2019 ANNUAL REPORT

Included in the 2019 Annual Report:
Form 10-K filed with the U.S. Securities and Exchange Commission on
March 11, 2020

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, 2019
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 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 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 is a shell company (as defined in Rule 12b-2 of the Exchange 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, 2019 (based on the closing price of $5.44 on June 28, 2019, the last business day of the registrant's most recently completed second fiscal quarter) was $81,295,262. 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 9, 2020, there were 57,609,033 outstanding shares of the registrant's common stock, par value $0.001 per share.

Documents Incorporated by Reference: Portions of the registrant's Definitive Proxy Statement to be filed with the Securities and Exchange Commission no later than 120 days after the end of the registrant's fiscal year ended December 31, 2019, are incorporated by reference in Part III of this Annual Report on Form 10-K.

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PART I

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 integration of the companies and their personnel; 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 the neurological assets and 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.

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

Item 1. Business.

Overview

Cerecor Inc. (the "Company" or "Cerecor") is a biopharmaceutical company focused on becoming a leader in development and commercialization of treatments for rare pediatric and orphan diseases. The Company is advancing an emerging clinical-stage pipeline of innovative therapies that address unmet patient needs within rare pediatric and orphan diseases. The Company's pediatric rare disease pipeline is led by CERC-801, CERC-802 and CERC-803 ("CERC-800 compounds"), which are therapies for inherited metabolic disorders known as Congenital Disorders of Glycosylation ("CDGs"). The U.S. Food and Drug Administration ("FDA") granted Rare Pediatric Disease designation ("RPDD") and Orphan Drug Designation ("ODD") to all three CERC-800 compounds, thus potentially qualifying the Company to receive a Priority Review Voucher ("PRV") upon approval of each New Drug Application ("NDA"). Each PRV may be sold or transferred an unlimited number of times. The Company plans to leverage the 505(b)(2) NDA pathway for all three compounds to accelerate development and approval. Additionally, CERC-801 and CERC-802 were granted Fast Track Designation ("FTD") from the FDA which can help facilitate and potentially expedite development of each compound.

The Company is also developing CERC-002, CERC-006 and CERC-007. CERC-007 is an anti-IL-18 monoclonal antibody being developed for the treatment of autoimmune inflammatory diseases such as Adult Onset Stills Disease ("AOSD") and Multiple Myeloma. CERC-006 is a dual mTOR inhibitor being developed for the treatment of complex Lymphatic Malformations. CERC-002 is an anti-LIGHT (**L**ymphotoxin-like, exhibits **I**nducible expression, and competes with HSV **G**lycoprotein D for **H**VEM, a receptor expressed by **T** lymphocytes) monoclonal antibody being developed for the treatment of Pediatric-onset Crohn's Disease.

The Company continues to explore strategic alternatives for its non-core assets, including CERC-301, as well as its sole commercialized product, Millipred®, an oral prednisolone indicated across a wide variety of inflammatory conditions.

Recent Developments

Aevi Merger

On February 3, 2020, the Company consummated its two-step merger (the "Merger") with Aevi Genomic Medicine, Inc. ("Aevi") in accordance with the terms of the Agreement and Plan of Merger and Reorganization dated December 5, 2019. The Merger consideration included stock valued at approximately $15.6 million, thus resulting in the issuance of approximately 3.9 million shares of Cerecor common stock to Aevi stockholders, forgiveness of a $4.1 million loan that Cerecor loaned Aevi in December 2019, and contingent value rights ("CVRs") for up to an additional $6.5 million in subsequent payments based on clinical and/or regulatory milestones. Cerecor is in-process of determining the financial effect of the Merger, including whether the Merger will be recorded as an asset purchase or a business combination, and will perform preliminary purchase accounting during the first quarter of 2020.

As part of the Merger, Cerecor acquired CERC-002, CERC-006 and CERC-007, expanding Cerecor's pipeline to six clinical stage assets being developed for rare pediatric and orphan diseases. Effective upon the consummation of the Merger, Cerecor entered into an employment agreement with Mike Cola for him to serve as Cerecor's Chief Executive Officer, an employment agreement with Dr. Garry Neil for him to serve as Cerecor's Chief Medical Officer and appointed Mike Cola and Sol J. Barer, Ph.D. to the Company's Board of Directors.

Sale of Pediatric Portfolio and Related Commercial Infrastructure to Aytu BioScience

On October 10, 2019, the Company entered into, and subsequently closed on, an asset purchase agreement (the "Aytu Purchase Agreement") with Aytu BioScience, Inc. (“Aytu”) 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"). Aytu paid consideration of $4.5 million in cash and approximately 9.8 million shares of Aytu convertible preferred stock (the "Investment") and assumed certain of the Company’s liabilities, including the Company’s payment obligations payable to Deerfield CSF, LLC of $15.1 million and certain other liabilities of $11 million. The Company recognized a gain of $8.0 million upon the close of the Aytu Divestiture. In addition, Aytu assumed future contractual obligations under existing license agreements associated with the Pediatric Portfolio. The Aytu Divestiture closed on November 1, 2019.

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. James Harrell, Cerecor's former Executive Vice President of Marketing and Investor Relations, was promoted to Chief Commercial Officer upon close of the Aytu Divestiture. Additionally, Cerecor retained all rights to Millipred®. Pursuant to a transition services agreement entered into between Aytu and Cerecor, Aytu will manage Millipred® commercial operations until the Company establishes an independent commercial infrastructure for the product.

The Company believes the consideration received as part of the Aytu Divestiture, including the extinguishment of the debt obligation and future obligations under the license agreements associated with the Pediatric Portfolio, will allow the Company to focus on significant value drivers, which include the near-term development of the CERC-800 assets and the advancement and expansion of the newly acquired CERC-002, CERC-006 and CERC-007 programs.

