral and steroid medications utilized as standard of care for the treatment of COVID-19 (including dexamethasone and baracitinib), only one therapeutic (remdesivir) has been approved by the FDA for the treatment of COVD-19. Further, the United States has issued multiple Emergency Use Authorizations ("EUAs") for COVID-19 vaccines. Vaccines have also been authorized or approved in other countries around the world. Vaccine distribution is ongoing and additional vaccine candidates are in development. The broad distribution of COVID-19 vaccines may reduce demand for our COVID-19 ARDS treatment.

  - **Pediatric-onset Crohn's Disease:** There are numerous options available for the stepwise treatment of pediatric-onset Crohn's disease. Patients with mild or moderate disease may be treated with 5-aminosalicylic acid ("5-ASA") and/or antibiotics. Additionally, children with moderate or severe disease may be treated with corticosteroids. Immunomodulators, including 6-mercaptopurine, azathioprine, and methotrexate, may be used to induce or prolong remissions from Crohn's disease. Biologics, such as infliximab and adalimumab, may also be used to treat pediatric-onset Crohn's disease.

- **License:** In May 2020, the Company entered into an Amended and Restated Clinical Development and Option Agreement with Kyowa Kirin Co., Ltd. ("KKC"), which replaced that certain 2016 Development and Option Agreement pursuant to which the Company acquired certain rights with respect to the development and potential commercialization of CERC-002 in specified indications, which are discussed below.

  - **ARDS:** Cerecor was granted the right to conduct a signal finding study testing CERC-002 in the treatment of COVID-19 ARDS. Additionally, Cerecor was granted an additional option (the "ARDS Option") separate from the above to obtain exclusive rights for the development, manufacture and commercialization of CERC-002 in the treatment, prevention, and diagnosis of acute lung injury and ARDS (collectively, the "ARDS/ALI Field").

    If Cerecor exercises the ARDS Option, Cerecor will have the exclusive right to develop, manufacture and commercialize CERC-002 globally in the ARDS/ALI Field pursuant to a pre-agreed license agreement. Cerecor will be responsible for manufacturing for use in clinical trials as well as for commercialization in the ARDS/ALI Field. Upon exercise of the ARDS Option, Cerecor will be required to pay KKC an initial license fee in the low single-digit millions of dollars. The Company may pay KKC up to an additional $14 million upon the achievement of certain regulatory milestones related to CERC-002 in the ARDS/ALI Field. Cerecor and KKC will split profits from the Company's sales of CERC-002 in the ARDS/ALI Field with the Company being entitled to 74% of such profits and KKC being entitled to 26% of such profits. KKC will pay the Company low double-digit royalties for sales of CERC-002 outside the ARDS/ALI Field. The Company will be responsible for costs of development of CERC-002 in the ARDS/ALI Field. KKC will have the right to purchase CERC-002 from Cerecor for use outside the ARDS/ALI Field.

  - **Specified pediatric onset rare and orphan inflammatory diseases** (including severe pediatric-onset inflammatory bowel diseases such as Crohn's disease and ulcerative colitis and other specified pediatric onset rare and orphan auto-immune diseases): If Cerecor exercises its option, KKC may select one of two development and commercialization structures as follows:

    - **Plan A: Co-Development/Co-Commercialization Arrangement-** If KKC selects the co-development/co-commercialization arrangement (Plan A), Cerecor will have the exclusive right to develop, manufacture and commercialize the Antibody Licensed Products in the treatment, prevention, and diagnosis of specified pediatric onset rare and orphan inflammatory diseases (including severe pediatric onset inflammatory bowel diseases such as Crohn's disease and ulcerative colitis, or IBD) and other specified pediatric onset rare and orphan auto-immune diseases, or collectively, the Field, in the United States and Canada. Cerecor will also be responsible for development and regulatory approval of the first Antibody Licensed Product in the European Union and then transferring such regulatory approval to KKC or its designee. Cerecor will be responsible for the manufacture of the Antibody Licensed Products for use by the parties in clinical trials as well as for commercialization in their respective fields and/or territories, with KKC purchasing the Antibody Licensed Products from Cerecor.

Cerecor will be required to pay KKC an initial license fee in the low single-digit millions of dollars upon the co-development/co-commercialization arrangement becoming effective. Cerecor may pay KKC up to an additional $18 million upon the achievement of certain regulatory milestones related to the Antibody Licensed Products. The parties will share the anticipated costs of development of the first Antibody Licensed Product in the Field in the United States, Canada and the European Union with Cerecor being responsible for any costs in excess of an agreed cap. The parties will split profits from Cerecor's sales of Antibody Licensed Products in the United States and Canada equally. KKC will pay Cerecor low double-digit royalties for sales of Antibody Licensed Products outside the United States and Canada and outside the Field in the United States and Canada.

- **Plan B: Licensing Arrangement-** If KKC selects the licensing arrangement (Plan B), Cerecor will have the exclusive right to develop, manufacture and commercialize the Antibody Licensed Products in the Field in the United States, Canada and the European Union. Cerecor will be responsible for the manufacture of the Antibody Licensed Products for use by the parties in clinical trials as well as for commercialization in their respective fields and/or territories.

  Cerecor will be required to pay KKC an initial license fee in the low single-digit millions of dollars upon the licensing arrangement becoming effective. Cerecor may pay KKC up to an additional $28 million upon the achievement of certain regulatory milestones related to the Antibody Licensed Products. The parties will split profits from Cerecor's sales of Antibody Licensed Products in the United States, Canada and the European Union with Cerecor being entitled to 74% of such profits and KKC being entitled to 26% of such profits. KKC will pay Cerecor low double-digit royalties for sales of Antibody Licensed Products outside the United States, Canada and the European Union and outside the Field in the United States, Canada and the European Union. Cerecor will be responsible for costs of development of Licensed Products in the United States, Canada and the European Union. KKC will have the right to purchase the Antibody Licensed Products from Cerecor.

- **Intellectual Property:** At a minimum, we plan to rely on patent protection in all major jurisdictions (including the United States) through the patent's expiration in 2027. Additionally, if we receive marketing approval, we expect to receive biologics data exclusivity in the United States, which may provide twelve years of marketing exclusivity in the United States.

CERC-007: ***Anti-IL-18 Monoclonal antibody for treatment of Still's disease and MM.***

- **Overview:** CERC-007 is a high affinity, fully human monoclonal antibody targeting the proinflammatory cytokine IL-18. We are developing CERC-007 for the treatment of multiple auto-immune diseases, including Still's disease (AOSD and sJIA), and MM.

- **About Still's disease:** Still's disease is a serious and rare auto-inflammatory disorder that affects the entire body. AOSD refers to Still's disease in adult patients, while sJIA refers to Still's disease in pediatric patients. AOSD and sJIA share common clinical manifestations, including episodes of high, spiking fevers, rash, joint pain, muscle pain, sore throat, multiorgan involvement and elevated levels of IL-18.

- **About MM:** MM is a blood cancer characterized by an excess proliferation of plasma cells.

- **Competition:**
  - **Still's Disease:** Nonsteroidal anti-inflammatory agents, corticosteroids and methotrexate may be used in the initial treatment of Still's disease. Ilaris® (canakinumab) has been approved by the FDA for the treatment of sJIA and AOSD in the United States. Additionally, Ilaris® and Kineret® (anakinra) have been approved by the European Medicines Agency ("EMA") for the treatment of Still's Disease in the European Union.

  - **MM:** There are currently numerous therapeutic agents approved for the treatment of MM. MM is often treated with at least one of the three main classes of agents, utilized in combination across all lines of therapy: (i) immunomodulators, which include Revlimid® and Pomalyst®, (ii) proteosome inhibitors, which include Velcade® and Kyprolis®, and (iii) anti-CD38 monoclonal antibodies, which include Darzalex® and Sarclisa®.

- **License:** The Company has an exclusive global license to develop and commercialize a Phase 2-ready fully human, anti-IL-18 monoclonal antibody (which we refer to as CERC-007) from Medimmune Limited, a subsidiary of

AstraZeneca plc ("AstraZeneca"). Up to $162 million may be due to AstraZeneca upon achievement of certain development and sales-related milestones, in addition to tiered low double-digit royalties on global annual product sales. Cerecor is fully responsible for the development and commercialization of the program.

- **Intellectual Property:** CERC-007 is eligible to receive ODD for the treatment of MM and ODD for the treatment of Still's disease. Therefore, if we apply and are subsequently granted ODD in such indications, following market approval, we plan to rely on seven-year marketing exclusivity for each in the United States. Additionally, if we receive marketing approval, we expect to receive biologics data exclusivity in the United States, which may provide twelve years of marketing exclusivity in the United States.

  CERC-007 is also eligible to receive Orphan Designation ("OD") in the European Union and we plan to apply for such designation for CERC-007 for the treatment of sJIA. Therefore, if we apply and are subsequently granted OD in the European Union, we plan to rely on ten-year marketing exclusivity in the European Union.

CERC-006: ***Dual mTOR inhibitor for treatment of Complex Lymphatic Malformations.***

- **Overview:** CERC-006 is an orally available inhibitor of mTOR complex 1 and 2 that is being developed for the treatment of patients with serious lymphatic malformations ("LM") who are not eligible for surgery or sclerotherapy. Because a large majority of LM patients have activating mutations in the PK/AKT/mTOR pathway, we believe CERC-006 has the potential to specifically reduce proliferation of the abnormal cells that cause LM, reduce the size of neoplastic lesions and restore lymphatic function; ultimately improving and prolonging the lives of many affected children.

- **About Complex LM:** Lymphatic malformations are rare, non-malignant masses consisting of fluid-filled channels or spaces thought to be caused by the abnormal development of the lymphatic system. LM occurs mostly in infancy or early childhood and can persist throughout life.

- **Designations of CERC-006:**
  - ODD; the benefit of which, amongst other things, is a seven-year marketing exclusivity (upon approval) in the United States; and
  - RPDD, which provides eligibility for a PRV upon FDA approval. If received, the PRV, which may be sold and transferred an unlimited amount of times, can be used to obtain priority review for a subsequent new drug application ("NDA") or biologics license application ("BLA").

- **Competition:** There are currently no FDA approved drug therapies for LM. Existing therapeutic options for treatment of LM include percutaneous drainage, surgery, sclerotherapy, laser therapy, radiofrequency ablation, or medical therapy.

- **License:** The Company has an exclusive license agreement with OSI Pharmaceuticals, LLC, an indirect wholly, owned subsidiary of Astellas Pharma, Inc. ("Astellas"), for the worldwide development and commercialization of the novel, second generation mTORC1/2 inhibitor, which we refer to as CERC-006. Under the terms of the license agreement, we paid Astellas an up-front license fee of $0.5 million and Astellas will be eligible to receive milestone payments up to $5.5 million based upon the achievement of specified development and regulatory milestones. Upon commercialization, Astellas will be entitled to a tiered, single-digit royalty on worldwide annual net sales. Cerecor is fully responsible for the development and commercialization of the program.

- **Royalty:** Prior to Cerecor entering into the merger agreement with Aevi, in July 2019, Aevi entered into a royalty agreement with certain investors, including Mike Cola, its then Chief Executive Officer, and an entity on behalf of Dr. Garry Neil, its then Chief Scientific Officer, in exchange for a one-time aggregate payment of $2 million (the "Royalty Agreement"), which was approved by a majority of the independent members of the board of directors and the audit committee of Aevi. We assumed this Royalty Agreement upon closing of the Aevi Merger. Under the terms of such Royalty Agreement, the investors will be entitled to an aggregate amount equal to a low-single digit percentage of the aggregate net sales of CERC-006. At any time beginning three years after the date of the first public launch of CERC-006, we may exercise, at our sole discretion, a buyout option that terminates any further obligations under the Royalty Agreement in exchange for a payment to such investors of an aggregate of 75% of the net present value of the royalty payments.

- **Intellectual Property:** CERC-006 has received ODD from the FDA. As a result, at a minimum, following marketing approval, we plan to rely on seven-year marketing exclusivity in the United States.

CERC-800 Programs: ***Monosaccharide therapies for treatment of select Congenital Disorders of Glycosylation.***

- **Overview:** CERC-801, CERC-802 and CERC-803 are monosaccharide therapies with known therapeutic utility for the treatment of select congenital disorders of glycosylation ("CDGs"). Oral administration of CERC-801, CERC-802, and CERC-803 replenishes critical metabolic intermediates that are reduced or absent due to genetic mutations, overcoming single enzyme defects in respective CDGs to support glycoprotein synthesis, maintenance and function.

  CERC-801 is a D-galactose substrate replacement therapy for the treatment of phosphoglucomutase 1 ("PGM1") deficiency, also known as PGM1-CDG. CERC-802 is a D-mannose substrate replacement therapy for the treatment of Mannose Phosphate Isomerase ("MPI") deficiency, also known as MPI-CDG. CERC-803 is a L-fucose substrate replacement therapy for the treatment of LADII, also known as SLC35C1-CDG.

- **About CDGs:** CDGs are a group of rare, inherited, metabolic disorders caused by glycosylation defects that present as a broad range of clinical symptoms, including coagulopathy, hepatopathy, myopathy, hypoglycemia, protein-losing enteropathy and reduced cell counts. CDG patients are born with a genetic defect that hinders their ability to utilize certain monosaccharides in the production of glycoproteins. A deletion or misplacement of a sugar subunit produces a dysfunctional glycoprotein, resulting in a myriad of medical issues.

- **Designations of CERC-800 Compounds:**
  - ODD; the benefit of which, amongst other things, is a seven-year marketing exclusivity (upon approval) in the United States;
  - RPDD, which provides eligibility for a PRV upon FDA approval of each compound. If received, each PRV, which may be sold and transferred an unlimited amount of times, can be used to obtain priority review for a subsequent NDA or BLA; and
  - FTD, which features actions to expedite the development of drugs that target serious or life-threatening conditions, including eligibility for expedited review and rolling review of each NDA by the FDA.

The below chart depicts the potential benefits associated with ODD and RPDD for each of the CERC-800 compounds upon marketing approval and anticipated timing of pivotal data:

	CERC-801	CERC-802	CERC-803
Accelerated Pathway	✓	✓	✓
FDA ODD 7-yrs Exclusivity	✓	✓	✓
Priority Review Voucher	✓	✓	✓

- **Competition:** Currently there are no FDA approved treatments for the treatment of CDGs (including PGM1-CDG, MPI-CDG or LADII), however dietary monosaccharide formulations have been shown to alleviate several of the clinical manifestations in CDG patients.

  CERC-801, CERC-802 and CERC-803, are ultra-pure formulations of D-galactose, D-mannose and L-fucose, respectively. These formulations are naturally occurring substances contained in various foods, including dairy products and fruit. Additionally, D-galactose and D-mannose are also marketed by others as non-prescription dietary supplements.

- **Intellectual Property:** The CERC-800 compounds each were granted ODD by the FDA. As a result, at a minimum, following marketing approval, we plan to rely on seven-year marketing exclusivity in the United States.

Intellectual Property Overview

Our success depends in part on our ability to obtain and maintain proprietary protection for the technology and know-how upon which our products are based, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights.

We hold ownership, trademark rights and/or exclusivity to develop and commercialize our products and product candidates covered by patents and patent applications. Our portfolio of patents includes patents or patent applications with claims directed to compositions of matter, including compounds, pharmaceutical formulations, methods of use, methods of manufacturing the compounds, or a combination of these claims. Depending upon the timing, duration and specifics of FDA approval of the use of a compound for a specific indication, some of our U.S. patents may be eligible for a limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. Similar extensions to patent term may be available in other countries for particular patents in Cerecor's portfolio.

The Company has a license agreement ("License Agreement") and a sponsored research agreement ("Research Agreement") with the Children's Hospital of Philadelphia ("CHOP"). Under the terms of the License Agreement, the Company has an (i) an exclusive, sublicensable license to use certain patent rights covering potential diagnostic and therapeutic targets, and (ii) an exclusive, non-sublicensable license to use certain biospecimen and phenotypic data collected from patients with rare and orphan diseases and their family members, which terminates as of June 30, 2021 but can be extended for up to two additional one year periods subject to certain conditions specified therein.

We plan to augment our portfolio of compounds by focusing on the development (when possible) of new chemical entities ("NCEs"), which have not previously received FDA approval. Upon approval by the FDA, NCEs are entitled to market and data exclusivity in the United States with respect to generic drug competition for a period of five years from the date of FDA approval, even if the related patents have expired.

Intellectual Property for specific pipeline assets, if applicable, are discussed above within the "Product Pipeline Assets" section.

Competition Overview

We face, and will continue to face, intense competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, both in the United States and abroad. We compete, or will compete, with existing and new products being developed by our competitors. Some of these competitors are pursuing the development of pharmaceuticals that target the same diseases and conditions that our research and development programs target.

Competition for specific pipeline assets are discussed above within the "Product Pipeline Assets" section.

Manufacturing

We do not have any manufacturing facilities or personnel. We rely on contract manufacturing organizations to produce our drug candidates in accordance with applicable provisions of the FDA's current good manufacturing practices regulations ("cGMP") for use in our clinical studies. The manufacture of pharmaceuticals is subject to extensive good manufacturing practice ("GMP") regulations, which impose various procedural and documentation requirements and govern all areas of record keeping, production processes and controls, personnel and quality control.

Sales and Marketing

For our clinical stage pipeline assets, we may retain or partner United States commercialization rights and develop sales and marketing capabilities when needed. We may complement our own sales force with co-promotion agreements with partners in and outside the United States. We may also seek to commercialize any of our approved products outside of the United States and may do so either through an expansion of our sales force or through collaboration with third parties.

Overall Competitive Climate and Risks

Other competitors may have a variety of drugs in development or may be awaiting FDA approval that could reach the market and become established before we have a product to sell. Our competitors may also develop alternative therapies that could further limit the market for any drugs that we may develop. Many of our competitors are using technologies or methods different or similar to ours to identify and validate drug targets and to discover novel small compound drugs. Many of our competitors and their collaborators have significantly greater experience than we do in the following:

- identifying and validating targets;
- screening compounds against targets;

- preclinical and clinical trials of potential pharmaceutical products; and
- obtaining FDA and other regulatory clearances.

In addition, many of our competitors and their collaborators have substantially greater advantages in the following areas:

- capital resources;
- research and development resources;
- manufacturing capabilities; and
- sales and marketing.

Smaller companies might also prove to be significant competitors, particularly through proprietary research discoveries and collaborative arrangements with large pharmaceutical and established biotechnology companies. Many of our competitors have products that have been approved or are in advanced development. We face competition from other companies, academic institutions, governmental agencies and other public and private research organizations for collaborative arrangements with pharmaceutical and biotechnology companies, in recruiting and retaining highly qualified scientific and management personnel and for licenses to additional technologies. Our competitors, either alone or with their collaborators, may succeed in developing technologies or drugs that are more effective, safer, and more affordable or more easily administered than ours and may achieve patent protection or commercialize drugs sooner than us. Developments by others may render our product candidates or our technologies obsolete. Our failure to compete effectively could have a material adverse effect on our business.

For additional information on risks regarding our competition, refer to the section entitled “Risk Factors” in Item 1A of this Annual Report on Form 10-K.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export, pricing, and government contracting related to pharmaceutical products such as those we are developing. The processes for obtaining marketing approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

United States Government Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (“FDCA”) and its implementing regulations. The process of obtaining marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, or other actions, such as the FDA’s delay in review of or refusal to approve a pending NDA, withdrawal of an approval, imposition of a clinical hold or study termination, issuance of Warning Letters or Untitled Letters, mandated modifications to promotional materials or issuance of corrective information, requests for product recalls, consent decrees, corporate integrity agreements, deferred prosecution agreements, product seizures or detentions, refusal to allow product import or export, total or partial suspension of or restriction of or imposition of other requirements relating to production or distribution, injunctions, fines, debarment from government contracts and refusal of future orders under existing contracts, exclusion from participation in federal and state healthcare programs, FDA debarment, restitution, disgorgement or civil or criminal penalties, including fines and imprisonment.

FDA Marketing Approval

Obtaining FDA marketing approval for new products may take many years and require the expenditure of substantial financial resources. In order for FDA to determine that a product is safe and effective for the proposed indication, the product must first undergo testing in animals (nonclinical studies). The data generated from nonclinical studies is used to support the filing of an Investigational New Drug Application under which human studies are conducted. Human testing is generally conducted under an Investigational New Drug Application in three phases following GCP guidelines:

- Phase 1 studies evaluate the safety of the drug, generally in normal, healthy volunteers;

- Phase 2 studies evaluate safety and efficacy, as well as explore dosing ranges; these studies are typically conducted in patient volunteers who suffer from the particular disease condition that the drug is designed to treat; and
- Phase 3 studies evaluate safety and efficacy of the product at specific doses in one or more larger pivotal trials.

In addition to human testing, the manufacturing process of the potential product must be developed in accordance with GMP regulations. Prior to the approval of a new product, the FDA will inspect the facilities at which the proposed drug product is manufactured to ensure GMP compliance.

The cumulative safety and efficacy data generated from the clinical trials described above, chemistry, manufacturing and control ("CMC") information, nonclinical study data and proposed labeling are used as the basis to support approval of a marketing application (NDA or BLA) to FDA. The preparation of an NDA or BLA requires the expenditure of substantial funds and the commitment of substantial resources. Additionally, in most cases, the submission of an NDA or BLA is subject to a substantial application user fee paid at the time of submission. The FDA conducts a preliminary administrative review upon receipt of the NDA or BLA submission. The FDA then either accepts the NDA or BLA for filing and commences its technical review or it refuses to accept the filing with the filer then having to address the deficiencies cited by the FDA and re-file the NDA or BLA again.

After evaluating the NDA or BLA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing, or other information, in order for FDA to reconsider the application. The FDA has a review goal of completing its review of 90% of resubmissions within two or six months after receipt, depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA may issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

The development and approval of new drugs requires substantial time, effort and financial resources. Data obtained from the development program are not always conclusive and may be susceptible to varying interpretations. These instances may delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products. The FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial application of the products.

FDA Post-Approval Considerations

Drugs manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, manufacturing, periodic reporting, product sampling and distribution, advertising and promotion, and reporting of adverse experiences with the product and drug shortages. During the approval process, FDA and the sponsor may agree that specific studies or clinical trials should be conducted as post-marketing commitments, but they are not required. The FDA may also impose post-marketing requirements as a condition of approval of an NDA or BLA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product becomes available in the market.

After approval, most changes to the approved product, such as manufacturing changes and adding new indications or other labeling claims are subject to prior FDA review and approval. There also are annual user fee requirements for any marketed products and new application fees for supplemental applications with clinical data. Additionally, the FDA strictly regulates the labeling, advertising and promotion of products under an approved NDA or BLA. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly marketed or promoted off-label uses may be subject to significant liability, including criminal and civil penalties under the FDCA and False Claims Act, exclusion from participation in federal healthcare programs debarment from government contracts, refusal of future orders under existing contracts and mandatory compliance programs under corporate integrity agreements or deferred prosecution agreements.

Emergency Use Authorization

The FDA has the authority to grant an EUA to allow marketing and sale of unapproved medical products or unapproved uses of approved medical products in response to an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions, such as COVID-19, when there are no adequate, approved, and available alternatives. When issuing an EUA, the FDA imposes conditions of authorization, with which the company must comply. Such conditions include, but may not be limited to, compliance with labeling, distribution of materials designed to ensure proper use, reporting obligations, and restrictions on advertising and promotion. The EUA is only effective for the duration of the public health emergency, such as the ongoing COVID-19 pandemic. The FDA may revoke or terminate the EUA sooner if, for example, the company fails to comply with the conditions of authorization of the EUA or the drug is determined to be less effective or safe than it was initially believed to be.

Other Regulations of the Healthcare Industry

In addition to FDA regulations governing the marketing of pharmaceutical products, there are various other state and federal laws that may restrict business practices in the biopharmaceutical industry. These include the following:

- The federal Medicare and Medicaid Anti-Kickback laws, which prohibit persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- Other Medicare laws, regulations, rules, manual provisions and policies that prescribe the requirements for coverage and payment for services performed by our customers, including the amount of such payment;
- The federal False Claims Act, which imposes civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government;
- The Foreign Corrupt Practices Act ("FCPA"), which prohibits certain payments made to foreign government officials;
- State and foreign law equivalents of the foregoing and state laws regarding pharmaceutical company marketing compliance, reporting and disclosure obligations;
- The Patient Protection and Affordable Care Act, which among other things changes access to healthcare products and services; creates new fees for the pharmaceutical and medical device industries; changes rebates and prices for health care products and services; and requires additional reporting and *disclosure;*
- The Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, which creates federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program and which also imposes certain obligations on entities with respect to the privacy, security and transmission of individually identifiable health information; and
- The federal Physician Payment Sunshine Act, which requires certain pharmaceutical and biological manufacturers to engage in extensive tracking of payments or transfers of value to physicians and teaching hospitals and public reporting of the payment data.

If our operations are found to be in violation of any of these laws, regulations, rules or policies or any other law or governmental regulation, or if interpretations of the foregoing change, we may be subject to civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment or restructuring of our operations.

To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals. This is currently not applicable as none of our products are currently sold in a foreign country.

Coverage and Reimbursement

The commercial success of our product candidates and our ability to commercialize any approved product candidates successfully will depend in part on the extent to which governmental authorities, private health insurers and other third-party payers provide coverage for and establish adequate reimbursement levels for our therapeutic product candidates. In the United States, the European Union and other potentially significant markets for our product candidates, government authorities and third-party payers are increasingly imposing additional requirements and restrictions on coverage, attempting to limit reimbursement levels or regulate the price of drugs and other medical products and services, particularly for new and innovative

products and therapies, which often has resulted in average selling prices lower than they would otherwise be. For example, in the United States, federal and state governments reimburse covered prescription drugs at varying rates generally below average wholesale price. Federal programs also impose price controls through mandatory ceiling prices on purchases by federal agencies and federally funded hospitals and clinics and mandatory rebates on retail pharmacy prescriptions paid by Medicaid and Tricare. These restrictions and limitations influence the purchase of healthcare services and products. Legislative proposals to reform healthcare or reduce costs under government programs may result in lower reimbursement for our product candidates or exclusion of our product candidates from coverage. Moreover, the Medicare and Medicaid programs increasingly are used as models for how private payers and other governmental payers develop their coverage and reimbursement policies.

In addition, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and utilization, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, competition within therapeutic classes, availability of generic equivalents, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, coverage and reimbursement policies and pricing in general. The cost containment measures that healthcare payers and providers are instituting and any healthcare reform implemented in the future could significantly reduce our revenues from the sale of any approved product candidates. We cannot provide any assurances that we will be able to obtain and maintain third-party coverage or adequate reimbursement for our product candidates in whole or in part.

Healthcare Reform

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs.

In recent years, Congress has considered reductions in Medicare reimbursement levels for drugs administered by physicians. CMS, the agency that administers the Medicare and Medicaid programs, also has authority to revise reimbursement rates and to implement coverage restrictions for some drugs. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products. While Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payers.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the "Affordable Care Act"), substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Affordable Care Act is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms. Among other things, the Affordable Care Act expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum Medicaid rebate for both branded and generic drugs, expanded the 340B program, and revised the definition of AMP, which could increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The legislation also extended Medicaid drug rebates, previously due only on fee-for-service Medicaid utilization, to include the utilization of Medicaid managed care organizations as well and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the amount of rebates due on those drugs. On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate program under the Affordable Care Act. These regulations became effective on April 1, 2016. Since that time, there have been significant ongoing efforts to modify or eliminate the Affordable Care Act.

On January 20, 2017, President Trump signed an executive order directing federal agencies to exercise existing authorities to reduce burdens associated with the Affordable Care Act pending further action by Congress. In October 2017, he signed an Executive Order which directed federal agencies to modify how the Affordable Care Act is implemented. The Tax Cuts and Jobs Act (the "Tax Act"), enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986 (the "IRC"), as amended, commonly referred to as the individual mandate.

Other legislative changes have been proposed and adopted since passage of the Affordable Care Act. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of an amount greater than $1.2 trillion for the fiscal years 2012 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions included aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, which went into effect in April 2013. Subsequent litigation extended the 2% reduction, on average, to 2030 unless additional Congressional action is taken. However, pursuant to the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"), the 2% Medicare sequester reductions have been suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. On January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further legislative and regulatory changes under the Affordable Care Act remain possible, although the new Administration under President Biden has signaled that it plans to build on the Affordable Care Act and expand the number of people who are eligible for subsidies under it. President Biden indicated that he intends to use executive orders to undo changes to the Affordable Care Act made by the Trump administration and would advocate for legislation to build on the Affordable Care Act. It is unknown what form any such changes or any law would take, and how or whether it may affect our business in the future. We expect that changes or additions to the Affordable Care Act, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry.

The Affordable Care Act has been subject to challenges in the courts. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional and remanded the case to the Texas District Court to reconsider its earlier invalidation of the entire Affordable Care Act. An appeal was taken to the U.S. Supreme Court which heard oral arguments in the case on November 10, 2020. A ruling is expected in 2021.

The Affordable Care Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. Furthermore, the law requires manufacturers to provide a 50% discount off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the "donut hole." The Bipartisan Budget Act of 2018 (the "BBA"), among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole," by increasing from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D.

The Affordable Care Act also expanded the Public Health Service's 340B drug pricing program. As noted above, the 340B drug pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. The Affordable Care Act expanded the 340B program to include additional types of covered entities: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the Affordable Care Act. Because the 340B ceiling price is determined based on AMP and Medicaid drug rebate data, revisions to the Medicaid rebate formula and AMP definition could cause the required 340B discounts to increase.

Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives as well. For example, CMS may develop new payment and delivery models, such as bundled payment models. Recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Such scrutiny has resulted in several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for pharmaceutical products.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that additional federal, state and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

The Foreign Corrupt Practices Act

The FCPA prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight, and debarment from government contracts.

Exclusivity and Approval of Competing Products

Hatch-Waxman Patent Exclusivity

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's product or a method of using the product. Upon approval of a NDA, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application ("ANDA") or 505(b)(2) NDA. Generally, an ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths, dosage form and route of administration as the listed drug and has been shown to be bioequivalent through *in vitro* or *in vivo* testing or otherwise to the listed drug. ANDA applicants are not required to conduct or submit results of preclinical or clinical tests to prove the safety or effectiveness of their drug product, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the reference listed drug.

The ANDA or 505(b)(2) NDA applicant is required to provide a certification to the FDA in the product application concerning any patents listed for the approved product in the FDA's Orange Book, except for patents covering methods of use for which the applicant is not seeking approval. Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable, or will not be infringed by the new product.

Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except when the ANDA or 505(b)(2) NDA applicant challenges a listed patent or if the listed patent is a patented method of use for which approval is not being sought. A certification that the proposed product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or does not indicate that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA or 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of notice of the

Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, a decision in the infringement case that is favorable to the ANDA applicant or other period determined by a court.

Hatch-Waxman Non-Patent Exclusivity

Market and data exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications for competing products. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA, or supplement to an existing NDA or 505(b)(2) NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant, are deemed by the FDA to be essential to the approval of the application or supplement. Three-year exclusivity may be awarded for changes to a previously approved drug product, such as new indications, dosages, strengths or dosage forms of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and, as a general matter, does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Approval of Biosimilars and Biologic Exclusivity

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which was enacted as part of the Affordable Care Act, created an abbreviated approval pathway for biological products that are demonstrated to be "biosimilar" or "interchangeable" with an FDA-licensed reference biological product via an approved BLA. Biosimilarity to an approved reference product requires that there be no differences in conditions of use, route of administration, dosage form, and strength, and no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. Biosimilarity is demonstrated in steps beginning with rigorous analytical studies or "fingerprinting", in vitro studies, in vivo animal studies, and generally at least one clinical study, absent a waiver from the Secretary of Health and Human Services. The biosimilarity exercise tests the hypothesis that the investigational product and the reference product are the same. If at any point in the stepwise biosimilarity process a significant difference is observed, then the products are not biosimilar, and the product will have to developed and approved using a traditional NDA or BLA. In order to meet the higher hurdle of interchangeability, a sponsor must demonstrate that the biosimilar product can be expected to produce the same clinical result as the reference product, and for a product that is administered more than once, that the risk of switching between the reference product and biosimilar product is not greater than the risk of maintaining the patient on the reference product. Complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being evaluated by the FDA.

Upon approval of a BLA, the biologic is listed in the Purple Book along with the date it was licensed; whether the biological product licensed has been determined by the FDA to be biosimilar to or interchangeable with a reference biological product (an already-licensed FDA biological product) and the date of expiration of applicable exclusivity. Under the BPCIA, a reference biologic is granted 12 years of exclusivity from the time of first licensure of the reference product. This 12 year period includes 4 years before the FDA may accept for filing an application for a biologic that references a branded (reference) product.

Pediatric Exclusivity.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent exclusivity period described above. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve an ANDA or 505(b)(2) application owing to regulatory exclusivity or listed patents.

Orphan Drug Designation and Exclusivity.

The Orphan Drug Act provides incentives for the development of drugs intended to treat rare diseases or conditions, which generally are diseases or conditions affecting less than 200,000 individuals annually in the United States, or affecting more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making the drug available in the United States will be recovered from United States sales. Additionally, sponsors must present a plausible hypothesis for clinical superiority to obtain orphan designation if there is a drug already approved by the FDA that is intended for the same indication and that is considered by the FDA to be the same drug as the already approved drug. Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical study costs, tax advantages, and user-fee waivers. In addition, if a product receives FDA approval for the indication for which it has orphan designation, the product is generally 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 seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity.

Rare Pediatric Disease Designation

Under Section 529 to the Federal Food, Drug, and Cosmetic Act (“FD&C Act”), the FDA will award priority review vouchers to sponsors of rare pediatric disease product applications that meet certain criteria. Under this program, a sponsor who receives an approval for a drug or biologic for a rare pediatric disease" may qualify for a PRV that can be redeemed to receive a priority review of a subsequent marketing application for a different product. The PRV may be sold or transferred an unlimited number of times. Under the PRV program, any drug that is granted RPDD by September 30, 2024 and receives approval by September 20, 2026 may qualify for a PRV.

Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding drug development and commercialization. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

European Union Drug Approval Process

To obtain a marketing authorization of a drug in the European Union, we may submit marketing authorization applications (“MAAs”) either under the so-called centralized or national authorization procedures.

Centralized procedure

The centralized procedure provides for the grant of a single marketing authorization following a favorable opinion by the European Medicines Agency (“EMA”) that is valid in all European Union member states, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for medicines produced by specified biotechnological processes, products designated as orphan medicinal products, and products with a new active substance indicated for the treatment of specified diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions. The centralized procedure is optional for products that represent a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public health. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA 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 Committee of Medicinal Products for Human Use ("CHMP"). Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is of 150 days, excluding stop-clocks.

National authorization procedures

There are also two other possible routes to authorize medicinal products in several European Union countries, which are available for investigational medicinal 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.

In the European Union, new products authorized for marketing (i.e., reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic applicant from commercializing its product in the EU until ten years have elapsed from the initial authorization of the reference product in the EU. The ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Commercially Marketed Product

The Company currently has one marketed product, Millipred®, an oral prednisolone indicated across a wide variety of inflammatory conditions and indications. Prednisolone is a man-made form of a natural substance (corticosteroid hormone) made by the adrenal gland. It is used to treat conditions such as arthritis, blood disorders, immune system disorders, skin and eye conditions, respiratory disorders, cancer, and severe allergies. Prednisolone decreases an individual's immune response to various diseases to reduce symptoms such as pain, swelling and allergic-type reactions. Millipred® is supplied in 5mg tablets.

Millipred® tablets primarily compete in the generic prednisolone market. We believe our primary point of differentiation is that we offer the lowest strength prednisolone in the marketplace allowing healthcare professionals greater flexibility when dosing a glucocorticoid steroid across a variety of pediatric and adult indications. Additionally, Millipred® utilizes the proprietary double taste-masking technology to provide a pleasant grape taste with no bitterness, which makes the product easier to administer to children.

Prior to selling our rights, titles and interest in, assets relating to its Pediatric Portfolio, namely Aciphex® Sprinkle™, Cefaclor for Oral Suspension, Karbinal™ ER, Flexichamber™ , Poly-Vi-Flor® and Tri-Vi-Flor™ (the "Pediatric Portfolio") as well as the corresponding commercial infrastructure consisting of the right to offer employment to Cerecor's sales force and the assignment of supporting commercial contracts (the "Aytu Divestiture") to Aytu BioScience, Inc. ("Aytu") in the fourth quarter of 2019, we promoted our commercially marketed products, which included Millipred®, through a sales force of territory managers. As part of the Aytu Divestiture, Cerecor terminated all sales force personnel. Cerecor entered into a transition services agreement with Aytu in which Aytu will manage the commercial operations of Millipred® for a monthly fee of $12,000 for up to 18 months (post November 1, 2019) or until the Company establishes an independent commercial infrastructure for the product or the Company executes on strategic alternatives for the product.

Employees and Human Capital Management

As of December 31, 2020, we had 32 employees, thirty of whom are full-time, one of whom is part-time and nineteen of whom were primarily engaged in research and development activities. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

We believe that our future success largely depends upon our continued ability to attract and retain highly skilled and qualified personnel. We provide our employees with competitive salaries and bonuses, opportunities for equity ownership, and an employment package that promotes well-being across all aspects of their lives, including health care, retirement planning and paid time off. We value diversity and inclusiveness at all levels.

Information about Our Executive Officers

Information about our executive officers is set forth under the caption "Executive Officers" in Part III — Item 10. "Directors, Executive Officers and Corporate Governance" of this 2020 Form 10-K and is incorporated herein by reference.

Corporate Information

We were incorporated in 2011 and commenced operations in the second quarter of 2011. Our principal executive offices are located at 540 Gaither Road, Suite 400, Rockville, Maryland 20850, and our phone number is (410) 522-8707. Our website address is www.cerecor.com. The information on, or that can be accessed through, our website is not part of this report.

Available Information

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act"), are available free of charge on our website at www.cerecor.com as soon as reasonably practicable after electronically filing or furnishing such material to the Securities and Exchange Commission. The Securities and Exchange Commission maintains a website (www.sec.gov) that includes our reports, proxy statements and other information.

Item 1A. Risk Factors.

You should consider carefully the following information about the risks described below, together with the other information contained in this Annual Report on Form 10-K and in our other public filings, in evaluating our business. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our warrants and common stock would likely decline.

Risks Related to Our Financial Position and Capital Needs

We will need substantial additional capital for the continued development of our product candidates and for our long-term operations.

We will need to raise capital to continue product development. Our capital requirements depend on many factors, including:

- the rate and level of patient recruitment into clinical trials, particularly those in Phase 2 and Phase 3 stages of development;
- the level of research and development investment required to develop product candidates;
- changes in product development plans needed to address any difficulties that may arise in manufacturing, preclinical activities, clinical trials or commercialization;
- revenue from sales of Millipred;
- the ability and willingness to enter into new agreements with strategic partners, and the terms of these agreements;
- the success rate in pre-clinical and clinical efforts;
- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution;
- proceeds, if any, from sales of any priority review vouchers received;
- revenue, if any, received from commercial sales of product candidates, should any of our product candidates receive marketing approval;
- the effect of competing product and market developments;
- the timing and amount of milestone payments we are required to make under license agreements;
- in-licensing and/or acquisition or other transaction costs (if any) for potential product development candidates;
- time and costs involved in obtaining regulatory approvals; and
- costs of filing, prosecuting, defending, and enforcing patent claims and other intellectual property rights.

We will likely require significant amounts of additional capital in the future, and such capital might not be available on favorable terms when needed, if at all. We might never progress to the point where we have commercially successful product sales or other revenue sufficient to sustain operations. Accordingly, we may seek to raise these funds through public or private equity offerings, debt financings, credit facilities, partnering or other corporate collaborations and licensing arrangements. If adequate funds are not available or are not available on acceptable terms, our ability to fund our operations, take advantage of opportunities, develop products and technologies, and otherwise respond to competitive pressures could be significantly delayed or limited, and we might need to downsize or halt our operations.

Our current revenue depends on one product, which is not sufficient to provide adequate capital for the continued development of our product candidates and therefore could require us to raise additional financing.

Following the sale of the Pediatric Portfolio to Aytu in 2019, we currently have rights to only one commercial pharmaceutical product, Millipred. We entered into an amendment related to the underlying Millipred license and supply agreement in the fourth quarter of 2020, which extends the original agreement for a period of thirty months (from April 1, 2021 through September 30, 2023). Beginning April 1, 2021, Cerecor will split fifty percent of the net profit of the Millipred product following each calendar quarter, subject to a $0.5 million quarterly minimum payment.

We do not expect Millipred, which we consider a non-core asset, to generate significant revenue and profits, but we currently rely on it for all our commercial revenue. Our operations may not produce significant revenues in the near term, or at all, which may harm our ability to obtain additional financing and may require us to reduce or discontinue our operations. You must consider our business and prospects in light of the risks and difficulties we will encounter as a company operating in a rapidly evolving industry. We may not be able to successfully address these risks and difficulties, which could significantly harm our business, operating results, and financial condition.

We are currently exploring strategic alternatives for our non-core assets. Therefore, our ability to increase revenue in the future will depend on developing and commercializing our current clinical pipeline of product candidates. Identifying, developing, obtaining regulatory approval and commercializing product candidates is prone to the risks of failure inherent in clinical development. Developing product candidates is expensive, and we expect to spend substantial amounts as we fund our product development. We

cannot provide any assurance that we will be able to successfully advance any product candidates through the development process or successfully commercialize any product candidates, or that any such product candidate will be widely accepted in the marketplace or be more effective than other commercially available alternatives. Any failure to develop or commercialize a product candidate in our current clinical pipeline could require us to raise additional financing.

The ongoing COVID-19 pandemic has had an impact on our business operations and clinical trials and could continue, directly or indirectly, to adversely affect our business, results of operations and financial condition and our stock price.

The COVID-19 pandemic has had an impact on our business operations and we continue to monitor applicable government recommendations. We have made modifications to our normal operations because of the COVID-19 pandemic, including allowing our employees to work remotely. Notwithstanding these measures, the COVID-19 pandemic could affect the health and availability of our workforce as well as those of the third parties whom we are relying on to take similar measures. In addition, we have experienced and will continue to experience disruptions to our business operations resulting from shelter-in-place policies and other restrictions on the ability of our employees to perform their jobs.

Our business could be materially adversely affected, directly or indirectly, by the ongoing COVID-19 pandemic, which has spread to the countries in which we, our contract manufacturers, our clinical research contractors and our collaborators in clinical research do business. National, state and local governments in affected regions have implemented and may continue to implement safety precautions, including quarantines, border closures, increased border controls, travel restrictions, shelter-in-place orders and shutdowns, business closures, cancellations of public gatherings and other measures. Organizations and individuals are taking additional steps to avoid or reduce infection, including limiting travel and staying home from work. These measures are disrupting normal business operations both inside and outside of affected areas and have had significant negative impacts on businesses and financial markets worldwide.

The extent and severity of the impact on our business and clinical trials will be determined largely by the extent of disruptions in the supply chains for our research and clinical trial materials, such as committed manufacturing slots being reallocated to other customers of our contract manufacturers pursuant to government orders under the Defense Production Act, and by delays in the conduct and recruitment of current and future clinical trials. These impacts of COVID-19 could affect our other ongoing clinical trials and delay their timelines.

The continued spread of COVID-19 globally could adversely impact our clinical trial operations in the United States and in Europe, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. In addition, if the FDA elects to delay face-to-face meetings for an extended period of time, we may have to delay the initiation of any additional clinical trials for which we require additional approval from the FDA, or, if we are seeking to commercialize our product candidates, such delay could force us to delay commercialization. Any decision by the FDA to delay meeting with us in light of COVID-19 could have a material adverse effect on our scheduled clinical trials or on our efforts to obtain commercialization approval, which could increase our operating expenses and have a material adverse effect on our financial results.

Moreover, COVID-19 may also affect employees of third-party contract research organizations located in affected geographies that we rely upon to carry out such enrollments and trials. Any negative impact COVID-19 has to patient enrollment or treatment could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and have a material adverse effect on our financial results.

Although it is not possible at this time to estimate the entirety of the impact that the COVID-19 pandemic will have on our business, operations and employees, our contract manufacturers, our clinical research contractors, and our collaborators in clinical research, any continued spread of COVID-19, measures taken by governments, actions taken to protect employees from this disease, and the broad impact of the pandemic on all business activities and financial markets, may materially and adversely affect our business, results of operations and financial condition and our stock price.

We might require additional capital to continue to fund our operations and to finance the further advancement of our product candidates, which might not be available to us on acceptable terms, or at all. Failure to obtain any necessary capital will force us to delay, limit or terminate our product development efforts or cease our operations.

At December 31, 2020, we had $18.9 million in cash and cash equivalents and $15.2 million in current liabilities. Accordingly, we might not currently have sufficient funds to finance our continuing operations beyond the short term or to further advance any of our product candidates.