Recent Financings

During the first quarter of 2020, the Company closed on a registered direct offering with certain institutional investors for sale by the Company of 1,306,282 shares of the Company's common stock at a purchase price of $3.98 per share, which represents the closing stock price the day prior to entering into the agreement. Armistice participated in the offering by purchasing 1,256,282 shares of common stock from the Company. The net proceeds of the offering were approximately $5 million.

During the third quarter of 2019, the Company entered into a securities purchase agreement with Armistice Capital Master Fund Ltd. ("Armistice"), our largest stockholder, pursuant to which the Company sold 1,200,000 shares of the Company's common stock for a purchase price of $3.132 per share, which represents the average closing price of the Common Stock on Nasdaq for the five trading days immediately preceding September 4, 2019. Net proceeds of the private placement were approximately $3.7 million.

During the first quarter of 2019, the Company closed on an underwritten public offering of common stock for 1,818,182 shares of common stock of the Company, at a price to the public of $5.50 per share. Armistice participated in the offering by purchasing 363,637 shares of common stock of the Company from the underwriter at the public price. The net proceeds to the Company from the offering were approximately $9.0 million.

Our Strategy

The Company is building a robust pipeline of innovative therapies that address unmet needs within rare pediatric and orphan diseases with the goal of making life-changing medicines available to under-served patient populations. The Company plans to continue exploring strategic alternatives for its non-core assets, including CERC-301, as well its sole commercialized product, Millipred®, and pursuing equity financings to generate proceeds for use towards the development of its novel drug candidates that have unique mechanisms of action and can change the lives of patients with rare orphan diseases.

We systematically identify and pursue potential development candidates, ideally those for which human proof of concept exists in the intended indication, for either the target or the compound. We target conditions where current treatments fail to address unmet medical needs, and where we believe we can apply clinical strategies to increase efficacy signal detection with a view to optimizing the clinical development and regulatory pathway for our product candidates.

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 assets;
- Developing the go-to-market strategy to quickly and effectively market, launch, and distribute each of our assets that receive marketing approval;
- Opportunistically out-licensing rights to indications or geographies; and
- Opportunistically out-licensing rights or sale of non-core assets.

Product Pipeline Assets— Overview, Competition and Intellectual Property

Emerging Clinical-Stage Rare Disease Pipeline

The following table summarizes key information about our emerging clinical-stage rare disease pipeline and is followed by further detail, including an overview, competition and intellectual property (if applicable), regarding each program:

	Program	Mechanism of Action	Lead Indication	Development Stage		
				Preclinical	Phase 1	Upcoming Milestone
CERECOR	CERC-801*	D-Galactose replacement	PGM1-CDG	Pivotal Study Ready		Initial data from CDG-FIRST 1H20
	CERC-802*	D-Mannose replacement	MPI-CDG	Pivotal Study Ready		
	CERC-803*	L-Fucose replacement	SLC35C1-CDG	IND-Enabling		
	CERC-007	Anti-IL-18 mAb	Auto-inflammatory diseases (AOSD, MM)	Phase 1/2 Ready		Initial Data 4Q20/1Q21
	CERC-006**	Dual mTOR inhibitor	Complex Lymphatic Malformations	Phase 1/2 Ready		Initial Data 1H21
	CERC-002	Anti-LIGHT mAb	Pediatric Onset Crohn's Disease	Phase 1/2 Study Ongoing		Initial Data 2H20

*Rare Pediatric Disease Designation Granted
**Rare Pediatric Disease Designation Eligible

CERC-800 Series: *Substrate Replacement Therapies for CDGs.*

- **Overview:** CERC-801, CERC-802 and CERC-803 are monosaccharide substrate replacement therapies with known therapeutic utility for the treatment of CDGs. Oral administration of these substrates replenishes critical metabolic intermediates that are reduced or absent due to genetic mutation, overcoming single enzyme defects to support glycoprotein synthesis, maintenance and function.

  All three CERC-800 compounds have been granted RPDD and ODD by the FDA. There are numerous benefits associated with receipt of ODD, which include seven-year marketing exclusivity (upon approval) in the United States, tax credits (up to 25% of clinical development costs) and waiver of Prescription Drug User Fee Act application fees (filing fees). RPDD provides potential eligibility for receipt of a PRV upon approval of an NDA of each compound. The PRV, which may be sold and transferred an unlimited amount of times, can be used to obtain priority review for a subsequent NDA or biologics license application. Under the current regulations, the PRV program is set to expire on September 30, 2020. At that time, the FDA may not award any new PRVs unless a product was granted RPDD prior to September 30, 2020. Under the two-year sunset provision, these products can receive a PRV if they are approved by September 30, 2022. It is also possible that the program will be reauthorized prior to the September 30, 2020 expiration. All three CERC-800 compounds have received RPDD. The below chart depicts the potential benefits associated with ODD and RPDD for each of the CERC-800 compounds upon marketing approval:

Eligibility	CERC-801	CERC-802	CERC-803
Accelerated Pathway	✓	✓	✓
NCE 5-yrs Exclusivity	✓	✓	✓
FDA ODD 7-yrs Exclusivity	✓	✓	✓
EMA ODD 10-yrs Exclusivity	✓	✓	✓
Priority Review Voucher	✓	✓	✓

Additionally, CERC-801 and CERC-802 have been granted FTD by the FDA. 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 and helps to facilitate and expedite development. Sponsors of drugs that receive FTD have the opportunity for more frequent interactions with the FDA review team throughout the development program. These may include meetings to discuss study design, data required to support approval, or other aspects of the clinical program. Additionally, products that have been granted FTD may be eligible for priority review of an NDA and the FDA may consider reviewing portions of an NDA before the sponsor submits the complete application (known as a rolling review).

CERC-801 and CERC-802 have completed phase 1 studies. The Company has an ongoing retrospective study, the CDG FIRST Trial, which seeks to collect natural history and treatment-related data for patients diagnosed with PGM1-CDG, MPI-CDG or LADII/SLC35C1-CDG who are either treated with or without D-galactose, D-mannose and L-fucose, respectively, as well as patients with other CDGs who are treated with one of the three monosaccharides. Cerecor plans to leverage data from the CDG FIRST Trial, existing clinical and nonclinical data from published literature and sponsor-initiated studies to accelerate development and time to approval of all three compounds under the 505(b)(2) pathway.

- **Competition:** Currently there are no FDA or EMA approved products for the treatment of CDG using the following: D-Galactose Substrate replacement therapy for PGM1 CDG (CERC-801), Mannose Phosphate Isomerase ("MPI") deficiency, also known as MPI-CDG (CERC-802), and L-Fucose Substrate replacement therapy for the treatment of Leukocyte Adhesion Deficiency Type II (LADII), also known as SLC35C1-CDG (CERC-803).

- **Intellectual Property:** As the CERC-800 compounds received ODD from the FDA, at a minimum, upon approval, we plan to rely on seven-year marketing exclusivity in the United States. Additionally, if the CERC-800 compounds are granted ODD from EMA, we will rely on ten-year marketing exclusivity in Europe upon approval.

CERC-007: ***Anti-IL18 Monoclonal Antibody for auto-inflammatory diseases.***

- **Overview:** CERC-007 (formerly AEVI-007) is a fully human, anti-IL-18 monoclonal antibody with the potential to address multiple auto-inflammatory diseases, including Adult Onset Stills Disease ("AOSD") and Multiple Myeloma ("MM"). IL-18 is a pro-inflammatory cytokine that stimulates the production of interferon gamma. Patients with ASOD and MM show elevated serum levels of IL-18.

  MM is a cancer characterized by the neoplastic proliferation of plasma cells producing a monoclonal immunoglobulin. The plasma cells proliferate in the bone marrow and may produce anemia, skeletal destruction with osteolytic lesions, hypercalcemia and pathologic fractures. Accumulation of abnormal immunoglobulins or fragments of immunoglobulins produced by neoplastic plasma cells might result in renal injury or failure. MM accounts for approximately 1 to 2 percent of all cancers in the United States. The annual incidence in the United States is approximately 4 to 5 per 100,000. Worldwide, there are approximately 160,000 cases and 106,000 deaths per year attributed to MM.

  AOSD is a serious rare and orphan rheumatological disease affecting adults. The disease is similar to systemic onset juvenile idiopathic arthritis that affects children. The etiology of AOSD is unknown with both genetic and infectious factors being implicated. The hallmarks of the disease are persistent daily fever, rash and arthralgias. Many patients suffer complications including splenomegaly, heart and liver disease. Some AOSD patients develop macrophage activation syndrome, a severe acute complication that might cause rapid multi-organ failure and even death.

- **Competition:** There are currently no FDA or EMA approved anti-IL18 therapies in any market for any indication. Additionally, there are currently no FDA or EMA approved biologic therapies in the United States for the treatment of AOSD.

- **Intellectual Property (Licenses):** In August 2019, Aevi obtained the right to exercise an exclusive global license from Medimmune Limited, a subsidiary of AstraZeneca, for a Phase 2-ready fully human monoclonal antibody that targets interleukin 18 ("IL-18"), CERC-007. Under the terms of the agreement, we have the right to exercise an exclusive global license to develop and commercialize CERC-007. In December 2019, Aevi exercised the option and paid AstraZeneca a combined mid-single digit millions in cash and equity. 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. Post Merger, Cerecor is fully responsible for the development and commercialization of the program.

  CERC-007 is eligible to receive ODD and therefore, at a minimum, upon approval, we plan to rely on seven-year marketing exclusivity in the United States and ten-year marketing exclusivity in Europe. Additionally, we expect to receive biologics data exclusivity, which may extend our marketing exclusivity in the United States to twelve years.

CERC-006: ***Dual mTOR Inhibitor for Complex Lymphatic Malformations.***

- **Overview:** CERC-006 (formerly AEVI-006) is a dual mTOR inhibitor (a class of drugs that inhibit the **m**ammalian **t**arget **o**f **r**apamy**c**in) being developed as a treatment for complex Lymphatic Malformations ("LM"). LM patients often have activating mutations along the PI3K/AKT/mTOR pathway; sirolimus, an mTORC1 inhibitor, has

demonstrated clinical utility in LM. CERC-006 has the potential to improve upon both the safety and efficacy of mTOR inhibition in LM.

Lymphatic Malformations are rare and orphan congenital and potentially life-threatening diseases of the lymphatic system. Some of the diseases involved are Generalized Lymphatic Anomaly ("GLA"), Kaposiform lymphangiomatosis ("KLA"), and Gorham-Stoudt disease ("GSD"). Most lymphatic malformations are evident at birth or within the first two years of age. The exact prevalence of lymphatic malformations in the general population is unknown, but is thought to be approximately 1 in every 4,000 live births. There may be as many as 30,000 to 60,000 Americans living with congenital lymphatic malformations. In some cases, the disease may be familial and have a recognizable genetic cause. In most cases it appears to be sporadic, although somatic genetic mutations are often present. The mTORC1/2 pathway is believed to be involved in greater than 80% of patients with congenital LM.

- **Competition:** There are currently no FDA or EMA approved drug therapies for Lymphatic Malformations. CERC-006 is a new targeted therapy that may address the underlying cause in the majority of these patients.

- **Intellectual Property (Licenses):** In July 2019, Aevi entered into an exclusive license agreement with OSI Pharmaceuticals, LLC, an indirect wholly, owned subsidiary of Astellas, for the worldwide development and commercialization of Astellas' novel, second generation mTORC1/2 inhibitor, CERC-006 (formerly AEVI-006). Under the terms of the license agreement, Aevi paid Astellas an up-front license fee of $0.5 million and Astellas will be eligible to receive milestones 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. Post Merger, Cerecor is fully responsible for the development and commercialization of the program.

  CERC-006 is eligible to receive ODD and therefore, upon approval, at a minimum, we plan to rely on seven-year marketing exclusivity in the United States and ten-year marketing exclusivity in Europe.