As a research and development company, our operations have consumed substantial amounts of cash since inception. Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance our product candidates into clinical trials or obtain and advance additional product candidates. Circumstances may cause us to consume capital more rapidly than we currently anticipate. We may need to raise additional funds or otherwise obtain funding through collaborations if we choose to initiate additional clinical trials for product candidates.

Additional fundraising efforts may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we do not raise additional capital when required or on acceptable terms, we may need to:

- significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or cease operations altogether;
- seek strategic alliances for research and development programs at an earlier stage than we would otherwise desire or on terms less favorable than might otherwise be available; or
- relinquish, or license on unfavorable terms, our rights to technologies or any future product candidates that we otherwise would seek to develop or commercialize itself.

Our future funding requirements, both short and long term, will depend on many factors, including:

- the initiation, progress, timing, costs and results of preclinical and clinical studies for our product candidates and future product candidates we may develop;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more studies than we currently expect to perform;
- the cost to establish, maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing any patents or other intellectual property rights;
- the effect of competing technological and market developments;
- market acceptance of any approved product candidates;
- the costs of acquiring, licensing or investing in additional businesses, products, product candidates and technologies;
- the cost and timing of selecting, auditing and potentially validating a manufacturing site for commercial-scale manufacturing; and
- the cost of developing our sales, marketing and distribution capabilities to accommodate any of our product candidates for which we receive marketing approval and that we determine to commercialize ourselves or in collaboration with our partners.

Our role as a guarantor of Certain Obligations assigned to Aytu exposes us to risk of loss or illiquidity.

In connection with the Aytu Divestiture, Aytu assumed our financial obligations to Deerfield CSF, LLC ("Deerfield"), which includes minimum monthly and royalty payments of the higher of 15% of net sales or $100,000 through the earlier of February 2026 or reaching the maximum aggregated royalty payment of $12.5 million (the "Deerfield Obligation"). The Deerfield Obligation could be accelerated upon default or a breach of covenants.

We also assigned payment obligations ("TRIS Obligations") to Aytu under a supply and distribution agreement (the "Karbinal Agreement") with TRIS Pharma Inc ("TRIS"), which includes a per-unit royalty make whole payment for each unit sold under an annual minimum sales commitment through 2033. The total future make whole payments to be made by Aytu are unknown as the amount owed to TRIS is dependent on the number of units sold.

As a part of these assignments, we also became a guarantor to the Deerfield Obligation and the TRIS Obligation. If Aytu defaults under the terms of the agreement with Deerfield or TRIS, we could be liable as a guarantor for unpaid amounts of the Deerfield Obligation and the TRIS Obligation. Any amount we would be required to pay under the remaining Deerfield Obligation and the TRIS Obligation would limit the amount of cash available for development of our clinical pipeline and may expose us to significant losses, which would materially and adversely affect our results of operations.

We have incurred significant net losses in most periods since our inception and we might continue to incur net losses in the future.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate an adequate effect or acceptable safety profile, gain marketing approval and become commercially viable. Historically, we financed our operations primarily through public and private equity offerings and convertible debt. We incurred net loss of $63.5 million for the year ended December 31, 2020. As of December 31, 2020, we had an accumulated deficit of $177.8 million. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development program and from general and administrative costs associated with our operations.

We expect to continue to incur losses in the future and we might never achieve profitability on an annual basis. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Our future profitability will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We have a significant amount of gross net operating losses ("NOLs") for federal and state purposes. The NOLs accumulated through the end of 2017 will begin to expire in 2031. Unused NOLs for the current tax year and prior tax years will carry forward to offset future taxable income, if any, until such unused losses expire. Unused NOLs generated after December 31, 2017, will not expire and may be carried forward indefinitely but will be only deductible to the extent of 80% of current year taxable income in any given year. In addition, both the deductibility of current and future unused NOL carryovers may be subject to limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "IRC"). Sections 382 and 383 of the IRC subject the future utilization of NOLs and certain other tax attributes, such as research and experimental tax credits, to an annual limitation in the event of certain ownership changes. In general, an "ownership change" is defined as a greater than 50% change (by value) in equity ownership over a three-year period).

Our operating results fluctuate from quarter to quarter and year-to-year, making future operating results difficult to predict.

Our quarterly and annual operating results historically have fluctuated and are likely to continue to fluctuate depending on several factors, many of which are beyond our control. Accordingly, our quarterly and annual results are difficult to predict prior to the end of the quarter or year, and we may be unable to confirm or adjust expectations with respect to our operating results for a particular period until that period has closed. Any failure to meet our quarterly or annual revenue or earnings targets could adversely impact the market price of our securities. Therefore, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

Risks Related to the Discovery and Development of Our Product Candidates

Our product candidates that we intend to commercialize are in early stages of development. If we do not successfully complete preclinical testing and clinical development of our product candidates or experience significant delays in doing so, our business may be materially harmed.

We have invested a significant portion of our efforts and financial resources in the identification and preclinical and clinical development of product candidates. Our ability to increase product revenues will depend on our ability to advance our clinical product candidates towards approval and our preclinical product candidates into clinical development. The outcome of preclinical studies and earlier clinical trials might not predict the success of future clinical trials. Preclinical data and clinical trial data may be susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and early clinical trials have nonetheless failed in later clinical development. Our inability to successfully complete development of our product candidates could result in additional costs to us relating to product development and obtaining marketing approval and impair our ability to generate product revenues and commercialization and sales milestone payments and royalties on product sales.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining required approvals from regulatory authorities for the sale of future product candidates, we alone, or with a partner, must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive and difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure

of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early clinical trials might not predict the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. Our product candidates will require additional clinical and preclinical development, management of clinical, preclinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply on our own or from a third party, expansion of our commercial organization, and substantial investment and significant marketing efforts before we generate any revenues from sales of any of those product candidates approved for marketing. We do not know whether the clinical trials we or our partners may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of our product candidates in any particular jurisdiction or jurisdictions. If later stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates would be adversely impacted.

If we experience delays in clinical testing, we will be delayed in obtaining regulatory approvals and commercializing our product candidates, our costs may increase and our business may be harmed.

We do not know whether any clinical trials will begin as planned, whether the design will be revised prior to or during conduct of the study, completed on schedule or conducted at all. Our product development costs will increase if we experience delays in clinical testing. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may harm our business, results of operations and prospects.

Events which may result in a delay or unsuccessful completion of clinical development include:

- delays in reaching an agreement with or failure in obtaining authorization from the FDA, other regulatory authorities or institutional review boards (“IRBs”) to commence or amend a clinical trial;
- imposition of a clinical hold or trial termination following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities, or due to concerns about trial design, or a decision by the FDA, other regulatory authorities, IRBs or the company, or recommendation by a data safety monitoring board, to place the trial on hold or otherwise suspend or terminate clinical trials at any time for safety issues or for any other reason;
- delays in reaching agreement on acceptable terms with prospective contract research organizations (“CROs”) and clinical trial sites;
- deviations from the trial protocol by clinical trial sites and investigators, or failing to conduct the trial in accordance with regulatory requirements;
- failure of our third parties, such as CROs, to satisfy their contractual duties or meet expected deadlines;
- failure to enter into agreements with third parties to obtain the results of clinical trials;
- delays in the importation and manufacture of clinical supply;
- delays in the testing, validation and delivery of the clinical supply of the product candidates to the clinical sites;
- for clinical trials in selected subject populations, delays in identification and auditing of central or other laboratories and the transfer and validation of assays or tests to be used to identify selected subjects;
- delays in recruiting suitable subjects to participate in a trial;
- delays in having subjects complete participation in a trial or return for post-treatment follow-up;
- delays caused by subjects dropping out of a trial due to side effects or disease progression;
- delays in adding new investigators and clinical trial sites;
- delays resulting from the ongoing COVID-19 pandemic;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials; or
- changes in government regulations or administrative actions or lack of adequate funding to continue the clinical trials.

Any inability by us or our partners to timely complete clinical development could result in additional costs to us relating to product development and obtaining marketing approval and impair our ability to generate product revenues and commercialization and sales milestone payments and royalties on product sales.

If we are unable to enroll appropriate subjects in clinical trials or retain patients in the clinical trials we perform, we will be unable to complete these trials on a timely basis or at all.

Identifying and qualifying subjects to participate in clinical trials of our product candidates, and retaining the subjects once qualified, is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit appropriate subjects to participate in testing our product candidates as well as completion of required follow-up periods. If subjects are unwilling to

participate in our trials, the timeline for recruiting subjects, conducting trials and obtaining marketing approval of potential products may be delayed.

Difficulty or delays in patient recruitment into our trials could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether. Many factors affect subject enrollment, including:

- the size and nature of the subject population;
- the number and location of clinical sites we enroll;
- the proximity of subjects to clinical sites;
- perceived risks and benefits of the product candidate under trial;
- competition with other companies for clinical sites or subjects;
- competing clinical trials;
- the eligibility and exclusion criteria for the trial;
- the design of the clinical trial;
- effectiveness of publicity for the clinical trials;
- inability to obtain and maintain subject consents;
- ability to monitor subjects adequately during and after the administration of the product candidate and the ability of subjects to comply with the clinical trial requirements;
- risk that enrolled subjects will drop out or be withdrawn before completion; and
- clinicians' and subjects' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their committed activities, we have limited influence over their actual performance. If we are unable to enroll sufficient subjects in our clinical trials, if enrollment is slower than we anticipate, or if our clinical trials require more subjects than we anticipate, our clinical trials may be delayed or might not be completed. If we experience delays in our clinical trials, the commercial prospects of our product candidates will be harmed. 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. In addition, many of the factors that could cause a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our lead product candidates or our other product candidates.

Furthermore, because several of our programs are focused on the treatment of patients with rare, orphan or ultra-orphan diseases, our ability to enroll eligible patients in these trials may be limited or slower than we anticipate in light of the small patient populations involved and the specific age range required for treatment eligibility in some indications. In addition, our potential competitors, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions, may seek to develop competing therapies, which would further limit the small patient pool available for our studies.

Completion of orphan clinical trials may take considerably more time than other trials, sometimes years, depending on factors such as type, complexity, novelty and intended use of a product candidate. As a result of the uncertainties described above, there can be no assurance that we will meet timelines that we establish for any of our rare and orphan clinical trials.

We may fail to successfully identify, in-license, acquire, develop or commercialize potential product candidates.

The success of our business depends in part upon our ability to identify and validate new therapeutic targets and identify, develop and commercialize therapeutics, which we may develop ourselves, in-license or acquire from others. Research programs designed to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research efforts may initially show promise in identifying potential therapeutic targets or candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- Our methodology, including our screening technology, might not successfully identify medically relevant potential product candidates;
- Our competitors may develop alternatives that render our product candidates obsolete;
- We may encounter product manufacturing difficulties that limit yield or produce undesirable characteristics that increase the cost of goods, cause delays or make the product candidates unmarketable;
- Our product candidates may cause adverse effects in subjects, even after successful initial toxicology studies, which may make the product candidates unmarketable;

- Our product candidates might not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- Our product candidates might not demonstrate a meaningful benefit to subjects;
- Our potential collaboration partners may change their development profiles or plans for potential product candidates or abandon a therapeutic area or the development of a partnered product; and
- Our reliance on third party clinical trials may cause us to be denied access to clinical results that may be significant to further clinical development.

Additionally, we may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business, operating results and prospects and could potentially cause us to cease operations.

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

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to issue a clinical hold and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or other comparable foreign regulatory authority. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

Should our clinical studies of our product candidates reveal undesirable side effects, we could suspend or terminate our trials or the FDA or comparable foreign regulatory authorities as well as IRBs could order us to suspend or cease clinical trials. The FDA or comparable regulatory authorities could also deny approval of our product candidates for any or all targeted indications or only for a limited indication or patient population or could require label warnings, contraindications or precautions, including black box warnings, post-market studies, testing and surveillance programs or other conditions including distribution restrictions or other risk management mechanisms under a costly risk evaluation and mitigation strategy ("REMS"). Drug-related side effects could affect subject recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

- We may suspend marketing of, or withdraw or recall, such product;
- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label or other label modifications;
- the FDA or other regulatory bodies may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- the FDA or comparable foreign regulatory authorities may require the establishment or modification of a REMS or other restrictions on marketing and distribution, or a comparable foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, require us to issue a medication guide outlining the risks of such side effects for distribution to patients or restrict distribution of our products and impose burdensome implementation requirements on us;
- regulatory authorities may require that we conduct post-marketing studies; and
- We could be sued and held liable for harm caused to subjects or patients.

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

Changes in product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates are developed through preclinical studies to late-stage clinical trials towards regulatory approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical

trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA or comparable foreign regulatory authorities notification or approval.

Similarly, changes in the location of manufacturing or addition of manufacturing facilities may increase our costs and require additional studies and FDA approval. This may require us to ensure that the new facility meets all applicable regulatory requirements, is adequately validated and qualified, and to conduct additional studies of product candidates manufactured at the new location. Any of the above could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay regulatory approval of our product candidates and jeopardize our ability to commence product sales and generate revenue.

Even if we were able to commercialize our products focused on rare orphan diseases, product sales of these products might not justify the cost of development.

Because of the small patient population for a rare orphan disease, if pricing is not approved or accepted in the market at an appropriate level for an approved therapeutic product with orphan drug designation, such drug may not generate enough revenue to offset costs of development, manufacturing, marketing, and commercialization despite any benefits received from the rare orphan drug designation, such as market exclusivity, assistance in clinical trial design, or a reduction in user fees or tax credits related to development expense. Furthermore, our estimates regarding potential market size for any rare indication may be materially different from what we discover to exist at the time we commence commercialization, if any, for a therapeutic product, which could result in significant changes in our business plan and have a material adverse effect on our business, financial condition, results of operations, and prospects.

We face substantial competition and rapid technological change and the possibility that others may discover, develop or commercialize products before or more successfully than us.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We face competition with respect to our current product candidates and will face competition with respect to any future product candidates from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Many of our competitors have significantly greater financial, technical and human resources. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our competitors may obtain marketing approval of their products more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products.

Our competitors will also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

There are numerous currently approved therapies for treating the pediatric conditions our products address and, consequently, competition in these markets is intense. Many of these approved drugs are well established therapies or products and are widely accepted by physicians, patients and third-party payors. Some of these drugs are branded and subject to patent protection and non-patent regulatory exclusivity, and others are available on a generic basis.

Insurers and other third-party payors may also encourage the use of generic products or specific branded products. We expect that any of our product candidates, if approved, would be priced at a significant premium over competitive generic, including branded generic, products, but, 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. This may make it difficult for us to differentiate our product from currently approved therapies, which may adversely impact our business strategy. If we are not able to compete effectively against our current and future competitors, our business will not grow, and our financial condition and operations will suffer.

Our products might not achieve adequate market acceptance among physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if our product candidates have or receive marketing approval, they might not gain adequate market acceptance among physicians, patients and others in the medical community. Our commercial success also depends on coverage and adequate

reimbursement of our product candidates by third-party payors, including government payors, generally, which may be difficult or time-consuming to obtain, may be limited in scope or might not be obtained in all jurisdictions in which we may seek to market our products. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile of our product candidates, including relative to marketed products and product candidates in development by third parties;
- prevalence and severity of any side effects of our product candidates;
- relative convenience and ease of administration of our product candidates;
- cost effectiveness of our product candidates;
- the claims we may make for our product candidates based on the approved label or any restrictions placed upon our marketing and distribution of our product candidates;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
- how quickly and effectively we alone, or with a partner, can market, launch, and distribute any of our product candidates that receive marketing approval;
- the ability to commercialize any of our product candidates that receive marketing approval;
- the price of our products, including in comparison to branded or generic competitors and relative to alternative treatments;
- potential or perceived advantages of disadvantages over alternative treatments;
- the ability to collaborate with others in the development and commercialization of new products;
- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare;
- the ability to establish, maintain and protect intellectual property rights related to our product candidates;
- the entry of generic versions of our products onto the market;
- the number of products in the same therapeutic class as our product candidates;
- the effect of current and future healthcare laws on our drug candidates;
- the ability to secure favorable managed care formulary positions, including federal healthcare program formularies;
- the ability to manufacture commercial quantities of any of our product candidates that receive marketing approval;
- acceptance of any of our product candidates that receive marketing approval by physicians and other healthcare providers; and
- potential post-marketing commitments imposed on regulatory authorities, such as patient registries.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, third-party payors and patients, we might not generate or derive sufficient revenue from that product candidate and might not become or remain profitable.

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

Given our limited resources, we are focused on a limited number of product development opportunities. If these efforts are unsuccessful or, if successful but the products do not achieve an adequate level of market acceptance, we may no longer have the ability or resources to further develop any other product candidates. 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 might not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Risks Related to Regulatory Approval of Our Product Candidates

We may in the future conduct clinical trials for certain of our product candidates at sites outside the United States, and the FDA might not accept data from trials conducted in such locations.

We may in the future choose to conduct one or more of our clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to seek approval in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from any of our

clinical trials that we determine to conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of the product candidate.

The marketing approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming, costly and inherently unpredictable. Our inability to obtain regulatory approval for our product candidates would substantially harm our business.

The time required to obtain approval to market new drugs by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval. Moreover, the filing of an NDA or biologics license application ("BLA") for products that have not been granted ODD requires a payment of a significant application fee under the Prescription Drug User Fee Act upon submission. Any subsequent clinical data submissions to the NDA or BLA (i.e. for new indications) are also assessed an application fee. The filing of an NDA or BLA for our product candidates that do not have ODD may be delayed due to our lack of financial resources to pay such user fee.

Our product candidates could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree on the design or implementation of our clinical trials, including the methodology used in our trial, our chosen endpoints, our statistical analysis, or our proposed product indication. For instance, the FDA may find that the designs that we are utilizing in our planned clinical trial does not support an adequate and well-controlled study. The FDA also might not agree with the various disease scales and evaluation tools that we may use in our clinical trials to assess the efficacy of our product candidates. Further, the FDA might not agree with our endpoints and/or indications selected for our development programs;
- the FDA or comparable foreign regulatory authorities may disagree with our development plans for our product candidates;
- Our failure to demonstrate to the satisfaction of the FDA or comparable regulatory authorities that a product candidate is safe and effective for its proposed indication;
- Our clinical trials may fail to meet the level of statistical significance required for approval;
- We may fail to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- data collected from clinical trials of our product candidates may be insufficient to support the submission and filing of an NDA, other submission or to obtain marketing approval, and FDA may require additional studies to show that our product candidates are safe or effective;
- We may fail to obtain approval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; or
- there may be changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or comparable foreign regulatory authority may require more information, including additional preclinical or clinical studies to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain 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 or all of our product candidates for fewer or more limited indications than we request, may require that contraindications, warnings or precautions be included in the product labeling, including a black-box warning, may grant approval with a requirement of costly post-marketing clinical trials or other post-market requirements, 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.

Even if we complete the necessary clinical trials, we cannot predict when or if we will obtain marketing approval to commercialize a product candidate or the approval may be for a narrower indication than we expect.

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if our product candidates demonstrate safety and efficacy in clinical trials, the regulatory agencies might not

complete their review processes in a timely manner, or we might not be able to obtain marketing approval from the relevant regulatory agencies. Additional delays may result if the FDA, an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials and the review process. Regulatory authorities also may approve a product candidate for fewer or more limited indications than requested, may impose significant limitations in the form of narrow indications, warnings, including black-box warnings, precautions or contra-indications with respect to conditions of use or may grant approval subject to the performance of costly post-marketing clinical trials or other post-marketing requirements, including a REMS. In addition, regulatory agencies might not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Our drugs, if approved, may be required to carry warnings comparable to this and other class-wide warnings. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Even if we were to obtain approval for our product candidates with the Rare Pediatric Disease Designation, the Rare Pediatric Disease Priority Review Voucher Program may no longer be in effect at the time of such approval or we might not be able to capture the value of the Rare Pediatric Disease Priority Review Voucher Program.

Rare Pediatric Disease Designation ("RPDD") by the FDA is granted in the case of serious or life-threatening diseases affecting fewer than 200,000 people in the United States in which the serious or life-threatening manifestations are primarily in individuals 18 years of age and younger. The designation provides regulatory incentives for companies to develop and market therapies that treat these conditions. The sponsor of a drug for a rare pediatric disease may be eligible for a priority review voucher ("PRV") upon approval of the drug that can be used to obtain a priority review of a subsequent marketing application. The Consolidated Appropriations Act, 2021 was signed into law on December 27, 2020. As part of this legislation, the FDA Rare Pediatric Disease PRV Program has been extended through 2024, permitting the issuance of PRVs through September 30, 2024 for drugs and biologics receiving FDA approval before September 30, 2026. CERC-006, 801, 802 and 803 are each eligible for a PRV upon FDA approval of each drug, but there is no guarantee that we will receive such voucher(s). Moreover, any PRV may be sold or transferred an unlimited number of times. Although PRVs may be sold or transferred to third parties, there is no guarantee that we will be able to realize any value if we receive and were to sell a PRV.

There can be no assurance that we will apply for EUA for the product we are developing for the treatment of COVID-19 ARDS or, if we do apply, that it will be granted an EUA by the FDA. If no EUA is granted or, once granted, it is terminated, we will be unable to sell our product in the near future and will be required to pursue the drug approval process, which is lengthy and expensive.

We may seek an EUA from the FDA for the product we are developing for the treatment of COVID-19 induced ARDS. If granted, an EUA will allow us to market and sell our COVID-19 treatment without the need to pursue the lengthy and expensive drug approval process. The FDA may issue an EUA during a Public Health Emergency if it determines that the potential benefits of a product outweigh the potential risks and if other regulatory criteria are met. There is no guarantee that we will be able to obtain an EUA. If granted, we will rely on the FDA policies and guidance in connection with the marketing and sale of our product. If these policies and guidance change unexpectedly and/or materially or if we misinterpret them, potential sales of our product could be adversely impacted.

An EUA allowing the marketing and sale of our product will terminate upon expiration of the Public Health Emergency. The FDA may also terminate the EUA if safety issues or other concerns about our product arise or if we fail to comply with the conditions of authorization. Failure to obtain an EUA or the termination of such an authorization, if obtained, would adversely impact our business, financial condition and results of operations.

Even if our product candidates receive marketing approval, we will still be subject to ongoing regulatory 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 administrative sanctions or penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Even if we obtain marketing approval for a product candidate, we would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and annual reporting of safety and other post-market information. The FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may withdraw approval, require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. In addition, any marketing approvals that we

obtain 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 and other requirements, including Phase 4 clinical trials, imposition of a REMS and surveillance to monitor the safety and efficacy of the product candidate.

In addition, manufacturers of drug products and their facilities, including contracted facilities, are subject to periodic inspections by the FDA and other regulatory authorities for compliance with GMP regulations and standards. If we or a regulatory agency discover previously unknown problems with the facility where the product is manufactured, we may be subject to reporting obligations and a regulatory agency may impose restrictions on that product, the manufacturing facility, us, or our suppliers, including requesting recalls or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates, our contractors, the manufacturing facilities for our product candidates or others working on our behalf fail to comply with applicable regulatory requirements, either before or after marketing approval, a regulatory agency may:

- issue Warning Letters, Untitled Letters, or Form 483s, all of which document compliance issues identified by FDA;
- mandate modifications to promotional materials or labeling, or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines, restitution or disgorgement, as well as imprisonment;
- suspend or withdraw marketing approval;
- suspend or terminate any ongoing clinical studies;
- refuse to approve pending applications or supplements to applications filed by us;
- debar us from submitting marketing applications, exclude us from participation in federal healthcare programs, require a corporate integrity agreement or deferred prosecution agreements, debar us from government contracts and refuse future orders under existing contracts;
- suspend or impose restrictions on operations, including restrictions on marketing, distribution or manufacturing of the product, or the imposition of costly new manufacturing requirements or use of alternative suppliers; or
- seize or detain products, refuse to permit the import or export of products, or request that we initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to continue our development programs, commercialize our products and generate revenue.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice, the Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress and the public. While the FDA does not restrict physicians from prescribing approved drugs for uses outside of the drugs' approved labeling, known as off-label use, pharmaceutical manufacturers are strictly prohibited from promoting and marketing their products for such uses. Violations, including promotion of our products for off-label uses, are subject to enforcement letters, inquiries, investigations, civil and criminal sanctions by the government, corporate integrity agreements, deferred prosecution agreements, debarment from government contracts and refusal of future orders under existing contracts, and exclusion from participation in federal healthcare programs. Additionally, comparable foreign regulatory authorities will heavily scrutinize advertising and promotion of any product candidate that obtains approval outside of the United States.

In the United States, engaging in the impermissible promotion of our products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines, debarment from government contracts and refusal of future orders under existing contracts, deferred prosecution agreements, and corporate integrity agreements with governmental authorities that materially restrict the manner in which a company promotes or distributes drug products. These false claims statutes include the federal civil False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual will share in any fines or settlement funds. If the government does not intervene, the individual may proceed on his or her own. Since 2004, these False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements, such as settlements regarding certain sales practices promoting off-label drug uses involving fines that are as much as $3.0 billion. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations and prospects.

The FDA's policies may change, and additional government regulations may be enacted that could prevent, limit or delay marketing approval, and the sale and promotion 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.

If we are unable to obtain, or are delayed in obtaining, state regulatory licenses for the distribution of our products, we would not be able to sell our product candidates in such states.

The majority of states require manufacturer and/or wholesaler licenses for the sale and distribution of drugs into that state. The application process is complicated, time consuming, costly and requires dedicated personnel or a third party to oversee and manage. If we are delayed in obtaining these state licenses, or denied the licenses, even with FDA approval, we would not be able to sell or ship product into that state which would adversely affect our sales and revenues.

Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidates outside the United States, which would limit our market opportunities and adversely affect our business.

In order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country might not be accepted by regulatory authorities in other countries. If we fail to comply with the regulatory requirements in international markets and receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We might not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions. Approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. Also, regulatory approval for any of our product candidates may be withdrawn. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval in another jurisdiction. Our failure to obtain approval of any of our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business prospects could decline.

Risks Related to the Commercialization of Our Product Candidates

We might not be successful in our efforts to develop and commercialize our preclinical product candidates.

Our continued development of our preclinical product candidates will be dependent on receiving positive preclinical data that, in our judgment, merits advancing such programs. Even if we are successful in continuing to build and expand our pipeline, the potential product candidates that we identify might not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. Similarly, even if the FDA accepts our Investigational New Drug Applications ("INDs"), there is no guarantee that we will be successful in our efforts to advance our preclinical product candidates into clinical trials.

There can be no assurance of market acceptance for our treatment of COVID-19 ARDS.

The commercial success of our treatment of COVID-19 ARDS will depend upon its acceptance as efficacious, safe, cost-effective and medically necessary by healthcare providers, patients, the medical community and third-party payers. There can be no assurance our COVID-19ARDS treatment will gain market acceptance on a timely basis, if at all. Healthcare providers and patients may choose COVID-19 ARDS treatments sold by our competitors. Third party payers may prefer competitor products when making formulary and reimbursement decisions. If our product does gain market acceptance, there is no guarantee that we will be able to maintain it as new products enter the market. The United States and other countries around the world have approved and commenced distributing COVID-19 vaccines in their jurisdictions. Additional vaccine candidates are in development. The broad distribution of COVID-19 vaccines may reduce demand for our COVID-19 ARDS treatment as it may no longer be considered medically necessary. Failure to achieve and maintain market acceptance will have a material adverse impact on our business, financial condition and results of operations.

Once commercialized, some of our products may face significant competition from non-prescription competition and consumer substitution, and our operating results will suffer if we fail to compete effectively.

We may be subject to non-prescription competition and consumer substitution for certain of our pipeline assets. For example, the three preclinical therapies in our pediatric orphan rare disease pipeline, CERC-801, CERC-802 and CERC-803, are ultra-pure formulations of D-galactose, D-mannose and L-fucose, respectively. These formulations are naturally occurring substances contained in various foods, including dairy products and fruit. Additionally, D-galactose and D-mannose are also marketed by others as non-prescription dietary supplements. Once approved by the FDA and commercially available, we cannot be sure physicians will view the pharmaceutical grade purity and tested safety of CERC-801, CERC-802 or CERC-803 as having a superior therapeutic profile to the naturally occurring formulations and dietary supplements. In addition, to the extent the net price of CERC-801, CERC-802 or CERC-803, after insurance and offered discounts, is significantly higher than the prices of commercially available formulations marketed by other companies as dietary supplements (through that lack of coverage by insurers or otherwise), physicians and pharmacists may recommend these commercial alternatives instead of writing or filling prescriptions for CERC-801, CERC-802 or CERC-803, or patients may elect on their own to take commercially available supplements. Either of these outcomes may adversely impact our results of operations by limiting how we price our product and limiting the revenue we receive from the sale of CERC-801, CERC-802 and CERC-803 due to reduced market acceptance.

If we obtain approval to commercialize our product candidates outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If any of our product candidates are approved for commercialization, we may enter into agreements with third parties to market them on a worldwide basis or in more limited geographical regions. We expect that we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for approval of drugs in foreign countries;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- foreign reimbursement, pricing and insurance regimes;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- foreign taxes;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or comparable foreign regulations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

Even if we commercialize any of our product candidates, these products may become subject to unfavorable third-party coverage and reimbursement policies, healthcare reform initiatives, or pricing regulations, any of which could negatively impact our business.

Our ability to commercialize any products successfully will depend in part on the extent to which coverage and adequate reimbursement for these products will be available from government authorities, private health insurers, health maintenance organizations and other entities. These third-party payors determine which medications they will cover and establish reimbursement levels, and increasingly attempt to control costs by limiting coverage and the amount of reimbursement for particular medications. Several third-party payors are requiring that drug companies provide them with predetermined discounts from list prices, are using preferred drug lists to leverage greater discounts in competitive classes and are challenging the prices charged for drugs. In addition, federal programs impose penalties on drug manufacturers in the form of mandatory additional rebates and/or discounts if commercial prices increase at a rate greater than the Consumer Price Index-Urban, and these rebates and/or discounts, which can be substantial, may impact our ability to raise commercial prices. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if coverage is available, what the level of reimbursement will be. Coverage and reimbursement

may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or available only to limited levels, we might not successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates for a drug may vary according to the clinical setting in which it is used and may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Prices paid for a drug also vary depending on the class of trade. Prices charged to government customers are subject to price controls and private institutions obtain discounts through group purchasing organizations. Net prices for drugs may be further reduced by mandatory discounts or rebates required by government healthcare programs and demanded by private payors, and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Moreover, the regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates even if our product candidates obtain marketing approval.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and related to the commercial sale of our products. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our products. For example, we may be sued if any product we sell 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 claims that our product candidates or products that we may develop caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- diversion of management and scientific resources from our business operations;
- the inability to commercialize any products that we may develop; and
- a decline in our stock price.

We currently hold product and clinical trial liability insurance coverage, but it might not adequately cover all liabilities that we incur. We might not be able to maintain clinical trial insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We also maintain insurance coverage for our commercially available products, which might not adequately cover all liabilities that we may incur. We might not be able to maintain insurance coverage for our approved products at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A product liability claim or series of claims brought against us, whether or not successful, but particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our reputation and business.

If, in the future, we are unable to grow our own sales, or establish marketing and distribution capabilities or enter into licensing or collaboration agreements for these purposes, we might not be successful in commercializing our product candidates.

We do not currently have a robust sales or marketing infrastructure. To develop our internal sales, distribution and marketing capabilities for new product candidates, we will have to invest significant amounts of financial and management resources, some of which will be committed prior to any confirmation that any new product candidates will be approved. For product candidates for which we decide to perform sales, marketing and distribution functions ourselves, we could face a number of additional risks, including:

- Our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- inability of marketing personnel to develop effective marketing materials;
- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the clinical benefits of our products to achieve market acceptance;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- the costs associated with training sales personnel on legal compliance matters and monitoring their actions;
- liability for sales personnel failing to comply with the applicable legal requirements; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Where and when appropriate, we may elect to utilize contract sales forces or strategic partners to assist in the commercialization of our product candidates. If we enter into arrangements with third parties to perform sales, marketing and distribution services for our products, the resulting revenues or the profitability from these revenues to us are likely to be lower than if we had sold, marketed and distributed our products ourselves. In addition, we might not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell, market and distribute our products effectively. Such third parties may also not comply with the applicable regulatory requirements, which could potentially expose us to regulatory and legal enforcement actions.

Risks Related to Our Dependence on Third Parties

We might not succeed in establishing and maintaining development collaborations, which could adversely affect our ability to develop and commercialize product candidates.

A part of our strategy is to enter into product development collaborations in the future, including collaborations with major biotechnology or pharmaceutical companies for the development or commercialization of our current and future product candidates. We also face significant competition in seeking appropriate development partners and the negotiation process is time-consuming and complex. We might not succeed in our efforts to establish development collaborations or other alternative arrangements for any of our existing or future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early a stage of development for collaborative effort and/or third parties might not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy.

Furthermore, any collaborations that we enter into might not be successful. The success of our development collaborations will depend heavily on the efforts and activities of our collaborators. Furthermore, any collaborations that we enter into might not be successful. The success of our development collaborations will depend heavily on the efforts and activities of our collaborators. Our relationship with any future collaborations may pose several risks, including the following:

- collaborators have significant discretion in determining the amount and timing of the efforts and resources that they will apply to these collaborations;
- collaborators might not perform their obligations as expected;
- the nonclinical studies and clinical trials conducted as part of these collaborations might not be successful;
- collaborators might not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on nonclinical study or clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay nonclinical studies and clinical trials, provide insufficient funding for nonclinical studies and clinical trials, stop a nonclinical study or clinical trial or abandon a product candidate, repeat or conduct new nonclinical studies or clinical trials or require a new formulation of a product candidate for nonclinical studies or clinical trials;
- We might not have access to, or may be restricted from disclosing, certain information regarding product candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our stockholders about the status of such product candidates;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates developed in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval might not commit sufficient resources to the marketing and distribution of any such product candidate;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any product candidates, may cause delays or termination of the research, development or commercialization of such product candidates, may lead to additional responsibilities for us with respect to such product candidates or may result in litigation or arbitration, any of which would be time consuming and expensive;
- collaborators might not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the ownership or inventorship of intellectual property developed pursuant to our collaborations;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- the terms of our collaboration agreement may restrict us from entering into certain relationships with other third parties, thereby limiting our options; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Even if we are successful in our efforts to establish development collaborations, the terms that we agree upon might not be favorable to us and we might not be able to maintain such development collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product candidate are disappointing. Any delay in entering into development collaboration agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market. Additionally, collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

If we fail to establish and maintain additional development collaborations related to our product candidates:

- the development of certain of our current or future product candidates may be terminated or delayed;
- our cash expenditures related to development of certain of our current or future product candidates would increase significantly and we may need to seek additional financing, which might not be available on favorable terms, or at all;
- we may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for which we have not budgeted;
- we will bear all of the risk related to the development of any such product candidates;
- we may have to expend unexpected efforts and funds if we are unable to obtain the results of third-party clinical trials; and
- the competitiveness of any product candidate that is commercialized could be reduced.

We rely on third parties to conduct, supervise and monitor our clinical trials. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we might not obtain marketing approval for or commercialize our product candidates in a timely manner or at all.

We rely upon third-party CROs to monitor and manage data for our clinical programs. We rely on these parties for execution of our clinical trials and, while we have agreements governing their activities, we have limited influence over their actual performance 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, our clinical trial sites, and our CROs are required to comply with GCP requirements, 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 products in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we, any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications, if at all. In addition, we are required to report certain financial interests of our third-party investigators if these

relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by principal investigators who previously served or currently serve as scientific advisors or consultants to us from time to time and receive cash compensation in connection with such services or otherwise receive compensation from us that could be deemed to impact study outcome, proprietary interests in a product candidate, certain company equity interests, or significant payments of other sorts. 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 GCP requirements. In addition, we must conduct our clinical trials with product produced under applicable GMP requirements. Failure to comply with these regulations may require us to repeat preclinical and clinical trials, which would delay the marketing approval process.

Our CROs and clinical trial sites are not our employees, and, except for remedies available to us under our agreements with such CROs and clinical trial sites, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. These CROs and clinical trial sites may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If CROs or clinical trial sites do not successfully carry out their contractual duties or obligations or meet expected deadlines, 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 might not be able to obtain marketing approval for or successfully commercialize our product candidates or we may be subject to regulatory enforcement actions. 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. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be adversely affected.

Switching or adding CROs involves substantial cost and requires extensive 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, prospects, financial condition and results of operations.

We use third parties to manufacture all of our product candidates. This may increase the risk that we will not have sufficient quantities of our product candidates to conduct our clinical trials or such quantities at an acceptable cost, which could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates.

We do not own or operate, and have no plans to establish, any manufacturing facilities for our product candidates. We have limited personnel with experience in drug manufacturing and we lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale.

We currently outsource all manufacturing of our product candidates to third parties typically without any guarantee that there will be sufficient supplies to fulfill our requirements or that we may obtain such supplies on acceptable terms. Any delays in obtaining adequate supplies with respect to our product candidates may delay the development or commercialization of our other product candidates.

In addition, we do not currently have agreements with all third-party manufacturers for the long-term commercial supply of our product candidates. We may be unable to enter agreements for commercial supply with third-party manufacturers, or may be unable to do so on acceptable terms. Even if we enter into these agreements, the various manufacturers of each product candidate will likely be single source suppliers to us for a significant period of time.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA or BLA to the FDA. While we are ultimately responsible for the manufacture of our product candidates, other than through our contractual arrangements, we do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with GMP requirements for manufacture of both active drug substances and finished drug products for clinical supply and eventually for commercial supply, if we receive regulatory approval. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. Failure of our contract manufacturers to comply with the applicable regulatory requirements may also subject us to regulatory enforcement actions. In addition, other than through our contractual agreements, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved.

Reliance on third-party manufacturers subjects us to risks that would not affect us if we manufactured the product candidates ourselves, including:

- reliance on the third parties for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreements by the third parties because of factors beyond our control;
- the possible misappropriation of our proprietary information, including trade secrets and know-how;
- the possibility of termination or nonrenewal of the agreements by the third parties because of our breach of the manufacturing agreement or based on our own business priorities;
- the disruption and costs associated with changing suppliers, including additional regulatory filings.
- failure to satisfy our contractual duties or obligations;
- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and/or product quality issues related to manufacturing development and scale-up;
- costs and validation of new equipment and facilities required for scale-up;
- failure to comply with applicable laws, regulations, and standards, including cGMP and similar foreign standards;
- deficient or improper record-keeping;
- contractual restrictions on our ability to engage additional or alternative manufacturers;
- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell our product candidates or any future product candidate in a timely fashion, in sufficient quantities or under acceptable terms;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- lack of access or licenses to proprietary manufacturing methods used by third-party manufacturers to make our product candidates;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or regulatory sanctions related to the manufacture of our or other company's products;
- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our products under specified storage conditions and in a timely manner.

Our product candidates may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing for us and willing to do so. In addition, the manufacture of biologics requires significant expertise, including the development of advanced manufacturing techniques and process controls. The process is highly complex and we may encounter difficulties in production. These issues may include difficulties with production costs, production yields and quality control, including stability of the product candidate. Further, our product candidates may require new or specialized manufacturing with limited third-party manufacturers available to provide these services. The occurrence of any of these problems could significantly delay our clinical trials or the commercial availability of our product candidates. If our existing third-party manufacturers, or the third parties that we engage in the future to manufacture a product for commercial sale or for our clinical trials, should cease to continue to do so for any reason, we likely would experience delays in obtaining sufficient quantities of our product candidates for us to meet commercial demand or to advance our clinical trials while we identify and qualify replacement suppliers. If for any reason we are unable to obtain adequate supplies of our product candidates or the drug substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively.

Our suppliers are subject to regulatory requirements, covering manufacturing, testing, quality control, manufacturing, and record keeping relating to our product candidates, and subject to ongoing inspections by the regulatory agencies. Failure by any of our suppliers to comply with applicable regulations may result in long delays and interruptions to our manufacturing capacity while we seek to secure another supplier that meets all regulatory requirements, as well as market disruption related to any necessary recalls or other corrective actions.

We will continue to depend on Aytu to provide us with certain services to manage the operations of Millipred.

In connection with the Aytu Divestiture, we retained the rights to Millipred and entered into a Transition Services Agreement with Aytu. Pursuant to the Transition Services Agreement, Aytu is responsible for managing the commercial operations of Millipred, including providing accounting reporting services and managing the third-party logistics provider for up to 18 months (post November 1, 2019). We exercise no control over the activities of Aytu, other than the contractual rights we have pursuant to our Transition

Services Agreement. If Aytu were to fail to fulfill all of its obligations under the Transition Service Agreement, we could suffer operational difficulties or a significant reduction in our net revenue from sales of Millipred. If Aytu ceases to provide services pursuant to the Transition Services Agreement, including upon expiration of the term of the Agreement, we might not be able to reestablish our commercial infrastructure to replace these services in a timely manner, if at all, which would materially adversely affect our financial position. Furthermore, upon expiration of the Transition Service Agreement, we might not be able to renegotiate such agreement or if we are able to renegotiate such agreement it might not be available on favorable terms.

The revenue generated by sales of Millipred will be received by Aytu and subsequently transferred to us, and any delay or default in payment by Aytu to us of these revenues could adversely affect our cash flows, financial condition, and results of operations. Pursuant to the Transition Services Agreement, Aytu is responsible for managing the commercial operations of Millipred and is obligated to transfer the revenue generated by sales of Millipred to us on a timely basis. Adverse economic conditions or financial difficulties of Aytu could impair its ability to remit such payment or could cause Aytu to delay such payments. Furthermore, if Aytu were unable to meet its obligations, it could consider restructuring under the bankruptcy laws, which might make it difficult for us to collect all or a significant portion of the revenues generated by Millipred. Our inability to collect our revenues generated by Millipred from Aytu could adversely affect our cash flows, financial condition, and results of operations.

Risks Related to Intellectual Property

As appropriate, we intend to seek all available periods of regulatory exclusivity for our product candidates. However, there is no guarantee that we will be granted these periods of regulatory exclusivity or that we will be able to maintain these periods of exclusivity.

The FDA grants product sponsors certain periods of regulatory exclusivity, during which the agency might not approve, and in certain instances, might not accept, certain marketing applications for competing drugs. For example, product sponsors may be eligible for five years of exclusivity from the date of approval of a new chemical entity, seven years of exclusivity for drugs that are designated to be orphan drugs, and/or a six-month period of exclusivity added to any existing exclusivity period or patent life for the submission of FDA requested pediatric data. While we intend to apply for all periods of market exclusivity that we may be eligible for, there is no guarantee that we will receive all such periods of market exclusivity. Additionally, under certain circumstances, the FDA may revoke the period of market exclusivity. As a result, there is no guarantee that we will be able to maintain a period of market exclusivity, even if granted. In the case of ODD, other benefits, such as tax credits and exemption from user fees may be available. If we are not able to obtain or maintain orphan drug designation or any period of market exclusivity to which we may be entitled, we will be materially harmed, as we will potentially be subject to greater market competition and may lose the benefits associated with programs.

If we are unable to obtain or maintain intellectual property rights, or if the scope of patent protection is not sufficiently broad, competitors could develop and commercialize products similar or identical to ours, and we might not be able to compete effectively in our market.

Our success depends in significant part on our and our licensors', licensees' or collaborators' ability to establish, maintain and protect patents and other intellectual property rights and operate without infringing the intellectual property rights of others. We have filed numerous patent applications both in the United States and in foreign jurisdictions to obtain patent rights to inventions we have discovered. We have also licensed from third parties' rights to patent portfolios.

The patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees or collaborators might not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors, licensees or collaborators will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, in some circumstances, we might not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors, licensees or collaborators. Therefore, these patents and applications might not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors, licensees or collaborators fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors, licensees or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaborators' patent rights are highly

uncertain. Our and our licensors', licensees' or collaborators' pending and future patent applications might not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our licensors, licensees or collaborators to narrow the scope of the claims of our or our licensors', licensees' or collaborators' pending and future patent applications, which may limit the scope of patent protection that may be obtained. Our and our licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology.

Furthermore, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio might not provide us with sufficient rights to exclude others from commercializing products similar or identical to our products. We expect to seek extensions of patent terms where these are available in any countries where we are prosecuting patents. This includes in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, which permits a patent term extension of up to five years beyond the expiration of the patent. However, the applicable authorities, including the FDA in the United States, and any equivalent regulatory authority in other countries, might not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

If we breach the license and development agreements related to our product candidates, we could lose the ability to develop and commercialize our product candidates.