CERC-002: ***Anti-LIGHT Monoclonal Antibody for Pediatric-onset Crohn's Disease.***

- **Overview:** CERC-002 (formerly AEVI-002) is an anti-LIGHT (**L**ymphotoxin-like, exhibits **I**nducible expression, and competes with HSV Glycoprotein D for **H**VEM, a receptor expressed by **T** lymphocytes (part of the Tumor Necrosis Super Family 14)), fully human, monoclonal antibody being developed as a treatment for Pediatric-onset Crohn's Disease.

  Pediatric-onset Crohn's disease has a more aggressive phenotype than adult onset disease. The genomic rationale for the use of anti-LIGHT antibody in Crohn's disease resulted from Center for Applied Genomics ("CAG") research showing the association to a loss of function mutation in decoy receptor 3 (DcR3). Aevi has subsequently shown that a majority of pediatric patients with active Crohn's disease have elevated levels of free LIGHT, in serum.

- **Competition:** There are currently no FDA or EMA approved drugs aimed at LIGHT in any disease.

- **Intellectual Property (Licenses):** In June 2016, Aevi entered into the Development and Option Agreement with KHK pursuant to which Aevi acquired certain rights with respect to the development and potential commercialization of CERC-002. Regarding CERC-002, if Cerecor exercises its option under the Development and Option Agreement, KHK has 60 days to select one of two development and commercialization structures as follows:

  - **Plan A: Co-Development/Co-Commercialization Arrangement-** If KHK 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 KHK 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 KHK purchasing the Antibody Licensed Products from Cerecor.

    Cerecor will be required to pay KHK an initial license fee in the low single-digit millions of dollars upon the co-development/co-commercialization arrangement becoming effective. Cerecor may pay KHK 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 Aevi 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. KHK 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 KHK 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 KHK an initial license fee in the low single-digit millions of dollars upon the licensing arrangement becoming effective.

  Cerecor may pay KHK 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 approximately 74% of such profits and KHK being entitled to approximately 26% of such profits. KHK 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. KHK will have the right to purchase the Antibody Licensed Products from Cerecor.

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, we expect to receive biologics data exclusivity, which may provide twelve years of marketing exclusivity in the United States upon FDA approval and ten years of marketing exclusivity in Europe upon EMA approval.

Early Stage Rare Disease Pipeline

CERC-913: *ProTide Nucleotide for Mitochondrial Disorder.*

- **Overview:** CERC-913 is a genetically-targeted, small molecule substrate replacement therapy that uses a prodrug approach to overcome a single enzyme defect to treat mitochondrial DNA ("mtDNA") depletion syndromes ("MDS"). A prodrug is a medication or compound that, after administration, is metabolized into a pharmacologically active substance. The ProTide prodrug platform is a clinically-validated approach to nucleoside monophosphate prodrugs. Some patients suffering from MDS lack a nucleoside kinase that produces nucleoside monophosphates for mtDNA synthesis. Direct substrate replacement of nucleoside monophosphates is impractical due to instability in plasma and low cell permeability. By masking a nucleoside monophosphate as a prodrug with improved drug-like properties, we can deliver the substrate to the desired subcellular compartment and bypass the missing nucleoside kinase. CERC-913 is intended for pediatric MDS patients with symptoms that manifest primarily in the liver, with 50% of patients experiencing liver failure in the first few years of life.

CERC-005: *Monoclonal Antibody for rare auto-inflammatory disease(s).*

- **Overview:** CERC-005 (formerly AEVI-005) is a monoclonal antibody with a novel mechanism of action for auto-inflammatory disorders. Cerecor is studying CERC-005 in an undisclosed ultra-orphan auto-immune pediatric disease. Preclinical research was initiated for this compound in the second quarter of 2018.

Neurology Pipeline

We are currently seeking strategic alternatives including strategic partnerships and collaboration opportunities for our neurology pipeline which include CERC-301 and CERC-406. Detail, including an overview, competition and intellectual property (if applicable), regarding each program is discussed below.

CERC-301: *NMDA Receptor for OH.*

- **Overview:** CERC-301 is an orally available, NR2B-specific, the N-methyl-D-aspartate ("NMDA") receptor antagonist. NMDA receptor is a receptor subtype of the glutamate neurotransmitter system that is responsible for controlling

neurologic adaptation. We believe CERC-301 selectively blocks the NMDA receptor subunit 2B ("NR2B") (also called GluN2B). CERC-301 is currently being developed for treatment of symptomatic Orthostatic Hypotension ("OH").

The Company previously announced final positive results from its completed Phase 1 study of CERC-301 for the treatment of Neurogenic Orthostatic Hypotension ("nOH") in Parkinson's disease patients which demonstrated that CERC-301 produces a rapid, robust and sustained improvement in systolic blood pressure ("SBP") upon standing in Parkinson's patients suffering from nOH in all doses studied. As part of the study, a single 20 mg dose of CERC-301, which was the highest dose tested, achieved clinically meaningful improvements over baseline and placebo with a maximum improvement of 29.1 mmHg upon standing throughout the 6-hour study period. The Company believes this data may support a single daily dose and has the potential to be used in a broader OH patient population.

OH is a sudden fall in blood pressure that occurs when a person assumes a standing position. It can be due to a lesion of the baroreflex loop, which senses a change in blood pressure and adjusts heart rate and activates sympathetic nerve system fibers to cause the blood vessels to narrow and correct blood pressure. It may also be caused by hypovolemia (a decreased amount of blood in the body), resulting from the excessive use of diuretics, vasodilators, or other types of drugs, dehydration, or prolonged bed rest. The disorder may be associated with Addison's Disease, diabetes, spinal cord injuries, dialysis, advanced age and certain neurological disorders including Multiple System Atrophy with Orthostatic Hypotension (formerly known as Shy-Drager syndrome), autonomic system neuropathies, and other dysautonomias. Symptoms, which generally occur after sudden standing, include dizziness, lightheadedness, blurred vision, and syncope (temporary loss of consciousness).Current treatment options for OH target symptom burden reductions to increase quality of life such as correcting aggravating factors (i.e. discontinuation of hypotension drugs and correction of anemia and vitamin deficiencies); nonpharmacologic measures such as intravascular volume expansion, increased physical activity, reduction of meal size, compression stocking/abdominal binder, and sleeping arrangement; and drug therapies (i.e. droxidopa, midodrine). OH affects numerous comorbid disease conditions with significant underserved patient populations in the United States and in the rest of the world.