Our commercial success depends upon our ability, and the ability of our licensors and collaborators, to develop, manufacture, market and sell our product candidates and use our and our licensors' or collaborators' proprietary technologies without infringing the proprietary rights of third parties. If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose the ability to continue the development and commercialization of our product candidates or face other penalties under these agreements. We are party to the following agreements:

- exclusive license agreements with Merck & Co., Inc. and its affiliates for the compounds used in CERC-301 and the COMTi platform, including CERC-406;
- a License Agreement and a Sponsored Research Agreement with CHOP, and an Amended and Restated Clinical Development and Option Agreement with Kyowa Kirin Co., Ltd. pursuant to which we exclusively license certain technology related to CERC-002;
- an Exclusive License Agreement with OSI Pharmaceuticals, LLC, a wholly owned subsidiary of Astellas Pharma, Inc., for CERC-006; and
- an Option and License Agreement with MedImmune Limited, a subsidiary of AstraZeneca plc, for CERC-007 (the "AZ Agreement").

If we fail to comply with the obligations under these agreements, including payment terms, our licensors may have the right to terminate any of these agreements, in which event we might not be able to develop, market or sell the relevant product candidate. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in us having to negotiate new or reinstated agreements, which might not be available to us on equally favorable terms, or at all, or cause us to lose our rights under these agreements, including our rights to intellectual property or technology important to our development programs. Any of these occurrences may harm our business, financial condition and prospects significantly.

We may be required to make significant payments in connection with our license and development agreements.

We are party to license and development agreements with various third parties. For example, we are party to a License Agreement and a Sponsored Research Agreement with CHOP, and an Amended and Restated Clinical Development and Option Agreement with Kyowa Kirin Co., Ltd. (the "KKC Development and Option Agreement") pursuant to which we exclusively license certain technology related to CERC-002, an Exclusive License Agreement with OSI Pharmaceuticals, LLC, a wholly owned subsidiary of Astellas Pharma, Inc. ("Astellas"), for CERC-006 (the "Astellas Agreement") and the AZ Agreement. We may be required to make significant payments in connection with the License Agreement and Sponsored Research Agreement with CHOP and have certain ongoing payment obligations with respect to the Sponsored Research Agreement with CHOP. If we exercise our option under the terms of the KKC Development and Option Agreement, we will be obligated to cover significant development costs for CERC-002 and make significant payments in connection with certain milestones and the sale of resulting products. As a result of our exercise of the option granted under the AZ Agreement, we are obligated to spend significant amounts to develop the program.

Because we are developing CERC-006, we will have significant obligations to Astellas under the Astellas Agreement. If the obligations become due under the terms any of these agreements, we might not have sufficient funds available to meet our obligations and our development efforts may be negatively impacted. In addition, if we do not have sufficient funds to pay our ongoing obligations under the agreements with CHOP, we may lose our rights under the License Agreement and Sponsored Research Agreement with CHOP, which could negatively impact CERC-002 as well as our ongoing efforts to identify new targets and programs for development.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO, and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, 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. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors or collaborators fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Third parties may initiate legal proceedings against us alleging that we infringed their intellectual property rights, or we may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Third parties may initiate legal proceedings against us or our licensors or collaborators alleging that we or our licensors or collaborators infringe their intellectual property rights or we or our licensors or collaborators may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, interferences, reexaminations, inter partes reviews or derivation proceedings before the United States or other jurisdictions. These proceedings can be expensive and time-consuming and many of our or our licensors' or collaborators' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaborators can.

An unfavorable outcome could require us or our licensors or collaborators to cease using the related technology or developing or commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license on commercially reasonable terms or at all. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business.

Third parties may infringe on our or our licensors' or collaborators' patents or misappropriate or otherwise violate our or our licensors' or collaborators' intellectual property rights. In the future, we or our licensors or collaborators may initiate legal proceedings to enforce or defend our or our licensors' or collaborators' intellectual property rights, to protect our or our licensors' or collaborators' trade secrets or to determine the validity or scope of intellectual property rights we own or control. Also, third parties may initiate legal proceedings against us or our licensors or collaborators to challenge the validity or scope of intellectual property rights we own or control. The proceedings can be expensive and time-consuming and many of our or our licensors' or collaborators' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaborators can. Accordingly, despite our or our licensors' or collaborators' efforts, we or our licensors or collaborators might not prevent third parties from infringing upon or misappropriating intellectual property rights we own or control, particularly in countries where the laws might not protect those rights as fully as in the United States. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using

the technology at issue on the grounds that we or our licensors' or collaborators' patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our or our licensors' or collaborators' patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Third party pre-issuance submission of prior art to the USPTO, or opposition, derivation, reexamination, inter partes review or interference proceedings, or other pre-issuance or post-grant proceedings in the United States or other jurisdictions provoked by third parties or brought by us or our licensors or collaborators may be necessary to determine the priority of inventions with respect to our or our licensors' or collaborators' patents or patent applications. An unfavorable outcome could require us or our licensors or collaborators to cease using the related technology and commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license on commercially reasonable terms or at all. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators. In addition, if the breadth or strength of protection provided by our or our licensors' or collaborators' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and it may distract our management and other employees. We could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent.

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 this type of 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 our warrants or shares of our common stock.

Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Though we seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties, as well as by entering into confidentiality and invention or patent assignment agreements with our employees and consultants, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we might not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. If a competitor lawfully and without breach of a confidentiality obligation obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time-consuming, and inherently uncertain. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors' or collaborators' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts, and the USPTO the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensors' or collaborators' ability to obtain new patents or to enforce existing patents and patents we and our licensors or collaborators may obtain in the future. Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents. On September 16, 2011, the America Invents Act was signed into law. The America Invents Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO also developed regulations and procedures to govern administration of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and in particular, the first to file provisions, only became effective on March 16, 2013. The America Invents Act and its implementation could increase the uncertainties and costs surrounding the

prosecution of our or our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents, all of which could have a material adverse effect on our business and financial condition.

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

Filing, prosecuting, enforcing and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our or our licensors' or collaborators' intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we and our licensors or collaborators might not be able to prevent third parties from practicing our and our licensors' or collaborators' inventions in all countries outside the United States, or from selling or importing products made using our and our licensors' or collaborators' inventions in and into the United States or other jurisdictions. Competitors may use our and our licensors' or collaborators' 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 and our licensors or collaborators have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and our and our licensors' or collaborators' patents or other intellectual property rights might not be effective or sufficient to prevent them from 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 and our licensors or collaborators to stop the infringement of our and our licensors' or collaborators' patents or marketing of competing products in violation of our and our licensors' or collaborators' proprietary rights generally. Proceedings to enforce our and our licensors' or collaborators' patent rights in foreign jurisdictions could result in substantial costs and divert our and our licensors' or collaborators' efforts and attention from other aspects of our business, could put our and our licensors' or collaborators' patents at risk of being invalidated or interpreted narrowly and our and our licensors' or collaborators' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors or collaborators. We or our licensors or collaborators might not prevail in any lawsuits that we or our licensors or collaborators initiate and the damages or other remedies awarded, if any, might not be commercially meaningful.

The requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. Furthermore, generic or biosimilar drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' or collaborators' patents, requiring us or our licensors or collaborators to engage in complex, lengthy and costly litigation or other proceedings. Generic or biosimilar drug manufacturers may develop, seek approval for, and launch biosimilar versions of our products. Certain countries, including India and China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors or collaborators may have limited remedies if patents are infringed or if we or our licensors or collaborators are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensors' or collaborators' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

Risks Related to Legal Compliance

The Affordable Care Act and any changes in healthcare law may increase the difficulty and cost for us to commercialize our products and affect the prices we may obtain.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that may affect our ability to profitably sell our product and product candidates, if approved. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. The Affordable Care Act was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the Affordable Care Act that have been implemented since enactment and are of importance to the commercialization of our product and product candidates, if approved, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs or biologic agents;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the U.S. civil False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- requirements to report certain financial arrangements with physicians and teaching hospitals;
- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There have been significant ongoing judicial, administrative, executive and legislative efforts to modify or eliminate the Affordable Care Act. For example, the Tax Act enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the IRC, commonly referred to as the individual mandate. The Trump administration issued executive orders which sought to reduce burdens associated with the Affordable Care Act and modified how it was implemented. Other legislative changes have been proposed and adopted since passage of the Affordable Care Act. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of an amount greater than $1.2 trillion for the fiscal years 2012 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions included aggregate reductions to Medicare payments to healthcare providers of up to 2% per fiscal year, which went into effect in April 2013. Subsequent litigation extended the 2% reduction, on average, to 2030 unless additional Congressional action is taken. However, pursuant to the Coronavirus Aid, Relief and Economic Security Act, the 2% Medicare sequester reductions have been suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. On January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

The Affordable Care Act has also been subject to challenges in the courts. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional and remanded the case to the Texas District Court to reconsider its earlier invalidation of the entire Affordable Care Act. An appeal was taken to the U.S. Supreme Court which heard oral arguments in the case on November 10, 2020. A ruling is expected in 2021.

Further changes to and under the Affordable Care Act remain possible, although the new Biden administration has signaled that it plans to build on the Affordable Care Act and expand the number of people who are eligible for subsidies under it. President Biden indicated that he intends to use executive orders to undo changes to the Affordable Care Act made by the Trump administration and would advocate for legislation to build on the Affordable Care Act. It is unknown what form any such changes or any law proposed to replace the Affordable Care Act would take, and how or whether it may affect our business in the future. We expect that changes to the Affordable Care Act, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry.

We expect that the Affordable Care Act, as well as other healthcare reform measures that have and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for our product and product candidates, if approved, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain and maintain profitability of our product and product candidates, if approved.

Our relationships with commercial and government customers, healthcare providers, and third party payors and others are subject to applicable anti-kickback, fraud and abuse, transparency and other healthcare related laws, regulations and requirements, which

could expose us to criminal sanctions, civil penalties, exclusion from participation in federal healthcare programs, contractual damages and consequences, reputational harm, administrative burdens and diminished profits and future earnings.

Pharmaceutical companies participating in federal and/or state healthcare programs such as Medicare and Medicaid are subject to a multitude of federal and state laws and regulations which are intended to address and prevent "fraud and abuse". These laws also apply to the physicians and third-party payors who play a primary role in the recommendation and prescription of our commercially available products. Our arrangements with providers, payors, and patients may expose us to broadly applicable fraud and abuse laws. These laws may constrain the business or financial arrangements and relationships through which we market, sell, and distribute our products. There are also laws, regulations, and requirements applicable to the award and performance of federal grants and contracts.

Actions resulting in violations of these laws regulations, and requirements may result in civil and criminal liability, damages and restitution, as well as exclusion from participation in federal healthcare programs, corporate integrity agreements, deferred prosecution agreements, debarment from government contracts and grants and refusal of future orders under existing contracts or contractual damages, and other consequences. Restrictions under applicable federal and state healthcare related laws and regulations, include the following:

- the federal Anti Kickback Statute prohibits persons from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending purchase, lease or order, of any good or service for which payment may be made under a federal healthcare program;
- the civil federal False Claims Act imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; conspiring to defraud the government by getting a false or fraudulent claim paid or approved by the government; or knowingly making, using or causing to be made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the criminal federal False Claims Act imposes criminal fines or imprisonment against individuals or entities who willfully make or present a claim to the government knowing such claim to be false, fictitious or fraudulent;
- the Veterans Health Care Act requires manufacturers of covered drugs to offer them for sale on the Federal Supply Schedule, which requires compliance with applicable federal procurement laws and regulations and subject us to contractual remedies as well as administrative, civil and criminal sanctions;
- HIPAA and its related regulations impose criminal liability for, among other actions, knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, or knowingly and willfully making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, also imposes obligations on certain covered entity health care providers, health plans, and health care clearinghouses as well as their business associates that perform certain services involving individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, as well as directly applicable privacy and security standards and requirements
- the civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent;
- the federal Physician Sunshine Act, created under Section 6002 of the Affordable Care Act and its implementing regulations, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare and Medicaid Services, or CMS, information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians (as defined above) and their immediate family members;
- the FCPA prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including

international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations; and

- analogous or similar state, federal, and foreign laws, regulations, and requirements such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; laws, regulations, and requirements applicable to the award and performance of federal contracts and grants and state, federal and foreign laws that govern the privacy and security of health and other information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations involve substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. In addition, recent health care reform legislation has strengthened these laws. If our operations are found to be in violation of any of these laws or any other governmental regulations or requirements that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, restitution exclusion from government funded healthcare programs, such as Medicare and Medicaid, corporate integrity agreements, deferred prosecution agreements, debarment from government contracts and grants and refusal of future orders under existing contracts, contractual damages, the curtailment or restructuring of our operations and other consequences. If any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Moreover, availability of any federal grant funds which we may receive or for which we may apply is subject to federal appropriations law. Grant funding may also be withdrawn or denied for other reasons.

Our business and operations could suffer in the event of computer system failures, cyber-attacks or deficiencies in our cyber-security.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, research data, our proprietary business information and that of our suppliers, technical information about our products, clinical trial plans and employee records. Similarly, our third-party providers possess certain of our sensitive data and confidential information. The secure maintenance of this information is critical to our operations and business strategy. Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, ransomware, cyber fraud, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, encrypted, lost or stolen. Any such access, inappropriate disclosure of confidential or proprietary information or other loss of information, including our data being breached at third-party providers, could result in legal claims or proceedings, liability or financial loss under laws that protect the privacy of personal information, disruption of our operations or the development of our pipeline assets and damage to our reputation, which could adversely affect our business. 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. Furthermore, as a result of cyber-attacks we may inadvertently misappropriate assets that we may not be able to fully recover.

We may be subject to future litigation against us, including securities litigation, which could be costly and time-consuming to defend.

The market price of our securities may be volatile, and in the past, companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business. Any adverse determination in litigation could also subject us to significant liabilities.

We may also become subject, from time to time, to legal proceedings and claims that arise in the ordinary course of business such as claims brought by our clients in connection with commercial disputes, or employment claims made by our current or former associates. Litigation might result in substantial costs and may divert management's attention and resources, which might seriously harm our business, overall financial condition, and operating results. Insurance might not cover such claims, might not provide sufficient payments to cover all the costs to resolve one or more such claims, and might not continue to be available on terms acceptable to us. A claim brought against us that is uninsured or underinsured could result in unanticipated costs, thereby reducing our operating results and leading analysts or potential investors to reduce their expectations of our performance, which could reduce the trading price of our stock.

Risks Related to Employee Matters and Managing Our Growth

If we fail to attract and keep management and other key personnel, as well as our board members, we may be unable to develop our product candidates or otherwise implement our business plan.

Our success will depend on the retention of our directors and members of our management and technical team including Michael F. Cola, Chief Executive Officer, Dr. Younok Dumortier Shin, Chief Technology Officer, Dr. Garry A. Neil, Chief Scientific Officer, James A. Harrell, Jr., Chief Commercial Officer, Schond L. Greenway, Chief Financial Officer, Chris Sullivan, Chief Accounting Officer, Dr. H. Jeffrey Wilkins, Chief Medical Officer, Lisa Hegg Ph.D., Vice President of Research and Development Programs and Project Management, and Colleen Matkowski, Vice President of Global Regulatory Affairs, and on our ability to continue to attract and retain highly skilled and qualified personnel. We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. As such, we could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. Many of the other biotechnology and pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we will have. 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 that which we have to offer. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will impede significantly our ability to implement our business strategy and achieve our business objectives. There can be no assurance that we will retain the services of any of our directors, officers or employees, or attract or retain additional senior managers or skilled employees. Furthermore, we do not intend to carry key man insurance with respect to any of such individuals.

Our Chief Executive Officer and our Chief Scientific Officer have interests in the development of CERC-006 that may conflict with interests of stockholders.

Mike Cola, our Chief Executive Officer, and entities affiliated with Dr. Garry Neil, our Chief Scientific Officer, are parties, along with other investors (collectively, the "Investors"), to a Royalty Agreement with us relating to CERC-006. The Royalty Agreement was entered into in July 2019 and we assumed the agreement in the Aevi Merger. The Investors will be entitled to an aggregate amount equal to a low-single digit percentage of the aggregate net sales of CERC-006 products. At any time beginning three years after the date of the first public launch of CERC-006 product, we may exercise, at our sole discretion, a buyout option that terminates any further obligations under the Royalty Agreement in exchange for a payment to the Investors of an aggregate of 75% of the net present value of the royalty payments. As a result of this arrangement, the interests of Mr. Cola and Dr. Neil with respect to our development programs may conflict with the interests of our stockholders. These individuals could make substantial profits as a result of opportunities related to CERC-006, which may result in them having more interest in advancing programs related to CERC-006 as opposed to our other pipeline programs. In addition, there would be a conflict of interest if the Company determines to exercise its buyout rights under the Royalty Agreement, the exercise of which would be subject to certain approvals including by our Audit Committee and a majority of our independent directors.

If our employees, independent contractors, principal investigators, CROs, manufacturers, consultants or vendors commit fraud or other misconduct, including noncompliance with regulatory standards and requirements and insider trading, our business may experience serious adverse consequences.

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, manufacturers, consultants and vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (1) FDA regulations, including those laws requiring the reporting of true, complete and accurate information, (2) manufacturing standards, (3) federal and state healthcare fraud and abuse laws and regulations or (4) laws that require the true, complete and accurate reporting of financial information or data. Specifically, 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. The improper use of information obtained in the course of clinical trials could also result in significant legal sanctions and serious harm to our reputation. In addition, federal procurement laws and regulations impose substantial penalties for misconduct in connection with government contracts and require contractors to maintain a code of business conduct and ethics. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity might 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, including regulatory enforcement action, the imposition of significant criminal and civil fines, penalties, or other sanctions, including imprisonment, exclusion from participation in federal healthcare programs, and deferred prosecution and corporate integrity agreements.

In addition, during the course of our operations, our directors, executives and employees may have access to material, nonpublic information regarding our business, our results of operations or potential transactions we are considering. We have adopted an Insider Trading and Window Period Policy, but despite the adoption of such policy, we might not be able to prevent a director, an executive or an employee from trading in our common stock on the basis of, or while having access to, material, nonpublic information. If a director, executive or employee was to be investigated, or an action was to be brought against a director, executive or employee for insider trading, it could have a negative impact on our reputation and our stock price. Such a claim, with or without merit, could also result in substantial expenditures of time and money, and divert attention of our management team from other tasks important to the success of our business.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. We may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. In addition, we may be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patents or other intellectual property. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement to each party who in fact develops intellectual property that we regard as our own. We could be subject to ownership disputes arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these claims.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license might not be available on commercially reasonable terms or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance our product candidates through clinical trials, we will need to expand our development, regulatory, manufacturing, administrative, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. The hiring, training and integration of new employees may be more difficult, costly and/or time-consuming for us because we have fewer resources than a larger organization. We might not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

Risks Related to our Stock

If we are not able to comply with the applicable continued listing requirements or standards of The Nasdaq Stock Market, Nasdaq could delist our common stock.

Our common stock is currently listed on The Nasdaq Stock Market. In order to maintain that listing, we must satisfy minimum financial and other continued listing requirements and standards, including those regarding director independence and independent committee requirements, minimum stockholders' equity, minimum share price, and certain corporate governance requirements. There can be no assurances that we will be able to comply with the applicable listing standards.

In the event that our common stock is delisted from The Nasdaq Stock Market and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further. Also, it may be difficult for us to raise additional capital if we are not listed on a major exchange.

Such a de-listing would also likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a de-listing, we may take actions to restore our compliance with The Nasdaq Stock Market's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below The Nasdaq Stock Market minimum bid price requirement or prevent future non-compliance with The Nasdaq Stock Market's listing requirements.

The market price of our stock is volatile, and you could lose all or part of your investment.

The market price of our shares of our common stock has been highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. From our initial public offering in October 2015 through December 31, 2020, the per share trading price of our common stock has been as high as $7.65 and as low as $0.34. As a result of this volatility, you might not be able to sell your shares of our common stock at a favorable price. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K, these factors that could negatively affect or result in fluctuations in the market price of shares of our common stock include:

- our ability to generate significant product revenues, cash flows and a profit;
- the development status of our product candidates, and when any of our product candidates receive marketing approval;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- our failure to commercialize our product candidates, if approved;
- the success of competitive products or technologies;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by our or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- results of preclinical studies and clinical trials of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- the performance of third parties on whom we rely to manufacture our products and product candidates, supply API and conduct our clinical trials, including their ability to comply with regulatory requirements;
- variations in our financial results or those of companies that are perceived to be similar to us;
- variations in the level of expenses related to our product candidates or preclinical and clinical development programs, including relating to the timing of invoices from, and other billing practices of, our CROs and clinical trial sites;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- warrant or share price and volume fluctuations attributable to inconsistent trading volume levels of our warrants or shares;
- announcement or expectation of additional financing efforts;
- sales of our warrants or shares of our common stock by us, our insiders or our other security holders;
- changes in the structure of healthcare payment systems;
- changes in operating performance and stock market valuations of other pharmaceutical companies;
- market conditions in the pharmaceutical and biotechnology sectors;

- our execution of collaborative, co-promotion, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements;
- additional state and federal healthcare reform measures that could put downward pricing pressure on our products;
- the public's response to press releases or other public announcements by us or third parties, including our filings with the U.S. Securities and Exchange Commission ("SEC") and announcements relating to litigation or other disputes, strategic transactions or intellectual property impacting us or our business;
- announcement related to litigation;
- fluctuations in quarterly operating results, as well as differences between our actual financial and operating results and those expected by investors;
- the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- changes in financial estimates by any securities analysts who follow our warrants or shares of common stock, our failure to meet these estimates or failure of those analysts to initiate or maintain coverage of our warrants or shares of common stock;
- ratings downgrades by any securities analysts who follow our warrants or shares of common stock;
- the development and sustainability of an active trading market for our shares of common stock;
- future sales of our shares of common stock by our officers, directors and significant stockholders;
- other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events;
- changes in accounting principles; and
- general economic, industry and market conditions.

In addition, the stock market in general, and the market for biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of shares of common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a material adverse impact on the market price of our shares of common stock. When the market price of a stock is volatile, security holders may institute class action litigation against the company that issued the stock. If we become involved in this type of litigation, regardless of the outcome, we could incur substantial legal costs and our management's attention could be diverted from the operation of our business, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Future sales and issuances of shares of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to our existing stockholders.

We are authorized to grant equity awards, including stock grants and stock options, to our employees, directors and consultants. As of December 31, 2020, there were 2,971,623 shares available for future issuance under the Third Amended and Restated 2016 Equity Incentive Plan (the "2016 Amended Plan"). During the term of the 2016 Amended Plan, the share reserve will automatically increase on the first trading day in January of each calendar year, by an amount equal to 4% of the total number of outstanding shares of our common stock on the last trading day in December of the prior calendar year. On January 1, 2021, on the terms of the 2016 Amended Plan, an additional 3,000,165 shares were made available for issuance. In addition, as of December 31, 2020, there were 1,425,308 shares available for future issuance under the 2016 Employee Stock Purchase Plan (the "ESPP"). On January 1 of each calendar year, the aggregate number of shares that may be issued under the ESPP will automatically increase by a number equal to the lesser of (i) 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, and (ii) 500,000 shares of our common stock, or (iii) a number of shares of our common stock as determined by our board of directors or compensation committee. On January 1, 2021, the number of shares available for issuance under the ESPP increased by 500,000 shares available for issuance. Future issuances, as well as the possibility of future issuances, under the 2016 Amended Plan or the ESPP or other equity incentive plans could cause the market price of our common stock to decrease.

Armistice has significant influence over us, and its interests may be different from or conflict with those of our other stockholders.

Armistice beneficially owns approximately 44% of our outstanding common stock. As a consequence, Armistice continues to be able to exert a significant degree of influence over our management, affairs, and matters requiring stockholder approval, including the election of directors, a merger, consolidation or sale of all or substantially all of our assets, and any other significant transaction. The interests of Armistice might not always coincide with our interests or the interests of our other stockholders. For instance, this concentration of ownership may have the effect of delaying or preventing a change in control of us otherwise favored by our other stockholders and could depress our stock price.

Armistice makes investments in companies and may, from time to time, acquire and hold interests in businesses that compete directly or indirectly with us. Armistice may also pursue, for its own account, acquisition opportunities that may be complementary to our business, and as a result, those acquisition opportunities might not be available to us. The interests of the Armistice may supersede ours, causing Armistice or their affiliates to compete against us or to pursue opportunities instead of us, for which we have no recourse. Such actions on the part of Armistice and inaction on our part could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Armistice controls a seat on our board of directors. Since Armistice could invest in entities that directly or indirectly compete with us, when conflicts arise between the interests of Armistice and the interests of our stockholders, this director might not be disinterested.

A significant percentage of the outstanding shares of our common stock are held by a single stockholder, which could impact your liquidity, and future sales of shares of our common stock by this stockholder may lower the trading price of shares of our common stock.

Armistice beneficially owns approximately 44% of our outstanding common stock. Continuation of this concentrated ownership would result in a limited amount of shares being available to be traded in the market, resulting in reduced liquidity. Certain of the shares owned by Armistice have been registered for resale under the Securities Act. Sales of substantial amounts of shares of our common stock by Armistice in the public market, or the perception that such sales will occur, could adversely affect the market price of shares of our common stock and make it difficult for it to raise funds through securities offerings in the future.

We have never paid cash dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

The continued operation and expansion of our business will require substantial funding. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. Accordingly, we do not anticipate that we will pay any cash dividends on shares of our common stock for the foreseeable future. Consequently, currently stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

We are no longer an "emerging growth company" but qualify as a "smaller reporting company," and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

As of December 31, 2020, we lost our status as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012. Notwithstanding, we qualify as a "smaller reporting company," which allows us to take advantage of many of the same exemptions from disclosure requirements applicable to us as a former emerging growth company, including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict whether investors will find our common stock less attractive because of our reliance on any of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

The requirements of being a public company may strain our resources and divert management's attention, and our minimal public company operating experience may impact our business and stock price.

As a public company, we incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC, The Nasdaq Stock Market and other applicable securities rules and regulations imposed on public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more

time-consuming and costly. The increased costs will increase our net loss. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

Because these rules and regulations are often subject to varying interpretations, it is difficult to accurately estimate or predict the amount or timing of these additional costs. Further, the lack of specificity of many of the rules and regulations may result in an application in practice that may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Our amended and restated certificate of incorporation provides that unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be 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 certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our amended and restated certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This choice of forum provision does not preclude or contract the scope of exclusive federal or concurrent jurisdiction for any actions brought under the Securities Act or the Exchange Act. Accordingly, our exclusive forum provision will not relieve us of our duties to comply with the 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.

Any person or entity purchasing or otherwise acquiring any interest in any of our securities will be deemed to have notice of and consented to these provisions. These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum of its choosing for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees.

If a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and other employees.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would benefit our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and second amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which we may establish and shares of which we may issue without stockholder approval;
- prohibiting cumulative voting in the election of directors, which would otherwise allow for less than a majority of stockholders to elect director candidates;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under the DGCL, a corporation might not, in general, engage in a business combination with any

holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors approved the transaction. Any provision of our amended and restated certificate of incorporation or second amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change of control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our securities.

General Risk Factors

In connection with the reporting of our financial condition and results of operations, we are required to make estimates and judgments which involve uncertainties, and any significant differences between our estimates and actual results could have an adverse impact on our financial position, results of operations and cash flows.

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, expenses and revenues and related disclosure of contingent assets and liabilities. For example, we estimate returns, wholesaler fees, prompt payment discounts, chargebacks and government rebates. We also estimate clinical trial costs incurred using subject data and information from our CROs. If we underestimate or overestimate these expenses, adjustments to expenses may be necessary in future periods. Any significant differences between our actual results and our estimates and assumptions could negatively impact our financial position, results of operations and cash flows.

We may be subject to numerous and varying privacy and security laws, and our failure to comply could result in penalties and reputational damage.

We maintain a large quantity of sensitive information, including confidential business information and information associated with clinical trials. Because of the sensitivity of this information, our privacy and security measures related to such information are very important. Although we have privacy and security measures in place designed to protect sensitive data and our systems, techniques used to obtain unauthorized access or to sabotage systems and data change frequently and often are not recognized until launched against a target. It is also possible that, due to the surreptitious nature of certain data breaches and other incidents, they may remain undetected for an extended period, which may exacerbate harm to the company. We cannot ensure that our privacy and security measures will not be breached or otherwise fail to protect sensitive information or prevent disruption of our operations, including as a result of inadvertent disclosures through technological or human error (including employee or service provider error), malfeasance, hacking, ransomware, social engineering (including phishing schemes), computer viruses, malware, or otherwise. Unauthorized individuals may acquire or obtain unauthorized access to sensitive information. Data breaches, failures of our privacy or security measures, inadvertent disclosures, disruptions of our services, and other incidents could result in serious harm to our reputation, our business might suffer, and we could incur serious liability and other expenses related to litigation (such as damages associated with breach-of-contract claims), penalties for violation of applicable laws or regulations, costly litigation or government investigations, and significant costs for remediation and remediation efforts to prevent future occurrences. The harm associated with these negative results is likely to be exacerbated if the affected information is personally identifiable.

We may be subject to certain laws and regulations governing the privacy and security of personal information, including regulations pertaining to health information. The legislative and regulatory landscape for privacy and data security continues to evolve, and there has been an increasing focus on privacy and data security issues that may affect our business. In the United States, there are numerous federal and state privacy and data security laws and regulations that govern the collection, use, disclosure, and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws, and federal and state consumer protection laws. Each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues for us. If we fail to comply with applicable laws and regulations, we could be subject to lawsuits, penalties, or sanctions. The HHS Office for Civil Rights, which enforces HIPAA, remains active in its enforcement of the law. Additionally, state attorneys general may bring civil actions seeking either injunctions or damages in response to violations of HIPAA that threaten the privacy of state residents. Privacy and data security has become an area of emphasis for some state legislatures, resulting in the enactment of the California Consumer Privacy Act of 2018, among other laws. In addition to the risk associated with enforcement, compliance with these evolving laws, rules, and regulations regarding the privacy, security and protection of personal information could result in higher compliance and technology costs for us and present challenges for our business model.

There are numerous federal and state laws that generally require notice to affected individuals, regulators, and sometimes the media or credit reporting agencies in the event of a data breach impacting personal information. For example, at the federal level, HIPAA Breach Notification Rule mandates notification of breaches affecting protected health information to affected individuals and

regulators under conditions set forth in the Rule. Covered entities must report breaches of unsecured protected health information to affected individuals without unreasonable delay, but not to exceed 60 days of discovery of the breach by a covered entity or its agents. Notification must also be made to HHS and, in certain circumstances involving large breaches, to the media. Business Associates must report breaches of unsecured protected health information to covered entities. All states, the District of Columbia, Guam, Puerto Rico, and the Virgin Islands have enacted data breach notification laws. These laws may impose notification obligations in addition to, or inconsistent with, the HIPAA Breach Notification Rule when a data breach implicates protected health information. In that event that we fail to detect or timely report a data breach it may be subject to significant penalties under federal and state law. In the event that we report a data breach as required by federal or state law, federal or state regulators may initiate an investigation into, and/or litigation related to, our privacy or data security practices. Private plaintiffs may also initiate costly class action litigation following a data breach.

Numerous other countries have, or are developing, laws governing the collection, use, and transmission of personal information. These laws often impose significant compliance obligations. For example, the General Data Protection Regulation ("GDPR") has imposed more stringent obligations and restrictions on the ability to collect, analyze, and transfer personal information, including health data from clinical trials and substantial fines for breaches of the data protection rules in the European Economic Area. To the extent that our activities are or become subject to the GDPR, we may need to devote significant effort and resources to complying with those legal regimes. Any failure to comply with the rules arising from the GDPR could lead to government enforcement actions and significant penalties against us and adversely impact our operating results.

Our disclosure controls and procedures might not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act, Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act") and The Nasdaq Stock Market rules and regulations. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. We cannot assure, in the future, a material weakness or significant deficiency will not exist or otherwise be discovered. If that were to happen, it could harm our operating results and cause stockholders to lose confidence in our reported financial information. Any such loss of confidence would have a negative effect on the trading price of our securities.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of 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 an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Low trading volume of our common stock on the NASDAQ Capital Market may increase price volatility.

Our common stock may be subject to price volatility, low trading volume and large spreads in bid and ask prices quoted by market makers. Due to the low volume of shares traded on any trading day, persons buying or selling in relatively small quantities may easily influence prices of our common stock. This low trading volume could also cause the price of our stock to fluctuate greatly, with large percentage changes in price occurring in any trading day session. Holders of our common stock may also not be able to readily liquidate their investment or may be forced to sell at depressed prices due to low trading volume. If large spreads between the bid and ask prices of our common stock exist at the time of a purchase, the stock would have to appreciate substantially on a relative percentage basis for an investor to recoup their investment. No assurance can be given that a higher volume active market in our common stock will develop or be sustained. If a higher volume active market does not develop, holders of our common stock may be unable to readily sell the shares they hold or may not be able to sell their shares at all.

Sales of a significant number of shares of our common stock in the public markets, or the perception that such sales could occur, could depress the market price of our common stock.

Sales of a substantial number of shares of our common stock in the public markets could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities. As additional shares of our common stock become available for resale in the public market pursuant to this offering, and otherwise, the supply of our common stock will increase, which could decrease its price. In addition, some or all of the shares of common stock may be offered from time to time in the open market pursuant to Rule 144, and these sales may have a depressive effect on the market for our shares of common

stock. Therefore, we cannot predict the effect that future sales of our common stock would have on the market price of our common stock.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our securities prices and trading volume could decline.

The trading market for our securities will depend in part on the research and reports that securities or industry analysts publish about us or our business. We currently have limited, and might not sustain, research coverage by securities and industry analysts. If we do not sustain coverage of ourselves, the trading price for securities would be negatively impacted. If the securities and industry analysts are unable to predict accurately the cost of advancing our pipeline, that could result in our reported costs being different than expectations, which could negatively affect our stock price. If we do obtain securities or industry analyst coverage and if one or more of the analysts who covers us downgrades our securities or publishes inaccurate or unfavorable research about our business, our securities prices would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our securities could decrease, which could cause our securities prices and trading volume to decline.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our headquarters are located in Rockville, Maryland, where we occupy approximately 5,000 square feet of administrative office space. The lease expires January 31, 2030.

The Company also occupies approximately 11,000 square feet of administrative office space in Chesterbrook, Pennsylvania. The lease expires in November 2021. Upon expiration of this lease, we do not anticipate difficulties in finding suitable property to lease on commercially reasonable terms.

Item 3. Legal Proceedings.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock is listed and publicly traded on the NASDAQ Capital Market under the symbol "CERC."

Holders

As of March 4, 2021, there were approximately 105 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

Dividends

We have never declared or paid cash dividends on our capital stock. We intend to retain all of our available funds and future earnings, if any, to finance the growth and development of our business. We do not intend to pay cash dividends to our stockholders in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Recent Sales of Unregistered Securities

Except for sales of unregistered securities that have been previously reported by the Company in either its quarterly reports on Form 10-Q or current reports on Form 8-K, there were no sales of unregistered securities of the Company during the period covered by this report.

Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Part III "Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters".

Item 6. Selected Financial Data.

As a smaller reporting company, we are not required to provide the information required by this Item.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section in 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

Cerecor Inc. (the "Company" or "Cerecor" or "we") is a biopharmaceutical company focused on becoming a leader in development and commercialization of treatments for rare and orphan diseases. We are advancing a diverse pipeline of six assets in eight clinical development programs across immunology, oncology, and rare diseases. The management team spent the majority of their time in 2020 focusing on both progressing the pipeline and also on financing activities to fund pipeline development. These will also be the primary areas of focus in 2021.

On February 3, 2020, the Company consummated its merger with Aevi Genomic Medicine, Inc. ("Aevi"), in which Cerecor acquired the rights to CERC-002, CERC-006 and CERC-007 (the "Aevi Merger"). The Aevi Merger was a transformative event in 2020 and it significantly broadened Cerecor's pipeline by adding the rights to these three key new assets, as well as bringing in critical leadership to guide the Company and research and development of the expanded pipeline.

The Company successfully raised capital in 2020 and early 2021 which we believe is principally due to successfully improving our pipeline, development milestones and leadership team but also due in part to a robust biotechnology favorable capital markets environment which may not continue. The Company will continue to focus on raising capital, however, with a broader focus on both non-dilutive and dilutive funding opportunities, as well as potential business development related opportunities such as the out-license or partnering of Company assets. The Company believes the potential monetization of the priority review vouchers that may be granted in 2022 (if each compound is approved by the U.S. Food and Drug Administration) related to CERC-801, CERC-802 and CERC-803, which are in development for therapies for congenital disorders of glycosylation, to be an important part of the Company's capital plan.

The COVID-19 pandemic presented both challenges and opportunities to the Company in 2020 and we expect that to continue in 2021. The Company adapted to new ways to work remotely and, pursuant to the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"), the Company benefited from favorable tax reform and loan programs. Most importantly, the Company created, initiated and executed a successful exploratory Phase 2 randomized, double-blind placebo-controlled proof of concept trial for the treatment of COVID-19 associated mild-to-moderate acute respiratory distress syndrome ("ARDS"). We are excited by the efficacy data of our primary endpoint (patients alive and free of respiratory failure over 28 days) and mortality. The development path for this compound in COVID-19 ARDS and/or potentially generalized ARDS will be an important focus of 2021. The rapidly changing environment of COVID-19 continues to present both risks and opportunities in the successful development of this asset.

Management's primary evaluation of the success of the Company is the ability to progress its pipeline assets forward towards commercialization or successful out-license. We believe the ability to timely achieve the anticipated milestones as presented in the section entitled "Business" in Item 1 of this Annual Report on Form 10-K represents our most immediate evaluation points as to the progress of our goal to move the pipeline forward.

Aevi Merger

As discussed briefly above, on February 3, 2020, the Company consummated the Aevi Merger, in which Cerecor acquired the rights to CERC-002, CERC-006 and CERC-007, thus expanding the Company's core pipeline to six assets in eight clinical development programs across immunology, oncology and rare diseases. We expect operating expenses, notably research and development expenses, to continue to outpace historic periods, as the Company advances its expanded pipeline.

Cerecor also entered into an employment agreement with Aevi's Chief Executive Officer, Mike Cola, for him to serve as Cerecor's Chief Executive Officer and an employment agreement with Aevi's Chief Scientific Officer, Dr. Garry Neil, for him to serve as Cerecor's Chief Medical Officer (shortly thereafter promoted to Chief Scientific Officer). Additionally, Mr. Cola and Dr. Sol Barer, the former Chairman of the Board of Aevi, were appointed to the Company's Board of Directors. Dr. Barer serves as the Chairman of

the Company's Board.

Aytu Divestiture

During the fourth quarter of 2019, the Company sold to Aytu BioScience, Inc. ("Aytu") its rights, titles and interest in, assets relating to certain commercialized products (the "Pediatric Portfolio"), as well as the corresponding commercial infrastructure consisting of the right to offer employment to Cerecor's sales force and the assignment of supporting commercial contracts (the "Aytu Divestiture"). Thus, our only commercial product is Millipred®, an oral prednisolone indicated across a wide variety of inflammatory conditions.

Upon the sale of the Pediatric Portfolio to Aytu, the Pediatric Portfolio met all conditions required to be classified as discontinued operations. Accordingly, unless otherwise noted, the following section focuses on results of operations from continuing operations only for all periods discussed.

Financial Operations Overview

Research and development expense for the year ended December 31, 2020 significantly increased as compared to the prior year, which was driven by the advancement of our expanded and maturing pipeline. Additionally, there was a $25.5 million acquired in-process research and development ("IPR&D") charge in 2020 directly related to the Aevi Merger. There was also a moderate increase to general and administrative expense related to the infrastructure needed to support the Company's expansion of its research and development efforts. Such increases were the main drivers to our net loss of $63.5 million for the year ended December 31, 2020. Additionally, our net cash used in operations significantly increased to $40.5 million for the year ended December 31, 2020, which was also driven by the advancement of our expanded and maturing pipeline. We expect such trends to continue to outpace historic periods, as we continue to advance our pipeline in anticipation of multiple clinical data readouts in 2021.

As of December 31, 2020, Cerecor had $18.9 million in cash and cash equivalents. In January 2021, the Company closed an underwritten public offering for net proceeds of approximately $37.6 million. We plan to use our current cash on hand along with cash inflows from investing and/or financing activities to support the ongoing clinical development of our expanded and maturing pipeline and for general corporate purposes to support such pipeline development.

Smaller Reporting Company Status

We are a "smaller reporting company," as such term is defined in Rule 12b-2 of the Exchange Act, meaning that the market value of our common stock held by non-affiliates is less than $700 million and our annual revenue is less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our common stock held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our common stock held by non-affiliates is less than $700 million. As of December 31, 2020, we lost our status as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012. Notwithstanding, our status as a "smaller reporting company" allows us to take advantage of many of the same exemptions from disclosure requirements applicable to us as a former emerging growth company, including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

Product Revenue, net

Net product revenue was $6.7 million for the year ended December 31, 2020, which was consistent with the net product revenue for the year ended December 31, 2019.

In the fourth quarter of 2020, the Company entered into an amended License and Supply Agreement for the Millipred® product with a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. ("Teva"), which extends the original license agreement for a period of thirty months (from April 1, 2021 through September 30, 2023). Beginning April 1, 2021, Cerecor will pay Teva fifty percent of the net profit of the Millipred product following each calendar quarter, subject to a $0.5 million quarterly minimum payment. We are currently exploring strategic alternatives for our non-core assets, which includes Millipred® . Therefore,

our ability to increase revenue in the future will depend on developing and commercializing our current clinical pipeline of product candidates.

License and Other Revenue

During the third quarter of 2019, the Company assigned and transferred its rights, title, interest, and obligations with respect to CERC-611 to ES Therapeutics, LLC ("ES Therapeutics") in exchange for initial gross proceeds of $0.1 million, which was recognized as license and other revenue for the year ended December 31, 2019. The Company is also eligible for potential milestone payments upon achievement of certain targets of cumulative net sales of the licensed product. There was no license and other revenue for the year ended December 31, 2020.

Cost of Product Sales

Cost of product sales were $0.3 million for the year ended December 31, 2020, as compared to $(0.6) million for the year ended December 31, 2019. During the second quarter of 2019, the Company entered into a settlement agreement related to the Ulesfia product, which fully released the Company of its minimum purchase obligations and minimum royalty provisions related to the Ulesfia product resulting in a reversal of expense of approximately $1.6 million. The reversal of expense was partially offset by minimum royalty obligations related to the Ulesfia product recognized in the first quarter of 2019 prior to entering into the settlement agreement.

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2020 and 2019:

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Preclinical expenses	$ 6,487	$ 2,982
Clinical expenses	10,803	3,826
CMC expenses	7,645	3,788
Internal expenses not allocated to programs:		
Salaries, benefits and related costs	5,763	1,909
Stock-based compensation expense	1,339	464
Other	155	(1,205)
	$ 32,192	$ 11,764

Research and development expenses increased $20.4 million for the year ended December 31, 2020 compared to the year ended December 31, 2019. The overall increase was driven by an increase in research and development activities in 2020 as the Company expanded and advanced its pipeline assets, including the rights to the additional assets acquired in the Aevi Merger.

Clinical expenses increased $7.0 million primarily due to costs incurred for the CERC-002 proof-of-concept trial in patients with COVID-19 ARDS, which began in July 2020, and increased spending related to development of the other core pipeline assets. Chemistry, Manufacturing, and Controls ("CMC") expenses increased $3.9 million due to additional spending on manufacturing to support clinical development of the expanded pipeline. Preclinical expenses increased $3.5 million primarily due to the development of a more robust pipeline given the rights acquired to develop additional assets in the Aevi Merger.

Salaries, benefits and related costs increased by $3.9 million mainly due to an increase in headcount as a result of the Aevi Merger and salary-related costs to grow our research and development activities as we continue to invest in our expanded pipeline. Stock-based compensation increased by $0.9 million mainly due to an increase in stock option grants as a result of the increased headcount.

The $1.4 million increase to other expenses was primarily driven by the reversal of $1.3 million of research and development expense for the year ended December 31, 2019, which was reversed as a result of the Company's assignment of the CERC-611 license agreement to ES Therapeutics in the third quarter of 2019. As part of the assignment, the Company was released of a contingent payment liability of $1.3 million to Eli Lilly and Company ("Lilly") upon the first subject dosage of CERC-611 in a multiple

ascending dose study, which was previously recorded as a license obligation on the balance sheet. The decrease of the license obligation to $0 resulted in an offset of research and development expense for the year ended December 31, 2019. There was no such reversal in the year ended December 31, 2020.

We expect research and development expenses to continue to outpace historic periods, as the Company advances its expanded and maturing pipeline in anticipation of multiple clinical data readouts in 2021.

Acquired In-Process Research and Development Expenses

On February 3, 2020, the Company consummated its merger with Aevi. As a result, the Company acquired $25.5 million of IPR&D. The fair value of the IPR&D was immediately recognized as acquired in-process research and development expense as the IPR&D asset has no other alternate use due to the stage of development. There was no acquired in-process research and development expense for the year ended December 31, 2019.