- **Competition:** CERC-301 will compete with other drugs used as therapies for the treatment of nOH. Medication management of nOH is added when patients have persistent symptoms despite these non-pharmacological approaches. Fludrocortisone is a synthetic mineralocorticoid that acts to retain sodium and water. Midodrine is an alpha-adrenergic agonist that can increase blood pressure by increasing peripheral vascular resistance. Pyridostigmine has also been used to treat nOH. Pyridostigmine is a peripheral inhibitor of acetylcholinesterase, which can cause a mild increase in standing blood pressure without significantly increasing supine blood pressure. Droxidopa (L-threo-3-4-dihydroxyphenylserine ("L-threo DOPS")) is an oral prodrug converted by decarboxylation to norepinephrine in both the central and the peripheral nervous systems.

- **Intellectual Property:** We possess worldwide exclusive rights to manufacture, use, and sell certain NR2B antagonist compounds. The CERC-301 patent portfolio consists of three patent families. The first family consists of patents that have issued in the United States, Germany, France, and United Kingdom. The patents in the first family include composition of matter claims and use claims that generically cover CERC-301. The expiration date of the U.S. patent is June 3, 2022, not including any potential patent term extension or market exclusivity period. The second family consists of patents that have issued in United States, Australia, Canada, Germany, France, Switzerland, United Kingdom, and Japan. The patents in the second family include composition of matter and use claims of varying scope (foreign patents only), including picture claims to CERC-301 or a pharmaceutically acceptable salt thereof. The expiration date of the U.S. patent in the second family is August 31, 2026, not including any patent term extension or market exclusivity period which may apply. The third family consists of a patent issued in the United States and patent applications in the United States, Australia, Canada, China, Europe, India, and Japan, with claims to compositions of matter, methods of use, and methods of manufacture that cover the crystalline form of CERC-301. The expiration date of the U.S. patent is December 18, 2035 and any patents issuing from the pending applications would expire on December 18, 2035 at the earliest, not including any potential patent term adjustment, patent term extension, or market exclusivity period.

CERC-406 and COMTi Platform: ***Adjunctive Treatment of Parkinson's Disease.***

- **Overview:** CERC-406 is a preclinical candidate from our proprietary platform of compounds that inhibit catechol-O-methyltransferase ("COMT") within the brain, which we refer to as our COMTi platform. We believe it may have the potential to be developed for the adjunct treatment of Parkinson’s Disease. Preclinically, CERC-406 has demonstrated a greater selectivity for Central Nervous System COMT as compared to peripheral COMT, which we believe may represent an opportunity to treat both the neuromuscular and cognitive manifestations of Parkinson's Disease while minimizing the systemic toxicities associated with the currently approved COMTi’s.

COMT is an enzyme that is critical for the inactivation and metabolism of dopamine and its inhibition in the brain has potential applicability in treating subjects with neuropsychiatric conditions, including major depressive disorder ("MDD"), schizophrenia, Parkinson's Disease and pathological gambling. CERC-406 is our first preclinical candidate from the COMTi platform, specifically designed to preferentially inhibit Central Nervous System COMT over peripheral COMT. COMT inhibitors have shown to be clinically effective in increasing the "on" and decreasing the "off" times of levodopa/decarboxylase inhibitor therapy in PD patients. Tolcapone is the only approved COMTi that crosses the blood brain barrier but is associated with serious liver toxicities. In preclinical testing, CERC-406 had a lower potential for peripheral (non-CNS) side effects, rapid absorption and bioavailability, good brain penetration and a favorable dose dependent biomarker profile. We have also observed in rats, that CERC-406 appears to have an "off rate" on brain COMT that is slower than tolcapone, implying it may have a superior duration of effect.

- **Competition:** There are no approved pharmacologic treatments for cognitive impairment associated in the U.S. at this time. In March 2015, vortioxetine (Brintellix®), marketed in the United States by Lundbeck Pharmaceuticals, which was originally developed and commercialized for the treatment of MDD, received a positive opinion from the Committee for Medicinal Products for Human Use of the European Medicines Agency to expand the label to include information for cognitive function in patients with depression. A supplemental application for the addition of clinical data to the FDA approved product label for Brintellix was not approved by the FDA.

  Our potential products for the treatment of the cognitive and motoric impairment of Parkinson's disease may compete with existing COMT inhibitors Comtan (entacapone), marketed by Novartis Pharmaceuticals Corp. ("Novartis") (licensed from Orion), Tasmar (tolcapone), marketed by Valeant, and Stalevo (fixed combinations of entacapone and levodopa/carbidopa), also marketed by Novartis (licensed from Orion). Comtan, Tasmar, and Stalevo are all generic in the United States. Currently, no treatments are approved for cognitive impairment in Parkinson's disease.

- **Intellectual Property:** We possess worldwide exclusive rights to manufacture, use, and sell COMT inhibitor compounds. The COMT patent portfolio consists of two patent families. The first family consists of patents that have issued in the United States, Australia, Canada, China, Japan, and patent applications in Europe and India with claims to compositions of matter and methods of use. The expiration date of the United States patent in the first family, exclusive of any patent term extension, is February 28, 2031. The second family consists of patents that have issued in the United States, Australia, China, Europe, Japan, and patent applications in Canada and India with claims to compositions of matter and methods of use. The expiration date of the U.S. patent in the second family, exclusive of any patent term extension, is February 28, 2031.

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 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.