General and Administrative Expenses

The following table summarizes our general and administrative expenses of continuing operations for the years ended December 31, 2020 and 2019:

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Salaries, benefits and related costs	$ 4,704	$ 4,196
Legal, consulting and other professional expenses	6,606	3,943
Stock-based compensation expense	5,135	1,550
Other	972	434
	$ 17,417	$ 10,123

General and administrative expenses increased $7.3 million for the year ended December 31, 2020 compared to the same period in 2019. The increase was largely driven by a $3.6 million increase to stock-based compensation expense as a result of equity awards granted to newly appointed executive leadership and board members.

Legal, consulting and other professional expenses increased by $2.7 million, which was largely driven by a $0.9 million expense recognized related to a payment made pursuant to a settlement agreement entered into during the third quarter with the former owners of TRx. The remainder of this increase was attributable to a variety of factors including increased recruiting costs incurred to grow headcount to support the expanded pipeline development.

We expect general and administrative expenses to moderately increase compared to historic periods as a result of increased infrastructure to support the Company's expanded research and development efforts.

Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses of continuing operations for the years ended December 31, 2020 and 2019:

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Salaries, benefits and related costs	$ 749	$ 628
Stock-based compensation expense	315	191
Advertising and marketing expense	1,240	606
Other	37	59
	$ 2,341	$ 1,484

Sales and marketing expenses of continuing operations consist of expenses related to advertising and marketing initiatives to support the go-to-market strategy of our pipeline assets and the respective salaries and stock-based compensation to support such initiatives. The overall $0.9 million increase for the year ended December 31, 2020 as compared to the prior year was driven by a $0.6 million increase in advertising and marketing expense related to market research, a $0.1 million increase in salaries, benefits and related costs driven by increased headcount to support such initiatives.

Amortization expense

The following table summarizes amortization expense for the years ended December 31, 2020 and 2019:

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Amortization of intangible assets	$ 1,741	$ 1,339

Amortization expense relates to the amortization of the assembled workforces acquired as part of previous acquisitions and mergers. In 2020, as a result of the asset acquisition accounting treatment of the Aevi Merger, the Company recorded an assembled workforce intangible asset of $0.9 million, which was assigned a two-year useful life. Therefore, the $0.3 million increase to amortization expense was primarily driven by the amortization of the assembled workforce acquired as part of the Aevi Merger.

Change in fair value of contingent consideration

The following table summarizes our change in fair value of contingent consideration from continuing operations for the years ended December 31, 2020 and 2019:

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Change in fair value of contingent consideration	$ —	$ (1,256)

The Company recognized a gain on the change in fair value of contingent consideration of $1.3 million for the year ended December 31, 2019. The contingent consideration was related to the potential for future payment of consideration that was contingent upon the achievement of operation and commercial milestones related to the Ulesfia product, which was acquired as part of the Company's acquisition of TRx in 2017.

During the second quarter of 2019, the Company entered into a settlement agreement related to the Ulesfia product, which released the Company from the potential contingent payments related to the TRx Acquisition, reducing the fair value down to $0. This represented a gain on the change of fair value of contingent consideration of $1.3 million for the year ended December 31, 2019. As the Company was released from the contingent payment in 2019, there was no change in fair value of contingent consideration for the year ended December 31, 2020.

Other income, net

The following table summarizes our other income, net from continuing operations for the years ended December 31, 2020 and 2019:

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Change in fair value of Investment in Aytu (as defined below)	$ 5,208	$ 54
Other (expense) income, net	410	(28)
Interest income, net	49	121
	$ 5,667	$ 147

Other income, net increased $5.5 million for the year ended December 31, 2020 as compared to the prior year. Other income, net is mainly comprised of a $5.2 million gain on change in the fair value of the Company's investment in Aytu. As consideration of the Aytu Divestiture in 2019, the Company received 9,805,845 shares of Aytu Series G Preferred Stock (the "Investment in Aytu"), which was remeasured at the current fair value each reporting period. In April 2020, the Company converted its shares of Aytu Series G Preferred Stock into 9,805,845 shares of common stock and sold that common stock for net proceeds of approximately $12.8 million, which resulted in the Company recognizing a realized gain of $5.2 million from its estimated fair value as of the divestiture date. The gain was primarily driven by a significant increase in Aytu's stock price from December 31, 2019 to the dates the Company sold its shares of Aytu common stock in mid-April 2020. Additionally, the Company recognized $0.4 million of other income for the year ended December 31, 2020 related to the Paycheck Protection Program ("PPP") Loan received during the second quarter of 2020 as the Company believes it meets the criteria for loan forgiveness. Both transactions were unique to 2020, thus causing the increase as compared to the prior year period.

Income tax (benefit) expense

The Company recognized an income tax benefit of $2.8 million for the year ended December 31, 2020 and income tax expense of $0.3 million for the year ended December 31, 2019. The tax benefit recognized for the year ended December 31, 2020 was a result of a current year tax law change and the ability of the Company to now carry back certain losses related to the CARES Act for taxes paid in fiscal year 2017. This benefit was recognized in the first and second quarters. The expense recognized for the year ended December 31, 2019 was a primarily the result of estimated state cash taxes and interest on an unpaid tax liability. The annual effective tax rate was 4.21% and (1.75)% for the years ended December 31, 2020 and 2019, respectively.

Liquidity and Capital Resources, including Capital Expenditure and Cash Requirements

In 2020, the Company closed three equity offerings for net proceeds of approximately $44.4 million and in April 2020, the Company sold an investment for net proceeds of $12.8 million. The Company also closed an underwritten public offering in January 2021 for net proceeds of approximately $37.6 million. As of December 31, 2020, Cerecor had $18.9 million in cash and cash equivalents.

The CARES Act provides stimulus measures, including the PPP, to provide certain small businesses with liquidity to support their operations (such as to retain employees and maintain payroll and lease payments) during the COVID-19 pandemic. Cerecor received a $0.4 million PPP loan during the second quarter of 2020. PPP loans have a 1% fixed annual interest rate and mature in two years, and are eligible for forgiveness under certain conditions. If approved by the lender, the lender will submit the forgiveness application to the Small Business Administration (the "SBA") for ultimate approval. The SBA has 90 days from receipt to approve or reject the forgiveness application. As of December 31, 2020, the Company believes it meets the criteria for forgiveness and submitted an application for forgiveness with its lender in 2020.

In order to meet its cash flow needs, the Company applies a disciplined decision-making methodology as it evaluates the optimal allocation of the Company's resources between investing in the Company's existing pipeline assets and acquisitions or in-licensing of new assets. For the year ended December 31, 2020, Cerecor generated a net loss of $63.5 million and negative cash flows from operations of $40.5 million. As of December 31, 2020, Cerecor had an accumulated deficit of $177.8 million.

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern; however, losses are expected to continue as the Company continues to invest in its core research and development pipeline assets. The Company will require additional financing to fund its operations and to continue to execute its business strategy at least one year after the date the financial statements included herein were issued. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

To mitigate these conditions and to meet the Company's capital requirements, management plans to use its current cash on hand along with some combination of the following: (i) equity and/or debt financings, (ii) federal and/or private grants, (iii) other out-licensing or strategic alliances/collaborations of its current pipeline assets, and (iv) out-licensing or sale of its non-core assets. If the Company raises additional funds through collaborations, strategic alliances or licensing arrangements with third parties, the Company might have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates. If the Company requires but is unable to obtain additional funding, the Company may be forced to make reductions in spending, delay, suspend, reduce or eliminate some or all of its planned research and development programs, or liquidate assets where possible. Due to the uncertainty regarding future financings and other potential options to raise additional funds, management has concluded that substantial doubt exists with respect to the Company's ability to continue as a going concern within one year after the date that the financial statements in this Annual Report on Form 10-K were issued.

Over the long term, the Company's ultimate ability to achieve and maintain profitability will depend on, among other things, the development, regulatory approval, and commercialization of its pipeline assets, and the potential receipt and sale of any PRVs it receives.

Uses of Liquidity

The Company uses cash to primarily fund the ongoing development of our research and development pipeline assets and costs associated with its organizational infrastructure.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2020 and 2019:

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (40,540)	$ (19,134)
Investing activities	11,132	(443)
Financing activities	44,785	12,559
Net increase (decrease) in cash and cash equivalents	$ 15,377	$ (7,018)

Net cash used in operating activities

Net cash used in operating activities was $40.5 million for the year ended December 31, 2020, consisting primarily of a net loss of $63.5 million, which was driven by increased research and development activities as the Company continued to fund its expanded pipeline of development assets and non-cash adjustments to reconcile net loss to net cash used in operating activities including a $5.2 million realized gain related to the change in fair value of the Investment in Aytu and a $1.8 million gain related to the change in value of the Guarantee associated with the Aytu Divestiture. This decrease was offset by the following non-cash adjustments: non-cash acquired IPR&D expense of $25.5 million and non-cash stock-based compensation of $6.8 million. Additionally, changes in net liabilities increased by $4.4 million, mainly driven by a $2.1 million decrease in other receivables and a $1.9 million decrease in prepaid expenses, partially offset by a $0.2 million decrease in accrued expenses and other current liabilities.

We expect net cash used in operating activities to continue to outpace historic periods due to our continued advancement of our expanded and maturing pipeline.

Further, net cash used in operating activities includes offsets from the collection of sales from Millipred. In the fourth quarter of 2020, the Company and Teva entered into an amended License and Supply Agreement for the Millipred product, which extends the original license agreement for a period of thirty months (from April 1, 2021 through September 30, 2023). Beginning April 1, 2021, Cerecor will pay Teva fifty percent of the net profit of the Millipred product following each calendar quarter, subject to a $0.5 million quarterly minimum payment.

Net cash used in operating activities was $19.1 million for the year ended December 31, 2019, consisting primarily of a net loss of $16.1 million, which was driven by research and development expenses to fund the Company's pipeline of development assets.

Net cash provided (used in) by investing activities

Net cash provided by investing activities was $11.1 million for the year ended December 31, 2020 and consisted primarily of net proceeds of $12.8 million from the sale of the Aytu common stock during the second quarter of 2020 underlying the Company's previous Investment in Aytu, slightly offset by transaction costs incurred as part of the Aevi Merger.

Net cash used in investing activities was $0.4 million for the year ended December 31, 2019, consisting primarily of the Company's $4.1 million loan to Aevi in December 2019 (prior to the close of the Aevi Merger in February 2020), largely offset by $4.0 million net cash received as consideration for the Aytu Divestiture. Refer to Note 5 to the audited consolidated financial statements for more information regarding the loan to Aevi in 2019.

Net cash provided by financing activities

Net cash provided by financing activities was $44.8 million for the year ended December 31, 2020 and consisted primarily of net proceeds of $35.4 million from an underwritten public offering of common stock for 15,180,000 shares of common stock of the Company. The Company also received net proceeds of $5.1 million from a registered direct offering with certain institutional investors, which included Armistice Capital Master Fund Ltd. (“Armistice”), that closed in February 2020 for the sale of 1,306,282 shares of common stock of the Company and net proceeds of $3.9 million from a private placement of equity securities with Armistice during March 2020.

Net cash provided by financing activities was $12.6 million for the year ended December 31, 2019 and consisted primarily of net proceeds of approximately $9.0 million from the underwritten public offering of common stock for 1,818,182 shares of common stock of the Company, that closed in the first quarter of 2019. The Company also received $3.7 million from a private placement of equity securities with Armistice during the third quarter of 2019. The cash inflows were partially offset by $0.9 million of contingent consideration payments related to a historical acquisition.

Critical Accounting Estimates and Assumptions

In preparing the financial statements, the Company makes estimates and assumptions that have an impact on assets, liabilities, revenue and expenses reported. These estimates can also affect supplemental information disclosed by us, including information about contingencies, risk and financial condition. The Company believes, given current facts and circumstances, our estimates and assumptions are reasonable, adhere to GAAP and are consistently applied. Inherent in the nature of an estimate or assumption is the fact that actual results may differ from estimates, and estimates may vary as new facts and circumstances arise.

While our significant accounting policies are more fully described in Note 2 to the audited consolidated financial statements appearing at the end of this Annual Report on Form 10-K, we believe the following accounting policies are critical to the understanding of our financial condition and results.

Stock-Based Compensation

The Company applies the provisions of ASC 718, Compensation—Stock Compensation, which requires the measurement and recognition of compensation expense for all stock-based awards made to employees, including employee stock options, in the statements of operations and comprehensive loss.

For stock options issued to employees and members of the board of directors for their services, the Company estimates the grant date fair value of each option using the Black-Scholes option pricing model. The use of the Black-Scholes option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected life of the option, risk-free interest rates and expected dividend yields of the common stock. For awards subject to service-based vesting conditions, including those with a graded vesting schedule, the Company recognizes stock-based compensation expense equal to the grant date fair value of stock options on a straight-line basis over the requisite service period, which is generally the vesting term. Forfeitures are recorded as they are incurred as opposed to being estimated at the time of grant and revised.

For stock option grants with market-based conditions, compensation expense is recognized ratably over the attribution period. The Company estimates the fair value of the market-based stock option grants using a Monte-Carlo simulation. The Company generally estimates fair value using assumptions, including the expected term of the option, the expected volatility of peer group of similar companies, risk free interest rate and the expected dividend yield.

The assumptions we used to determine the fair value of stock options granted to employees and members of the board of directors are as follows:

	Year Ended December 31,					
Service-based options	**2020**			**2019**		
Risk-free interest rate	0.19%	—	1.48%	1.47%	—	2.59%
Expected term of options (in years)	1.75	—	6.25	5.0	—	6.25
Expected stock price volatility	70 %		79 %	55%		
Expected annual dividend yield	0%			0%		
Market-based options						
Risk-free interest rate	0.30%		0.34%	2.32%		
Expected term of options (in years)	4.3	—	5.0	10		
Expected stock price volatility	80%			60%		
Expected annual dividend yield	0%			0%		

The estimates involved in the valuations include inherent uncertainties and the application of our judgment. As a result, if factors change and we use significantly different assumptions or estimates when valuing our stock options, our stock-based compensation expense could be materially different. We recognize compensation expense for only the portion of awards that are expected to vest.

Acquired In-Process Research and Development Expenses

Acquired in-process research and development expense includes the initial costs of IPR&D projects, acquired directly in a transaction other than a business combination, that do not have an alternative future use.

Acquisitions

For acquisitions that meet the definition of a business under ASC 805, the Company records the acquisition using the acquisition method of accounting. All of the assets acquired, liabilities assumed, contractual contingencies, and contingent consideration, when applicable, are recorded at fair value at the acquisition date. Any excess of the purchase price over the fair value of the net assets acquired is recorded as goodwill. The application of the acquisition method of accounting requires management to make significant estimates and assumptions in the determination of the fair value of assets acquired and liabilities assumed in order to properly allocate purchase price consideration. For acquisitions that do not meet the definition of a business under ASC 805, the Company accounts for the transaction as an asset acquisition.

Off-Balance Sheet Arrangements

The Company does not have any off-balance sheet arrangements, as defined by applicable SEC rules and regulations.

Recently Adopted Accounting Pronouncements

For a discussion of new accounting standards please see Note 2 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K.

Internal Control Over Financial Reporting

Assessing our staffing and training procedures to improve our internal control over financial reporting is an ongoing process. We are not currently required to comply with all of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. For the year ended December 31, 2020, management is required to make an assessment of the effectiveness of our internal control over financial reporting as required by Section 404(a) of the Sarbanes-Oxley Act, as further described in Item 9A of this Annual Report on Form 10-K. In March 2020, certain smaller reporting companies were excluded from compliance with Section 404(b) of the Sarbanes-Oxley Act, which relates to the independent auditor's attestation on the effectiveness of the issuer's internal control over financial reporting. As such, our independent registered public accounting firm has not been engaged to express, nor have they expressed, an opinion on the effectiveness of our internal control over financial reporting as of December 31, 2020.

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

Interest Rate Risk

As a smaller reporting company, we are not required to provide the information required by this Item.

Item 8. Financial Statements and Supplementary Data.

The consolidated financial statements required to be filed pursuant to this Item 8 are appended to this report. An index of those consolidated financial statements is found in Item 15 of Part IV 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.

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this report.

In designing and evaluating our disclosure controls and procedures, management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Based on their evaluation, our principal executive officer and principal financial officer concluded that as of December 31, 2020, our disclosure controls and procedures are designed to, and are effective to, provide assurance at a reasonable level that the information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosures as of December 31, 2020.

Management's Annual Report on Internal Control Over Financial Reporting

Our management, including our principal executive officer and principal financial officer, is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). 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 GAAP. Our internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2020, based on the Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) (2013 Framework). Based on this evaluation under the 2013 Framework, our principal executive officer and principal financial officer have concluded that our internal control over financial reporting was effective at a reasonable level of assurance as of December 31, 2020.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the most recent fiscal quarter that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Attestation Report of Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to an exclusion for certain smaller reporting companies.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

BOARD OF DIRECTORS

The Board currently consists of eight members, each of which serve for a one-year term or until a successor has been elected and qualified. Vacancies on the Board may be filled only by persons elected by a majority of the remaining directors in office. A director elected by the Board to fill a vacancy, including vacancies created by an increase in the number of directors, shall serve for the remainder of the year term and until the director's successor is duly elected and qualified.

In connection with the Securities Purchase Agreement dated April 27, 2017, between the Company and Armistice Capital Master Fund Ltd. (an affiliate of Armistice Capital, LLC and collectively "Armistice"), the Company agreed that as long as Armistice maintains beneficial ownership of at least 13% of our outstanding common stock, Armistice, exclusively and as a separate class, has the right to designate two directors to our Board, and as along as Armistice maintains beneficial ownership of at least 10% of our outstanding common stock, Armistice, exclusively and as a separate class, has the right to designate one director. Armistice's Chief Investment Officer, Steven Boyd, currently sits on the Board.

The following table sets forth information of the members of our Board:

Name	Age	Director Since	Position(s) with Cerecor
Sol Barer, Ph.D.	73	February 2020	Chairman of the Board of Directors and Director
Steven Boyd	40	May 2017	Director
Suzanne Bruhn, Ph.D.	57	April 2020	Director
Michael Cola	61	February 2020	Director and Chief Executive Officer
Phil Gutry	47	April 2015	Director
Gilla Kaplan, Ph.D.	74	October 2020	Director
Joseph Miller	47	April 2020	Director
Magnus Persson, M.D., Ph.D.	60	April 2012	Director

The following is a brief biography of each current director.

Sol Barer, Ph.D. Dr. Barer has served on our Board since February 2020 and was appointed Chairman of the Board in April 2020. Dr. Barer spent most of his professional career with the Celgene Corporation where he was Chairman from January 2011 until June 2011, Executive Chairman from June 2010 until January 2011, and Chairman and Chief Executive Officer from May 2006 until June 2010. Previously he was appointed President in 1993 and Chief Operating Officer in 1994 before assuming the CEO position. Prior to these appointments, he served in several senior positions and was the founder of the biotechnology group at the Celanese Research Company which was subsequently spun out to form Celgene. In addition to serving as the Company's Chairman of the Board, Dr. Barer currently serves as Chairman of the board of directors of Teva Pharmaceutical Industries Ltd., a publicly-traded multinational pharmaceutical company, and Neximmune, Inc., a publicly-traded clinical-stage biopharmaceutical company. Dr. Barer also serves as Lead Director of ContraFect Corporation, a publicly-traded biotechnology company, Chair of the private company Centrexion Therapeutics Corporation, a late clinical-state biopharmaceutical company, and as a director of 3D Biotherapeutics, Inc., a biologics and bioprinting company. He is also the Founding Chair of the Hackensack Meridian Medical School Center for Discovery and Innovation. Dr. Barer is a Founder of MIG, an organization dedicated to helping Israeli biotech entrepreneurs, and is a Venture Advisor to the Israel Biotechnology Fund. In 2011, Dr. Barer was Chairman of the University of Medicine and Dentistry of New Jersey Governor's Advisory Committee which resulted in sweeping changes in the structure of New Jersey's medical schools and public research universities. He previously served as a Commissioner of the New Jersey Commission on Science and Technology. He also served as a member of the Board of Trustees of Rutgers University (until 2013) and as Chair of the Board of Trustees of BioNJ, a New Jersey biotechnology organization, from 2010 to 2012. Dr. Barer received his Ph.D. in organic and physical chemistry from Rutgers University and his B.S. in chemistry from Brooklyn College of the City University of New York. Our Board believes that Dr. Barer's wealth of experience in the biotechnology industry makes him a valuable member of our Board.

Steven Boyd. Mr. Boyd has served on our Board since May 2017. He is the Chief Investment Officer of Armistice Capital, a long-short equity hedge fund focused on the health care and consumer sectors. Previously, Mr. Boyd had been a research analyst at Senator Investment Group, York Capital, and SAB Capital Management, where he focused on healthcare. Mr. Boyd began his career at McKinsey & Company. Mr. Boyd received a B.S. in Economics and a B.A. in Political Science from The Wharton School of the University of Pennsylvania. Our Board believes that Mr. Boyd's experience in the capital markets and strategic transactions, and his focus on the healthcare industry makes him a valuable member of our Board.

Suzanne Bruhn, Ph.D. Dr. Bruhn has served on our Board since April 2020. Dr. Bruhn brings to the Company her extensive experience in the biopharmaceutical industry, including expertise in the development, commercialization and partnering of products for the treatments for serious and rare diseases. Dr. Bruhn currently serves as the President and Chief Executive Officer, and as a director of Tiaki Therapeutics, Inc., a private biotechnology company. Prior to that, she served as the President and Chief Executive Officer and as a director of Proclara Biosciences, Inc., a clinical-stage biotechnology company from April 2017 to September 2018. From May 2012 to November 2015, Dr. Bruhn served as President and Chief Executive Officer and as a director of Promedior, Inc., a clinical-stage biotechnology company. Dr. Bruhn currently serves on the boards of directors of Travere Therapeutics, Inc., a publicly-traded commercial biotechnology company focused on the treatment of rare genetic diseases and cancer, Retrophin, Inc., a publicly-traded biopharmaceutical company focused on identifying, developing and delivering life-changing therapies to people living with rare diseases, and Pliant Therapeutics, Inc., a publicly-traded biotechnology company. She served as a member of the board of directors of Raptor Pharmaceuticals Corp., a publicly-traded commercial-stage biopharmaceutical company focused on rare diseases, from April 2011 until it was acquired by Horizon Pharma plc in October 2016. She also served as a member of the board of directors of Novelion Therapeutics Inc., a publicly-traded commercial-stage company focused on rare diseases, from October 2017 until January 2020, and Aeglea BioTherapeutics, Inc., a publicly-traded biotechnology company focused on the treatment of rare genetic diseases and cancer from February 2017 to August 2020. Previously, Dr. Bruhn served in a number of roles of increasing responsibility at Shire plc, a publicly-traded biopharmaceutical company, from December 1998 until February 2012, most recently as Senior Vice President, Strategic Planning and Program Management. Dr. Bruhn received her B.S. degree in Chemistry from Iowa State University and her Ph.D. in Chemistry from Massachusetts Institute of Technology. Our Board believes that Dr. Bruhn's experience in the development, commercialization and partnering of products for the treatments for serious and rare diseases makes her a valuable member of our Board.

Michael Cola. Mr. Cola has served on our Board and as the Company's Chief Executive Officer and Principal Executive Officer since February 2020, when Aevi Genomic Medicine, Inc. ("Aevi") was acquired by the Company (the "Aevi Merger"). Mr. Cola served as President and Chief Executive Officer of Aevi from September 2013 until February 2020. Prior to joining Aevi, Mr. Cola served as President of Specialty Pharmaceuticals at Shire plc, a global specialty pharmaceutical company, from 2007 until April 2012. He joined Shire in 2005 as EVP of Global Therapeutic Business Units and Portfolio Management. Prior to joining Shire, he was with Safeguard Scientifics, Inc., a growth capital provider to life sciences and technology companies, where he served as President of the Life Sciences Group. While at Safeguard Scientifics, Mr. Cola served as Chairman and CEO of Clarient, Inc., a cancer diagnostics company subsequently acquired by GE Healthcare, and as Chairman of Laureate Pharma, Inc., a full-service contract manufacturing organization serving research-based biologics companies. Prior to that, Mr. Cola held senior positions in product development and commercialization at AstraMerck, a top 20 U.S. pharmaceutical company, and at AstraZeneca plc, a publicly-traded global biopharmaceutical company. He currently serves on the board of directors of Sage Therapeutics, Inc., a publicly-traded biopharmaceutical company, and serves as Chairman of the Board of Governors of the Boys & Girls Clubs of Philadelphia. Mr. Cola also served on the Life Sciences Pennsylvania Board (formerly named Pennsylvania Bio) from 2009 until 2015. Mr. Cola received a B.A. in biology and physics from Ursinus College and an M.S. in biomedical science from Drexel University. Our Board believes that Mr. Cola brings to the Board substantial leadership skills and a wealth of experience in the rare and orphan disease sector of the biotechnology industry, which makes him a valuable member of our Board.

Phil Gutry. Mr. Gutry has served on our Board since April 2015. Mr. Gutry has 20 years of experience in the biopharmaceutical industry in a variety of senior investment, business development, and strategic roles. Mr. Gutry currently serves as Chief Business Officer, Head of Finance & Investor Relations at Graphite Bio, Inc, a next-generation gene editing company. Prior to that, Mr. Gutry was the Chief Business Officer at Kronos Bio, Inc., a clinical-stage oncology company focused on targeting dysregulated transcription. He previously led oncology business development and strategy serving as Executive Director, Business Development at Regeneron Pharmaceuticals, Inc., an integrated biopharmaceutical company from July 2015 to October 2018. From May 2011 to June 2015, Mr. Gutry served as Principal at MPM Capital, Inc., a healthcare investment firm ("MPM"), where he led new company formation and venture investments in oncology and neuroscience, and managed MPM's pharmaceutical partnerships with Pharmaceuticals, Inc. and Astellas Pharma Inc. Prior to joining MPM, Mr. Gutry worked in corporate development at Gilead Sciences, Inc., a research-based biopharmaceutical company, where he focused on M&A and licensing in oncology, respiratory, liver, and infectious diseases. Mr. Gutry received his M.B.A. in Healthcare Management from The Wharton School and an A.B. in Earth Sciences from Dartmouth College. Our Board believes that Mr. Gutry's experience in the biopharmaceutical industry makes him a valuable member of our Board.

Gilla Kaplan, Ph.D. Dr. Kaplan has served on our Board since October 2020. Dr. Kaplan is recognized as an authority on various aspects of the host immune response to mycobacterial pathogens, including the causative agents of leprosy and tuberculosis. She was the Director of the Global Health Program, Tuberculosis, at the Bill and Melinda Gates Foundation ("BMGF") from January 2014 until April 2018. Dr. Kaplan's work has encompassed developing a deep understanding of the cellular immune response and how to harness it for host adjunctive therapies. She spent her career as an academic research scientist leading her laboratory in investigations focusing on human disease, and exploring novel experimental medicine approaches that modulate the immune response for disease control. Building on her research experience at Rockefeller University in New York City (for 20 years) and then at the Public Health Research Institute Center at the University of Medicine and Dentistry of New Jersey (for 10 years), she led the reshaping of the tuberculosis program at BMGF. Dr. Kaplan is the recipient of multiple grants from the NIH-National Institute of Allergy and Infectious Diseases and other funding organizations for her research. Dr. Kaplan served on the board of directors of Celgene from 1998 to 2018 and currently serves as a member of the board of directors of Tyra Biosciences, Inc., a biotechnology company. Our Board believe that Dr. Kaplan's academic and industry experience in immunology and rare diseases makes her a valuable member of Board.

Joseph Miller. Mr. Miller has served on our Board since April 2020. Mr. Miller brings over 20 years of experience and a wealth of financial knowledge as a senior executive with extensive hands-on experience in managing financial operations and supporting enterprise growth across the health sciences, biotech and pharmaceutical sectors. Mr. Miller currently serves as the Chief Financial Officer of Aurinia Pharmaceuticals Inc. (NASDAQ: AUPH), a late-stage clinical biopharmaceutical company. Prior to that, he served as the Company's Chief Financial Officer and principal financial officer from July 2018 until April 2020 and as the Company's principal executive officer from April 2019 to February 2020. Prior to joining the Company, Mr. Miller was the Vice President of Finance at Sucampo Pharmaceuticals, Inc., a global biopharmaceutical company, from 2015 to April 2018 where he was responsible for building out the finance organization to effectively support the company's rapid growth, ultimately resulting in the $1.2 billion merger with Mallinckrodt plc in early 2018. From 2006 to 2015, Mr. Miller was the Senior Director of Accounting at QIAGEN N.V., a provider of sample and assay technologies for molecular diagnostics, applied testing, academic and pharmaceutical research, and from 2002 to 2006, he served as Vice President of Finance and Chief Financial Officer of Eppendorf-5 Prime. Mr. Miller began his career at KPMG LLP, an international accounting firm. Mr. Miller holds a B.S. degree in accounting from Villanova University and is a Certified Public Accountant. Our Board believes that Mr. Miller's experience in managing the financial operations and supporting enterprise growth across the health sciences, biotech and pharmaceutical sectors makes him a valuable member of our Board.

Magnus Persson, M.D., Ph.D. Dr. Persson has served on our Board since August 2012. Dr. Persson is currently serving as Chief Executive Officer of Karolinska Institutet Holding AB in Stockholm, Sweden. Dr. Persson has served as an Associate Professor in Physiology at the Karolinska Institutet since September 1994. Dr. Persson has served as a practicing pediatrician at CityAkuten and Barnsjukhuset Martina in Stockholm, Sweden since December 2012. Previously, Dr. Persson served as a Partner at HealthCap, a Swedish-based venture capital firm, from January 1996 to December 2009, and as a Managing Partner at The Column Group, a San Francisco-based venture capital firm, from January 2010 through November 2011. Dr. Persson co-founded Aerocrine AB, a medical technology company in 1994. Dr. Persson has also served on the board of directors of Galecto AB, a biotechnology company, since January 2013, Gyros Protein Technologies AB, a provider of peptide synthesis and bioanalytical tools, since March 2012, ADDI Medical AB, a healthcare IT-software company, since October 2015, Immunicum AB, a biotechnology company, since December 2015, and Attgeno AB, a biotechnology company, since January 2018. Dr. Persson received his M.D. and Ph.D. in physiology from the Karolinska Institutet. Our Board believes that Dr. Persson's extensive experience in medicine, life sciences and biotechnology financing and his experience founding and leading public biotechnology and medical technology companies make him a valuable member of our Board who will assist in the development of our growth strategy and business plans.

EXECUTIVE OFFICERS

The following table sets forth information of our executive officers:

Name	Age	Position(s) with Cerecor
Michael Cola	61	Chief Executive Officer and principal executive officer
Schond Greenway	49	Chief Financial Officer, principal financial officer and Treasurer
James Harrell, Jr.	51	Chief Commercial Officer
Garry Neil, M.D.	67	Chief Scientific Officer
Christopher Sullivan	37	Chief Accounting Officer and principal accounting officer
H. Jeffrey Wilkins	59	Chief Medical Officer

The following is a brief biography of each current executive officer:

Michael Cola. The biography for Michael Cola, our Chief Executive Officer and member of the Board, is located in "Board of Directors" above.

Schond Greenway. Mr. Greenway was appointed the Chief Financial Officer of the Company in March 2021. Mr. Greenway comes to the Company with over 20 years' experience in investment banking, finance and corporate advisory and investment analysis in the life sciences and financial services industries. Prior to joining the Company, Mr. Greenway served as Vice President, Investor Relations at Mesoblast Limited ("Mesoblast"), an allogeneic cellular medicines company, from April 2016 to February 2021. At Mesoblast, Mr. Greenway led investor relations activities and successfully concluded several strategic corporate finance transactions and capital markets initiatives. Prior to Mesoblast, he served as Executive Director, Strategy & Investor Relations at Halozyme Therapeutics, Inc., a late stage oncology and biopharmaceutical company, from November 2013 to January 2016. Prior to that, Mr. Greenway served in positions of increasing responsibility at investment banking firms and healthcare companies such as Morgan Stanley, Barclays Capital and DURECT Corporation, predominantly focused on healthcare and technology. Mr. Greenway received a B.S. from Florida A&M University and an M.B.A. from the Darden Graduate School of Business at the University of Virginia.

James Harrell, Jr. Mr. Harrell has served as the Chief Commercial Officer of the Company since November 2019. Prior to being promoted to the Company's Chief Commercial Officer, Mr. Harrell previously served as the Company's Executive Vice President of Marketing and External Communications from May 2018 to November 2019. Mr. Harrell has a great breadth of biopharmaceutical industry experience. From May 2013 until May 2018, he was an owner and principal with the NSCI Group, Inc., a privately held medical communications and education company, where he focused on new business development and brand strategy. Mr. Harrell was Vice President and General Manager of Specialty Pharmaceuticals for Covidien, running a 350-person commercial operations group in the area of pain management from 2011 to 2013. From 2007 to 2010, he was the Vice President of Marketing with MedImmune, Inc., responsible for their Global Pediatric Infectious Disease franchise. From 1999 until February 2007, Mr. Harrell held various commercial positions with Centocor, Inc., a biotechnology company, with increasing levels of responsibility and management focused on the marketing of immunotherapy and cardiovascular products. He began his career in field sales and hospital sales at Rhone-Poulenc Rorer in 1991. During his career he has helped to commercialize and market three blockbuster brands. Mr. Harrell holds a B.S. degree in Business Administration, with a double major in Marketing and Economics from Samford University.

Garry Neil. Dr. Neil has served as the Chief Scientific Officer of the Company since March 2020. Prior to being promoted to the Company's Chief Scientific Officer, Dr. Neil served as the Company's Chief Medical Officer from February 2020 to March 2020. Prior to joining the Company in connection with the Aevi Merger, Dr. Neil served as Chief Scientific Officer of Aevi from September 2012 to February 2020. Prior to that, Dr. Neil held a number of senior positions in the pharmaceutical industry, academia and venture capital. From September 2012 to September 2013, Dr. Neil was a Partner at Apple Tree Partners, a life sciences private equity fund. Prior to joining Apple Tree Partners, he held a number of senior positions at Johnson & Johnson, including most recently as Corporate VP of Science & Technology from November 2007 to August 2012., Dr. Neil also served as Group President at Johnson & Johnson Pharmaceutical Research and Development from September 2005 to November 2007. Prior to joining Johnson & Johnson, he held senior positions at AstraZeneca, EMD Pharmaceuticals Inc. and Merck KGaA. Under his leadership, a number of important new medicines for the treatment of cancer, anemia, infections, central nervous system and psychiatric disorders, pain, and genitourinary and gastrointestinal diseases gained initial or expanded approvals. Dr. Neil served on the board of directors of GTx, Inc., a publicly-traded pharmaceutical company, from September 2016 until its merger with Oncternal Therapeutics, Inc. in March 2019. Since February 2017, he has served on the board of directors of Arena Pharmaceuticals, Inc. (NASDAQ: ARNA), a publicly-traded biopharmaceutical company and in February 2021 he was named Chairman of Arena Pharmaceutical, Inc.'s Board. Dr. Neil also serves on the Board of Directors of the Reagan Udall Foundation and the Center for Discovery and Innovation (CDI). He is a past Chairman of the Pharmaceutical Research and Manufacturers Association ("PhRMA") Science and Regulatory Executive Committee and the PhRMA Foundation Board, as well as a past member of the Foundation for the U.S. National Institutes of Health ("NIH") and

the Science Management Review Board of the NIH. Dr. Neil holds a B.S. from the University of Saskatchewan and an M.D. from the University of Saskatchewan College of Medicine. He completed postdoctoral clinical training in internal medicine and gastroenterology at the University of Toronto. Dr. Neil also completed a postdoctoral research fellowship at the Research Institute of Scripps Clinic.

Christopher Sullivan. Mr. Sullivan has served as Chief Accounting Officer of the Company since March 2021. Previously, Mr. Sullivan served as the Company's Interim Chief Financial Officer, principal financial officer, and principal accounting officer from April 2020 to February 2021. Mr. Sullivan was the Vice President of Finance at the Company and served various other escalating roles since joining the Company in April 2018. Mr. Sullivan brings a strong technical and SEC reporting background to the Company along with a wealth of financial knowledge, including experience with multiple forms of capital raises, based on leading accounting and finance functions at various health sciences, biotech and pharmaceutical companies. Prior to joining the Company, Mr. Sullivan was the Corporate Controller for Sucampo Pharmaceuticals, Inc. from August 2017 to April 2018, when it was merged with Mallinckrodt in a $1.2 billion transaction. From November 2015 to August 2017, Mr. Sullivan was the Corporate Controller for OpGen Inc. (NASDAQ: OPGN), a microbial genetics analysis company, and prior to that was a Senior Manager at Ernst & Young, LLP where he was employed from August 2005 to October 2015. Mr. Sullivan received his B.S. degrees in Accounting and Finance from the University of Maryland, College Park and is a Certified Public Accountant.

H. Jeffrey Wilkins. Dr. Wilkins has served as the Chief Medical Officer of the Company since April 2020. Previously, Dr. Wilkins served as the Company's Chief Development Officer from February 2020 to April 2020. Prior to joining the Company, he served as Chief Medical Officer of Zyla Life Sciences, a pharmaceutical company, from June 2019 to February 2020; Onspria Therapeutics, a drug development company, from December 2018 to June 2019; and Lycera Corporation, a biopharmaceutical company, from March 2015 to December 2018. From January 2014 to February 2014, Dr. Wilkins was a Partner at NeXeption, LLC, a biopharmaceutical management company. From May 2011 to December 2013, Dr. Wilkins served as Chief Medical Officer of Ceptaris Therapeutics, Inc., a pharmaceutical company. In his career, he has led clinical programs from IND Phase I trials to regulatory approval (including Valchlor®). Prior to that, Dr. Wilkins served in positions of increasing responsibility at healthcare companies such as Cephalon, Inc., Ception Therapeutics, Inc. and GlaxoSmithKline plc. Earlier in his career as a practicing primary care physician, he was Co-Founder and Chief Executive Officer of TriValley Primary Care, a large multi-center primary care group, in Southeastern Pennsylvania. Dr. Wilkins received his M.D. from Temple University School of Medicine and his B.S. from Bucknell University.

CODE OF ETHICS

The Company has adopted the Cerecor Inc. Code of Business Conduct and Ethics that applies to all officers, directors and employees. The Code of Business Conduct and Ethics is available on the Company's website at ir.cerecor.com. If the Company makes any substantive amendments to the Code of Business Conduct and Ethics or grants any waiver from a provision of the Code to any executive officer or director, the Company will promptly disclose the nature of the amendment or waiver on its website**.**

CORPORATE GOVERNANCE GUIDELINES

In June 2015, the Board documented the governance practices followed by the Company by adopting Corporate Governance Guidelines to assure that the Board will have the necessary authority and practices in place to review and evaluate the Company's business operations as needed and to make decisions that are independent of the Company's management. The guidelines are also intended to align the interests of directors and management with those of the Company's stockholders. The Corporate Governance Guidelines set forth the practices the Board intends to follow with respect to Board composition and selection, the role of the Board, director orientation and education, Board meetings and involvement of senior management, Chief Executive Officer performance evaluation and succession planning and Board committees and compensation. The Corporate Governance Guidelines, as well as the charters for each committee of the Board, may be viewed at ir.cerecor.com.

Audit Committee and Audit Committee Financial Expert

The Audit Committee of the Board assists the Board in its oversight of the integrity of the Company's financial statements, the qualifications and independence of our independent auditors, and our internal financial and accounting controls. The Audit Committee has direct responsibility for the appointment, compensation, retention (including termination) and oversight of our independent auditors, and our independent auditors report directly to the Audit Committee. The Audit Committee also prepares the audit committee report that the SEC requires to be included in our annual proxy statement. The Audit Committee met four times during 2020. The Board has adopted a written Audit Committee charter that is available to stockholders on the Company's website at ir.cerecor.com.

The Audit Committee is currently composed of three directors: Mr. Gutry (Chair), Dr. Bruhn and Dr. Persson. Keith Schmidt served on our Board, and on the Audit Committee, until June 18, 2020. The Board reviews the NASDAQ Listing Rules definition of independence for Audit Committee members on an annual basis and has determined that, for the year ended December 31, 2020, all members of the Company's Audit Committee are independent as defined in Rule 5605(c)(2)(A)(i) and (ii) of the NASDAQ Listing Rules. The Board has also determined that Mr. Gutry qualifies as an "audit committee financial expert," as defined in applicable SEC rules. The Board made qualitative assessments of Mr. Gutry's level of knowledge and experience based on a number of factors, including formal education and experience.

SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Exchange Act requires the Company's directors and executive officers, and persons who own more than ten percent of a registered class of the Company's equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of common stock and other equity securities of the Company. Officers, directors and greater than ten percent stockholders are required by SEC regulation to furnish the Company with copies of all Section 16(a) forms they file.

To the Company's knowledge, based solely on a review of the copies of such reports furnished to the Company and written representations that no other reports were required, during the year ended December 31, 2020, all officers, directors and greater than ten percent beneficial owners were in compliance with applicable Section 16(a) filing requirements, except that each of Mr. Miller and Dr. Pericles Calias filed one late Form 4 reporting the withholding of stock to satisfy tax withholding obligations upon vesting of restricted stock units.

Item 11. Executive Compensation.

EXECUTIVE COMPENSATION

The following table shows for the fiscal years ended December 31, 2020 and 2019, compensation awarded to or paid to, or earned by, anyone serving as principal executive officer during the most recently completed fiscal year and our next two most highly compensated executive officers who were serving as executive officers during the year ended December 31, 2020 (the "Named Executive Officers").

Name and Principal Position	Year	Salary	Bonus[5]	Option Awards[6]	All Other Compensation	Total
Michael Cola[1] *Chief Executive Officer and Principal Executive Officer*	2020	$ 79,228	378,000	3,363,078	—	$ 3,820,306
	2019	$ —	—	—	—	$ —
Garry Neil, M.D.[2] *Chief Scientific Officer*	2020	$ 372,932	296,000	2,019,872	—	$ 2,688,804
	2019	$ —	—	—	—	$ —
H. Jeffrey Wilkins, M.D.[3] *Chief Medical Officer*	2020	$ 335,534	178,000	974,244	—	$ 1,487,778
	2019	$ —	—	—	—	$ —
Joseph Miller[4] *Former Chief Financial Officer, former Principal Financial Officer, and former Principal Executive Officer*	2020	$ 116,748	—	—	115,521 (7)	$ 232,269
	2019	$ 356,000	222,000	592,598	—	$ 1,170,598

(1) Mr. Cola's employment with the Company commenced on February 3, 2020.

(2) Mr. Neil's employment with the Company commenced on February 3, 2020.

(3) Dr. Wilkins' employment commenced with the Company on February 4, 2020.

(4) Mr. Miller's employment with the Company ceased on April 24, 2020.

(5) The amounts reflect the bonus relative to the achievement of goals for fiscal year 2020 as recommended by the Compensation Committee and approved by the Board.

(6) The amounts reflect the grant date fair value for option awards granted during 2020 and 2019, respectively, in accordance with FASB Topic ASC 718, excluding the estimate of forfeitures. Compensation will only be realized to the extent the market price of our common stock is greater than the exercise price of such option award.

(7) The amount listed is comprised of $50,759 of benefits accrued and due (and subsequently paid) as of the date of Mr. Miller's resignation and $64,762 of director compensation comprised of option awards for service as a non-employee director subsequent to being employed as an executive officer.

Narrative to Summary Compensation Table

We review compensation annually for all employees, including our Named Executive Officers. In setting annual base salaries and bonuses and granting equity incentive awards, we consider (i) compensation for comparable positions in the market, (ii) individual performance as compared to our expectations and objectives, (iii) our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders, and (iv) a long-term commitment to our Company.

Our Board historically has determined our executives' compensation based on the recommendations of our Compensation Committee, which typically reviews and discusses management's proposed compensation with the Chief Executive Officer or for all executives other than the Chief Executive Officer. Based on those discussions and its discretion, the Compensation Committee then recommends the compensation for each executive officer to the Board. Our Board, without members of management present, discusses the Compensation Committee's recommendations and ultimately approves the compensation of our executive officers.

Annual Base Salary

We have entered into employment agreements with each of our Named Executive Officers that establish annual base salaries, which are generally determined, approved and reviewed periodically by our Compensation Committee in order to compensate our Named Executive Officers for the satisfactory performance of duties to our Company. Annual base salaries are intended to provide a fixed component of compensation to our Named Executive Officers, reflecting their skill sets, experience, roles and responsibilities. Base salaries for our Named Executive Officers have generally been set at levels deemed necessary to attract and retain individuals with superior talent. The following table presents the annual base salaries for each of our Named Executive Officers for 2020, as determined by the Compensation Committee.