We are actively seeking to augment our portfolio of compounds by focusing on the development 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 ("CMOs") to produce our drug candidates in accordance with applicable provisions of the FDA's current Good Manufacturing Practice ("GMP") regulations for use in our clinical studies. The manufacture of pharmaceuticals is subject to extensive 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 rare disease pipeline assets (CERC-800s, CERC-002, CERC-005, CERC-006, CERC-007 and CERC-913), we intend to retain United States commercialization rights. We may complement 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.

For our neurology pipeline assets (CERC-301 and CERC-406), we are currently seeking strategic alternatives including strategic partnerships and collaboration opportunities for their development prior to the assets obtaining marketing approval.

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 HCPs 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 Pediatric Portfolio to 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 or until the Company establishes an independent commercial infrastructure for the product or the Company executes on strategic alternatives for the product.

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 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 (preclinical studies). The data generated from preclinical studies is used to support the filing of an IND Application under which human studies are conducted. There are three phases of human testing generally conducted under an IND, 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 a large clinical trial

In addition to human testing in clinical studies, the manufacturing process (Chemistry, Manufacturing and Controls ("CMC")) of the potential product must be developed in accordance with FDA cGMP 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 cGMP compliance.

The safety and efficacy data generated from the clinical study phases described above, CMC information, animal data and proposed labeling are used as the basis to support a NDA submission to FDA. The preparation of an NDA requires the expenditure of substantial funds and the commitment of substantial resources. Additionally, in most cases, the submission of an NDA is subject to a substantial application user fee, to be filed at the time of submission. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing and full review.

After evaluating the NDA 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. After approval, some types of changes to the approved product, such as manufacturing changes and additional labeling claims, are subject to further FDA review and approval.

FDA Post-Approval Requirements

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. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and new application fees for supplemental applications with clinical data. The FDA may also impose post-approval requirements as a condition of approval of an NDA. 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.

Additionally, the FDA strictly regulates the labeling, advertising and promotion of products under an approved NDA. 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 and refusal of future orders under existing contracts, and mandatory compliance programs under corporate integrity agreements or deferred prosecution agreements.

Other Regulations of the Healthcare Industry

In addition to FDA regulations for 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; and
- The Patient Protection and Affordable Care Act ("ACA"), 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.*

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.

Impact of Healthcare Reform on Coverage, Reimbursement, and Pricing

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA") imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription, pharmacy drugs pursuant to federal regulations. Part D plans include both standalone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. In general, Part D prescription drug plan sponsors have flexibility regarding coverage of Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class, with certain exceptions. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for any products for which we receive marketing approval. However, any negotiated prices for our future products covered by a

Part D prescription drug plan will likely be discounted, thereby lowering the net price realized on our sales to pharmacies. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from Medicare Part D may result in a similar reduction in payments from non-governmental payers.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payers, it is not clear what effect, if any, the research will have on the sales of any product, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates. If third-party payers do not consider our product candidates to be cost-effective compared to other available therapies, they may not cover our product candidates, once approved, as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The United States and some foreign jurisdictions are considering enacting or have enacted a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives, including, most recently, the Affordable Care Act, which became law in March 2010 and substantially changes the way healthcare is financed by both governmental and private insurers. Among other cost containment measures, the Affordable Care Act establishes an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; a new Medicare Part D coverage gap discount program; expansion of Medicaid benefits and a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program; and expansion of the 340B drug discount program that mandates discounts to certain hospitals, community centers and other qualifying providers. In the future, there may continue to be additional proposals relating to the reform of the United States healthcare system, some of which could further limit the prices we are able to charge or the amounts of reimbursement available for our product candidates once they are approved.

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 drug, 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. 505(b)(2) NDAs generally are submitted for changes to a previously approved drug product, such as a new dosage form or indication.

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.

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.

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.

Employees

As of December 31, 2019, we had 18 full-time employees, six 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.

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 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 Business and Industry

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, pre-clinical 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 acquired through the closing of the merger with Aevi;
- 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.

The success of the recently closed Merger with Aevi will depend, in large part, on our ability to realize the anticipated benefits from combining our business with the legacy businesses of Aevi.

The recently closed merger with Aevi involves the integration of two companies that previously have operated independently with principal offices in two distinct locations. Significant management attention and resources will be required to integrate the two companies. The failure to integrate successfully and to manage successfully the challenges presented by the integration process may result in our failure to achieve some or all of the anticipated benefits of the merger.

Potential difficulties that may be encountered in the integration process include the following:

- using our limited cash and other assets efficiently to develop our business;
- appropriately managing the liabilities of our business;
- potential unknown or currently unquantifiable liabilities associated with the merger and the operations of our business;
- potential unknown and unforeseen expenses, delays or regulatory conditions associated with the merger; and
- performance shortfalls as a result of the diversion of management's attention caused by completing the merger and integrating our operations.

Delays in the integration processes could adversely affect our business, financial results, financial condition and stock price following the merger. Even if we were able to integrate the business operations successfully, there can be no assurance that this integration will result in the realization of the full benefits of synergies, innovation and operational efficiencies that may be possible from this integration or that these potential benefits will be achieved within a reasonable period of time.

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 one clinical product candidate and our preclinical product candidates into clinical development and successfully complete preclinical testing of our clinical stage product candidates. The outcome of preclinical studies and Phase 1 clinical trials might not predict the success of future clinical trials. Preclinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies have nonetheless failed in 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, or IRBs, to commence or amend a clinical trial;

- imposition of a clinical hold (“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 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;
- 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, 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 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.

There is significant competition for recruiting subjects in clinical trials for product candidates for the treatment of neurological disorders and we or our partners may be unable to enroll the subjects we need to complete clinical trials on a timely basis or at all. Furthermore, 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.

We may face significant delays in our clinical studies and trials due to an inability to recruit patients for our clinical studies and trials or to retain patients in the clinical studies and trials we may perform.

We may not be able to locate and enroll enough eligible patients to participate in these trials as required by the FDA, the European Medicines Agency ("EMA ") or similar regulatory authorities outside the United States and the European Union. This may result in our failure to initiate or continue clinical trials for our product candidates or may cause us to abandon one or more clinical trials altogether. In particular, 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 clinical trials.