Name	2020 Base Salary
Michael Cola[(1)]	$115,048
Garry Neil, M.D.[(2)]	$410,000
H. Jeffrey Wilkins, M.D.[(3)]	$370,000
Joseph Miller[(4)]	$381,100

(1) Mr. Cola's employment with the Company commenced on February 3, 2020. The base salary above assumes he was employed for the entirety of 2020. The base salary pursuant to Mr. Cola's employment agreement entered into on January 29, 2020 was $450,000. On March 11, 2020, Mr. Cola and the Company entered into an amendment to the employment agreement in which his base salary in cash was reduced from an annual rate of $450,000 to an annual rate of $35,568 (the "Reduction"). In consideration for the Reduction, on a quarterly basis, the Company grants stock options, which vest immediately (the "Salary Options"), for the purchase of a number of shares of the Company's common stock with a total value (based on the Black-Scholes valuation methodology) based on a pro rata total annual value of $414,432 of the foregone salary.

(2) Mr. Neil's employment with the Company commenced on February 3, 2020. The base salary above assumes he was employed for the entirety of 2020.

(3) Dr. Wilkins' employment with the Company commenced on February 4, 2020. The base salary above assumes he was

employed for the entirety of 2020.

(4) Mr. Miller's employment with the Company ceased on April 24, 2020. The base salary above assumes he was employed for the entirety of 2020.

Annual Bonus

Our discretionary bonus plan motivates and rewards our Named Executive Officers for achievements relative to our goals and expectations for each fiscal year. Our Named Executive Officers are eligible to receive discretionary annual bonuses calculated as a target percentage of their annual base salaries, based on our Compensation Committee and Board's assessment of their individual performance and our Company's results of operations and financial condition. As recommended by the Compensation Committee and approved by the Board, our Named Executive Officers employed with the Company at end of the fiscal year ended December 31, 2020 received a bonus relative to achievement of goals for fiscal year 2020.

Equity-Based Awards

Our equity-based incentive awards are designed to align our interests with those of our employees and consultants, including our Named Executive Officers. Our Compensation Committee is generally responsible for approving equity grants. Vesting of equity awards is generally tied to continuous service with the Company and serves as an additional retention measure. Our executives are typically awarded an initial new hire grant upon commencement of employment. Additional grants may occur periodically in order to specifically incentivize executives.

Our Board adopted, and our stockholders approved, our 2016 Equity Incentive Plan (the "2016 Plan"), which replaced our 2015 Omnibus Incentive Compensation Plan. The 2016 Plan became effective on May 18, 2016. The plan was amended and restated in May 2018 to increase the share reserve by an additional 1.4 million shares. A Second Amended and Restated 2016 Equity Incentive Plan was approved by the Company's stockholders in August 2019, which increased the share reserve by an additional 850,000 shares. A Third Amended and Restated 2016 Equity Incentive Plan (the "2016 Amended Plan") was approved by the Company's stockholders in June 2020 which increased the share reserve by an additional 2,014,400 shares.

The purpose of our 2016 Amended Plan is to attract and retain employees, non-employee directors and consultants and advisors. Our 2016 Amended Plan authorizes us to make grants to eligible recipients of non-qualified stock options, incentive stock options, restricted stock awards, restricted stock units and stock-based awards.

Other Compensation

Our Named Executive Officers did not participate in, or otherwise receive any benefits under, any pension or deferred compensation plan sponsored by the Company during fiscal year 2020 or fiscal year 2019. We generally do not provide perquisites or personal benefits to our Named Executive Officers.

Employment Agreements and Potential Payments Upon Certain Events

Michael Cola

Mr. Cola entered into an employment agreement with the Company effective February 3, 2020. The offer letter initially provided for an annual base salary of $450,000. Mr. Cola is eligible to receive a discretionary annual bonus as determined by our Board or the Compensation Committee, in its sole discretion, with a target amount of up to seventy percent (70%) of his base salary, and conditioned on Mr. Cola being employed by the Company on the applicable bonus payment date. Such annual discretionary bonus may be paid in the form of cash or equity awards, consistent with bonuses paid to executives of similar grade at similarly situated companies in the biotechnology industry, subject to corporate and individual performance. Mr. Cola is also eligible for a discretionary annual bonus consisting of restricted stock or options at the discretion of the Board or Compensation Committee. The independent directors of the Board approved an inducement option grant to Mr. Cola to purchase 1.2 million shares of the Company's common stock, which was granted on February 3, 2020. The inducement option grant will vest over four years, with the first 25% of such option vesting on the first anniversary of the Aevi Merger, and the remainder vesting in equal monthly installments thereafter, provided that Mr. Cola remains an employee of the Company as of each such vesting date. Mr. Cola is also eligible to participate in the Company's other employee benefit plans as in effect from time to time on the same basis as are generally made available to the Company's other senior executive officers.

On March 11, 2020, Mr. Cola and the Company entered into the Reduction amendment to his employment agreement in which his base salary in cash was reduced from an annual rate of $450,000 to an annual rate of $35,568. In consideration for the Reduction, on a quarterly basis, the Company grants the Salary Options, which vest immediately, for the purchase of a number of shares of the Company's common stock with a total value (based on the Black-Scholes valuation methodology) based on a pro rata total annual value of $414,432 of the foregone salary. If the employment of Mr. Cola is terminated prior to the end of a calendar quarter, the portion of the Salary Options granted hereunder for such calendar quarter that reflects the percentage of calendar days remaining in such calendar quarter after such employment termination date shall be forfeited and deemed cancelled. Notwithstanding the foregoing, if the Fair Market Value (as defined in Mr. Cola's employment agreement) of the Company's common stock is below $2.07 or the grant of the Salary Options is prohibited by the 2016 Amended Plan, applicable law or the rules of any applicable stock exchange or trading market on which the Company's common stock is listed or trades, then the Salary Options will not be granted, and instead Mr. Cola will be deemed to have selected the Cash Selection (as defined in Mr. Cola's employment agreement) for such calendar quarter. The remainder of Mr. Cola's employment agreement remains in full force and effect, in accordance with its terms. The Board subsequently approved an increase to Mr. Cola's annual base salary, such that his annual base salary is currently $500,000.

Mr. Cola's employment agreement prohibits the disclosure or use of any proprietary or confidential information obtained by him as a result of his employment with the Company. Mr. Cola is obligated not to compete with the Company during his employment and for a period of one year following his termination of employment with the Company. In addition, his employment agreement contains restrictions related to the solicitation of, and interference with, customers, vendors, and employees of the Company for a period of one year following termination of employment.

Payments Upon Termination or Change in Control

If Mr. Cola's employment is terminated by the Company without "cause" or by Mr. Cola for "good reason" (each as defined in his employment agreement), in each case subject to Mr. Cola entering into and not revoking a separation agreement in a form acceptable to the Company, Mr. Cola his eligible to receive: (i) accrued benefits under his employment agreement; (ii) continued payment of his base salary for 18 consecutive months (subject to compliance with obligations set forth in his employment agreement); (iii) 100% of his annual bonus earned in the year in which the termination occurs, payable when such annual bonuses are paid to the Company's other executive employees; (iv) full vesting of options awarded by the Company which shall be exercisable for six (6) months following such termination; and (v) if he timely elects and remains eligible for continued coverage under COBRA, the COBRA premiums necessary to continue the health insurance coverage in effect for Mr. Cola and his covered dependents prior to the date of termination, until the earliest of (x) the first anniversary of his termination, (y) expiration of his continuation coverage under COBRA, or (z) the date when he is eligible for substantially equivalent health insurance.

If a termination without cause occurs within six months of a change in control (as defined in his employment agreement), then the amounts payable to Mr. Cola pursuant to clauses (i)-(iii) above are payable at the later of the closing of the change in control or the termination of his employment. If Mr. Cola's termination is by reason of death or disability, Mr. Cola is eligible to receive: (i) accrued benefits under his employment agreement; (ii) a prorated annual bonus earned in respect of the year in which the termination occurs, payable when such annual bonuses are paid to other executive employees of the Company; (iii) full vesting of options awarded by the Company, which shall be exercisable for six (6) months following such termination; and (iv) continued payment of his base salary for 6 months.

Garry Neil, M.D.

General

Dr. Neil entered into an employment agreement with the Company effective February 3, 2020. The offer letter initially provided for an annual base salary of $410,000. Dr. Neil is eligible to receive a discretionary annual bonus as determined by our Board or the Compensation Committee, in its sole discretion, with a target amount of up to sixty percent (60%) of his base salary, and conditioned on Dr. Neil being employed by the Company on the applicable bonus payment date. Such annual discretionary bonus may be paid in the form of cash or equity awards, consistent with bonuses paid to executives of similar grade at similarly situated companies in the biotechnology industry, subject to corporate and individual performance. Dr. Neil is also eligible for a discretionary annual bonus consisting of restricted stock or options at the discretion of the Board or Compensation Committee. The independent directors of the Board approved an inducement option grant to Dr. Neil to purchase 800,000 shares of common stock, which was granted on February 3, 2020. The inducement option grant will vest over four years, with the first 25% of such option vesting on the first anniversary of the Aevi Merger, and the remainder vesting in equal monthly installments, provided that Dr. Neil remains an employee of the Company as of each such vesting date. Dr. Neil is also eligible to participate in the Company's other employee benefit plans as in effect from time to time on the same basis as are generally made available to the Company's other senior

executives. The Board subsequently approved an increase to Dr. Neil's annual base salary, such that his annual base salary is currently $423,000.

Dr. Neil's employment agreement prohibits the disclosure or use of any proprietary or confidential information obtained by him as a result of his employment with the Company. Dr. Neil is obligated not to compete with the Company during his employment and for a period of one year following his termination of employment with the Company. In addition, his employment agreement contains restrictions related to the solicitation of, and interference with, customers, vendors and employees of the Company for a period of one year following termination of employment.

Payments Upon Termination or Change in Control

If Dr. Neil's employment is terminated by the Company without "cause" or by Dr. Neil for "good reason" (each as defined in his employment agreement), in each case subject to Dr. Neil entering into and not revoking a separation agreement in a form acceptable to the Company, Dr. Neil will be eligible to receive: (i) accrued benefits under his employment agreement; (ii) continued payment of his base salary for 18 consecutive months (subject to compliance with obligations set forth in his employment agreement),; (iii) 100% of his annual bonus earned in the year in which the termination occurs, payable when such annual bonuses are paid to the Company's other executive employees; (iv) full vesting of options awarded by the Company which shall be exercisable for six (6) months following such termination; and (v) if he timely elects and remains eligible for continued coverage under COBRA, the COBRA premiums necessary to continue the health insurance coverage in effect for Dr. Neil and his covered dependents prior to the date of termination, until the earliest of (x) the first anniversary of his termination, (y) expiration of the executive's continuation coverage under COBRA, or (z) the date when the he is eligible for substantially equivalent health insurance.

If a termination without cause occurs within six months of a change in control (as defined in his employment agreement), then the amounts payable to Dr. Neil pursuant to clauses (i)-(iii) above are payable at the later of the closing of the change in control or the termination of the his employment. If Dr. Neil's termination is by reason of death or disability, Dr. Neil is eligible to receive: (i) accrued benefits under his employment agreement; (ii) a prorated annual bonus earned in respect of the year in which the termination occurs, payable when such annual bonuses are paid to other executive employees of the Company; (iii) full vesting of options awarded by the Company, which shall be exercisable for six (6) months following such termination; and (iv) continued payment of his base salary for 6 months.

Joseph Miller

General

Mr. Miller entered into an offer letter with the Company effective July 12, 2018. The offer letter initially provided for an annual base salary of $320,000. The Board subsequently approved increases to Mr. Miller's annual base salary, such that his annual base salary was $370,000 effective April 1, 2020. Mr. Miller was eligible to receive a discretionary annual bonus of up to forty percent (40%) of his base salary as determined by our Board or the Compensation Committee, in its sole discretion, provided that Mr. Miller is employed by the Company on the applicable bonus payment date. Such annual discretionary bonus could be paid in the form of cash or equity awards, consistent with bonuses paid to executives at similar grade of similarly situated companies in the biotechnology industry, subject to corporate and individual performance.

Mr. Miller's employment agreement prohibits the disclosure or use of any proprietary or confidential information obtained by him as a result of his employment with the Company. Mr. Miller was also obligated not to compete with the Company during his employment and for a period of six months following his termination of employment with the Company. In addition, his employment agreement contained restrictions related to the solicitation of, and interference with, customers, vendors and employees of the Company for a period of one year following termination of employment.

Mr. Miller served as the Company's principal executive officer effective April 10, 2019 and continued to serve in this role until February 3, 2020. Effective April 24, 2020, Mr. Miller resigned his employment with the Company as our Chief Financial Officer of the Company. Mr. Miller was serving as the Company's principal financial and accounting officer. Mr. Miller's resignation was not related to any disagreement with the Company on any matter relating to the Company's operations, policies or practices. Upon his resignation, Mr. Miller was appointed to serve on the Board until the 2020 Annual Meeting of Stockholders and was subsequently re-elected to serve until the 2021 Annual Meeting of Stockholders or until his successor is duly elected and qualified.

Payments Upon Termination or Change in Control

Pursuant to the terms of Mr. Miller's employment agreement, Mr. Miller was not entitled to severance upon his resignation on April 24, 2020 since his resignation was voluntary and without "good reason" (as defined in Mr. Miller's employment agreement).

H. Jeffrey Wilkins

General

Dr. Wilkins entered into an offer letter with the Company effective February 4, 2020. The offer letter initially provided for an annual base salary of $370,000. Dr. Wilkins is eligible to receive a discretionary annual bonus as determined by our Board or the Compensation Committee, in its sole discretion, with a target amount of up to forty percent (40%) of his base salary, and conditioned on Dr. Wilkins being employed by the Company on the applicable bonus payment date. Such annual discretionary bonus may be paid in the form of cash or equity awards, consistent with bonuses paid to executives of similar grade at similarly situated companies in the biotechnology industry, subject to corporate and individual performance. Dr. Wilkins is also eligible for a discretionary annual bonus consisting of restricted stock or options at the discretion of the Board or Compensation Committee. The independent directors of the Board approved an inducement option grant to Dr. Wilkins to purchase 375,000 shares of common stock, which was granted on February 4, 2020. The inducement option grant will vest over four years, with the first 25% of such option vesting on February 4, 2021, and the remainder vesting in equal monthly installments thereafter, provided that Dr. Wilkins remains an employee of the Company as of each such vesting date. Dr. Wilkins is also eligible to participate in the Company's other employee benefit plans as in effect from time to time on the same basis as are generally made available to the Company's other senior executives. The Board subsequently approved increases to Mr. Wilkins' annual base salary, such that his annual base salary is currently $425,000.

In connection with his offer letter, Dr. Wilkins executed a confidentiality, assignment of inventions and non-solicitation agreement (the "Confidentiality Agreement") with the Company. The Confidentiality Agreement prohibits the disclosure or use of any proprietary or confidential information obtained by Dr. Wilkins as a result of his employment with the Company. The Confidentiality Agreement also contains restrictions related to the solicitation of, and interference with, customers and employees of the Company for a period of one year following termination of employment.

Pursuant to the terms of Dr. Wilkins' offer letter, Dr. Wilkins' employment with the Company is "at-will" and may be terminated at any time and for any reason, with or without cause, by the Company or Dr. Wilkins.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

The following table shows for the fiscal year ended December 31, 2020, certain information regarding outstanding equity awards at fiscal year-end for each of the Named Executive Officers.

Name	Grant Date	Unexercised Options Exercisable (#)	Unexercised Options Unexercisable (#)		Option Exercise Price ($)	Option Expiration Date	Unvested Restricted Stock Units (#)	
Michael Cola	2/3/2020	—	1,200,000	(1)	$ 3.98	2/3/2030		
	6/18/2020	84,322	—	(2)	$ 2.51	6/18/2030		
	7/1/2020	64,683	—	(2)	$ 2.56	7/1/2030		
	10/1/2020	76,674	—	(2)	$ 2.24	10/1/2030		
Garry Neil, M.D.	2/3/2020	—	800,000	(1)	$ 3.98	2/3/2030		
H. Jeffrey Wilkins M.D.	2/4/2020	—	375,000	(1)	$ 4.09	2/4/2030		
Joseph Miller	7/12/2018	63,437	41,563	(3)	4.50	7/11/2028		
	7/12/2018						22,500	(6)
	4/1/2019	72,917	102,083	(3)	$ 6.22	4/1/2029		
	6/18/2020	—	25,000	(4)	$ 2.51	6/18/2030		
	6/30/2020	4,005	—	(5)	$ 2.60	6/30/2030		
	9/30/2020	6,374	—	(5)	$ 2.28	9/30/2030		
	12/31/2020	5,472	—	(5)	$ 2.64	12/31/2030		

(1) One-fourth of the shares underlying the options shall vest and become exercisable on the first anniversary of the grant date, and the remaining three-fourths vest in equal monthly installments over the following 36 months, subject to the respective grantee providing continuous services to the Company.

(2) Such options vested in full on the grant date. Such options relate to the Salary Options granted to Mr. Cola in lieu of his foregone cash salary pursuant to the amendment to the employment agreement Mr. Cola and the Company entered into in March 2021. As part of such amendment (described in detail in the "Employment Arrangements and Potential Payments Upon Certain Events" section above), Mr. Cola's salary in cash was reduced from an annual rate of $450,000 to an annual rate of $35,568. In consideration for such reduction, on a quarterly basis, the Company grants stock options, which vest immediately, for the purchase of a number of shares of the Company's common stock with a total value (based on the Black-Scholes valuation methodology) based on a pro rata total annual value of the foregone cash salary.

(3) Such options were granted to Mr. Miller in his capacity as an executive of the Company and were set to vest according to the following schedule: one-fourth of the shares underlying the option shall vest and become exercisable on the first anniversary of the grant date, and the remaining three-fourths vest in equal monthly installments over the following 36 months, subject to Mr. Miller providing continuous service to the Company. Effective April 24, 2020, Mr. Miller resigned in his capacity as an executive of the Company. Simultaneously with his resignation, Mr. Miller was appointed to serve on the Board. The Company and Mr. Miller entered into a letter agreement in April 2020 pursuant to which the stock options and restricted stock units granted to him in 2018 and 2019 will continue to vest based on each award's initial vesting schedule, subject to Mr. Miller's continuous service on the Board.

(4) Such stock options were granted to Mr. Miller in his capacity as a non-employee Board member pursuant to the Company's non-employee director compensation policy. These options represent the annual grant of options to purchase 25,000 shares of our common stock and will vest in full on the one-year anniversary of the grant date, subject to continued service from the date of grant until the vesting date.

(5) Such stock options were granted to Mr. Miller in his capacity as a non-employee Board member pursuant to the Company's non-employee director compensation policy. These options represent his annual cash compensation (that is paid on a quarterly basis), which Mr. Miller elected to receive in the form of stock options pursuant to the Company's non-employee director compensation policy. Such options vested in full on the grant date.

(6) Such restricted stock units were granted to Mr. Miller in his capacity as an executive of the Company that were set to vest in four equal installments on June 8, 2019, 2020, 2021 and 2022, subject to Mr. Miller providing continuous service to the Company.

Effective April 24, 2020, Mr. Miller resigned in his capacity as an executive of the Company. Simultaneously with his resignation, Mr. Miller was appointed to serve on the Board. The Company and Mr. Miller entered into a letter agreement in April 2020 pursuant to which the stock options and restricted stock units granted to him in 2018 and 2019 will continue to vest based on each award's initial vesting schedule, subject to Mr. Miller's continuous service on the Board.

DIRECTOR COMPENSATION

After consultation with an independent compensation consultant, our Board approved a compensation policy for our non-employee directors that became effective upon the closing of our initial public offering. After consultation with an independent compensation consultant, the policy was most recently amended on January 26, 2021. In 2020, the policy provided for the following compensation to our non-employee directors, with increases in January 2021 as indicated below in parenthesis:

- The chair of our Board (if not an employee director) receives an annual fee of $60,000 ($70,000) and each other non-employee director receives $35,000 ($40,000);
- The chair of our Audit Committee receives an annual fee of $15,000 and each other member receives $7,500;
- The chair of our Compensation Committee receives an annual fee of $10,000 and each other member receives $5,000;
- The chair of our Nominating and Corporate Governance Committee receives an annual fee of $7,000 ($8,000) and each other member receives $3,500 ($4,000);
- The chair of our Science and Technology Advisory Committee receives an annual fee of $15,000 and each other member receives $7,500; and
- Each non-employee director is entitled to (i) an initial grant of stock options to purchase 50,000 (80,000) shares of our common stock and (ii) an annual grant of options to purchase 25,000 (40,000) shares of our common stock under the 2016 Amended Plan. The initial grant vests in three substantially equal annual installments over three years commencing on the first anniversary of the grant date. Each annual grant vests in full on the first anniversary of the grant date, in each case, subject to continued service from the date of grant until the applicable vesting dates.

Each non-employee director may make an election to receive all or a part of his annual cash compensation in the form of stock options to purchase shares of the Company's common stock. Elections must be made in multiples of 5% of an Eligible Director's (as defined in the 2016 Amended Plan) aggregate cash retainer. The stock options will be granted on the date on which the cash would have otherwise been paid, with an exercise price per share equal to the last reported sale price of the common stock on the Nasdaq Capital Market on the date of grant or, if such grant date is not a trading date, on the last trading date prior to the grant date, and with a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service). The actual number of shares subject to the stock options will be determined so that the options have a "fair value" on the date of grant, using a Black-Scholes or binominal valuation model consistent with the methodology.

All fees under the director compensation policy are paid on a rolling annual basis and no per meeting fees are paid. The Company reimburses non-employee directors for reasonable expenses incurred in connection with attending Board and committee meetings.

The following table sets forth information regarding the total compensation paid to the Company's non-employee directors during 2020. The compensation amounts presented in the table below are historical and are not indicative of the amounts the Company may pay directors in the future. Directors who are also Company employees receive no additional compensation for their services as directors and are not included in the table below.

Name	Current Non-Employee Director	Fees Earned or Paid in Cash[1] ($)	Option Awards[2] ($)	Total ($)	Option Awards Held at December 31, 2020 (#)
Sol Barer, Ph.D.	X	$50,675	$2,785,910	$2,836,585	1,537,500
Steven Boyd	X	$—	$—	$—	—
Suzanne Bruhn, Ph.D.	X	$16,206	$139,545	$155,751	85,709
Phil Gutry	X	$37,200	$65,551	$102,751	173,956
Gilla Kaplan, Ph.D.	X	$—	$90,997	$90,997	57,216
Joseph Miller[3]	X	$—	$64,765	$64,765	320,851[3]
Magnus Persson, M.D., Ph.D.	X	$28,865	$69,616	$98,481	220,613
Peter Greenleaf[4]		$4,181	$—	$4,181	—
Uli Hacksell, Ph.D.[5]		$13,446	$2,888	$16,334	663,060[5]
Simon Pedder, Ph.D.[6]		$24,014	$23,086	$47,100	354,756[6]
Keith Schmidt[7]		$22,167	$—	$22,167	75,000[7]

(1) The amounts shown in this column reflect fees earned for services rendered in fiscal year 2020.

(2) The amounts shown in this column represent the aggregate grant date fair value of stock options granted in fiscal year 2020 computed in accordance with ASC 718, Compensation—Stock Compensation. The assumptions used in valuing these options are described under the caption “Stock-Based Compensation” in Note 2 to our consolidated financial statements included in this Annual Report on Form 10-K, for the year ended December 31, 2020.

(3) Mr. Miller was appointed Chief Financial Officer of the Company in July 2018 and served in this role until his resignation on April 24, 2020. Simultaneously with his resignation as an executive officer of the Company, Mr. Miller was appointed to serve on the Board. Of his 320,851 options held at December 31, 2020, 280,000 relate to option awards granted in his capacity as an executive of the Company and 40,851 related to option awards granted in his capacity as a non-employee director. In addition, Mr. Miller held an aggregate of 22,500 restricted stock units as of December 31, 2020, which were granted in his capacity as an executive of the Company.

(4) Mr. Greenleaf served on the Board until February 12, 2020.

(5) Dr. Hacksell served on the Board until June 18, 2020. The Company and Dr. Hacksell entered into a letter agreement in which his option awards will continue to vest and remain exercisable for twelve months following his termination of service to the Company.

(6) Dr. Pedder joined the Board effective April 9, 2018 and served as a non-employee director until April 15, 2019, when he was named Executive Chairman of the Board. On April 24, 2020, the Company and Dr. Pedder entered into a separation agreement (the “Separation Agreement”). Pursuant to the Separation Agreement, Dr. Pedder resigned as a Company employee effective April 24, 2020 (the “Termination Date”). Dr. Pedder remained on the Board until June 18, 2020. Pursuant to the Separation Agreement, Dr. Pedder will serve as a special advisor to the Board for a period of up to 18 months following the 2020 Meeting (the “Consulting Period”). From the Termination Date through the end of the Consulting Period, Dr .Pedder will receive (i) continued vesting of his restricted stock units and service-based stock options, as those terms are defined in the Separation Agreement; and (ii) cash and equity payments in accordance with the Company’s non-employee director compensation policy. As of the Termination Date, Dr. Pedder forfeited the options previously granted to him with market-based vesting conditions. As displayed in the table above, Dr. Pedder held 354,756 options with service-based vesting conditions as of December 31, 2020. In addition, he held 133,333 unvested restricted stock units as of December 31, 2020.

(7) Mr. Schmidt served on the Board until June 18, 2020. The Company and Mr. Schmidt entered into a letter agreement in which his option awards will continue to vest and remain exercisable for twelve months following his termination of service to the Company.

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

EQUITY COMPENSATION PLAN INFORMATION

The following table contains certain information with respect to our equity compensation plan in effect as of December 31, 2020:

	(A)		(B)		(C)	
Plan category	Number of Securities to be Issued Upon Exercise of Outstanding Options and Vesting of Restricted Stock Units (#)		Weighted-Average Exercise Price of Outstanding Options ($)		Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans, excluding securities reflected in column (A) (#)	
Equity compensation plans approved by stockholders	7,611,507		$3.84	(1)	2,971,623	(2)
Equity compensation plans not approved by stockholders	2,375,000	(3)	$4.00		—	
Total	9,986,507		$3.88	(1)	2,971,623	

(1) The weighted-average exercise price does not take into account shares issuable upon the vesting of outstanding restricted stock units, which have no exercise price. As of December 31, 2020, there were 155,833 shares of unvested restricted stock units.

(2) Reflects shares of common stock available for future issuance under our Third Amended and Restated 2016 Equity Incentive Plan at December 31, 2020. In March 2018, our board of directors adopted the Amended and Restated 2016 Equity Incentive Plan, which was approved by our stockholders in May 2018. In June 2019, our board of directors adopted the Second Amended and Restated 2016 Equity Incentive Plan, which was approved by our stockholders in August 2019. In April 2020, our board of directors adopted the Third Amended and Restated Equity Incentive Plan, which was approved by our stockholders in June 2020. During the term of the Third Amended and Restated 2016 Equity Incentive Plan, the share reserve will automatically increase on the first trading day in January of each calendar year, by an amount equal to 4% of the total number of outstanding shares of common stock of the Company on the last trading day in December of the prior calendar year. On January 1, 2021, pursuant to the terms of the Third Amended and Restated Equity Inventive Plan an additional 3,000,165 shares were made available for issuance.

(3) Consists of shares of common stock issuable upon exercise of outstanding stock options granted pursuant to the Nasdaq inducement grant exception as a component of employment compensation for employees. The inducement grants were made as an inducement material to employees entering into employment with us in accordance with Nasdaq Listing Rule 5635(c)(4).

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

Except as otherwise indicated, the following table sets forth information regarding the ownership of the Company's common stock as of February 15, 2021 by: (i) each director and nominee for director; (ii) each of our Named Executive Officers; (iii) all executive officers and directors of the Company as a group; and (iv) all other parties known by the Company to be beneficial owners of more than five percent of its common stock.

Applicable percentage ownership is based on 89,076,016 shares of our common stock outstanding as of February 15, 2021, unless otherwise noted below, together with applicable options for each stockholder. Beneficial ownership is determined in accordance with the rules of the SEC, based on voting and investment power with respect to shares. Common stock subject to options currently exercisable, or exercisable within 60 days after February 15, 2021, are deemed outstanding for the purpose of computing the percentage ownership of the person holding those options, but are not deemed outstanding for computing the percentage ownership of

any other person. Unless otherwise indicated, the address for each listed stockholder is c/o Cerecor Inc., 540 Gaither Road, Suite 400, Rockville, Maryland 20850.

Beneficial Owner	Beneficial Ownership [1]	
	Number of Shares	Percent of Total
5% Stockholders:		
Armistice Capital Master Fund Ltd. [2]	42,920,000	43.2%
Nantahala Capital Management LLC [3]	6,233,316	7.0%
Directors and Named Executive Officers:		
Sol Barer, Ph.D. [4]	2,179,166	2.4%
Steven Boyd [2]	43,332,442	43.6%
Suzanne Bruhn, Ph.D. [5]	10,709	*
Michael Cola [6]	816,223	*
Phil Gutry [7]	148,956	*
Gilla Kaplan, Ph.D. [8]	7,216	*
Joseph Miller [9]	193,621	*
Garry Neil, M.D. [10]	311,013	*
Magnus Persson, M.D., Ph.D. [11]	195,613	*
H. Jeffrey Wilkins, M.D. [12]	135,465	*
All current executive officers and directors as a group	47,671,253	46.1%

*Less than one percent.

(1) This table is based upon information supplied by our executive officers, directors and principal stockholdersand the Schedules 13D and 13G filed with the SEC. Unless otherwise indicated in the footnotes to this table and subject to community property laws where applicable, the Company believes that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned.

(2) Based on a Schedule 13D filed with the SEC on January 12, 2021 by Armistice Capital LLC ("Armistice"). Consists of (i) 32,634,285 shares of common stock, (ii) 4,000,000 shares of common stock issuable upon the exercise of outstanding warrants within 60 days after February 15, 2021 and (iii) 6,285,715 shares of common stock issuable upon conversion of outstanding convertible preferred stock that converts to common stock on a 1 to 5 ratio, all held directly by Armistice Capital Master Fund, Ltd. ("Armistice Master") and may be deemed to be indirectly beneficially owned by Armistice, as the investment manager of Armistice Master. Steven J. Boyd is the managing member of Armistice and a director of Armistice Master and may be deemed to have voting and investment power with respect to the securities held by Armistice. Mr. Boyd serves on our Board of Directors and holds 412,442 shares of common stock that he has sole dispositive and voting power over. Armistice's and Mr. Boyd's address is c/o Armistice Capital, LLC, 510 Madison Avenue, 7th Floor, New York, NY 10022.

(3) Based on a Schedule 13G filed with the SEC on February 16, 2021 by Nantahala Capital Management, LLC, Wilmot B. Harkey and Daniel Mack (collectively, "Nantahala") reporting beneficial ownership as of December 31, 2020. Messrs. Harkey and Mack are Managing Members of Nantahala Capital Management LLC. Consists of 6,233,316 shares of common stock. Nantahala's address is c/o Nantahala Capital Management, LLC, 130 Main St. 2nd Floor, New Canaan, CT 06840.

(4) Consists of 2,179,166 shares issuable to Dr. Barer upon the exercise of options currently exercisable or exercisable within 60 days after February 15, 2021.

(5) Consists of 10,709 shares issuable to Dr. Bruhn upon the exercise of options currently exercisable or exercisable within 60 days after February 15, 2021.

(6) Consists of (i) 175,746 shares of common stock held by Mr. Cola and (ii) 640,477 shares issuable upon the exercise of options currently exercisable or exercisable within 60 days after February 15, 2021.

(7) Consists of 148,956 shares issuable to Mr. Gutry upon the exercise of options currently exercisable or exercisable within 60 days after February 15, 2021.

(8) Consists of 7,216 shares issuable to Dr. Kaplan upon the exercise of options currently exercisable or exercisable within 60 days after February 15, 2021.

(9) Consists of (i) 18,082 shares of common stock held by Mr. Miller and (ii) 175,539 shares issuable upon the exercise of options currently exercisable or exercisable within 60 days after February 15, 2021.

(10) Consists of (i) 77,680 shares of common stock held by Dr. Neil and (ii) 233,333 shares issuable upon the exercise of options currently exercisable or exercisable within 60 days after February 15, 2021.

(11) Consists of 195,613 shares issuable to Dr. Persson upon the exercise of options currently exercisable or exercisable within 60 days after February 15, 2021.

(12) Consists of (i) 26,090 shares of common stock held by Dr. Wilkins and (ii) 109,375 shares issuable upon the exercise of options currently exercisable or exercisable within 60 days after February 15, 2021.

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

RELATED PERSON TRANSACTIONS POLICY AND PROCEDURES

In 2015, in connection with our initial public offering, our Board adopted a written related person transaction policy to set forth policies and procedures for the review and approval or ratification of related person transactions. This policy covers any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which the Company is, was or will be a participant, and the amount involved exceeds $120,000 with one of our executive officers, directors, director nominees or 5% stockholders, or their immediate family members, each of whom we refer to as a "related person."

If a related person proposes to enter into such a transaction, arrangement or relationship, which we refer to as a "related person transaction," the related person must report the proposed related person transaction to our Audit Committee. The policy calls for the proposed related person transaction to be reviewed and, if deemed appropriate, approved by our Audit Committee. Whenever practicable, the reporting, review and approval will occur prior to entry into the transaction. If advance review and approval is not practicable, the Audit Committee will review, and, in its discretion, may ratify the related person transaction.

A related person transaction reviewed under the policy will be considered approved or ratified if it is authorized by the Audit Committee after full disclosure of the related person's interest in the transaction. As appropriate for the circumstances, the Audit Committee will review and consider:

- the interests, direct or indirect, of any related person in the transaction;
- the purpose of the transaction;
- the proposed aggregate value of such transaction, or, in the case of indebtedness, that amount of principal that would be involved;
- the risks, costs and benefits to the Company;
- the availability of other sources of comparable products or services;
- management's recommendation with respect to the proposed related person transaction;
- the terms of the transaction;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

Our Audit Committee will approve only those related person transactions that, in light of known circumstances, are in, or are not inconsistent with, the best interests of the Company and its stockholders, as the Audit Committee determines in the good faith exercise of its discretion.

In addition to the transactions that are excluded by the instructions to the SEC's related person transaction disclosure rule, our Board has determined that the following transactions do not create a material direct or indirect interest on behalf of related persons and, therefore, are not related person transactions for purposes of this policy:

- transactions involving compensation for services provided to the Company as an employee, consultant or director; and
- a transaction, arrangement or relationship in which a related person's participation is solely due to the related person's position as a director of an entity that is participating in such transaction, arrangement or relationship.

CERTAIN RELATED PERSON TRANSACTIONS

The following sets forth all transactions since January 1, 2019 to which the Company has been or is a participant, including currently proposed transactions, in which the amount involved in the transaction exceeds $120,000 and in which any of our directors, executive officers or beneficial holders of more than 5% of any class of our capital stock, or any immediate family member of, or person sharing the household with any of these individuals, had or has a direct or indirect material interest.

Indemnification Agreements

We have entered into indemnification agreements with each of our directors and certain of our executive officers. These agreements require us to indemnify these individuals and, in certain cases, affiliates of such individuals, to the fullest extent permitted under Delaware law against liabilities that may arise by reason of their service to the Company, and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified.

Employment Agreements

We have entered into employment agreements with our current and former executive officers. For more information regarding these agreements, please see "Executive Compensation – Narrative to Summary Compensation Table – Employment Arrangements and Potential Payments Upon Certain Events" above.

Stock Option Grants to Executive Officers and Directors

We have granted stock options to our named executive officers and directors as more fully described in "Executive Compensation" and "Director Compensation" above.

Financings with Related Party Participation

Q1 2021 Financing

In January 2021, the Company closed an underwritten public offering of 13,971,889 shares of its common stock and 1,676,923 pre-funded warrants for net proceeds of approximately $37.6 million. Armistice, which is a significant stockholder of the Company and whose chief investment officer, Steven Boyd, currently serves on the Board, participated in the offering by purchasing 2,500,000 shares of common stock, on the same terms as all other investors. In addition, certain affiliates of Nantahala Capital Management LLC (collectively, "Nantahala"), which beneficially owned greater than 5% of the Company's outstanding common stock at the time of the offering and, therefore, were considered a related party pursuant to the Company's written related person transaction policy, purchased the pre-funded warrants. Nantahala participated in this offering by purchasing 1,400,000 shares of common stock, on the same terms as all other investors. Additionally, as part of this offering, the Company sold pre-funded warrants to Nantahala to purchase 1,676,923 shares of the Company's common stock (the "Pre-Funded Warrants") at a public offering price of $2.599 per Pre-Funded Warrant. The Pre-Funded Warrants have an initial exercise price of $0.001 per share and are exercisable at any time after their original issuance at the option of each holder, in such holder's discretion.

Q2 2020 Financing

On June 11, 2020, the Company closed an underwritten public offering of 15,180,000 shares of its common stock for net proceeds of approximately $35.4 million. Armistice participated in the offering by purchasing 2,000,000 shares of common stock on the same terms as all other investors. Additionally, certain of the Company's officers participated in the offering by purchasing an aggregate of 110,000 shares of common stock, on the same terms as all other investors.

Q1 2020 Financings

On March 17, 2020, the Company entered into a securities purchase agreement with Armistice pursuant to which the Company sold 1,951,219 shares of its common stock for net proceeds of approximately $3.9 million.

On February 6, 2020, the Company closed a registered direct offering with certain institutional investors for the sale by the Company of 1,306,282 shares of its common stock for net proceeds of approximately $5.1 million. Armistice participated in the offering by purchasing 1,256,282 shares of common stock from the Company.

Q3 2019 Armistice Private Placement

On September 4, 2019, the Company entered into a securities purchase agreement with Armistice, pursuant to which the Company sold 1,200,000 shares of its common stock for net proceeds of approximately $3.7 million.

Q1 2019 Common Stock Offering

On March 8, 2019, the Company closed on an underwritten public offering of common stock for 1,818,182 shares of common stock of the Company for net proceeds of approximately $9.0 million. Armistice participated in the offering by purchasing 363,637 shares of common stock of the Company from the underwriter at the public price.

CERC-006 Royalty Agreement with Certain Related Parties

Effective upon the consummation of the Aevi Merger, the Company entered into employment agreements with Aevi's Chief Executive Officer, Michael Cola, to serve as the Company's Chief Executive Officer and with Aevi's Chief Scientific Officer, Dr. Garry Neil, to serve as the Company's Chief Medical Officer (shortly thereafter promoted to Chief Scientific Officer).

Prior to the Company entering into the merger agreement with Aevi, in July 2019, Aevi entered into a royalty agreement with certain investors, including Mr. Cola, its then Chief Executive Officer, and an entity on behalf of Dr. Neil, its then Chief Scientific Officer, in exchange for a one-time aggregate payment of $2 million (the "Royalty Agreement"), which was approved by a majority of the independent members of the board of directors and the audit committee of Aevi. The Company assumed this Royalty Agreement upon closing of the Aevi Merger. Under the terms of such Royalty Agreement, the investors will be entitled to an aggregate amount equal to a low-single digit percentage of the aggregate net sales of Astellas's second generation mTORC1/2 inhibitor, CERC-006. At any time beginning three years after the date of the first public launch of CERC-006, we may exercise, at our sole discretion, a buyout option that terminates any further obligations under the Royalty Agreement in exchange for a payment to such investors of an aggregate of 75% of the net present value of the royalty payments.

Millipred License and Supply Agreement

The Company has a license and supply agreement (the "License and Supply Agreement") for Millipred with Watson Laboratories, Inc., which is now part of Teva Pharmaceutical Industries Ltd. ("Teva"). Pursuant to the License and Supply Agreement, the Company is required to make license payments of $75,000 in February and August of each year through April 2021 and purchases inventory on an ad-hoc basis. Dr. Sol Barer is the Chairman of the Board and he also serves as the Chairman of Teva's board of directors.

In the fourth quarter of 2020, the parties entered into an amendment (the "Amended License and Supply Agreement"), which extends the agreement for a period of thirty months from April 1, 2021 through September 30, 2023. In lieu of the previous license payments, beginning April 1, 2021, the Company will pay Teva 50% of the net profit of the Millipred product following each calendar quarter, subject to a $0.5 million quarterly minimum payment.

Lachlan Pharmaceuticals Settlement

In November 2017, Cerecor acquired TRx Pharmaceuticals, LLC ("TRx") and its wholly-owned subsidiaries, including Zylera Pharmaceuticals, LLC, and its franchise of commercial medications (the "TRx Acquisition"). TRx was owned by Fremantle LLC ("Fremantle") and LRS International, LLC ("LRS", and collectively, the "former TRx owners"). Zylera, entered into an agreement with Lachlan Pharmaceuticals, an Irish company controlled by the previous owners of TRx ("Lachlan"), effective December 18, 2015 (the "Lachlan Agreement"). Pursuant to the Lachlan Agreement, Lachlan named Zylera as its exclusive distributor of Ulesfia in the United States and agreed to supply Ulesfia to Zylera exclusively for marketing and sale in the United States.

A portion of the consideration for TRx Acquisition included shares of Cerecor common stock. The TRx Acquisition also involved the potential for future payment of consideration that is contingent upon the achievement of operational and commercial milestones. The Company would have been required to pay $3.0 million to the TRx Sellers if the gross profit related to TRx products equaled or exceeded $12.6 million in 2018. The Company did not achieve this contingent event in 2018 and therefore no value was assigned to the contingent payout. Additionally, pursuant to the TRx Purchase Agreement, the Company was required to pay the

following: (1) $2.0 million upon the transfer of the Ulesfia NDA to the Company (the "NDA Transfer Milestone"), and (2) $2.0 million upon FDA approval of a new dosage of Ulesfia (the "FDA Approval Milestone").

On May 22, 2019, the Company, Lachlan, the owners of Lachlan and Concordia Pharmaceuticals Inc., Sarl ("Concordia"), which is the unrelated third party from which Lachlan obtained rights to distribute Ulesfia, entered into a settlement agreement and related side letter and terminated the Lachlan Agreement (the settlement agreement and related side letter collectively the "Settlement"). At the time of this Settlement, the former TRx owners beneficially owned more than 10% of Cerecor's outstanding stock. As a result, the Settlement released the Company from the potential contingent payments related to the NDA Transfer Milestone and FDA Approval Milestone.

Aytu Divestiture and Deerfield Guarantee

On October 10, 2019, the Company entered into the Aytu Purchase Agreement to sell the Company's rights, titles and interest in, assets relating to certain commercialized products, as well as the corresponding commercial infrastructure consisting of the right to offer employment to Cerecor's sales force and the assignment of supporting commercial contracts (the "Aytu Divestiture"). The Aytu Divestiture closed on November 1, 2019. Aytu paid consideration of $4.5 million in cash and approximately 9.8 million shares of Aytu convertible preferred stock, and assumed certain of the Company's liabilities, including the Company's payment obligations payable to Deerfield CSF, LLC ("Deerfield") of $15.1 million and certain other liabilities of $11.0 million primarily related to contingent consideration, Medicaid rebates and sales returns. The Company recognized a gain of $8.0 million upon the closing of the Aytu Divestiture for the year ended December 31, 2019. In addition, Aytu assumed future contractual obligations under existing license agreements associated with the Pediatric Portfolio. Armistice is a significant stockholder of the Company and Armistice's Chief Investment Officer, Steve Boyd, serves on each company's board of directors.

On November 1, 2019, in conjunction with the closing of the Aytu Divestiture, the Company entered into a guarantee in favor of Deerfield, which guarantees the payment of the assumed liabilities to Deerfield, which includes both the debt obligation and the contingent consideration related to future potential royalties on Avadel Pharmaceuticals PLC's ("Avadel") pediatric products (the "Deerfield Guarantee"). Additionally, on November 1, 2019, the Company entered into a contribution agreement with Armistice and Avadel that governs contribution rights and obligations of the Company, Armistice and Avadel with respect to amounts that are paid by Armistice and Avadel to Deerfield under certain guarantees made by Armistice and Avadel to Deerfield.

Aytu publicly reported that it had paid the $15.0 million balloon payment to Deerfield before it came due in June 2020, thus satisfying that portion of the debt obligation assumed as part of the divestiture. The remaining minimum commitments payable related to the future potential royalties on Avadel's pediatric products was $7.3 million as of June 30, 2020 (as most recently publicly reported by Aytu).

CERC-611 License Assignment

In August 2019, the Company entered into an assignment of license agreement (the "Assignment Agreement") with ES Therapeutics, LLC ("ES Therapeutics"), a wholly-owned subsidiary of Armistice, a significant stockholder of the Company. Pursuant to the Assignment Agreement, the Company assigned and transferred its rights, title, interest, and obligations with respect to CERC-611 to ES Therapeutics. The Company initially licensed the compound from Eli Lilly and Company ("Lilly") in September 2016. Under the Assignment Agreement, Armistice paid the Company an upfront payment of $0.1 million. The Assignment Agreement also provides for: (a) a $7.5 million milestone payment to the Company upon cumulative net sales of licensed products reaching $750.0 million; and (b) a $12.5 million milestone payment to the Company upon cumulative net sales of licensed products reaching $1.3 billion. The Assignment Agreement also releases the Company of obligations related to CERC-611, including the $1.3 million contingent payment to Lilly upon the first subject dosage of CERC-611 in a multiple ascending dose study and from additional potential future payments due to Lilly upon achievement of certain development and commercialization milestones.