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.

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.

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 and clinical 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 approves 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. If we do not successfully develop and commercialize product candidates based upon our technological approach, we will not be able to obtain product revenues in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

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 for products that have not been granted Orphan Drug Designation requires a payment of a significant NDA application fee under the Prescription Drug User Fee Act ("PDUFA") upon submission. Any subsequent clinical data submissions to the NDA (i.e. for new indications) are also assessed an NDA application fee. The filing of an NDA for our product candidates 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.

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. Moreover, we have not sought to obtain orphan drug designation for any of our product candidates, which the FDA must first grant to be eligible for orphan drug exclusivity, but may if we determine that we may be eligible. In the case of orphan designation, 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.

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 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 notification or FDA 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 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 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 upon approval of the drug that can be used to obtain a priority review of a subsequent marketing application. The priority review voucher may be sold or transferred an unlimited number of times. Congress has extended the priority review voucher program until September 30, 2020 with new drug approvals that meet the voucher criteria grandfathered through 2022. This program has been subject to criticism, including by the FDA, and it is possible that even if we obtain approval for some of our product candidates and qualify for such a priority review voucher, the program may no longer be in effect at the time of approval. Also, although priority review vouchers may be sold or transferred to third parties, there is no guaranty that we will be able to realize any value if we were to sell a priority review voucher.

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.

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, these formulations, particularly 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.

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 cGMP 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 or Untitled Letters;
- 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, 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.

If any of our product candidates are ultimately regulated as controlled substances, we, our contract manufacturers, as well as distributors, prescribers, and dispensers will be required to comply with additional regulatory requirements which could delay the marketing of our product candidates, and increase the cost and burden of manufacturing, distributing, dispensing, and prescribing our product candidates.

Before we can commercialize our product candidates, the United States Drug Enforcement Administration, or DEA, may need to determine the controlled substance Schedule, taking into account the recommendation of the FDA. This may be a lengthy process that could delay our marketing of a product candidate and could potentially diminish any regulatory exclusivity periods for which we may be eligible. While we currently do not know whether any of our product candidates will be considered to be controlled substances, certain of our product candidates may be regulated as controlled substances.

If any of our product candidates are regulated as controlled substances, depending on the controlled substance schedule in which the product candidates are placed, we, our contract manufacturers, and any distributers, prescribers, and dispensers of the scheduled product candidates may be subject to significant regulatory requirements, such as registration, security, recordkeeping,

reporting, storage, distribution, importation, exportation, inventory, quota and other requirements administered by the DEA. Moreover, if any of our product candidates are regulated as controlled substances, we and our contract manufacturers would be subject to initial and periodic DEA inspection. If we or our contract manufacturers are not able to obtain or maintain any necessary DEA registrations, we might not be able to commercialize any product candidates that are deemed to be controlled substances or we may need to find alternative contract manufacturers, which would take time and cause us to incur additional costs, delaying or limit our commercialization efforts.

Because of their restrictive nature, these laws and regulations could limit commercialization of our product candidates, should they be deemed to contain controlled substances. Failure to comply with the applicable controlled substance laws and regulations can also result in administrative, civil or criminal enforcement. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate administrative proceedings to revoke those registrations. In some circumstances, violations could result in criminal proceedings or consent decrees. Individual states also independently regulate controlled substances.

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.

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.

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.

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.

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.

Because we have limited financial and managerial resources, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. 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.

Our current revenue depends on one product; so if we do not grow sales of that product, our revenue might not grow, which could affect our stock price.

Following the sale of our Pediatric Portfolio, we currently have rights to only one commercial pharmaceutical product, Millipred. We do not expect Millipred to generate significant revenue and profits, but we currently rely on it for all our commercial revenue. Our ability to increase revenue in the future will depend on commercializing it successfully, as well as developing and commercializing our current pipeline of product candidates. Any failure to do so could require us to raise additional financing, and could negatively impact our stock price.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

Legislative and regulatory changes in the United States and abroad may prevent or delay marketing approval of our product candidates, restrict or regulate post approval activities, increase competition from overseas manufacturers, and/or otherwise affect our ability to profitably sell any product candidates for which we obtain marketing approval, among other things. The 2010 Patient Protection and Affordable Care Act (“ACA”), for instance, was among the most significant pieces of healthcare legislation passed in the last twenty years and contained several measures intended to lower the prices paid by federal healthcare programs for pharmaceuticals. Among the provisions of the ACA of importance to our business are:

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

- revised the definition of "average manufacturer price," or AMP, for reporting purposes, which can increase the amount of Medicaid drug rebates manufacturers are required to pay to states, and created a separate AMP for certain categories of drugs provided in non-retail outpatient settings;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;

- 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;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer (70%) point of sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries under their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;

- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;

- expansion of eligibility criteria for Medicaid programs in certain states;

- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;

- a new Patient Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and

- enacted substantial new provisions affecting compliance which may affect our business practices with healthcare practitioners.

Although the ACA was enacted into law in 2010, we cannot fully predict its impact on pharmaceutical companies because many of the reforms enacted by the ACA require the promulgation of detailed regulations implementing the statutory provisions, some of which have not yet been adopted and others of which are targets for repeal. Since January 2017, for instance, the President has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. In addition, the Tax Cuts and Jobs Act ("TCJA") of 2018 included a provision repealing the tax based shared responsibility payment, commonly referred to as the "Individual Mandate", imposed by the ACA on certain individuals who fail to maintain qualifying health coverage. This change in the law reduced the number of individuals covered by health insurance and spurred several new lawsuits challenging the constitutionality of the ACA that are wending their way through the court system.