DIRECTOR INDEPENDENCE

After review of all relevant identified transactions or relationships between each director, or any of his or her family members, and the Company, its senior management and its independent auditors, the Board has affirmatively determined that the following directors are independent directors within the meaning of the applicable NASDAQ listing standards and the independence criteria set forth in our Corporate Governance Guidelines: Dr. Barer, Dr. Bruhn, Mr. Gutry, Dr. Kaplan and Dr. Persson. In making this determination, the Board found that none of these directors or nominees for director had a material or other disqualifying relationship with the Company.

In making those independence determinations, the Board took into account certain relationships and transactions that occurred in the ordinary course of business between the Company and entities with which some of its directors are or have been affiliated. The Board considered all relationships and transactions that occurred during any 12-month period within the last three fiscal years, including the participation by our directors and entities affiliated with our directors in various financing transactions with the Company, and determined that there were no relationships that would interfere with their exercise of independent judgment in carrying out their responsibilities as directors.

For information related to the Board and committees of the Board, please refer to "Information Regarding Committees of the Board" within Item 10 of this Annual Report on Form 10-K, which is incorporated into this Item 13 by reference.

Item 14. Principal Accounting Fees and Services.

The following table represents aggregate fees billed to the Company for the fiscal years ended December 31, 2020 and 2019, by Ernst & Young LLP, the Company's principal accountant. All fees described below were pre-approved by the Audit Committee.

	Fiscal Year Ended December 31,	
	2020	2019
Audit fees[1]	$ 655,500	$ 571,991
Audit-related fees[2]	18,000	226,149
Tax fees[3]	46,909	26,910
All other fees[4]	1,995	1,995
Total	$ 722,404	$ 827,045

[1] Audit fees consisted of audit work performed in the audit of our financial statements, as well as work generally only the independent registered public accounting firm can reasonably be expected to provide, such as accounting consultations billed as audit services, and consents and assistance with and review of documents filed with the SEC.

[2] Audit-related fees consist of consulting and advisory fees related to potential acquisitions and strategic transactions and audit fees related to acquired entities.

[3] Tax services principally include tax compliance, tax advice and tax planning.

[4] All other fees consisted of all other products and services provided by the independent registered public accounting firm that are not reflected in any of the previous categories, such as the use of online accounting research tools.

PRE-APPROVAL POLICIES AND PROCEDURES

The Audit Committee has adopted a policy and procedures for the pre-approval of audit and non-audit services rendered by the Company's independent registered public accounting firm, Ernst & Young LLP. 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 auditor or on an individual, explicit, case-by-case basis before the independent auditor is engaged to provide each service. The pre-approval of services may be delegated to one or more of the Audit Committee's members, but the decision must be reported to the full Audit Committee at its next scheduled meeting.

The Audit Committee has determined that the rendering of non-audit services by Ernst & Young LLP is compatible with maintaining the principal accountant's independence for the period of time during which it has served as our independent auditor.

PART IV

Item 15. Exhibits; Financial Statement Schedules.

(a) *Documents filed as part of this report.*

1. The following consolidated financial statements of Cerecor Inc. and Report of Ernst & Young, LLP, Independent Registered Public Accounting Firm, are included in this report:

2. List of financial statement schedules. All schedules are omitted because they are not applicable or the required information is shown in the financial statements described above.

3. List of Exhibits required by Item 601 of Regulation S-K. See part (b) below.

(b) *Exhibits.*

The following is a list of exhibits filed as part of this Annual Report on Form 10-K. Where so indicated by footnote, exhibits that were previously filed are incorporated by reference. For exhibits incorporated by reference, the location of the exhibit in the previous filing is indicated.

Exhibit Number	Description of Exhibit
2.1	Asset Purchase Agreement, dated October 10, 2019, between Aytu Bioscience, Inc. and Cerecor Inc. (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed on October 15, 2019).
2.2	First Amendment to Asset Purchase Agreement, dated November 1, 2019, entered into by and between Aytu Bioscience, Inc. and Cerecor Inc. (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed on November 4, 2019).
2.3	Agreement and Plan of Merger and Reorganization, dated as of December 5, 2019, by and among Cerecor Inc., Genie Merger Sub, Inc., Second Genie Merger Sub, LLC and Aevi Genomic Medicine, Inc. (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K/A filed on December 11, 2019).
3.1	Amended and Restated Certificate of Incorporation of Cerecor Inc. (incorporated by reference to Exhibit 3.1.2 to the Current Report on Form 8-K filed on May 17, 2018).
3.1.1	Form of Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of Cerecor Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on April 28, 2017).
3.1.2	Form of Certificate of Designation of Series B Non-Voting Convertible Preferred Stock of Cerecor Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on December 27, 2018).

3.2	Cerecor Inc. Second Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2.1 to the Current Report on Form 8-K filed on May 17, 2018).
4.1	Second Amended and Restated Investors' Rights Agreement, dated as of July 11, 2014 (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-1 filed on June 12, 2015).
4.2	Specimen Unit Certificate (incorporated by reference to Exhibit 4.13 to the Registration Statement on Form S-1/A filed on October 13, 2015).
4.3	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.3 to the Registration Statement on Form S-8 filed on May 20, 2016).
4.4	Registration Rights Agreement, dated as of September 8, 2016, by and between Aspire Capital Fund, LLC and Cerecor Inc. (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed on September 12, 2016).
4.5	Form of Warrant to Purchase Shares of Common Stock of Cerecor Inc. issued to Armistice Capital Master Fund Ltd. (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed on April 28, 2017).
4.6	Form of Warrant to Purchase Shares of Series B Non-Voting Convertible Preferred Stock of Cerecor Inc. issued to Armistice Capital Master Fund Ltd. (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed on December 27, 2018).
4.7	Form of Warrant to Purchase Shares of Common Stock of Cerecor Inc. issued to Armistice Capital Master Fund Ltd. (incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed on December 27, 2018).
4.8	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed on January 8, 2021).
4.9‡	Description of Registered Securities.
10.1 *	Exclusive Patent and Know-How License Agreement, effective as of March 19, 2013, by and between Essex Chemie AG and Cerecor Inc. (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form S-1 filed on June 12, 2015).
10.2 *	Exclusive Patent and Know-How License Agreement, effective as of March 19, 2013, by and between Essex Chemie AG and Cerecor Inc. (incorporated by reference to Exhibit 10.2 to the Registration Statement on Form S-1 filed on June 12, 2015).
10.3 *	Exclusive Patent and Know-How License Agreement, effective as of February 18, 2015, by and between Eli Lilly and Company and Cerecor Inc. (incorporated by reference to Exhibit 10.3 to the Registration Statement on Form S-1 filed on June 12, 2015).
10.4 +	Form of Director Indemnification Agreement (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form S-1/A filed on September 8, 2015).
10.5	Non-Employee Director Compensation Policy, amended January 10, 2016 (incorporated by reference to Exhibit 10.17 to the Annual Report on Form 10-K filed on March 23, 2016).

10.6 +	Cerecor Inc. 2016 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on May 20, 2016).
10.7 *	License Agreement, dated as of September 8, 2016, by and between Cerecor Inc. and Eli Lilly and Company (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed on November 8, 2016).
10.8	Addendum to Exclusive License Agreement, dated as of October 13, 2016, by and between Cerecor Inc. and Eli Lilly and Company (incorporated by reference to Exhibit 10.1.1 to the Quarterly Report on Form 10-Q filed on November 8, 2016).
10.9	Registration Rights Agreement, dated as of April 27, 2017, by and between Cerecor, Inc. and Armistice Capital Master Fund Ltd. (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on April 28, 2017).
10.10 *	License and Development Agreement, dated February 16, 2018, by and between Cerecor Inc. and Flamel Ireland Limited (incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q filed on May 11, 2018).
10.11.1 +	Employment Agreement, dated April 19, 2018, by and between Cerecor Inc. and James A. Harrell, Jr. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on April 27, 2018).
10.11.2 +	Amendment to Employment Agreement of James A. Harrell, Jr., dated October 14, 2019.
10.12	Registration Rights Agreement, made and entered into as of August 20, 2018, between Cerecor Inc. and each of the several purchasers (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on August 20, 2018).
10.13	Lease dated September 14, 2018, by and between FP 540 Gaither, LLC and Cerecor Inc. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on September 18, 2018).
10.14	Registration Rights Agreement, made and entered into as of December 27, 2018, between Cerecor, Inc. and Armistice Capital Master Fund Ltd. (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on December 27, 2018).
10.15 +	Cerecor Inc. Second Amended and Restated 2016 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on August 8, 2019).
10.16	Securities Purchase Agreement, dated as of September 4, 2019, by and among Cerecor Inc. and Armistice Capital Master Fund Ltd. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on September 9, 2019).
10.17	Registration Rights Agreement, dated as of September 4, 2019, between Cerecor Inc. and Armistice Capital Master Fund Ltd. (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on September 9, 2019).
10.18	Guarantee, dated as of November 1, 2019, made by Cerecor Inc. in favor of Deerfield CSF, LLC (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on November 4, 2019).

10.19	Contribution Agreement, made and entered into as of November 1, 2019, by and among Cerecor Inc., Armistice Capital Master Fund, Ltd. and Avadel US Holdings Inc. (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on November 4, 2019).
10.20	Assignment of License Agreement, dated August 8, 2019, entered into by and between Cerecor Inc., ES Therapeutics, LLC, and Armistice Capital Master Fund Ltd. (incorporated by reference to Exhibit 10.32 to the Annual Report on Form 10-K filed on March 11, 2020).
10.21	Contingent Value Rights Agreement, effective February 3, 2020, by and between Cerecor Inc. and American Stock Transfer & Trust Company, LLC (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on February 3, 2020).
10.22 +	Employment Agreement, effective February 3, 2020, by and between Cerecor Inc. and Michael F. Cola (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed on February 3, 2020).
10.23 +	Employment Agreement, effective February 3, 2020, by and between Cerecor Inc. and Garry A. Neil (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed on February 3, 2020).
10.24	Form of Securities Purchase Agreement, dated February 3, 2020 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on February 4, 2020).
10.25 +	Amendment to Employment Agreement, effective March 11, 2020, by and between Cerecor Inc. and Michael F. Cola (incorporated by reference to Exhibit 10.5 to the Quarterly Report on Form 10-Q filed on May 7, 2020).
10.26	Securities Purchase Agreement, dated March 17, 2020, between Cerecor Inc. and the investor(s) named therein (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on March 18, 2020).
10.27	Registration Rights Agreement, dated March 17, 2020, between Cerecor Inc. and the investor(s) named therein (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on March 18, 2020).
10.28 +	Separation Agreement, dated March 25, 2020, by and between Cerecor Inc. and Pericles Calias(incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on March 27, 2020).
10.29 *	Sponsored Research Agreement, dated as of November 12, 2014, between Medgenics Medical Israel Ltd. and The Children's Hospital of Philadelphia (previously filed as Exhibit 10.28 to Aevi's Annual Report on Form 10-K for the year ended December 31, 2014 and incorporated herein by reference).
10.30	Amendment #1 to Sponsored Research Agreement, dated December 18, 2015, by and between Medgenics Medical Israel Ltd. and the Children's Hospital of Philadelphia (previously filed as Exhibit 10.1 to Aevi's Current Report on Form 8-K filed December 22, 2015 and incorporated herein by reference).

10.31 *	License Agreement, dated as of November 12, 2014, between Medgenics Medical Israel Ltd. and The Children's Hospital of Philadelphia (previously filed as Exhibit 10.29 to Aevi's Annual Report on Form 10-K for the year ended December 31, 2014 and incorporated herein by reference).
10.32 *	License Agreement, dated as of September 9, 2015, between neuroFix, LLC and The Children's Hospital of Philadelphia (previously filed as Exhibit 10.2 to Aevi's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015 and incorporated herein by reference).
10.33 *	Clinical Development and Option Agreement, by and between Medgenics, Inc. and Kyowa Hakko Kirin Co., Ltd., dated June 6, 2016 (previously filed as Exhibit 10.1 to Aevi's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 and incorporated herein by reference).
10.34 *	Amendment No. 1 to License Agreement, dated as of February 14, 2017, by and between The Children's Hospital of Philadelphia and Medgenics Medical Israel Ltd. (previously filed as Exhibit 10.1 to Aevi's Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 and incorporated herein by reference).
10.35	Amendment No. 2 to Sponsored Research Agreement, dated as of February 16, 2017, by and between The Children's Hospital of Philadelphia and Medgenics Medical Israel, Ltd. (previously filed as Exhibit 10.2 to Aevi's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 and incorporated herein by reference).
10.36	Amendment No. 1 to License Agreement, dated March 29, 2019, by and between neuroFix LLC and the Children's Hospital of Philadelphia (previously filed as Exhibit 10.3 to Aevi's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019 and incorporated herein by reference).
10.37	Amendment No. 2 to License Agreement, dated March 29, 2019, by and between Medgenics Medical Israel Ltd. and the Children's Hospital of Philadelphia. (previously filed as Exhibit 10.4 to Aevi's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019 and incorporated herein by reference).
10.38	Amendment No. 3 to Sponsored Research Agreement, dated March 29, 2019, by and between Medgenics Medical Israel Ltd. and the Children's Hospital of Philadelphia (previously filed as Exhibit 10.5 to Aevi's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019 and incorporated herein by reference).
10.39	Letter Agreement, dated March 29, 2019, by and between the Company and the Children's Hospital of Philadelphia (previously filed as Exhibit 10.6 to Aevi's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019 and incorporated herein by reference).
10.40 **	Exclusive License Agreement, dated as of July 15, 2019, by and between Aevi Genomic Medicine, Inc. and OSI Pharmaceuticals, LLC (previously filed as Exhibit 10.1 to Aevi's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 and incorporated herein by reference).

10.41	Amendment No. 3 to License Agreement, dated as of August 12, 2019, by and between Medgenics Medical Israel Ltd. and The Children's Hospital of Philadelphia (previously filed as Exhibit 10.3 to Aevi's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 and incorporated herein by reference).
10.42	Amendment No. 4 to Sponsored Research Agreement, dated as of August 12, 2019, by and between Medgenics Medical Israel Ltd. and The Children's Hospital of Philadelphia (previously filed as Exhibit 10.4 to Aevi's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 and incorporated herein by reference).
10.43 **	Option and License Agreement, dated as of August 6, 2019, by and between Aevi Genomic Medicine, Inc. and MedImmune Limited (previously filed as Exhibit 10.1 to Aevi's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 and incorporated herein by reference).
10.44 **	Royalty Agreement, dated as of July 19, 2019, between and among Aevi Genomic Medicine, Inc., Michael F. Cola Joseph J. Grano, Jr., Kathleen Jane Grano, Joseph C. Grano, The Grano Children's Trust, Joseph C. Grano, trustee and LeoGroup Private Investment Access, LLC on behalf of Garry A. Neil (previously filed as Exhibit 10.2 to Aevi's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 and incorporated herein by reference).
10.45 +	Employment Agreement, dated September 26, 2019, by and between Cerecor Inc. and Christopher Sullivan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on April 27, 2020).
10.46 +	Letter Agreement, dated April 23, 2020, by and between Cerecor Inc. and Christopher Sullivan (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on April 27, 2020).
10.47 +	Separation Agreement, dated April 24, 2020, by and between Cerecor Inc. and Simon Pedder (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed on April 27, 2020).
10.48 **	Amended and Restated Clinical Development and Option Agreement, dated May 28, 2020, by and between Aevi Genomic Medicine, LLC and Kyowa Kirin Co., Ltd., formerly known as Kyowa Kirin Co., Ltd. (incorporated by reference to Exhibit 10.28 to the Quarterly Report on Form 10-Q filed on August 6, 2020).
10.49 +	Cerecor Inc. Third Amended and Restated 2016 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on June 18, 2020).
10.50	Amendment No. 6 to License Agreement, dated as of November 16, 2020, by and between Medgenics Medical Israel Ltd. and The Children's Hospital of Philadelphia (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on November 20, 2020).

10.51	Amendment No. 6 to Sponsored Research Agreement, dated as of November 16, 2020, by and between Medgenics Medical Israel Ltd. and The Children's Hospital of Philadelphia (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on November 20, 2020).
10.52 +	Employment Agreement, dated February 10, 2021, by and between Cerecor Inc. and Schond L. Greenway (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on March 1, 2021).
10.53 +	Stock Option Agreement, dated March 1, 2021, by and between Cerecor Inc. and Schond L. Greenway (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on March 1, 2021).
10.54 +‡	Offer Letter, dated February 19, 2020, from Cerecor Inc. to H. Jeffrey Wilkins, M.D.
21.1	List of Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Annual Report on Form 10-K filed on March 11, 2020).
23.1 ‡	Consent of Ernst & Young LLP, independent registered public accounting firm.
31.1 ‡	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2 ‡	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1 # ‡	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance 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, formatted in inline XBRL (included in Exhibit 101).

* Confidential treatment has been requested for portions of this exhibit.

** Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10).

+ Management contract or compensatory agreement.

‡ Filed herewith.

This certification is being furnished solely to accompany this 10-K pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 16. 10-K Summary.

None.

SIGNATURES

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

Cerecor Inc.

/s/ Schond L. Greenway

Schond L. Greenway
Chief Financial Officer

Date: March 8, 2021

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

Signature	Title	Date
/s/ Michael Cola **Michael Cola**	Chief Executive Officer and Director *(Principal Executive Officer)*	March 8, 2021
/s/ Schond L. Greenway **Schond L. Greenway**	Chief Financial Officer *(Principal Financial Officer)*	March 8, 2021
/s/ Christopher Sullivan **Christopher Sullivan**	Chief Accounting Officer *(Principal Accounting Officer)*	March 8, 2021
/s/ Sol J. Barer **Dr. Sol J. Barer**	Chairman of the Board of Directors and Director	March 8, 2021
/s/ Steven J. Boyd **Steven J. Boyd**	Director	March 8, 2021
/s/ Suzanne Bruhn, Ph.D. **Suzanne Bruhn, Ph.D.**	Director	March 8, 2021
/s/ Phil Gutry **Phil Gutry**	Director	March 8, 2021
/s/ Gilla Kaplan, Ph.D. **Gilla Kaplan, Ph.D.**	Director	March 8, 2021
/s/ Joseph Miller **Joseph Miller**	Director	March 8, 2021
/s/ Magnus Persson **Magnus Persson**	Director	March 8, 2021

CERECOR INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Cerecor Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Cerecor Inc. and subsidiaries (the Company) as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, changes in 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, 2020 and 2019, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

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 1 to the financial statements, the Company has suffered recurring losses from operations, has used significant cash in operations, expects to continue to incur losses, 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 1. 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 Public Company Accounting Oversight Board (United States) (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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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 Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter 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 matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accounting for Acquisition of Aevi Genomic Medicine

Description of the Matter	As discussed in Note 5 to the consolidated financial statements, the Company completed its acquisition of Aevi Genomic Medicine ("Aevi") on February 3, 2020. In connection with this acquisition, the Company concluded that substantially all the value received was related to one group of similar identifiable assets, which was in-process research and development (IPR&D) for two early phase therapies for rare and orphan diseases. Accordingly, the Company accounted for the transaction as an asset acquisition rather than a business combination. The consideration transferred associated with this acquisition was allocated to the assets acquired and liabilities assumed, resulting in $25.5 million being assigned to an IPR&D asset with no alternative future use and was therefore immediately recognized as acquired in-process research and development expense in the consolidated statement of operations and comprehensive loss. Auditing the acquisition of Aevi was complex due to the high degree of auditor judgment required when evaluating the reasonableness of management's conclusion that substantially all of the fair value of the gross assets acquired was concentrated in a group of similar identifiable assets and therefore should be accounted for as an asset acquisition rather than as a business combination. In reaching this conclusion, management was required to evaluate subjective considerations such as similarities in risks and stage of development, regulatory pathways, patient populations, and economics of commercialization.
How We Addressed the Matter in Our Audit	To test management's conclusion that the acquisition of Aevi should be accounted for as an asset acquisition, our audit procedures included, among others, evaluating management's assessment of the qualitative and quantitative considerations utilized when determining if substantially all of the fair value of the gross assets acquired were concentrated in a group of similar identifiable assets by comparing it to evidence supporting the subjective considerations described above. We also evaluated the reasonableness of the significant assumptions used in the Company's estimate of the gross fair value of the assets acquired by considering the sensitivity of these assumptions to management's asset acquisition conclusion.

/s/ Ernst & Young LLP
We have served as the Company's auditor since 2013.
Baltimore, Maryland
March 8, 2021

CERECOR INC. and SUBSIDIARIES

Consolidated Balance Sheets

	December 31,	
	2020	**2019**
Assets		
Current assets:		
Cash and cash equivalents	$ 18,919,448	$ 3,609,438
Accounts receivable, net	2,177,323	1,001,645
Other receivables	2,207,995	4,240,572
Inventory, net	3,136	21,334
Prepaid expenses and other current assets	2,659,520	706,968
Restricted cash, current portion	37,922	17,535
Investment in Aytu	—	7,628,947
Current assets of discontinued operations	—	497,577
Total current assets	26,005,344	17,724,016
Property and equipment, net	1,607,070	1,447,663
Intangible assets, net	1,585,175	2,426,258
Goodwill	14,409,088	14,409,088
Restricted cash, net of current portion	148,642	101,945
Total assets	$ 43,755,319	$ 36,108,970
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,573,548	$ 2,077,524
Accrued expenses and other current liabilities	11,309,721	5,640,252
Income taxes payable	—	551,671
Current liabilities of discontinued operations	1,341,667	3,891,012
Total current liabilities	15,224,936	12,160,459
Royalty obligation	2,000,000	—
Deferred tax liability, net	90,395	85,981
Other long-term liabilities	1,878,395	1,111,965
Long-term liabilities of discontinued operations	—	1,755,000
Total liabilities	19,193,726	15,113,405
Stockholders' equity:		
Common stock—$0.001 par value; 200,000,000 shares authorized at December 31, 2020 and 2019; 75,004,127 and 44,384,222 shares issued and outstanding at December 31, 2020 and 2019, respectively	75,003	44,384
Preferred stock—$0.001 par value; 5,000,000 shares authorized at December 31, 2020 and 2019; 1,257,143 and 2,857,143 shares issued and outstanding at December 31, 2020 and 2019, respectively	1,257	2,857
Additional paid-in capital	202,275,722	135,238,941
Accumulated deficit	(177,790,389)	(114,290,617)
Total stockholders' equity	24,561,593	20,995,565
Total liabilities and stockholders' equity	$ 43,755,319	$ 36,108,970

See accompanying notes to the consolidated financial statements.

CERECOR INC. and SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss

	Year Ended December 31,	
	2020	**2019**
Revenues:		
Product revenue, net	$ 6,698,615	$ 6,650,351
License and other revenue	—	100,000
Total revenues, net	6,698,615	6,750,351
Operating expenses:		
Cost of product sales	300,199	(566,523)
Research and development	32,192,335	11,764,133
Acquired in-process research and development	25,549,344	—
General and administrative	17,417,450	10,123,320
Sales and marketing	2,341,231	1,484,044
Amortization expense	1,741,083	1,338,996
Change in fair value of contingent consideration	—	(1,256,211)
Total operating expenses	79,541,642	22,887,759
	(72,843,027)	(16,137,408)
Other income:		
Change in fair value of Investment in Aytu	5,207,789	53,932
Other income (expense), net	409,853	(28,287)
Interest income, net	48,873	121,326
Total other income, net from continuing operations	5,666,515	146,971
Loss from continuing operations before taxes	(67,176,512)	(15,990,437)
Income tax (benefit) expense	(2,792,961)	280,316
Loss from continuing operations	$ (64,383,551)	$ (16,270,753)
Income from discontinued operations, net of tax	883,779	198,206
Net loss	$ (63,499,772)	$ (16,072,547)
Net (loss) income per share of common stock, basic and diluted:		
Continuing operations	$ (0.87)	$ (0.28)
Discontinued operations	0.01	0.00
Net loss per share of common stock, basic and diluted	$ (0.86)	$ (0.28)
Net (loss) income per share of preferred stock, basic and diluted:		
Continuing operations	$ (4.38)	$ (1.42)
Discontinued operations	0.06	0.01
Net loss per share of preferred stock, basic and diluted	$ (4.32)	$ (1.41)

See accompanying notes to the consolidated financial statements.

CERECOR INC. and SUBSIDIARIES

Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2020	**2019**
Operating activities		
Net loss	$ (63,499,772)	$ (16,072,547)
Adjustments to reconcile net loss used in operating activities:		
Depreciation and amortization	1,843,178	3,883,567
Impairment of intangible assets	—	1,449,121
Stock-based compensation	6,785,686	2,532,257
Acquired in-process research and development	25,549,344	—
Deferred taxes	195,585	16,743
Amortization of inventory fair value adjustment associated with acquisition of TRx and Avadel's pediatric products	—	107,271
Gain on Aytu Divestiture	—	(7,964,924)
Change in fair value of Investment in Aytu	(5,207,789)	(53,932)
Change in fair value of Guarantee	(1,755,000)	—
Change in fair value of contingent consideration liability	—	(1,009,169)
Change in fair value of warrant liability and unit purchase option liability	(14,054)	3,888
Changes in assets and liabilities:		
Accounts receivable, net	(678,101)	1,658,333
Other receivables	(2,106,828)	5,120,247
Inventory, net	18,198	532,947
Prepaid expenses and other assets	(1,859,402)	(917,016)
Accounts payable	98,520	1,019,358
Income taxes payable	288,329	(1,480,587)
Accrued expenses and other liabilities	(195,712)	(6,835,395)
License obligations	—	(1,250,000)
Lease liability, net	(1,882)	125,506
Net cash used in operating activities	(40,539,700)	(19,134,332)
Investing activities		
Proceeds from sale of Investment in Aytu, net	12,836,736	—
Net cash paid in merger with Aevi	(1,641,819)	—
Loan to Aevi	—	(4,139,401)
Net cash received from Aytu Divestiture	—	3,958,412
Purchase of property and equipment	(62,659)	(262,013)
Net cash provided by (used in) investing activities	11,132,258	(443,002)
Financing activities		
Proceeds from underwritten public offering, net	35,427,963	8,975,960
Proceeds from registered direct offering, net	5,136,184	—
Proceeds from private placement, net	3,887,991	3,708,602
Proceeds from exercise of stock options and warrants	114,092	836,188
Proceeds from shares purchased through employee stock purchase plan	312,175	210,777
Restricted stock units withheld for taxes	(93,869)	(33,959)
Payment of contingent consideration	—	(881,932)
Payment of long-term debt	—	(256,140)
Net cash provided by financing activities	44,784,536	12,559,496
Increase (decrease) in cash, cash equivalents, and restricted cash	15,377,094	(7,017,838)

Cash, cash equivalents, and restricted cash at beginning of period	3,728,918	10,746,756
Cash, cash equivalents, and restricted cash at end of period	$ 19,106,012	$ 3,728,918
Supplemental disclosures of cash flow information		
Cash paid for interest	$ —	$ 1,050,000
Cash paid for taxes	$ 474,000	$ 1,803,665
Supplemental disclosures of non-cash activities		
Issuance of common stock in Aevi Merger	$ 15,495,578	$ —
Leased asset obtained in exchange for new operating lease liability	$ 376,448	$ 743,025

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets that sum to the total of the same such amounts shown in the consolidated statements of cash flows:

	December 31,	
	2020	**2019**
Cash and cash equivalents	$ 18,919,448	$ 3,609,438
Restricted cash, current portion	37,922	17,535
Restricted cash, net of current portion	148,642	101,945
Total cash, cash equivalents and restricted cash	$ 19,106,012	$ 3,728,918

See accompanying notes to the consolidated financial statements.

CERECOR INC. and SUBSIDIARIES

Consolidated Statements of Changes in Stockholders' Equity

	Common stock		Preferred Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount			
Balance, December 31, 2018	40,804,189	$ 40,804	2,857,143	$ 2,857	$ 119,082,157	$ (98,218,070)	$ 20,907,748
Issuance of shares of common stock in underwritten public offering, net of offering costs	1,818,182	1,818		—	8,974,142	—	8,975,960
Issuance of shares pursuant to common stock private placement, net of offering costs	1,200,000	1,200		—	3,707,402	—	3,708,602
Exercise of stock options and warrants	323,177	323		—	835,865	—	836,188
Restricted stock units vested during the period	172,500	173		—	(173)	—	—
Restricted stock units withheld for taxes	(6,969)	(7)		—	(33,952)	—	(33,959)
Shares purchased through employee stock purchase plan	73,143	73		—	210,704	—	210,777
Stock-based compensation		—		—	2,462,796	—	2,462,796
Net loss		—		—	—	(16,072,547)	(16,072,547)
Balance, December 31, 2019	44,384,222	$ 44,384	2,857,143	$ 2,857	$ 135,238,941	$ (114,290,617)	$ 20,995,565
Conversion of preferred stock to common stock	8,000,000	8,000	(1,600,000)	(1,600)	(6,400)	—	—
Issuance of shares related to Aevi Merger	3,893,361	3,894		—	15,491,684	—	15,495,578
Issuance of shares pursuant to registered direct offering, net of offering costs	1,306,282	1,306		—	5,134,878	—	5,136,184
Issuance of shares pursuant to common stock private placement, net of offering costs	1,951,219	1,951		—	3,886,040	—	3,887,991
Issuance of shares of common stock in underwritten public offering, net of offering costs	15,180,000	15,180		—	35,412,783	—	35,427,963
Exercise of stock options and warrants	75,239	75		—	114,017	—	114,092
Restricted stock units vested during period	111,667	111		—	(111)	—	—
Restricted stock units withheld for taxes	(35,279)	(35)		—	(93,834)	—	(93,869)
Shares purchased through employee stock purchase plan	137,416	137		—	312,038	—	312,175
Stock-based compensation		—		—	6,785,686	—	6,785,686
Net loss		—		—	—	(63,499,772)	(63,499,772)
Balance, December 31, 2020	75,004,127	$ 75,003	1,257,143	$ 1,257	$ 202,275,722	$ (177,790,389)	$ 24,561,593

See accompanying notes to the consolidated financial statements.

CERECOR INC. and SUBSIDIARIES

Notes to Consolidated Financial Statements

As of and for the Years Ended December 31, 2020 and 2019

1. Business

Cerecor Inc. (the "Company" or "Cerecor") is a biopharmaceutical company focused on becoming a leader in development and commercialization of treatments for rare and orphan diseases. The Company is advancing its clinical-stage pipeline of innovative therapies that address unmet patient needs within rare and orphan diseases.

The Company's rare disease pipeline includes CERC-801, CERC-802 and CERC-803 ("CERC-800 compounds"), which are in development for therapies for congenital disorders of glycosylation and CERC-006, an oral mTORC1/2 inhibitor in development for the treatment of complex lymphatic malformations. The Company is also developing two monoclonal antibodies, CERC-002 and CERC-007. CERC-002 targets the cytokine LIGHT (TNFSF14) and is in clinical development for the treatment of severe pediatric-onset Crohn's disease and COVID-19 acute respiratory distress syndrome ("ARDS"). CERC-007 targets the cytokine IL-18 and is in clinical development for the treatment of Still's disease (adult onset Still's disease ("AOSD") and systemic juvenile idiopathic arthritis ("sJIA")) and multiple myeloma ("MM"). CERC-006, 801, 802 and 803 have all received Orphan Drug Designation ("ODD") and Rare Pediatric Disease Designation ("RPDD"), which makes all four eligible for a priority review voucher ("PRV") upon approval from the U.S. Food and Drug Administration ("FDA").

The Company continues to explore strategic alternatives for its non-core assets, including its commercialized product, Millipred®, an oral prednisolone indicated across a wide variety of inflammatory conditions, and for its neurology pipeline assets.

On February 3, 2020, the Company consummated its merger with Aevi Genomic Medicine, Inc. ("Aevi"), in which Cerecor acquired the rights to CERC-002, CERC-006 and CERC-007 (the "Merger" or the "Aevi Merger"). Cerecor also entered into an employment agreement with Aevi's Chief Executive Officer, Mike Cola, for him to serve as Cerecor's Chief Executive Officer and an employment agreement with Aevi's Chief Scientific Officer, Dr. Garry Neil, for him to serve as Cerecor's Chief Medical Officer (shortly thereafter promoted to Chief Scientific Officer). Additionally, Mr. Cola and Dr. Sol Barer, the former Chairman of the Board of Aevi, were appointed to the Company's Board of Directors. Dr. Barer serves as the Chairman of the Company's Board. See Note 5 for more information.

Cerecor was incorporated and commenced operation in 2011 and completed its initial public offering in October 2015.

Liquidity

In 2020, the Company closed three equity offerings for net proceeds of approximately $44.4 million (see Note 10 for more information regarding these financings) and in April 2020, the Company sold an investment for net proceeds of $12.8 million (see Note 6 for more information). The Company also closed an underwritten public offering in January 2021 for net proceeds of approximately $37.6 million (see Note 10 for more information). As of December 31, 2020, Cerecor had $18.9 million in cash and cash equivalents.

In order to meet its cash flow needs, the Company applies a disciplined decision-making methodology as it evaluates the optimal allocation of the Company's resources between investing in the Company's existing pipeline assets and acquisitions or in-licensing of new assets. For the year ended December 31, 2020, Cerecor generated a net loss of $63.5 million and negative cash flows from operations of $40.5 million. As of December 31, 2020, Cerecor had an accumulated deficit of $177.8 million.

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern; however, losses are expected to continue as the Company continues to invest in its core research and development pipeline assets. The Company will require additional financing to fund its operations and to continue to execute its business strategy at least one year after the date the financial statements included herein were issued. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

To mitigate these conditions and to meet the Company's capital requirements, management plans to use its current cash on hand along with some combination of the following: (i) equity and/or debt financings, (ii) federal and/or private grants, (iii) other out-licensing or strategic alliances/collaborations of its current pipeline assets, and (iv) out-licensing or sale of its non-core assets. If the Company raises additional funds through collaborations, strategic alliances or licensing arrangements with third parties, the Company

might have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates. If the Company requires but is unable to obtain additional funding, the Company may be forced to make reductions in spending, delay, suspend, reduce or eliminate some or all of its planned research and development programs, or liquidate assets where possible. Due to the uncertainty regarding future financings and other potential options to raise additional funds, management has concluded that substantial doubt exists with respect to the Company's ability to continue as a going concern within one year after the date that the financial statements in this Annual Report on Form 10-K were issued.

Over the long term, the Company's ultimate ability to achieve and maintain profitability will depend on, among other things, the development, regulatory approval, and commercialization of its pipeline assets, and the potential receipt and sale of any PRVs it receives.

2. Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board (the "FASB"). The consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets, and the satisfaction of liabilities in the ordinary course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded assets and liabilities that might be necessary should the Company be unable to continue as a going concern (see Note 1).

Principles of Consolidation

The consolidated financial statements include the accounts of Cerecor Inc. and its wholly-owned subsidiaries after elimination of all intercompany balances and transactions.

Discontinued Operations

On October 10, 2019, the Company entered into an asset purchase agreement with Aytu (the "Aytu Purchase Agreement") to sell the Company's rights, title and interest in assets relating to its pediatric portfolio, namely Aciphex® Sprinkle™, Cefaclor for Oral Suspension, Karbinal™ ER, Flexichamber™, Poly-Vi-Flor® and Tri-Vi-Flor™ (the "Pediatric Portfolio"), as well as the corresponding commercial infrastructure consisting of the right to offer employment to Cerecor's sales force and the assignment of supporting commercial contracts (the "Aytu Divestiture"). The Aytu Divestiture closed on November 1, 2019.

Upon the sale of the Pediatric Portfolio during the fourth quarter of 2019, the Pediatric Portfolio met all conditions required to be classified as discontinued operations. Therefore, the operating results of the Pediatric Portfolio are reported as income from discontinued operations, net of tax in the accompanying consolidated financial statements for the years ended December 31, 2020 (due to our continued involvement) and 2019. Additionally, the gain recognized as a result of the sale of the Pediatric Portfolio is reported within income from discontinued operations, net of tax for the year ended December 31, 2019. The assets and liabilities related to the Pediatric Portfolio are reported as assets and liabilities of discontinued operations in the accompanying consolidated balance sheets as of December 31, 2020 and 2019. For additional information, see Note 3.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosures. On an ongoing basis, management evaluates its estimates, including estimates related to but not limited to, revenue recognition, cost of product sales, stock-based compensation, fair value measurements, cash flows used in management's going concern assessment, income taxes, goodwill and other intangible assets, and clinical trial accruals. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. The carrying amounts reported in the balance sheets for cash and cash equivalents are valued at cost, which approximates their fair value.

Restricted Cash

Restricted cash consists of the 2016 Employee Stock Purchase Plan (the "ESPP") deposits, credit card deposits, and security deposits for our leased corporate offices.

Accounts Receivable, net

Accounts receivable, net is comprised of amounts due from customers in the ordinary course of business. Management considers all accounts receivable to be fully collectible at December 31, 2020, and accordingly, no allowance for doubtful accounts has been recorded. Bad debt expense is charged to operations as amounts are determined to be uncollectible. Accounts receivable are written off when deemed uncollectible and recoveries of receivables previously written off are recorded when received.

Accounts receivable are considered to be past due if any portion of the receivable balance is outstanding for more than the payment terms negotiated with the customer. The Company generally negotiates payment terms of 30 days. The Company offers wholesale distributors a prompt payment discount, which is typically 2% as an incentive to remit payment within this timeframe. Accounts receivable are stated net of the estimated prompt pay discount.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash and cash equivalents. The Company maintains a portion of its cash and cash equivalent balances in the form of a money market account with a financial institution that management believes to be creditworthy. The Company has no financial instruments with off-balance sheet risk of loss.

Leases

The Company determines if an arrangement is a lease at inception. If an arrangement contains a lease, the Company performs a lease classification test to determine if the lease is an operating lease or a finance lease. The Company has identified two operating leases, which both serve as administrative office space. Right-of-use ("ROU") assets represent the right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease liabilities are recognized on the commencement date of the lease based on the present value of the future lease payments over the lease term and are included in other long-term liabilities and other current liabilities on the Company's consolidated balance sheet. ROU assets are valued at the initial measurement of the lease liability, plus any indirect costs or rent prepayments, and reduced by any lease incentives and any deferred lease payments. Operating ROU assets are recorded in property and equipment, net on the consolidated balance sheets and are amortized over the lease term. To determine the present value of lease payments on lease commencement, the Company uses the implicit rate when readily determinable, however, as most leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on information available at commencement date. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Furthermore, the Company has elected the practical expedient to account for the lease and non-lease components as a single lease component for the leased property asset class. Lease expense is recognized on a straight-line basis over the life of the lease and is included within general and administrative expenses.

Property and Equipment

Property and equipment consists of computers, office equipment, furniture, ROU assets (discussed above), and leasehold improvements and is recorded at cost. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed to operations as incurred. Property and equipment are depreciated on a straight-line basis over their estimated useful lives. The Company uses a life of four years for computers and software, and five years for equipment and furniture. For leasehold improvements, deprecation of the asset will begin at the date it is placed in service and the depreciable life of the leasehold improvement is the shorter of the lease term or the improvement's useful life. The Company uses the lesser of the lease term or ten years for leasehold improvements. Upon retirement or sale, the cost of the disposed asset and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is recognized.

Acquisitions

For acquisitions that meet the definition of a business under ASC 805, the Company records the acquisition using the acquisition method of accounting. All of the assets acquired, liabilities assumed, contractual contingencies, and contingent consideration, when applicable, are recorded at fair value at the acquisition date. Any excess of the purchase price over the fair value of the net assets acquired is recorded as goodwill. The application of the acquisition method of accounting requires management to make significant estimates and assumptions in the determination of the fair value of assets acquired and liabilities assumed in order to properly allocate purchase price consideration. For acquisitions that do not meet the definition of a business under ASC 805, the Company accounts for the transaction as an asset acquisition.

Segment Information

Operating segments are identified as components of an enterprise for which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions on how to allocate resources and assess performance. As of December 31, 2020, the Company's chief operating decision makers was the Chief Executive Officer. The Chief Executive Officer views the Company's operations and manages the business as one operating segment. All long-lived assets of the Company reside in the United States.

Goodwill

The Company's goodwill relates to the amount that arose in connection with the Company's historical acquisitions which were accounted for as business combinations. Goodwill represents the excess of the purchase price over the fair value of the net assets acquired when accounted for using the acquisition method of accounting for business combinations. Goodwill is not amortized but is evaluated for impairment on an annual basis or more frequently if an event occurs or circumstances change that would more-likely-than-not reduce the fair value of the Company's reporting unit below its carrying amount. The Company consists of one reporting unit.

Upon disposal of a portion of a reporting unit that constitutes a business, the Company assigns goodwill based on the relative fair values of the portion of the reporting unit being disposed and the portion of the reporting unit remaining. This approach requires a determination of the fair value of both the business to be disposed of and the business (or businesses) within the reporting unit that will be retained. As a result of the Aytu Divestiture, goodwill was assigned to the Pediatric Portfolio using the relative fair value approach discussed above.

Intangible Assets

Intangible assets with definite useful lives are amortized over their estimated useful lives and reviewed for impairment if certain events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Intangible assets subject to amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an intangible asset might not be recoverable. Impairment losses are measured and recognized to the extent the carrying value of such assets exceeds their fair value.

Product Revenues, net

The Company generates substantially all of its revenue from sales of prescription drugs to its customers. Revenue from sales of prescription drugs was $6.7 million for the years ended December 31, 2020 and 2019.

The Company has identified a single product delivery performance obligation, which is the provision of prescription drugs to its customers based upon master service agreements in place with wholesaler distributors, purchase orders from retail pharmacies or other direct customers and a contractual arrangement with a specialty pharmacy. The performance obligation is satisfied at a point in time, when control of the product has been transferred to the customer, either at the time the product has been received by the customer or to a lesser extent when the product is shipped. The Company determines the transaction price based on fixed consideration in its contractual agreements and the transaction price is allocated entirely to the performance obligation to provide pharmaceutical products. In determining the transaction price, a significant financing component does not exist because the timing from when the Company delivers product to when the customers pay for the product is less than one year and the customers do not pay for product in advance of the transfer of the product.

Revenues from sales of products are recorded net of any variable consideration for estimated allowances for returns, chargebacks, distributor fees, prompt payment discounts, government rebates, and other common gross-to-net revenue adjustments. The identified variable consideration is recorded as a reduction of revenue at the time revenues from product sales are recognized.

The Company recognizes revenue only to the extent that it is probable that a significant revenue reversal will not occur in a future period.

Provisions for returns and government rebates are included within current liabilities in the consolidated balance sheet. Provisions for prompt payment discounts and distributor fees are included as a reduction to accounts receivable. Calculating these items involves estimates and judgments based on sales or invoice data, contractual terms, historical utilization rates, new information regarding changes in these programs' regulations and guidelines that would impact the amount of the actual rebates, our expectations regarding future utilization rates for these programs, and channel inventory data. These estimates may differ from actual consideration amount received and the Company will re-assess these estimates and judgments each reporting period to adjust accordingly.

Pursuant to a transition services agreement entered into between Aytu and Cerecor, Aytu manages Millipred® commercial operations for a monthly fee of $12,000 for up to 18 months (post November 1, 2019) or until the Company establishes an independent commercial infrastructure for the product.

As a result of the Aytu Divestiture in the fourth quarter of 2019, all product revenues for the year ended December 31, 2020 and 2019 related to the Pediatric Portfolio are included within net income from discontinued operations, net of tax.

Concentration with Customer

As is typical in the pharmaceutical industry, the Company sells its prescription drugs in the United States primarily through wholesale distributors and a specialty contracted pharmacy. Wholesale distributors account for substantially all of the Company's net product revenues and trade receivables. In addition, the Company earns revenue from sales of its prescription pharmaceutical products directly to retail pharmacies. For the year ended December 31, 2020, the Company's three largest customers accounted for approximately 46%, 25% and 27%, respectively, of the Company's total net product revenues of prescription drugs. For the year ended December 31, 2019, the Company's three largest customers accounted for approximately 41%, 30% and 28%, respectively, of the Company's total net product revenues of prescription drugs.

Returns and Allowances

Consistent with industry practice, the Company maintains a return policy that allows customers to return product within a specified period both prior to and, in certain cases, subsequent to the product's expiration date. The Company's return policy generally allows customers to receive credit for expired products within six months prior to expiration and within one year after expiration. The provision for returns and allowances consists of estimates for future product returns and pricing adjustments. The primary factors considered in estimating potential product returns include:

- the shelf life or expiration date of each product;
- historical levels of expired product returns;
- external data with respect to inventory levels in the wholesale distribution channel;
- external data with respect to prescription demand for each of the Company's products; and
- the estimated returns liability to be processed by year of sale based on analysis of lot information related to actual historical returns.

The Company's estimate for returns and allowances may be impacted by a number of factors noted above.

Rebates

The Company is subject to rebates on sales made under governmental pricing programs. For example, Medicaid rebates are amounts owed based upon contractual agreements or legal requirements with public sector (Medicaid) benefit providers after the final dispensing of the product by a pharmacy to a benefit plan participant. Medicaid reserves are based on expected payments, which are driven by patient usage, contract performance and field inventory that will be subject to a Medicaid rebate. Medicaid rebates are typically billed up to 180 days after the product is shipped, however this can be as much as 270 days after the quarter in which the product is dispensed to the Medicaid participant. In addition to the estimates mentioned above, the Company's calculation also requires other estimates, such as estimates of sales mix, to determine which sales are subject to rebates and the amount of such rebates. Periodically, the Company adjusts the Medicaid rebate provision based on actual claims paid. Due to the delay in billing, adjustments to actual claims paid may incorporate revisions of this provision for several periods. Because Medicaid pricing programs involve particularly difficult interpretations of complex statutes and regulatory guidance, the Company's estimates could differ from actual experience.

In determining estimates for these rebates, the Company considers the terms of the contracts, relevant statutes, historical relationships of rebates to revenues, past payment experience, estimated inventory levels and estimated future trends.

License and Other Revenue

The Company recognizes revenues from collaboration, license or other research or sale arrangements when or as performance obligations are satisfied. For milestone payments, the Company assesses, at contract inception, whether the milestones are considered probable of being achieved. If it is probable that a significant revenue reversal will occur, the Company will not record revenue until the uncertainty has been resolved. Milestone payments that are contingent upon regulatory approval are not considered probable until the approvals are obtained as it is outside of the control of the Company. If it is probable that significant revenue reversal will not occur, the Company will estimate the milestone payments using the most likely amount method. The Company will reassess the milestones each reporting period to determine the probability of achievement.

Cost of Product Sales

Cost of product sales is comprised of (i) costs to acquire products sold to customers, (ii) license payments and other agreements granting the Company rights to sell related products, and (iii) the value of any write-offs of obsolete or damaged inventory that cannot be sold. The Company acquired the rights to sell certain of its commercial products through license and assignment agreements with the original developers or other parties with interests in these products. These agreements obligate the Company to make payments under varying payment structures based on its net revenue from related products.

Research and Development Costs

Research and development costs are expensed as incurred. These costs include, but are not limited to, expenses incurred under agreements with contract research organizations and investigative sites that conduct clinical trials and preclinical studies; the cost of acquiring, developing and manufacturing clinical trial materials; costs associated with preclinical activities and regulatory operations, pharmacovigilance, quality and travel; and employee-related expenses, including salaries, benefits and stock-based compensation of research and development personnel.

Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to the Company by its vendors, such as clinical research organizations, with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development expense, as the case may be.

Clinical Trial Expense Accruals

As part of the process of preparing its financial statements, the Company is required to estimate its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. The Company's objective is to reflect the appropriate trial expenses in its financial statements by matching those expenses with the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the progress of the trial as measured by subject progression and the timing of various aspects of the trial. The Company determines accrual estimates by taking into account discussion with applicable personnel and outside service providers as to the progress or state of consummation of trials, or the services completed. During the course of a clinical trial, the Company adjusts its clinical expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. The Company's clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed might vary and might result in it reporting amounts that are too high or too low for any particular period.

Acquired In-Process Research and Development Expenses

Acquired in-process research and development ("IPR&D") expense includes the initial costs of IPR&D projects, acquired directly in a transaction other than a business combination, that do not have an alternative future use.

Amortization Expense

Amortization expense includes the amortization of the Company's acquired intangible assets. There is no amortization expense included in cost of product sales or sales and marketing expense as all amortization expense is included within its own standalone line in operating expenses in the Company's consolidated statements of operations and comprehensive loss.

Estimated Fair Value and Change in Fair Value of Contingent Consideration

The Company's historical business acquisition of TRx Pharmaceuticals, LLC ("TRx") in November 2017 (the "TRx Acquisition") involved the potential for future payment of consideration that is contingent upon the achievement of operational and commercial milestones. The fair value of contingent consideration was determined at the acquisition date utilizing unobservable inputs such as the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-adjusted discount rate used to present value the probability-weighted cash flows. Subsequent to the acquisition date, at each reporting period, the contingent consideration liability was remeasured at the current fair value with changes recorded in the consolidated statement of operations and comprehensive loss. As part of a settlement the Company entered into in the second quarter of 2019, the Company was released from its contingent consideration liability related to the TRx Acquisition. Therefore, the Company's contingent consideration liability was $0 as of December 31, 2020 and 2019. The change in fair value of contingent consideration was included within its own standalone line in operating expenses from continuing operations in the Company's consolidated statements of operations and comprehensive loss.

Estimated Fair Value of Investment in Aytu and Change in Fair Value of Investment in Aytu

As consideration for the sale of the Pediatric Portfolio to Aytu in the fourth quarter of 2019, the Company received9,805,845 shares of Aytu Series G Convertible Preferred Stock (the "Investment in Aytu"). Pursuant to ASC 323, the Company accounted for this investment as a financial instrument because Cerecor's investment does not result in a controlling financial interest, as the preferred stock received is in-substance common stock and Cerecor does not have the ability to exercise significant influence or joint control of Aytu. Therefore, the fair value of the Investment in Aytu was determined at the divestiture date utilizing quoted prices for Aytu's common stock price with a discount for lack of marketability due to the Company's shares being restricted as of December 31, 2019 and subject to a lockup period.

Subsequent to the divestiture date, at each reporting period prior to the sale of the underlying common stock, the Investment in Aytu was remeasured at its current fair value with the change in fair value recorded to other income, net in the accompanying statements of operations and comprehensive loss. In April 2020, Cerecor was permitted to convert the Aytu Series G Preferred Stock into 9,805,845 shares of Aytu's common stock (the "Aytu Common Shares"), and subsequently sold all of the Aytu Common Shares in a series of transactions. The sale resulted in a realized gain, calculated as the difference between the net proceeds received and the fair value of the Investment in Aytu at the divestiture date, which was recognized in change in fair value of Investment in Aytu within the accompanying consolidated statement of operations and comprehensive loss for the year ended December 31, 2020.

Estimated Fair Value of Guarantee and Change in Fair Value of Guarantee

As of the closing date of the Aytu Divestiture on November 1, 2019, Aytu assumed the Company's debt obligation to Deerfield CSF, LLC ("Deerfield") and the contingent consideration liability related to future royalties on Avadel Pharmaceuticals PLC's ("Avadel") pediatric products. In conjunction with the closing of this transaction, the Company entered into a Guarantee in favor of Deerfield, which guarantees the payment of the assumed liabilities to Deerfield, which included the debt obligation and the contingent consideration related to future potential royalties on Avadel's pediatric products (collectively referred to as the "Guarantee"). Aytu publicly reported that it had paid the $15.0 million balloon payment to Deerfield before it came due in June 2020, thus satisfying that portion of the debt obligation assumed as part of the divestiture. The remaining minimum commitments payable related to the future potential royalties on Avadel's pediatric products was $ 7.3 million as of June 30, 2020 (as most recently publicly reported by Aytu), which represents Cerecor's estimated maximum potential future payments under the Guarantee.

The fair value of the Guarantee, which relates to the Company's obligation to make future payments if Aytu defaults, was determined at the time of the divestiture as the difference between (i) the estimated fair value of the debt and contingent payments, respectively, using Cerecor's estimated cost of debt and (ii) the estimated fair value of the debt and contingent payments, respectively, using Aytu's estimated cost of debt. Subsequent to the close of the Aytu Divestiture, at each reporting period, the value of the Guarantee is determined based on the expected credit loss of the Guarantee with changes recorded in income from discontinued operations, net of tax within the consolidated statements of operations and comprehensive loss. Refer to Note 3 for more information.

Paycheck Protection Program Loan

The Coronavirus Aid, Relief and Economic Security Act (the "CARES Act") provides stimulus measures, including the Paycheck Protection Program ("PPP"), to provide certain small businesses with liquidity to support their operations (such as to retain employees and maintain payroll and lease payments) during the COVID-19 pandemic. Cerecor received a $0.4 million PPP Loan during the second quarter of 2020 (the "PPP Loan"). PPP loans have a 1% fixed annual interest rate and mature in two years, and are eligible for forgiveness under certain conditions. If there is reasonable assurance that the PPP Loan will be forgiven, the Company may elect to account for the PPP Loan either as debt under ASC 470 or as a government grant. If accounted for as a government grant, the Company may elect to present the PPP Loan as either a credit in the income statement within other income or as a reduction to the related expense.

As of December 31, 2020, the Company believes it meets the criteria for forgiveness and submitted an application for forgiveness with its lender in 2020. Once approved by the lender, the lender will submit the forgiveness application to the Small Business Administration (the "SBA") for ultimate approval. The SBA has 90 days from receipt to approve or reject the forgiveness application. Because the Company believes it meets the criteria for forgiveness and incurred the related expenses during the year, the Company elected to recognized the PPP Loan as other income within the accompanying consolidated statement of operations and comprehensive loss for the year ended December 31, 2020.

Stock-Based Compensation

The Company applies the provisions of ASC 718, Compensation—Stock Compensation, which requires the measurement and recognition of compensation expense for all stock-based awards made to employees, including employee stock options, in the statements of operations and comprehensive loss.

For stock options issued to employees and members of the board of directors for their services, the Company estimates the grant date fair value of each option using the Black-Scholes option pricing model. The use of the Black-Scholes option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected life of the option, risk-free interest rates and expected dividend yields of the common stock. For awards subject to service-based vesting conditions, including those with a graded vesting schedule, the Company recognizes stock-based compensation expense equal to the grant date fair value of stock options on a straight-line basis over the requisite service period, which is generally the vesting term. Forfeitures are recorded as they are incurred as opposed to being estimated at the time of grant and revised.

For stock option grants with market-based conditions, compensation expense is recognized ratably over the attribution period. The Company estimates the fair value of the market-based stock option grants using a Monte-Carlo simulation. The Company generally estimates fair value using assumptions, including the expected term of the option, the expected volatility of peer group of similar companies, risk free interest rate and the expected dividend yield.

These estimates involve inherent uncertainties and the application of management's judgment. If factors change and different assumptions are used, the Company's stock-based compensation expense could be materially different in the future.

Income Taxes

The Company accounts for income taxes under the asset and liability method in accordance with ASC 740, Income Taxes ("ASC 740"). Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Deferred tax assets primarily include net operating loss ("NOL") and tax credit carryforwards, accrued expenses not currently deductible and the cumulative temporary differences related to certain research and patent costs. Certain tax attributes, including NOLs and research and development credit carryforwards, may be subject to an annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "IRC"). See Note 12 for further information. The portion of any deferred tax asset for which it is more likely than not that a tax benefit will not be realized must then be offset by recording a valuation allowance. The Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not to be sustained upon examination based on the technical merits of the position. The amount for which an exposure exists is measured as the largest amount of benefit determined on a cumulative probability basis that the Company believes is more likely than not to be realized upon ultimate settlement of the position. The Company's policy is to record interest and penalties on uncertain tax positions as income tax expense. As of December 31, 2020, the Company did not believe any material uncertain tax positions were present.

Comprehensive Loss

Comprehensive loss comprises net loss and other changes in equity that are excluded from net loss. For the years ended December 31, 2020 and 2019, the Company's net loss was equal to comprehensive loss and, accordingly, no additional disclosure is presented.

Recently Adopted Accounting Pronouncements

Financial Instruments - Credit Losses

In June 2016, the FASB issued ASU No. 2016-13, "Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments" ("ASU 2016-13"). This guidance applies to all entities and impacts how entities account for credit losses for most financial assets and other instruments. For available-for-sale debt securities, entities will be required to recognize an allowance for credit losses rather than a reduction to the carrying value of the asset. For trade receivables, loans and held-to-maturity debt securities, entities will be required to estimate lifetime expected credit losses. This guidance is effective for fiscal years beginning after December 15, 2019 and interim periods therein.

Upon adoption of the new standard on January 1, 2020, the Company began recognizing an allowance using a forward-looking approach to estimate the expected credit loss related to financial assets. The Company began monitoring the financial performance and creditworthiness of its customers so that it can properly assess and respond to changes in the customers' credit profiles. Over 95% of sales were generated from three major industry wholesalers for the year ended December 31, 2020. Additionally, pursuant to the new standard, at each reporting period, the Company adjusts the Guarantee liability through earnings based on expected credit losses in accordance with Topic 326. The Company evaluated the impact of the adoption of this standard on its financial statements, concluding there was no significant impact on the Company's results of operations, financial position, cash flows or disclosures.

Fair Value Measurements

In August 2018, the FASB issued ASU No. 2018-13, "Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement." This new standard modifies certain disclosure requirements on fair value measurements. This new standard became effective for the Company on January 1, 2020. The Company evaluated the impact of the adoption of this new standard on its financial statements, concluding there was no significant impact.

Income Tax Simplification

In December 2019, the FASB issued ASU 2019-12, "Income Taxes (Topic 740)(ASU 2019-12)", which provides final guidance that simplifies the accounting for income taxes by eliminating certain exceptions to the guidance in ASC 740 related to the approach for intra-period tax allocation that is applicable to the Company, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences among other changes. For public business entities, the amendments in this update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. Early adoption of the amendments is permitted, including adoption in any interim period for public business entities for periods for which financial statements have not yet been issued. An entity that elects early adoption must adopt all the amendments in the same period. The Company elected to early adopt the ASU 2019-12 as of January 1, 2020. Management concluded that the adoption of the new standard did not have a material impact to income taxes reported on the financial statements for the year ended December 31, 2020.

3. Aytu Divestiture

Overview of Sale of Pediatric Portfolio and Related Commercial Infrastructure to Aytu BioScience

On October 10, 2019, the Company entered into the Aytu Purchase Agreement to sell the Company's rights, titles and interest in, assets relating to certain commercialized products, as well as the corresponding commercial infrastructure consisting of the right to offer employment to Cerecor's sales force and the assignment of supporting commercial contracts (the "Aytu Divestiture"). The Aytu Divestiture closed on November 1, 2019. Aytu paid consideration of $4.5 million in cash and approximately 9.8 million shares of Aytu convertible preferred stock, and assumed certain of the Company's liabilities, including the Company's payment obligations payable to Deerfield of $15.1 million and certain other liabilities of $11.0 million primarily related to contingent consideration, Medicaid rebates and sales returns. The Company recognized a gain of $8.0 million upon the closing of the Aytu Divestiture for the year ended December 31, 2019. In addition, Aytu assumed future contractual obligations under existing license agreements associated with the Pediatric Portfolio. Armistice Capital Master Fund Ltd. ("Armistice") is a significant stockholder of the Company and Armistice's Chief Investment Officer, Steve Boyd, serves on each company's board of directors.

Upon closing the Aytu Divestiture, Cerecor terminated all of its sales force personnel, which included both those offered employment by Aytu, as well as any remaining sales force personnel. Additionally, Cerecor retained all rights to Millipred®. Pursuant to a transition services agreement entered into between Aytu and Cerecor, Aytu is managing Millipred® commercial operations for a monthly fee of $12,000 for up to 18 months (post November 1, 2019) or until the Company establishes an independent commercial infrastructure for the product.

Upon the sale of the Pediatric Portfolio to Aytu, the Pediatric Portfolio met all conditions to be classified as discontinued operations. Therefore, the accompanying consolidated financial statements for the year ended December 31, 2020 and 2019 and as of December 31, 2020 and 2019 reflect the operations, net of taxes, and related assets and liabilities of the Pediatric Portfolio as discontinued operations. Refer to the "Discontinued Operations" section below for more information, including Cerecor's continuing involvement.

Deerfield Guarantee

On November 1, 2019, in conjunction with the closing of the Aytu Divestiture, the Company entered into a Guarantee in favor of Deerfield, which guarantees the payment of the assumed liabilities to Deerfield, which includes both the debt obligation ("Fixed Payment Guarantee") and the contingent consideration related to future potential royalties on Avadel's pediatric products ("Deferred Payment Guarantee"). Additionally, on November 1, 2019, the Company entered into a Contribution Agreement with Armistice and Avadel that governs contribution rights and obligations of the Company, Armistice and Avadel with respect to amounts that are paid by Armistice and Avadel to Deerfield under certain guarantees made by Armistice and Avadel to Deerfield.

The debt obligation assumed by Aytu consists of fixed monthly payments to Deerfield of $0.1 million until January 2021 and an additional balloon payment of $15.0 million to Deerfield on January 31, 2021. Aytu publicly reported that it had paid the $15.0 million balloon payment to Deerfield before it came due in June 2020, thus satisfying that portion of the debt obligation assumed as part of the divestiture.

The contingent consideration assumed by Aytu consists of quarterly deferred payments equal to 15% of net sales of certain Pediatric Portfolio products or at least $0.3 million paid in arrears each quarter until the earlier of (i) February 5, 2026, or (ii) upon $12.5 million in aggregate deferred payments has been paid to Deerfield. Of the contingent consideration, $3.2 million was paid to Deerfield prior to the Aytu Divestiture and therefore as of November 1, 2019, Aytu was responsible for the remaining $9.3 million. Aytu is required to pay an amount equal to at least $0.1 million per month. Cerecor's Deferred Payment Guarantee will end upon the earlier of (i) February 5, 2026, or (ii) upon $12.5 million in aggregate deferred payments has been paid to Deerfield. Cerecor is required to make payment under the Guarantee upon demand by Deerfield, which Deerfield can demand at any time if all or any part of the fixed payments and/or deferred payments are not paid by Aytu when due or upon breach of a covenant. The remaining minimum commitments payable as most recently publicly reported by Aytu was $7.3 million as of June 30, 2020, which represents Cerecor's estimated maximum potential future payments under the Guarantee.

The fair value of the Guarantee, which relates to the Company's obligation to make future payments if Aytu defaults, was determined at the time of the Aytu Divestiture as the difference between (i) the estimated fair value of the debt and contingent payments, respectively, using Cerecor's estimated cost of debt and (ii) the estimated fair value of the debt and contingent payments, respectively, using Aytu's estimated cost of debt. Subsequent to the close of the Aytu Divestiture, at each reporting period, the value of the Guarantee is determined based on the expected credit loss of the Guarantee with changes recorded in (loss) income from discontinued operations, net of tax within the consolidated statements of operations and comprehensive loss. In 2020, Aytu's credit

rating significantly improved as a result of recent developments to Aytu's business, including but not limited to, recent financings and expansion of its revenue products that substantially enhanced Aytu's cash position and its ability to meet its financial commitments. Based on these facts, the Company concluded that the expected credit loss of the Guarantee was de minimis as of December 31, 2020, thus recognizing a $1.8 million gain on the change in value in income from discontinued operations, net of tax within the accompanying consolidated statement of operations and comprehensive loss for the year ended December 31, 2020.

Discontinued Operations

The following tables summarizes the assets and liabilities of the discontinued operations as of December 31, 2020 and 2019:

	December 31,	
	2020	**2019**
Assets		
Current assets:		
Accounts receivable, net	$ —	$ 497,577
Total current assets of discontinued operations	—	497,577
Liabilities		
Current liabilities:		
Accounts payable	—	387,975
Accrued expenses and other current liabilities	1,341,667	3,503,037
Total current liabilities of discontinued operations	1,341,667	3,891,012
Other long-term liabilities	—	1,755,000
Total long-term liabilities of discontinued operations	—	1,755,000

Cerecor retains continuing involvement with the divested Pediatric Portfolio related to future sales returns made after November 1, 2019 for sales of the Pediatric Portfolio prior to the close date of the Aytu Divestiture and the Deerfield Guarantee. Pursuant to the Aytu Purchase Agreement, Aytu assumed sales returns of the Pediatric Portfolio made after the closing date of November 1, 2019 and primarily relating to sales prior to November 1, 2019 only to the extent such post-closing sales returns exceed $2.0 million and are less than $2.8 million (in other words, Aytu will only assume $0.8 million of such returns). Therefore, Cerecor is liable for future sales returns of the Pediatric Portfolio sold prior to November 1, 2019 in excess of the $0.8 million assumed by Aytu. Additionally, from November 1, 2019 through the second quarter of 2020, Cerecor collected cash on behalf of Aytu for post-divestiture sales of the Pediatric Portfolio. The collection of accounts receivable was fully transitioned to Aytu during the second quarter of 2020. As a result of this transition, beginning in the second quarter of 2020, Aytu collects cash on the sales of the Pediatric Portfolio and also on sales of Millipred® (on behalf of Cerecor).

As of December 31, 2020, the Company estimated its net liability, which includes cash collected on Aytu’s behalf, actual returns on sales of the Pediatric Portfolio made prior to the transaction close date and the Company's estimate of future returns on sales of the Pediatric Portfolio made prior to the transaction close date netted with the cash receipts Aytu owes Cerecor related to Aytu's collection of cash for sales of Millipred® , to be $1.0 million, which is included above in accrued expenses and other current liabilities of discontinued operations.

Changes in the Company's estimate of sales returns related to the Pediatric Portfolio is included within discontinued operations on the statement of operations and comprehensive loss and is shown within product sales, net in the table summarizing the results of discontinued operations below. In future periods, as additional information becomes available to the Company, the Company expects to recognize expense (or a benefit) related to actual sales returns of the Pediatric Portfolio in excess (or less than) the returns reserve recorded, which will be recognized within discontinued operations. The Company expects this involvement to continue until sales returns are no longer accepted on sales of the Pediatric Portfolio made prior to November 1, 2019. In line with the products' return policies, returns on these products may be accepted through the second quarter of 2022.

The following table summarizes the results of discontinued operations for the year ended December 31, 2020 and 2019:

	Year Ended December 31,	
	2020	2019
Product revenue, net	$ (871,221)	$ 10,166,611
Operating expenses:		
Cost of product sales	—	4,288,234
General and administrative	—	137,911
Sales and marketing	—	8,521,190
Amortization expense	—	2,425,083
Impairment of intangible assets	—	1,449,121
Change in fair value of contingent consideration	—	247,042
Total operating expenses	—	17,068,581
Other income (expense):		
Change in value of Guarantee	1,755,000	—
Interest expense, net	—	(793,860)
Total other income (expense)	1,755,000	(793,860)
Gain on sale of Pediatric Portfolio	—	7,964,924
Income from discontinued operations before tax	883,779	269,094
Income tax expense	—	70,888
Income from discontinued operations, net of tax	$ 883,779	$ 198,206

The Company recognized a gain of $8.0 million upon the close of the transaction, which is included in income from discontinued operations, net of tax within the accompanying consolidated statement of operation and comprehensive loss for the year ended December 31, 2019. The gain was comprised of $4.5 million of cash consideration received, $7.6 million of Aytu preferred stock consideration received (which represents its fair value on November 1, 2019 (see Note 6 for more information), $18.8 million of net assets transferred as of November 1, 2019 (excluding debt assumed), $15.1 million of debt assumed as of November 1, 2019, and $0.6 million of transaction expenses incurred.

The significant non-cash operating items from the discontinued operations for the years ended December 31, 2020 and 2019 are contained below. There were no non-cash investing items from the discontinued operations for the years ended December 31, 2020 and 2019.

	Year Ended December 31,	
	2020	2019
Operating activities		
Amortization	$ —	$ 2,425,083
Impairment of intangible assets	—	1,449,121
Stock-based compensation, excluding amount included within gain on sale of Pediatric Portfolio	—	327,180
Amortization of inventory fair value adjustment associated with acquisition of TRx and Avadel pediatric product	—	107,271
Change in fair value of contingent consideration liability	—	247,042
Change in fair value of Guarantee	(1,755,000)	—
Gain on Aytu Divestiture	—	(7,964,924)

4. Net Loss Per Share

The Company computes earnings per share ("EPS") using the two-class method. The two-class method of computing EPS is an earnings allocation formula that determines EPS for common stock and any participating securities according to dividends declared and participation rights in undistributed earnings. The Company has two classes of stock outstanding, common stock and preferred stock. The preferred stock was issued in December 2018, upon Armistice exercising warrants to acquire an aggregate of 2,857,143 shares of the Company's Series B Convertible Preferred Stock. Such convertible preferred stock has the same rights and preferences

as the Company's common stock, other than being non-voting, and is convertible into shares of common stock on a 1-for-5 ratio. During the first quarter of 2020, Armistice converted 1.6 million shares of Series B Convertible Preferred Stock into 8.0 million shares of Cerecor's common stock. Under the two-class method, the convertible preferred stock is considered a separate class of stock for EPS purposes and therefore basic and diluted EPS is provided below for both common stock and preferred stock.

EPS for common stock and EPS for preferred stock is computed by dividing the sum of distributed earnings and undistributed earnings for each class of stock by the weighted average number of shares outstanding for each class of stock for the period. In applying the two-class method, undistributed earnings are allocated to common stock and preferred stock based on the weighted average shares outstanding during the period, which assumes the convertible preferred stock has been converted to common stock.

Diluted net (loss) income per share includes the potential dilutive effect of common stock equivalents as if such securities were converted or exercised during the period, when the effect is dilutive. Common stock equivalents include: (i) outstanding stock options and restricted stock units, which are included under the "treasury stock method" when dilutive; and (ii) common stock to be issued upon the exercise of outstanding warrants, which are included under the "treasury stock method" when dilutive. Because the impact of these items is generally anti-dilutive during periods of net loss, there is no difference between basic and diluted loss per common share for periods with net losses. In periods of net loss, losses are allocated to the participating security only if the security has not only the right to participate in earnings, but also a contractual obligation to share in the Company's losses.

The following table sets forth the computation of basic and diluted net loss per share of common stock for continuing and discontinued operations for the years ended December 31, 2020 and 2019, which includes both classes of participating securities:

	Year Ended December 31, 2020			
	Common stock		Preferred Stock	
	Continuing Operations	Discontinued Operations	Continuing Operations	Discontinued Operations
Numerator:				
Allocation of undistributed net (loss) income	$ (58,439,575)	$ 802,188	$ (5,943,976)	$ 81,591
Denominator:				
Weighted average shares	66,688,464	66,688,464	1,356,597	1,356,597
Basic and diluted net (loss) income per share	$ (0.87)	$ 0.01	$ (4.38)	$ 0.06

	Year Ended December 31, 2019			
	Common stock		Preferred Stock	
	Continuing Operations	Discontinued Operations	Continuing Operations	Discontinued Operations
Numerator:				
Allocation of undistributed net (loss) income	$ (12,204,552)	$ 148,673	$ (4,066,201)	$ 49,533
Denominator:				
Weighted average shares	42,878,040	42,878,040	2,857,143	2,857,143
Basic and diluted net (loss) income per share	$ (0.28)	$ 0.00	$ (1.42)	$ 0.01

The following outstanding securities at December 31, 2020 and 2019 have been excluded from the computation of diluted weighted shares outstanding, as they could have been anti-dilutive:

	December 31,	
	2020	2019
Stock options	9,830,674	4,480,606
Warrants on common stock	4,002,380	4,024,708
Restricted Stock Units	155,833	267,500
Underwriters' unit purchase option	—	40,000

5. Asset Acquisition

Aevi Merger

On February 3, 2020, the Company consummated its two-step merger with Aevi, in accordance with the terms of the Merger Agreement dated December 5, 2019, by and between Cerecor, Genie Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of Cerecor ("Merger Sub"), Second Genie Merger Sub, LLC ("Second Merger Sub"), a Delaware limited liability company and wholly owned subsidiary of Cerecor, and Aevi. On February 3, 2020, Merger Sub merged with and into Aevi, with Aevi as the surviving corporation, and as part of the same transaction, Aevi then merged with and into Second Merger Sub, with Second Merger Sub as the surviving entity. The surviving entity from the second merger was renamed Aevi Genomic Medicine, LLC and is disregarded as an entity separate from Cerecor for U.S. federal income tax purposes. Cerecor retained its public reporting and current NASDAQ listing status. Effective upon the close of the Merger, Cerecor entered into an employment agreement with Aevi's Chief Executive Officer, Mike Cola, for him to serve as Cerecor's Chief Executive Officer and an employment agreement with Aevi's Chief Scientific Officer, Dr. Garry Neil, for him to serve as Cerecor's Chief Medical Officer, and appointed Mr. Cola and Dr. Sol Barer, the former Chairman of the Board of Aevi, to the Company's Board of Directors. Dr. Barer serves as the Chairman of the Company's Board. Dr. Neil was promoted to Cerecor's Chief Scientific Officer in March 2020. Additionally, the Company extended employment agreements to seven other individuals who were previously employed by Aevi.

Upon entering into the Merger Agreement on December 5, 2019, Cerecor agreed to loan Aevi $4.1 million related to the exercise of an exclusive license from MedImmune Limited to develop and commercialize a Phase 2-ready fully human monoclonal antibody that targets IL-18 (the "Aevi Loan"). All unpaid principal and accrued interest on the Aevi Loan was due and payable in full on the one year anniversary of the loan date (unless the Merger Agreement was terminated or upon consummation of the Merger). If the Merger Agreement was terminated for any reason, Aevi would be required to repay the amount borrowed under the Aevi Loan in full and if the Merger was consummated, the Aevi Loan was to be forgiven. As of December 31, 2019, it was unknown if the Merger would be consummated, and therefore, the Company recognized the $4.1 million loaned to Aevi as an other receivable within its accompanying consolidated balance sheet as of December 31, 2019.

On February 3, 2020, the Merger was consummated in accordance with the terms of the Merger Agreement. The Merger consideration included stock valued at approximately $15.5 million, resulting in the issuance of approximately 3.9 million shares of Cerecor common stock to Aevi stockholders, forgiveness of the $4.1 million Aevi Loan, contingent value rights for up to an additional $6.5 million in subsequent payments based on certain development milestones, payable in either shares of the Company's common stock or in cash at the election of the Company, and transaction costs of $1.5 million.

The fair value of the common stock transferred at closing was approximately $15.5 million using the Company's closing stock price on February 3, 2020. The assets acquired consisted primarily of $24.0 million of acquired in-process research and development, $0.3 million of cash and $0.9 million of assembled workforce. Refer to Note 6 for information regarding the valuation of the assembled workforce asset. The Company assumed net liabilities of $5.1 million. The Company recorded this transaction as an asset purchase as opposed to a business combination because management concluded that substantially all the value received was related to one group of similar identifiable assets, which was the IPR&D for two early phase therapies. The Company considered these assets similar due to similarities in the risks of development, stage of development, regulatory pathway, patient populations and economics of commercialization. The fair value of the IPR&D was immediately recognized as acquired in-process research and development expense in the Company's consolidated statement of operations and comprehensive loss for the year ended December 31, 2020 because the IPR&D asset has no alternate use due to the stage of development. The $1.5 million of transaction costs incurred were recorded to acquired IPR&D expense. The assembled workforce asset was recorded to intangible assets and will be amortized over an estimated useful life of two years.

In addition to the issuance of Cerecor common stock, Cerecor agreed to pay contingent consideration of up to an additional $6.5 million related to two future development milestones. The first milestone is the enrollment of a patient in a Phase II study related to CERC-002 for use in pediatric onset Crohn's disease, CERC-006 (any indication), or CERC-007 (any indication) prior to February 3, 2022. If this milestone is met, the Company is required to make a milestone payment of $2.0 million. The second milestone is the receipt of a NDA approval for either CERC-006 or CERC-007 from the FDA on or prior to February 3, 2025. If this milestone is met, the Company is required to make a milestone payment of $4.5 million. All milestones are payable in either shares of the Company's common stock or cash, at the election of the Company. Refer to Note 13 for further information.

6. Fair Value Measurements

ASC No. 820, *Fair Value Measurements and Disclosures* ("ASC 820") defines fair value as the price that would be received to sell an asset, or paid to transfer a liability, in the principal or most advantageous market in an orderly transaction between market

participants on the measurement date. The fair value standard also establishes a three-level hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The valuation hierarchy is based upon the transparency of inputs to the valuation of an asset or liability on the measurement date. The three levels are defined as follows:

- Level 1—inputs to the valuation methodology are quoted prices (unadjusted) for an identical asset or liability in an active market.
- Level 2—inputs to the valuation methodology include quoted prices for a similar asset or liability in an active market or model-derived valuations in which all significant inputs are observable for substantially the full term of the asset or liability.
- Level 3—inputs to the valuation methodology are unobservable and significant to the fair value measurement of the asset or liability.

The following tables present, for each of the fair value hierarchy levels required under ASC 820, the Company's assets and liabilities from continuing operations that are measured at fair value on a recurring basis:

	December 31, 2020 Fair Value Measurements Using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets			
Investments in money market funds*	$ 17,503,371	$ —	$ —

	December 31, 2019 Fair Value Measurements Using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets			
Investments in money market funds*	$ 2,240,230	$ —	$ —
Investment in Aytu	$ —	$ 7,628,947	$ —

*Investments in money market funds are reflected in cash and cash equivalents on the accompanying consolidated balance sheets.

As of December 31, 2020 and 2019, the Company's financial instruments included cash and cash equivalents, restricted cash, accounts receivable, other receivables, prepaid and other current assets, accounts payable, and accrued expenses and other current liabilities. The carrying amounts reported in the accompanying consolidated financial statements for cash and cash equivalents, restricted cash, accounts receivable, accounts payable, accrued expenses, and other current liabilities approximate their respective fair values because of the short-term nature of these accounts.

Level 2 Valuation

As part of the consideration for the Aytu Divestiture, Aytu issued to Cerecor 9,805,845 shares of Aytu Series G Convertible Preferred Stock at a price of $1.2747 per share, which comprised the Investment in Aytu.

Upon the close of the Aytu Divestiture on November 1, 2019, the Company recognized $7.6 million as the estimated fair value of the Investment in Aytu on that date, which was calculated using Aytu's stock price close on November 1, 2019 of $1.03 per share and offset by an estimated discount for lack of marketability of25% calculated using guideline public company volatility for comparable companies. Subsequent to the initial measurement, at each reporting period, the Investment in Aytu was remeasured at the current fair value with the change in fair value recorded to other income, net in the accompanying statements of operations and comprehensive loss.

As of December 31, 2019, the Investment of Aytu was $7.6 million, which was calculated using Aytu's closing stock price on December 31, 2019 of $0.9725 per share and offset by an estimated discount for lack of marketability of 20%. In April 2020, Cerecor was permitted to convert the Investment in Aytu into 9,805,845 shares of Aytu's common stock, and subsequently sold all of these Aytu Common Shares in a series of transactions in April, pursuant to an effective registration statement, which generated net proceeds of approximately $12.8 million. The sale resulted in a realized gain of $5.2 million, which was recognized in change in fair value of Investment in Aytu within the accompanying consolidated statement of operations and comprehensive loss for the year ended December 31, 2020.

Level 3 Valuation

The Company's historical business acquisition of TRx involved the potential for future payment of consideration that was contingent upon the achievement of operational and commercial milestones related to the Ulesfia product. The fair value of contingent consideration was $1.3 million as of December 31, 2018. During the second quarter of 2019, the Company entered into a settlement agreement related to the Ulesfia product, which released the Company from the potential contingent payments related to the TRx Acquisition, reducing the fair value down to $0 as of December 31, 2019. This represented a gain on the change of fair value of contingent consideration of $1.3 million for the year ended December 31, 2019. There was no contingent consideration as of December 31, 2020 and no change in contingent consideration for the year ended December 31, 2020.

Effective upon the consummation of the Aevi Merger during the first quarter of 2020, Cerecor entered into an employment agreement with Aevi's Chief Executive Officer, Mike Cola, for him to serve as Cerecor's Chief Executive Officer and an employment agreement with Aevi's Chief Scientific Officer, Dr. Garry Neil, for him to serve as Cerecor's Chief Medical Officer and as Chief Scientific Officer in connection with a subsequent promotion. Additionally, the Company extended employment to seven other individuals who were previously employed by Aevi. As a result, the Company recognized an assembled workforce intangible asset of $0.9 million which is a Level 3 non-recurring fair value measurement. The Company utilized the replacement cost method to estimate the fair value of the assembled workforce, which considers the costs Cerecor would have incurred to replace a comparable workforce to the workforce acquired from Aevi. Such costs include, but are not limited to, recruiting costs, training costs and cost of lost productivity. The replacement costs were estimated based on a percentage of each employee's salary. The assembled workforce intangible asset will be amortized over a useful life of two years.

No other changes in valuation techniques or inputs occurred during the years ended December 31, 2020 and 2019. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the years ended December 31, 2020 and 2019.

7. Property and Equipment

Property and equipment as of December 31, 2020 and 2019 consisted of the following:

	December 31,	
	2020	**2019**
Furniture and equipment	$ 152,940	$ 143,168
Computers and software	56,240	6,708
Right-of-use assets	917,472	718,628
Leasehold improvements	657,328	657,328
Total property and equipment	1,783,980	1,525,832
Less accumulated depreciation	(176,910)	(78,169)
Property and equipment, net	$ 1,607,070	$ 1,447,663

Depreciation expense was $102,095 and $119,488 for the years ended December 31, 2020 and December 31, 2019, respectively.

Leases

The Company currently occupies two leased properties, both of which serve as administrative office space. The Company determined that both leases are operating leases based on the lease classification test performed at lease commencement.

The annual base rent for the Company's office located in Rockville, Maryland is $161,671, subject to annual 2.5% increases over the term of the lease. The lease provided for a rent abatement for a period of 12 months following the Company's date of occupancy. The lease has an initial term of 10 years from the date the Company makes its first annual fixed rent payment, which occurred in January 2020. The Company has the option to extend the lease two times, each for a period of five years, and may terminate the lease as of the sixth anniversary of the first annual fixed rent payment, upon the payment of a termination fee. As of the lease commencement date, it was not reasonably certain that the Company will exercise the renewal periods or early terminate the lease and therefore, the end date of the lease for accounting purposes is January 31, 2030.

The Company entered into a sublease for additional administrative office space in Chesterbrook, Pennsylvania in May 2020 (the “Chesterbrook Lease””). The annual base rent under the Chesterbrook Lease is $280,185. The lease expires in November 2021.

The weighted average remaining term of the operating leases at December 31, 2020 was7.7 years.

Supplemental balance sheet information related to the leased properties include:

	As of	
	December 31, 2020	December 31, 2019
Property and equipment, net	$ 917,472	$ 718,626
Accrued expenses and other current liabilities	$ 426,346	$ 155,815
Other long-term liabilities	1,038,395	1,111,965
Total operating lease liabilities	$ 1,464,741	$ 1,267,780

The operating lease ROU assets are included in property and equipment and the lease liabilities are included in accrued expenses and other current liabilities and other long-term liabilities in our consolidated balance sheets. The Company utilized a weighted average discount rate of 7.4% to determine the present value of the lease payments.

The components of lease expense for the years ended December 31, 2020 and 2019 were as follows:

	Year Ended December 31,	
	2020	2019
Operating lease cost*	$ 344,625	$ 160,767

*Includes short-term leases, which are immaterial.

The following table shows a maturity analysis of the operating lease liability as of December 31, 2020:

	Undiscounted Cash Flows
2021	$ 426,346
2022	173,748
2023	178,092
2024	182,544
2025	187,108
Thereafter	813,638
Total lease payments	$ 1,961,476
Less implied interest	(496,735)
Total	$ 1,464,741

8. Goodwill and Intangible Assets

There were no changes in the carrying amount of goodwill for the years ended December 31, 2020 and 2019.

The changes in intangible assets for the years ended December 31, 2020 and 2019 were as follows:

Balance as of December 31, 2018	$	3,765,254
Amortization		(1,338,996)
Balance as of December 31, 2019	$	2,426,258
Additions	$	900,000
Amortization	$	(1,741,083)
Balance as of December 31, 2020	$	1,585,175

As a result of the asset acquisition accounting treatment of the Aevi Merger, the Company recognized an assembled workforce intangible asset of $0.9 million during the first quarter of 2020, which was assigned a two-year useful life. Refer to Notes 5 and 6 for more information.

The following is a summary of intangible assets held by the Company at December 31, 2020 and 2019, respectively:

	December 31, 2020			
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Weighted-Average Remaining Life
				(in years)
Acquired Product Marketing Rights	$ 5,056,000	$ (3,949,988)	$ 1,106,012	0.9
Acquired Assembled Workforce	1,050,000	(570,837)	479,163	1.1
Total Intangible Assets	$ 6,106,000	$ (4,520,825)	$ 1,585,175	0.9

	December 31, 2019			
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Weighted-Average Remaining Life
				(in years)
Acquired Product Marketing Rights	$ 5,056,000	$ (2,685,992)	$ 2,370,008	1.9
Acquired Assembled Workforce	150,000	(93,750)	56,250	0.8
Total Intangible Assets	$ 5,206,000	$ (2,779,742)	$ 2,426,258	1.9

Amortization of intangibles for the next five years and thereafter is expected to be as follows:

For the Years Ending December 31,	Estimated Amortization Expense
2021	1,556,016
2022	29,159
2023	—
2024	—
2025	—
Thereafter	—
Total future amortization expense	$ 1,585,175

9. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities as of December 31, 2020 and 2019 consisted of the following:

	December 31,	
	2020	2019
Research and development expenses	$ 4,939,095	$ 920,901
Compensation and benefits	3,119,399	1,591,964
General and administrative	771,381	360,016
Sales and marketing	30,795	120,056
Sales returns and allowances	1,793,811	2,284,175
Medicaid rebates	118,655	118,271
Lease liability, current	426,346	155,815
Other	110,239	89,054
Accrued expenses and other current liabilities	$ 11,309,721	$ 5,640,252

The increase in accrued research and development expenses to $4.9 million as of December 31, 2020 was driven by an increase in manufacturing, regulatory and clinical activities to support the advancement of our expanded and maturing pipeline.

10. Capital Structure

Pursuant to the Company's amended and restated certificate of incorporation, the Company is authorized to issuetwo classes of stock; common stock and preferred stock. At December 31, 2020, the total number of shares of capital stock the Company was authorized to issue was 205,000,000 of which 200,000,000 was common stock and 5,000,000 was preferred stock. All shares of common and preferred stock have a par value of $0.001 per share.

On December 26, 2018, the Company filed a Certificate of Designation of Preferences of Series B Non-Voting Convertible Preferred Stock ("Series B Convertible Preferred Stock") of Cerecor Inc. (the "Certificate of Designation of the Series B Preferred Stock") classifying and designating the rights, preferences and privileges of the Series B Convertible Preferred Stock. The Certificate of Designation of the Series B Preferred Stock authorized the issuance of 2,857,143 shares of convertible preferred stock to Armistice with a par value of $0.001 per share. The Series B Convertible Preferred Stock is convertible into shares of common stock on a 1-for-5 ratio and has the same rights, preferences, and privileges as common stock other than it holds no voting rights.

Common Stock

Q1 2021 Financing

In January 2021, the Company closed an underwritten public offering of13,971,889 shares of its common stock and1,676,923 pre-funded warrants for net proceeds of approximately $37.6 million. Armistice participated in the offering by purchasing 2,500,000 shares of common stock, on the same terms as all other investors. Certain affiliates of Nantahala Capital Management LLC (collectively, "Nantahala"), which beneficially owned greater than 5% of the Company's outstanding common stock at the time of the offering and, therefore, were considered a related party pursuant to the Company's written related person transaction policy, purchased 1,400,000 shares of common stock, on the same terms as all other investors. Nantahala also purchased the pre-funded warrants. Refer to the "Common Stock Warrants" section below for more information regarding the pre-funded warrants.

Q2 2020 Financing

On June 11, 2020, the Company closed an underwritten public offering of15,180,000 shares of its common stock for net proceeds of approximately $35.4 million. Armistice participated in the offering by purchasing 2,000,000 shares of common stock on the same terms as all other investors. Additionally, certain of the Company's officers participated in the offering by purchasing an aggregate of 110,000 shares of common stock, on the same terms as all other investors.

Q1 2020 Financings

On March 17, 2020, the Company entered into a securities purchase agreement with Armistice pursuant to which the Company sold1,951,219 shares of its common stock for net proceeds of approximately $3.9 million.

On February 6, 2020, the Company closed a registered direct offering with certain institutional investors for the sale by the Company of1,306,282 shares of its common stock for net proceeds of approximately $5.1 million. Armistice participated in the offering by purchasing 1,256,282 shares of common stock from the Company.

Aevi Merger

On February 3, 2020, under the terms of the Aevi Merger discussed in Note 5, the Company issued3.9 million shares of its common stock.

Q3 2019 Armistice Private Placement

On September 4, 2019, the Company entered into a securities purchase agreement with Armistice, pursuant to which the Company sold1,200,000 shares of its common stock for net proceeds of approximately $3.7 million.

Q1 2019 Common Stock Offering

On March 8, 2019, the Company closed on an underwritten public offering of common stock for1,818,182 shares of common stock of the Company for net proceeds of approximately $9.0 million. Armistice participated in the offering by purchasing363,637 shares of common stock of the Company from the underwriter at the public price.

Description of Common Stock

Voting

Common stock is entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and does not have cumulative voting rights. Accordingly, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election.

Dividends

The holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

Liquidation

In the event of the Company's liquidation, dissolution or winding up, holders of the Company's common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders, including any preferred stock outstanding, after the payment of all debts and other liabilities.

Rights and Preferences

Holders of the Company's common stock haveno preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to the Company's common stock.

Common Stock Warrants

At December 31, 2020, the following common stock warrants were outstanding:

Number of shares underlying warrants	Exercise price per share	Expiration date
2,380	$ 8.68	May 2022
4,000,000	$ 12.50	June 2024
4,002,380		

As mentioned above in the section "Q1 2021 Financing," in January 2021, as part of an underwritten public offering, the Company sold Pre-Funded warrants to Nantahala to purchase 1,676,923 shares of Cerecor's common stock at a public offering price

of $2.599 per Pre-Funded Warrant. The Pre-Funded Warrants have an initial exercise price of $0.001 per share and are exercisable at any time after their original issuance at the option of each holder, in such holder's discretion.

Convertible Preferred Stock

December 2018 Armistice Private Placement

On December 27, 2018, the Company entered into a series of transactions as part of a private placement with its largest stockholder, Armistice, whose Chief Investment Officer, Steve Boyd, is a Cerecor director, in order to generate cash to continue to develop its pipeline assets and for general corporate purposes. The transactions are considered one transaction for accounting purposes. As part of the transaction, the Company exchanged common stock warrants issued on April 27, 2017 to Armistice for the purchase of up to 14,285,714 shares of the Company's common stock at an exercise price of $0.40 per share for like-kind warrants to purchase up to2,857,143 shares of the Company's newly designated Series B Convertible Preferred Stock with an exercise price of $2.00 per share (the "Exchanged Warrants"). Armistice immediately exercised the Exchanged Warrants and acquired an aggregate of 2,857,143 shares of the convertible preferred stock. Net proceeds of the transaction were approximately $5.7 million for the year ended December 31, 2018. In order to provide Armistice an incentive to exercise the Exchanged Warrants, the Company also entered into a securities purchase agreement with Armistice in December 2018 pursuant to which the Company issued warrants for 4,000,000 shares of common stock of the Company with a term of5.5 years and an exercise price of $12.50 per share.

During the first quarter of 2020, Armistice converted 1.6 million of Series B Convertible Preferred Stock (of its approximate2.9 million shares of convertible preferred stock) into 8.0 million shares of Cerecor's common stock.

Description of Preferred Stock

Voting

Holders of the Company's convertible preferred stock are not entitled to vote.

Dividends

The holders of convertible preferred stock are entitled to receive dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

Liquidation

In the event of the Company's liquidation, dissolution or winding up, holders of the Company's convertible preferred stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all debts and other liabilities.

Rights and Preferences

Each share of convertible preferred stock is convertible to shares of common stock on a 1-for-5 ratio. There are no other preemptive or subscription rights and there are no redemption or sinking fund provisions applicable to the Company's common stock.

11. Stock-Based Compensation

2016 Equity Incentive Plan

On April 5, 2016, the Company's board of directors adopted the 2016 Equity Incentive Plan (the "2016 Plan") as the successor to the 2015 Omnibus Plan (the "2015 Plan"). The 2016 Plan was approved by the Company's stockholders and became effective on May 18, 2016 (the "2016 Plan Effective Date"). Upon the 2016 Plan Effective Date, the 2016 Plan reserved and authorized up to 600,000 additional shares of common stock for issuance, as well as464,476 unallocated shares remaining available for grant of new awards under the 2015 Plan. An Amended and Restated 2016 Equity Incentive Plan (the "2016 Amended Plan") was approved by the Company's stockholders in May 2018, which increased the share reserve by an additional 1.4 million shares. A Second Amended and Restated 2016 Equity Incentive Plan (the "2016 Second Amended Plan") was approved by the Company's stockholders in August 2019, which increased the share reserve by an additional 850,000 shares. A Third Amended and Restated Equity Incentive Plan (the "2016 Third Amended Plan") was approved by the Company's stockholders in June 2020 which increased the share reserve by an additional 2,014,400 shares. During the term of the 2016 Third Amended Plan, the share reserve will

automatically increase on the first trading day in January of each calendar year, by an amount equal to4% of the total number of outstanding shares of common stock of the Company on the last trading day in December of the prior calendar year. As of December 31, 2020, there were 2,971,623 shares available for future issuance under the 2016 Third Amended Plan. On January 1, 2021, pursuant to the terms of the 2016 Third Amended Plan an additional 3,000,165 shares were made available for issuance.

Option grants expire after ten years. Employee options typically vest over three or four years. Employees typically receive a new hire option grant, as well as an annual grant in the first or second quarter of each year. Options granted to directors typically vest over one or three years. Directors may elect to receive stock options in lieu of board compensation, which vest immediately. For stock options granted to employees and non-employee directors, the estimated grant date fair market value of the Company's stock-based awards is amortized ratably over the individuals' service periods, which is the period in which the awards vest. Stock-based compensation expense includes expense related to stock options, restricted stock units and employee stock purchase plan shares. The amount of stock-based compensation expense recognized for the years ended December 31, 2020 and 2019 was as follows:

	Year Ended December 31,	
	2020	2019
Research and development	$ 1,338,916	$ 464,382
General and administrative	5,131,380	1,549,844
Sales and marketing	315,390	190,851
Total stock-based compensation, continuing operations	6,785,686	2,205,077
Total stock-based compensation, discontinued operations	—	257,719
Total stock-based compensation	$ 6,785,686	$ 2,462,796

Stock options with service-based vesting conditions

The Company has granted stock options that contain service-based vesting conditions. The compensation cost for these options is recognized on a straight-line basis over the vesting periods. The following table summarizes the Company's service-based option activity for the year ended December 31, 2020:

	Options Outstanding			
	Number of shares	Weighted average exercise price per share	Weighted average grant date fair value per share	Weighted average remaining contractual term (in years)
Balance at December 31, 2019	4,180,606	$ 4.80	$ 2.67	7.9
Granted	5,938,365	$ 3.38	$ 2.16	
Exercised	(75,239)	$ 1.52	$ 1.34	
Forfeited	(629,300)	$ 3.26	$ 1.95	
Expired	(583,758)	$ 5.42	$ 3.02	
Balance at December 31, 2020	8,830,674	$ 3.95	$ 2.36	7.7
Exercisable at December 31, 2020	2,906,450	$ 4.42	$ 2.46	5.0

In February 2020, the Company granted options to purchase2.4 million shares of common stock as inducement option grants, pursuant to NASDAQ Listing Rule 5635(c)(4), to certain executives who joined the Company in connection with the Aevi Merger. In March 2020, our Chief Executive Officer entered into an amended employment agreement in which his base salary in cash was reduced from an annual rate of $450,000 to an annual rate of $35,568 (the "Reduction"). In consideration for the Reduction, on a quarterly basis, the Company grants stock options, which vest immediately (the "Salary Options"), for the purchase of a number of shares of the Company's common stock with a total value (based on the Black-Scholes valuation methodology) based on a pro rata total annual value of $414,432 of the foregone salary. In April 2020, the Company granted options with service-based vesting conditions as part of its annual grant to employees. Throughout 2020, the Company granted options with service-based vesting conditions to new employees who started with the Company during the year.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. As of December 31, 2020, the aggregate intrinsic value of options outstanding and options currently exercisable was $0.9 million and $0.6 million, respectively. The aggregate intrinsic value of options exercised for the years ended December 31, 2020 and 2019 was $0.1 million and $0.9 million, respectively. There were 1,336,699 options that vested during the year ended December 31, 2020 with a weighted average exercise price of $4.43 per share. The total grant date fair value of shares which vested during the year ended December 31, 2020 and 2019 was $3.3 million and $2.2 million, respectively.

The Company recognized stock-based compensation expense of $4.6 million related to stock options with service-based vesting conditions for the year ended December 31, 2020. At December 31, 2020, there was $10.2 million of total unrecognized compensation cost related to unvested service-based vesting conditions awards. This unrecognized compensation cost is expected to be recognized over a weighted-average period of 2.9 years.

Stock options with market-based vesting conditions

The Company has granted stock options that contain market-based vesting conditions. The following table summarizes the Company's market-based option activity for the year ended December 31, 2020:

	Options Outstanding			
	Number of shares	Weighted average exercise price per share	Weighted average remaining contractual term (in years)	Aggregate intrinsic value (1)
Balance at December 31, 2019	300,000	$ 4.98	9.4	
Granted	1,000,000	$ 3.29		
Forfeited	(300,000)	$ 4.98		
Balance at December 31, 2020	1,000,000	$ 3.29	9.5	$ —
Exercisable at December 31, 2020	500,000	$ 2.51	9.5	$ 65,000

(1) The aggregate intrinsic value in the above table represents the total pre-tax amount that a participant would receive if the option had been exercised on the last day of the respective fiscal period. Options with a market value less than its exercise value are not included in the intrinsic value amount.

During the second quarter of 2020, 300,000 unvested market-based stock options were forfeited as a result of the resignation of an executive during that quarter. The forfeiture resulted in the reversal of the full expense previously recognized to date on this award of $0.4 million, which was recorded to general and administrative expense for the year ended December 31, 2020.

On June 18, 2020, the Company granted its Chairman of the Board an option to purchase 1,000,000 shares of Company common stock with market-based vesting conditions. 500,000 of the shares vested immediately on the date of grant with an exercise price of the closing stock price on the date of grant of $2.51 per share. 250,000 of the shares vest upon the Company's common stock reaching a 50% premium to the stock price on June 18, 2020 and will have an exercise price of the stock at that time and 250,000 of the shares vest upon the Company's common stock reaching a 75% premium to the stock price on June 18, 2020 and will have an exercise price of stock at that time. Each vesting tranche represents a unique requisite service period and therefore the compensation cost for each vesting tranche is recognized on a straight-line basis over its respective vesting period. The weighted-average grant date fair value of stock options with market-based vesting conditions granted during 2020 was $1.50 per share or $1.5 million. The total fair value of stock options with market-based vesting conditions that vested during 2020 was $0.8 million.

Subsequent to December 31, 2020, in the first quarter of 2021, the second tranche of 250,000 shares and the third tranche of 250,000 shares both vested upon the Company's stock price reaching a 50% and 75% premium to the stock price on June 18, 2020, respectively.

The Company recognized stock-based compensation expense of $1.1 million related to stock options with market-based vesting conditions for the year ended December 31, 2020, which is recorded in general and administrative expenses within the consolidated statement of operations and comprehensive loss. At December 31, 2020, there was $0.1 million of total unrecognized compensation cost related to the market-based vesting conditions awards. This compensation cost is expected to be recognized over a weighted-average period of 0.3 years.

Stock-based compensation assumptions

The following table shows the assumptions used to compute stock-based compensation expense for stock options granted to employees and members of the board of directors under the Black-Scholes valuation model, and the assumptions used to compute stock-based compensation expense for market-based stock option grants under a Monte Carlo simulation:

	Year Ended December 31,					
Service-based options	**2020**			**2019**		
Risk-free interest rate	0.19%	—	1.48%	1.47%	—	2.59%
Expected term of options (in years)	1.75	—	6.25	5.0	—	6.25
Expected stock price volatility	70 %		79 %	55%		
Expected annual dividend yield	0%			0%		
Market-based options						
Risk-free interest rate	0.30%		0.34%	2.32%		
Expected term of options (in years)	4.3	—	5.0	10		
Expected stock price volatility	80%			60%		
Expected annual dividend yield	0%			0%		

The valuation assumptions were determined as follows:

- Risk-free interest rate: The Company bases the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected option term.
- Expected term of options: Due to lack of sufficient historical data, the Company estimates the expected life of its stock options with service-based vesting granted to employees and members of the board of directors as the arithmetic average of the vesting term and the original contractual term of the option for service-based options.
- Expected stock price volatility: The Company estimated the expected volatility based on a blend of Cerecor's actual historical volatility of its stock price and the historical volatility of other similar publicly-traded biotechnology companies. The Company calculated the historical volatility of the selected companies by using weekly closing prices over a period of the expected term of the associated award. The companies were selected based on their enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected term of the associated award. A decrease in the selected volatility would decrease the fair value of the underlying instrument.
- Expected annual dividend yield: The Company estimated the expected dividend yield based on consideration of its historical dividend experience and future dividend expectations. The Company has not historically declared or paid dividends to stockholders. Moreover, it does not intend to pay dividends in the future, but instead expects to retain any earnings to invest in the continued growth of the business. Accordingly, the Company assumed an expected dividend yield of 0%.

Restricted Stock Units

The Company measures the fair value of the restricted stock units using the stock price on the date of the grant. The restricted shares typically vest annually over a four-year period beginning on the first anniversary of the award. The following table summarizes the Company's RSU activity for the year ended December 31, 2020:

	RSUs Outstanding	
	Number of shares	**Weighted average grant date fair value**
Unvested RSUs at December 31, 2019	267,500	$ 4.92
Vested	(111,667)	$ 4.93
Unvested RSUs at December 31, 2020	155,833	$ 4.91

The Company recognized expense of $0.8 million related to RSUs for the year ended December 31, 2020. The total fair value of restricted stock units that vested for the year ended December 31, 2020 and 2019 was $0.6 million and $0.8 million, respectively.

Employee Stock Purchase Plan

On April 5, 2016, the Company's board of directors approved the ESPP. The ESPP was approved by the Company's stockholders and became effective on May 18, 2016 (the "ESPP Effective Date").

Under the ESPP, eligible employees can purchase common stock through accumulated payroll deductions at such times as are established by the administrator. The ESPP is administered by the compensation committee of the Company's board of directors. Under the ESPP, eligible employees may purchase stock at 85% of the lower of the fair market value of a share of the Company's common stock (i) on the first day of an offering period or (ii) on the purchase date. Eligible employees may contribute up to 15% of their earnings during the offering period. The Company's board of directors may establish a maximum number of shares of the Company's common stock that may be purchased by any participant, or all participants in the aggregate, during each offering or offering period. Under the ESPP, a participant may not accrue rights to purchase more than $25,000 of the fair market value of the Company's common stock for each calendar year in which such right is outstanding.

Upon the ESPP Effective Date, the Company reserved and authorized up to 500,000 shares of common stock for issuance under the ESPP. On January 1 of each calendar year, the aggregate number of shares that may be issued under the ESPP automatically increases by a number equal to the lesser of (i) 1% of the total number of shares of the Company's capital stock outstanding on December 31 of the preceding calendar year, and (ii) 500,000 shares of the Company's common stock, or (iii) a number of shares of the Company's common stock as determined by the Company's board of directors or compensation committee. As of December 31, 2020, 1,425,308 shares remained available for issuance. On January 1, 2020, the number of shares available for issuance under the ESPP increased by 500,000.

In accordance with the guidance in ASC 718-50,*Employee Share Purchase Plans*, the ability to purchase shares of the Company's common stock at the lower of the offering date price or the purchase date price represents an option and, therefore, the ESPP is a compensatory plan under this guidance. Accordingly, stock-based compensation expense is determined based on the option's grant-date fair value and is recognized over the requisite service period of the option. The Company used the Black-Scholes valuation model and recognized stock-based compensation expense of $0.3 million for the year ended December 31, 2020.

Subsequent Equity Grants

In January 2021, the Company granted 2.7 million options with service-based vesting conditions at an exercise price of $3.32 per share to its employees as part of its annual stock option award. The options were granted under the 2016 Third Amended Plan and will vest over four years, with one-quarter of such options vesting on the first anniversary of the grant date and the remaining three-quarters of the options vesting in equal monthly installments over the following 36 months.

On March 1, 2021, the Company granted its newly appointed Chief Financial Officer, Schond L. Greenway, options to purchase 0.5 million shares of common stock at an exercise price of $3.73 per share as an inducement option grant, pursuant to NASDAQ Listing Rule 5635(c)(4). The options will vest over four years, with one-quarter of such options vesting on the first anniversary of the grant date and the remaining three-quarters of the options vesting in equal monthly installments over the following 36 months.

12. Income Taxes

The Company accounts for income taxes in accordance with ASC 740 (Topic 740, Income Taxes). ASC 740 is an asset and liability approach that requires the recognition of deferred tax assets and liabilities for the expected tax consequences or events that have been recognized in our financial statement or tax returns. ASC Topic 740 also clarifies the accounting for uncertainty in income taxes recognized in the financial statement. The interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken, or expected to be taken, in a tax return. There were no significant matters determined to be unrecognized tax benefits taken or expected to be taken in a tax return that have been recorded in our financial statement for the year ended December 31, 2020. Tax years beginning in 2017 are generally subject to examination by taxing authorities, although net operating losses from all years are subject to examinations and adjustments for at least three years following the year in which the attributes are used.

ASC Topic 740 provides guidance on the recognition of interest and penalties related to income taxes. It is the Company's policy to treat interest and penalties, to the extent they arise, as a component of income taxes. There was no interest or penalties related to uncertain tax positions arising in the years ended December 31, 2020 and 2019.

The income tax provision from continuing operations consisted of the following for the years ending December 31, 2020 and 2019:

	December 31,	
	2020	2019
Current:		
Federal	$ (2,158,004)	$ 209,001
State	(439,372)	54,572
Total Current	(2,597,376)	263,573
Deferred:		
Federal	(146,655)	24,458
State	(48,930)	(7,715)
Total Deferred	(195,585)	16,743
Net income tax (benefit) expense	$ (2,792,961)	$ 280,316

The net deferred tax liabilities consisted of the following for the years ending December 31, 2020 and 2019:

	December 31,	
	2020	2019
Deferred tax assets (liabilities):		
Net operating losses	$ 14,935,387	$ 7,596,955
Accrued compensation	893,098	321,748
Investment in Aytu	—	577,490
Tax credits	2,748,480	1,070,738
Stock-based compensation	2,848,797	1,872,442
Installment sale	461,593	441,305
Other reserves	542,852	399,885
Prepaid expenses	(246,771)	(120,863)
Right-of-use asset	(224,271)	(167,943)
Lease liability	358,025	296,259
Basis difference in tangible and intangible assets, net	1,935,389	1,968,008
Total deferred tax assets, net	24,252,579	14,256,024
Less valuation allowance	(24,342,973)	(14,342,005)
Net deferred taxes	$ (90,394)	$ (85,981)

As of December 31, 2020, the Company has roughly $61.1 million of gross NOLs for federal and state tax purposes that will begin to expire in 2031, including $5.4 million of gross NOLs for federal and state tax purposes that carry forward indefinitely. As of December 31, 2020, the Company has research and experimental tax credits of $2.7 million that will begin to expire in 2038.

The income tax benefit (expense) for the years ended December 31, 2020 and 2019 differed from the amounts computed by applying the U.S. federal income tax rate of 21% as follows:

	December 31,	
	2020	2019
Federal statutory rate	21.00 %	21.00 %
Stock compensation	(0.47)	(0.47)
State taxes	0.60	(0.13)
Research and development credit	2.53	5.13
Acquired in-process research and development	(8.09)	—
Fair value adjustment to contingent consideration	—	1.65
NOL carryback due to CARES Act	3.26	—
Other	(0.16)	(1.86)
Valuation allowance	(14.46)	(27.07)
Effective income tax rate	4.21 %	(1.75)%

The valuation allowance recorded by the Company as of December 31, 2020 and December 31, 2019 resulted from the uncertainties of the future utilization of deferred tax assets mainly resulting from net operating loss carry forwards for federal and state income tax purposes as well as the federal research and experimental and orphan drug tax credits. In assessing the realization of deferred tax assets, management considers the reversal of deferred tax liabilities, as well as whether it is more likely than not that all or some portion of the deferred tax assets will not be realized. The ultimate realization of the deferred tax assets is dependent upon generation of future taxable income during the periods in which temporary differences are expected to reverse. The Company has established deferred tax liabilities for indefinite lived intangible assets consisting of goodwill that are not amortized for financial reporting purposes but are tax deductible and therefore amortized over 15 years for tax purposes. The Company has concluded that the resulting deferred tax liability will also have an indefinite life unless there is an impairment of the related assets (for financial reporting purposes), or the disposal of the business to which the assets relate. Losses generated in years after 2017 will also have an indefinite life and will be available to offset 80 percent of any federal tax liability and will be available to offset many of the state deferred tax liabilities subject to utilization limits. A portion of existing deferred tax assets will reverse in the future, potentially generating net operating losses that will also be available to offset a portion of the indefinite lived deferred tax liability. Based on the consideration of these facts, the Company concluded it is more likely than not that a significant portion of its remaining gross deferred tax assets less the reversal of deferred tax liabilities will not be realized in the future, accordingly, a full valuation allowance continues to be recorded against the Company's deferred tax asset as of December 31, 2020 and December 31, 2019.

The Company will continue to assess and evaluate strategies that will enable the deferred tax asset, or portion thereof, to be utilized, and will reduce the valuation allowance appropriately as such time when it is determined that the "more likely than not" criteria is satisfied.

Sections 382 and 383 of the Internal Revenue Code of 1986 subject the future utilization of net operating losses and certain other tax attributes, such as research and experimental tax credits, to an annual limitation in the event of certain ownership changes, as defined. The Company has undergone an ownership change study through June 2020 and has determined that a "change in ownership" as defined by IRC Section 382 of the Internal Revenue Code of 1986, as amended, and the rules and regulations promulgated thereunder, did occur in February 2012, July 2014, and April 2017. Based on the Company having undergone multiple ownership changes throughout their history these NOLs will free up at varying rates each year. Subsequent to the changes in ownership previously listed, the NOL and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period. This could limit the amount of NOLs and research and development credits that the Company can utilize annually to offset future taxable income or tax liabilities. The Company has not analyzed the historical or potential impact of its equity financings on beneficial ownership after June 30, 2020 and therefore no determination has been made whether the entire NOL carryforward balance are subject to any additional Internal Revenue Code Section 382 limitation. To the extent there is a limitation, which could be significant, there would be a reduction in the deferred tax asset with an offsetting reduction in the valuation allowance. Subsequent ownership changes may further affect the limitation in future years. All of the Company's tax years are currently open to examination by each tax jurisdiction in which the Company is subject to taxation.

In March 2020, the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act") was signed into law, which provided a number of tax provisions. In particular, the CARES Act included temporary changes regarding the utilization and five year carry back of losses generated in 2018, 2019 and 2020, temporary changes regarding interest deductions, technical corrections from prior tax legislation related to qualified improvement property, and various other measures. The ability for the Company to carry back a portion of its 2018 loss to the 2017 tax year resulted in a refund claim of $2.6 million, which was reflected as a benefit in the current period. The Company has received $0.5 million of this amount and expects to receive the remainder in 2021.

13. Commitments and Contingencies

Litigation

Litigation – General

The Company may become party to various contractual disputes, litigation, and potential claims arising in the ordinary course of business. The Company currently does not believe that the resolution of such matters will have a material adverse effect on its financial position or results of operations except as otherwise disclosed in this report.

Karbinal Royalty Make-Whole Provision

On February 16, 2018, in connection with the acquisition of Avadel's pediatric products, the Company entered into a supply and distribution agreement with TRIS Pharma Inc. (“TRIS”) (the “Karbinal Agreement”). As part of this agreement, the Company had an annual minimum sales commitment, which is based on a commercial year that spans from August 1 through July 31, of 70,000 units through 2033. The Company was required to pay TRIS a royalty make whole payment (“Make-Whole Payments”) of $30 for each unit under the 70,000 units annual minimum sales commitment through 2033.

As a part of the Aytu Divestiture, which closed on November 1, 2019, the Company assigned all payment obligations, including the Make-Whole Payments, under the Karbinal Agreement (collectively, the “TRIS Obligations”) to Aytu. However, under the original license agreement, the Company could ultimately be liable for TRIS Obligations to the extent Aytu fails to make the required payments. The future Make-Whole Payments to be made by Aytu are unknown as the amount owed to TRIS is dependent on the number of units sold.

Millipred License and Supply Agreement

The Company has a License and Supply Agreement for Millipred with Watson Laboratories, Inc., which is now part of Teva Pharmaceutical Industries Ltd. (“Teva”). Pursuant to the License and Supply Agreement, the Company is required to make license payments of $75,000 in February and August of each year through April 2021 and purchases inventory on an ad-hoc basis. Dr. Sol Barer is the Chairman of Cerecor's board of directors and he also serves as the Chairman of Teva's board of directors.

In the fourth quarter of 2020, the parties entered into an amendment (the “Amended License and Supply Agreement”), which extends the agreement for a period of thirty months (from April 1, 2021 through September 30, 2023). In lieu of the previous license payments, beginning April 1, 2021, Cerecor will pay Teva fifty percent of the net profit of the Millipred product following each calendar quarter, subject to a $0.5 million quarterly minimum payment.

Possible Future Milestone Proceeds for Out-Licensed Compounds

CERC-611 License Assignment

In August 2019, the Company entered into an assignment of license agreement (the “Assignment Agreement”) with ES Therapeutics, LLC (“ES Therapeutics”), a wholly-owned subsidiary of Armistice, a significant stockholder of the Company. Pursuant to the Assignment Agreement, the Company assigned and transferred its rights, title, interest, and obligations with respect to CERC-611 to ES Therapeutics. The Company initially licensed the compound from Eli Lilly and Company (“Lilly”) in September 2016. Under the Assignment Agreement, Armistice paid the Company an upfront payment of $0.1 million. The Company recognized the payment as license and other revenue for the year ended December 31, 2019. The Assignment Agreement also provides for: (a) a $7.5 million milestone payment to the Company upon cumulative net sales of licensed products reaching $750.0 million; and (b) a $12.5 million milestone payment to the Company upon cumulative net sales of licensed products reaching $1.3 billion. The Assignment Agreement also releases the Company of obligations related to CERC-611, including the $1.3 million contingent payment to Lilly upon the first subject dosage of CERC-611 in a multiple ascending dose study and from additional potential future payments due to Lilly upon achievement of certain development and commercialization milestones.

CERC-501 Sale to Janssen

In August 2017, the Company sold its worldwide rights to CERC-501 to Janssen Pharmaceuticals, Inc. (“Janssen”) in exchange for initial gross proceeds of $25.0 million. There is a potential future $20.0 million regulatory milestone payment to the

Company upon acceptance of an NDA for any indication. The terms of the agreement provide that Janssen will assume ongoing clinical trials and be responsible for any new development and commercialization of CERC-501.

Related Party and Acquisition Related Contingent Liabilities

CERC-006 Royalty Agreement with Certain Related Parties

Prior to Cerecor entering into the Merger Agreement with Aevi, in July 2019, Aevi entered into a royalty agreement with Mike Cola, Cerecor's current Chief Executive Officer, Joseph J. Grano, Jr., Kathleen Jane Grano, Joseph C. Grano, The Grano Children's Trust, Joseph C. Grano, trustee and LeoGroup Private Investment Access, LLC on behalf of Dr. Garry Neil, Cerecor's current Chief Scientific Officer (collectively, the "Investors") in exchange for a one-time aggregate payment of $2 million (the "Royalty Agreement"). Collectively, the Investors will be entitled to an aggregate amount equal to a low-single digit percentage of the aggregate net sales of Astellas Pharma Inc.'s second generation mTORC1/2 inhibitor, CERC-006. At any time beginning three years after the date of the first public launch of CERC-006, Cerecor may exercise, at its sole discretion, a buyout option that terminates any further obligations under the Royalty Agreement in exchange for a payment to Investors of an aggregate of 75% of the net present value of the royalty payments. A majority of the independent members of the board of directors and the audit committee of Aevi approved the Royalty Agreement.

Cerecor assumed this Royalty Agreement upon closing of the Merger with Aevi and it is recorded as a royalty obligation within the Company's accompanying consolidated balance sheet as of December 31, 2020. Because there is a significant related party relationship between the Company and the Investors, the Company treated its obligation to make royalty payments under the Royalty Agreement as an implicit obligation to repay the funds advanced by the Investors. As the Company makes royalty payments in accordance with the Royalty Agreement, it will reduce the liability balance. At the time that such royalty payments become probable and estimable, and if such amounts exceed the liability balance, the Company will impute interest accordingly on a prospective basis based on such estimates, which would result in a corresponding increase in the liability balance.

Aevi Merger possible future milestone payments

A portion of the consideration for the Aevi Merger, which closed on February 3, 2020, includes two future contingent development milestones worth up to an additional $6.5 million. The first milestone is the enrollment of a patient in a Phase II study related to CERC-002 for use in pediatric onset Crohn's disease, CERC-006 (any indication), or CERC-007 (any indication) prior to February 3, 2022. If this milestone is met, the Company is required to make a milestone payment of $2.0 million. The second milestone is the receipt of a NDA approval for either CERC-006 or CERC-007 from the FDA on or prior to February 3, 2025. If this milestone is met, the Company is required to make a milestone payment of $4.5 million. All milestones are payable in either shares of the Company's common stock or cash, at the election of the Company.

The contingent consideration related to the development milestones will be recognized if and when such milestones are probable and can be reasonably estimated. As of the consummation of the Merger on February 3, 2020 and as of December 31, 2020, no contingent consideration related to the development milestone has been recognized. The Company will continue to monitor the development milestones at each reporting period.

Ichorion Acquisition possible future milestone payments

In September 2018, the Company acquired Ichorion Therapeutics, Inc. including acquiring three compounds for inherited metabolic disorders known as CDG (CERC-801, CERC-802 and CERC-803) and one other preclinical compound. Consideration for the transaction included shares of Cerecor common stock and three future contingent development milestones for the acquired compounds worth up to an additional $15.0 million. The first milestone is the first product being approved for marketing by the FDA on or prior to December 31, 2021. If this milestone is met, the Company is required to make a milestone payment of $6.0 million. The second milestone is the second product being approved for marketing by the FDA on or prior to December 31, 2021. If this milestone is met, the Company is required to make a milestone payment of $5.0 million. The third milestone is a protide molecule being approved by the FDA on or prior to December 31, 2023. If this milestone is met, the Company is required to make a milestone payment of $4.0 million. All milestones are payable in either shares of the Company's common stock or cash, at the election of the Company.

The contingent consideration related to the development milestones will be recognized if and when such milestones are probable and can be reasonably estimated. As of December 31, 2020, no contingent consideration related to the development milestone has been recognized. The Company will continue to monitor the development milestones at each reporting period.

DESCRIPTION OF REGISTERED SECURITIES

The following description of our capital stock and provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries. You should also refer to the amended and restated certificate of incorporation and the amended and restated bylaws, which are included as exhibits to this Annual Report on Form 10-K, and to the provisions of applicable Delaware law.

General

Under our amended and restated certificate of incorporation, we are authorized to issue up to 200,000,000 shares of common stock, $0.001 par value per share, and 5,000,000 shares of preferred stock, $0.001 par value per share, of which 2,857,143 shares are designated as our Series B Non-Voting Convertible Preferred Stock ("Series B Preferred Stock", as discussed below) and the remainder of which shares of preferred stock are undesignated. Our board of directors may establish the rights and preferences of the preferred stock from time to time.

Common Stock

Voting

Each holder of common stock is entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and does not have cumulative voting rights. Accordingly, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election.

Dividends

Subject to preferences that may be applicable to any then-outstanding preferred stock, the holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

Fully Paid and Nonassessable

All of our outstanding shares of common stock are fully paid and nonassessable.

Preferred Stock

Pursuant to our amended and restated certificate of incorporation, our board of directors has the authority, without further action by the stockholders (unless such stockholder action is required by applicable law or stock exchange listing rules), to designate and issue up to 5,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the designations, powers, preferences,

privileges and relative participating, optional or special rights and the qualifications, limitations or restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption and liquidation preferences, any or all of which may be greater than the rights of the common stock, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors, without stockholder approval, can issue preferred stock with voting, conversion or other rights that could adversely affect the voting power and other rights of the holders of common stock. Preferred stock could be issued quickly with terms designed to delay or prevent a change in control of our company or make removal of management more difficult. Additionally, the issuance of preferred stock may have the effect of decreasing the market price of the common stock and may adversely affect the voting power of holders of common stock and reduce the likelihood that common stockholders will receive dividend payments and payments upon liquidation.

Our board of directors will fix the designations, voting powers, preferences and rights of each series, as well as the qualifications, limitations or restrictions thereof, of the preferred stock of each series that we offer under the prospectus and applicable prospectus supplements in the certificate of designation relating to that series. We will file as an exhibit to the registration statement of which such prospectus forms a part, or will incorporate by reference from reports that we file with the SEC, the form of any certificate of designation that describes the terms of the series of preferred stock we may offer before the issuance of that series of preferred stock. This description will include:

- the title and stated value;
- the number of shares we are offering;
- the liquidation preference per share;
- the purchase price per share;
- the dividend rate per share, dividend period and payment dates and method of calculation for dividends;
- whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;
- our right, if any, to defer payment of dividends and the maximum length of any such deferral period;
- the procedures for any auction and remarketing, if any;
- the provisions for a sinking fund, if any;
- the provisions for redemption or repurchase, if applicable, and any restrictions on our ability to exercise those redemption and repurchase rights;
- any listing of the preferred stock on any securities exchange or market;
- whether the preferred stock will be convertible into our common stock or other securities of ours, including depositary shares and warrants, and, if applicable, the conversion period, the conversion price, or how it will be calculated, and under what circumstances it may be adjusted;
- whether the preferred stock will be exchangeable into debt securities, and, if applicable, the exchange period, the exchange price, or how it will be calculated, and under what circumstances it may be adjusted;
- voting rights, if any, of the preferred stock;
- preemption rights, if any;
- restrictions on transfer, sale or other assignment, if any;
- whether interests in the preferred stock will be represented by depositary shares;
- a discussion of any material or special U.S. federal income tax considerations applicable to the preferred stock;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs;
- any limitations on issuances of any class or series of preferred stock ranking senior to or on a parity with the series of preferred stock being issued as to dividend rights and rights if we liquidate, dissolve or wind up our affairs; and
- any other specific terms, rights, preferences, privileges, qualifications or restrictions of the preferred stock.

The Delaware General Corporation Law (“DGCL”), the corporate law of our state of our incorporation, provides that the holders of preferred stock will have the right to vote separately as a class (or, in some cases, as a series) on

an amendment to our certificate of incorporation if the amendment would change the par value or, unless the certificate of incorporation provided otherwise, the number of authorized shares of the class or change the powers, preferences or special rights of the class or series so as to adversely affect the class or series, as the case may be. This right is in addition to any voting rights that may be provided for in the applicable certificate of designation.

Anti-Takeover Effects of Delaware Law and Our Charter and Bylaws

Provisions of Delaware law and our amended and restated certificate of incorporation, including the Certificate of Designation of our Series B Preferred Stock, and our amended and restated bylaws could make it more difficult to acquire us by means of a tender offer, a proxy contest, open market purchases, removal of incumbent directors and otherwise. These provisions, summarized below, are expected to discourage types of coercive takeover practices and inadequate takeover bids and to encourage persons to acquire control of us to first negotiate with us. We believe that the benefits of increase protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging takeover or acquisition proposals because negotiation of these proposals could result in an improvement of their terms.

Delaware Anti-Takeover Law

We are subject to section 203 of the DGCL, or Section 203. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to such time the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- 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, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to such time the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, 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
- 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.

Subject to certain exceptions, Section 203 defines an "interested stockholder" as an entity or person (other than the corporation or any direct or indirect majority-owned subsidiary of the corporation) who, together with the entity or person's affiliates and associates, beneficially owns, or is an affiliate or associate of the corporation and within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

The existence of this provision generally will have an anti-takeover effect for transactions not approved in advance by the board of directors, including discouraging attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to 5,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);
- provide that the authorized number of directors may be changed only be resolution of our board of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose); and
- provide that special meetings of our stockholders may be called only by the chairman of the board, our chief executive officers or by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66 2/3% of our then outstanding common stock.

Choice of Forum

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty;
- any action asserting a claim against us arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; or
- any action asserting a claim against us that is governed by the internal affairs doctrine.

The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any action, a court could find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in such action. These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act, Securities Act or any other claim for which the federal courts have exclusive or concurrent jurisdiction. Any person or entity purchasing or otherwise acquiring any interest in our securities shall be deemed to have notice of and consented to these provisions. Our exclusive forum provision will not relieve us of our duties to

comply with the federal securities laws and the rules and regulations thereunder, and our shareholders will not be deemed to have waived our compliance with these laws, rules and regulations.

The provisions of the DGCL, our amended and restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and may also have the effect of preventing changes in our 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.

Nasdaq Capital Market Listing

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

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent and registrar's address is 6201 15th Avenue, Brooklyn, NY 11219.

February 19, 2020

H. Jeffrey Wilkins, M.D.
[Intentionally Omitted]

Re: Offer of Employment - REVISED

Dear Jeff:

On behalf of Cerecor Inc. (the "Company"), it is my great pleasure to offer you the full-time position of Chief Development Officer. This position reports to the Company's Chief Executive Officer. We are hopeful that you will accept this offer and look forward to the prospect of having a mutually successful relationship.

As a full-time employee, you will be required to devote all of your business time, energy, skill and best efforts to the performance of your duties with the Company, and you agree that you will not pursue any activities, whether or not for compensation, that materially interfere with the performance of your responsibilities to the Company, or that are in any way adverse to or competitive with the business of the Company. You will be self-directed for the most part, with minimal daily supervision. During your employment, we will engage in regular evaluation periods during which your performance will be discussed and evaluated.

Your base salary will be $370,000 equivalent to $15,416.67 per pay period, minus applicable federal, state and local payroll taxes, and other withholdings required by law or authorized by you. You will also be eligible to participate in the Company's Performance Incentive Plan in accordance with plan guidelines and as determined by the Board or the Compensation Committee of the Board, in its sole discretion. You must be employed on the date such annual bonus is paid. This program will provide the opportunity to receive a bonus award, based on performance against established company and individual strategic performance objectives. Your targeted bonus potential will pro-rated from your date of hire and will be 35% of your current annual salary. Your anticipated start date will be February 4, 2020.

As soon as practicable after the Effective Date, and subject to the approval of the Company's Board of Directors and your execution of a separate grant document, the Company will grant you a number of non-statutory stock options to purchase 375,000 shares of Company Common Stock. The stock options will vest over four (4) years, with a twelve-month cliff, such that the first 25% of such stock options will vest on the first anniversary following the Effective Date, and the remainder will vest in equal monthly installments, provided that you remain an employee of the Company as of each such vesting date, with an exercise price equal to the closing price of the common shares on the date of the grant on any exchange on which Company's shares are then traded. Such stock options will be granted to you pursuant to the inducement grant exception under NASDAQ Stock Market Rule 5635(c)(4), and not pursuant

to the Company's 2016 Equity Incentive Plan or any other equity incentive plan of the Company, as a material inducement to your employment with the Company.

You will be eligible for all paid holiday time observed by the Company. In addition, you will be provided paid vacation that will accrue and may be used in accordance with the Company's written policies.

You also will be eligible for other standard benefits as are provided to similarly-situated employees, subject to applicable eligibility requirements. Plan descriptions will be provided to you upon your start date concerning all employee benefit plans for which you are eligible. You will also receive a copy of our employment policies. The Company reserves the right to amend, add or discontinue benefits from time to time in its sole discretion.

Due to immigration laws, you are required to bring legally-required documentation of your identity and eligibility to work on your first day, so that we can complete your I-9 Employment Eligibility Form.

On or before your first day of employment you will be expected to sign a CONFIDENTIALITY, ASSIGNMENT OF INVENTIONS AND NON-SOLICITATION AGREEMENT providing for the protection of Company's good will, confidential information, trade secrets, customers, employees and inventions.

Please understand it is the policy of the Company not to solicit or accept proprietary information and/or trade secrets of other companies or third parties. If you have or have had access to trade secrets or other confidential, proprietary information from your former employer or another third party, the use of such information in performing your duties at the Company is prohibited. This may include, but is not limited to, confidential or proprietary information in the form of documents, magnetic media, software, customer lists, and business plans or strategies. You must also advise the Company before your employment start date of any restrictions on your ability to work for the Company, such as any covenants not to compete or solicit with any former employers. The Company reserves the right to rescind this offer should it determine that such restrictions pose a legal risk to the Company. You will also be expected to abide by the Company's code of conduct and all of the Company's employment policies, including but not limited to policies regarding employment discrimination and harassment.

Employment with the Company is "at will," and is not guaranteed for any specific length of service, nor is it guaranteed for any specific position; your employment will at all times remain at the mutual consent of the employee and the Company.

Finally, this offer is contingent upon the successful completion of the Company's pre-hire screening process, which includes background verification, reference checks and standard drug screening.

We look forward to your contribution to our organization. The Company has every hope that its employment relationship with you will be mutually beneficial and rewarding. To acknowledge and accept this offer, please sign below as indicated and return an original to our office by no later than February 20, 2020. For answers concerning questions about this offer please do not hesitate to contact me.

We wish you every success in your new position!

Sincerely,

/s/ Michael Cola

Michael Cola
Chief Executive Officer

I, the undersigned individual, hereby agree to the terms set out above for my employment with Cerecor Inc. I also understand that, subject to the terms set out above, I will be an employee at will, and either the Company or I may terminate my employment at any time for any or no reason.

/s/ Jeffrey Wilkins	2/26/2020
Jeffrey Wilkins	**Date**

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

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

(1) Registration Statement (Form S-1 No. 333-204905) as filed on June 12, 2015, and amended on September 8, 2015, September 22, 2015, October 1, 2015, and October 13, 2015,

(2) Registration Statement (Form S-8 No. 333-207949) pertaining to the 2015 Omnibus Incentive Compensation Plan,

(3) Registration Statement (Form S-8 No. 333-211490) pertaining to the 2016 Equity Incentive Plan,

(4) Registration Statement (Form S-8 No. 333-211491) pertaining to the 2016 Employee Stock Purchase Plan,

(5) Registration Statement (Form S-1 No. 333-213676) as filed on September 16, 2016,

(6) Registration Statement (Form S-3 No. 333-214507) as filed on November 8, 2016, and amended on December 1, 2016,

(7) Registration Statement (Form S-3 No. 333-218252) as filed on May 26, 2017,

(8) Registration Statement (Form S-8 No. 333-226767) pertaining to the Amended and Restated 2016 Equity Incentive Plan,

(9) Registration Statement (Form S-3 No. 333-227227) as filed on September 7, 2018, and amended on October 2, 2018,

(10) Registration Statement (Form S-3 No. 333-229283) as filed on January 17, 2019,

(11) Registration Statement (Form S-3 No. 333-233978) filed on September 27, 2019, and amended on October 18, 2019,

(12) Registration Statement (Form S-4 No. 333-235666) filed on December 20, 2019 and amended on December 30, 2019,

(13) Registration Statement (Form S-3 No. 333-238197) filed on May 12, 2020, and

(14) Registration Statement (Form S-8 No. 333-241661) pertaining to the Third Amended and Restated 2016 Equity Incentive Plan;

of our report dated March 8, 2021, with respect to the consolidated financial statements of Cerecor Inc. and subsidiaries included in this Annual Report (Form 10-K) of Cerecor Inc. for the year ended December 31, 2020.

/s/ Ernst & Young LLP
Baltimore, Maryland
March 8, 2021

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael Cola, certify that:

1. I have reviewed this Annual Report on Form 10-K of Cerecor Inc. (the "registrant");
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. The registrant's other certifying officer and I are 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 our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us 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 our 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 our 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. The registrant's other certifying officer and I have disclosed, based on our 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.

Date: March 8, 2021

/s/ Michael Cola

Michael Cola
Chief Executive Officer
(Registrant's Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Schond L. Greenway, certify that:

1. I have reviewed this Annual Report on Form 10-K of Cerecor Inc. (the "registrant");
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. The registrant's other certifying officer and I are 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 our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us 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 our 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 our 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. The registrant's other certifying officer and I have disclosed, based on our 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.

Date: March 8, 2021

/s/ Schond L. Greenway

Schond L. Greenway
Chief Financial Officer
(Registrant's Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Cerecor Inc. (the "Registrant") on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael Cola, Chief Executive Officer (principal executive officer) of the Registrant, and I, Schond L. Greenway, Chief Financial Officer (principal financial officer) of the Registrant, each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition at the end of the period covered by the Report and the results of operations of the Registrant for the periods covered by the Report.

Date: March 8, 2021	By:	/s/ Michael Cola
	Name:	**Michael Cola**
	Title:	**Chief Executive Officer** **(Registrant's Principal Executive Officer)**
Date: March 8, 2021	By:	/s/ Schond L. Greenway
	Name:	**Schond L. Greenway**
	Title:	**Chief Financial Officer** **(Registrant's Principal Financial Officer)**

The foregoing certifications are not deemed filed with the Securities and Exchange Commission for purposes of section 18 of the Securities Exchange Act of 1934, as amended (Exchange Act), and are not to be incorporated by reference into any filing of Cerecor Inc. under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.