Further, the Congress and the White House have continued to pursue additional legislative and regulatory objectives intended to reduce the cost to federal healthcare programs for pharmaceuticals. For instance, the Know the Lowest Price Act of 2019 became effective on January 1, 2020 and blocks Medicare Advantage plan providers or providers of a Medicare Part D prescription drug plan from using gag clauses that prohibit pharmacists from alerting Medicare customers of differences between their insurance copay and what the patient would pay without using health insurance coverage. In addition, there have been several Congressional inquiries and proposed 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 out of pocket cost of prescription drugs, and reform government program reimbursement methodologies and rebate programs for drugs. In October 2019, for example, the U.S. House of Representatives unanimously passed two pieces of legislation intended to increase transparency related to rebates and other price concessions granted to pharmacy benefit managers ("PBMs") by drug makers. Although this legislation has not been passed into law and was fairly narrow in scope, the unanimous vote demonstrated the growing bipartisan support to reform the drug rebate system and contain or reduce the costs of pharmaceuticals for the federal government. Similarly, the Trump administration's budget proposal for fiscal year 2020 contains several measures related to Medicare Parts B and D, Medicaid, and the 340B discount drug program that are intended to reduce prescription drug prices by increasing competition, incentivizing lower prices, and reducing out-of-pocket costs for beneficiaries. Although these and other proposals would require additional legislation and/or regulations to become effective, Congress and the White House have each indicated that they will continue to seek new legislative and/or regulatory measures to control drug costs.

At the state level, legislatures have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological 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. There are presently nearly 130 individual pieces of legislation under consideration at the state level designed to lower the cost of prescription drugs. For instance, legislative and regulatory proposals have been made at the state level in certain states to expand post approval requirements and restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, whether the current regulations, guidance or interpretations will be changed, or what the impact of such changes on our business, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post marketing testing and other requirements.

We expect that additional state and federal 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 reduced demand for our product candidates or additional pricing pressures. These, and other statutory and regulatory burdens may also increase our compliance and operating costs. We continue to evaluate the effect of healthcare reform on our business.

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.

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 ("VHCA") 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 ("HITECH") 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 ACA 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. For example, recent case law from the U.S. Supreme Court interpreted the federal False Claims Act to include liability for implied false certifications, in certain instances. 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.

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 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.

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. Pericles Calias, Chief Scientific Officer, James A. Harrell, Jr., Chief Commercial Officer, Joe Miller, Chief Financial Officer, and Garry A. Neil, Chief Medical Officer, 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. Key employees may depart because of issues relating to the uncertainty and difficulty of integration of the merger with Aevi or a desire not to remain following the merger. 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.

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 to the FDA, (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 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.

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.

Following the closing of the Merger, we assumed the liabilities of the royalty agreement with certain related parties on terms that could raise conflicts of interest and that some stockholders may consider not to be in our best interests.

In July 2019, Aevi entered into a royalty agreement with Michael F. Cola, our 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 Garry A. Neil, our Chief Medical Officer, 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' second generation mTORC1/2 inhibitor, CERC-006 (the "OSI Products"). At any time beginning three years after the date of the first public launch of an OSI 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 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 or the audit committee of Aevi approved the Royalty Agreement, which liability was assumed by us upon closing of our Merger with Aevi, but these arrangements could present Mr. Cola and Dr. Neil, officers of ours, might have a conflict of interest when making decisions on the priority of the development of our pipeline products. In addition, some stockholders might not consider the terms of the Royalty Agreement to be in their best interests.

We face risks related to health epidemics and other outbreaks, which could significantly disrupt the supply chain for some of our pipeline assets.

Our business could be adversely impacted by the effects of the coronavirus or other epidemics. Currently, we are susceptible to risks to our manufacturing and production from the outbreak of the coronavirus in China. For instance, raw materials for the manufacturing of one of our pipeline assets are sourced from China and are accordingly subject to disruption or product contamination. We cannot estimate whether this impact might extend to other countries outside of China. At the time of this filing, the outbreak has been largely concentrated in China, although cases have been confirmed in other countries, including the United States. At this point, the extent to which the coronavirus might impact our supply chain is uncertain. However, a health epidemic or other outbreak, including the current coronavirus outbreak, might materially and adversely affect our supply chain, which might negatively affect our business, financial condition and results of operations.

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 cGMP 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 any agreements with 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 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 cGMP 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. 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. 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 significant losses. If Aytu ceases to provide services pursuant to the Transition Services 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.

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

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 ("Merck") for the compounds used in CERC-301 and the COMTi platform, including CERC-406;
- a license agreement and a research agreement with The Children's Hospital of Philadelphia and the Center for Applied Genomics, and a development and option agreement with Kyowa Hakko Kirin Co., Ltd. pursuant to which we exclusively license certain technology related to the development of CERC-002;
- a license agreement with OSI Pharmaceuticals, LLC, a wholly owned subsidiary of Astellas Pharma, Inc., for CERC-006; and
- a license and option agreement with MedImmune Limited, a subsidiary of AstraZeneca plc, for CERC-007.

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 the license and development agreements we acquired in our Merger with Aevi.

Following the Merger with Aevi, we are now party to license agreements and a research agreement with The Children's Hospital of Philadelphia ("CHOP") and the Center for Applied Genomics ("CAG"), and a Development and Option Agreement with Kyowa Hakko Kirin Co., Ltd. (the "KHK Development and Option Agreement") pursuant to which we exclusively licenses certain technology related to the development of CERC-002 and CERC-005, a license agreement with OSI Pharmaceuticals, LLC, a wholly owned subsidiary of Astellas Pharma, Inc. ("Astellas"), for CERC-006 and a license and option agreement with MedImmune Limited, a subsidiary of AstraZeneca plc ("AstraZeneca"), for CERC-007. We may be required to make significant payments in connection with the license agreements and research agreement with CHOP and have certain ongoing payment obligations with respect to the Research Agreement. If we exercise our option under the terms of KHK 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. Pursuant to the exercise of the AZ Option, we are obligated to spend significant amounts to develop the program. If we develop CERC-006, it will have significant obligations to Astellas under the license agreement with OSI Pharmaceuticals, LLC, a wholly owned subsidiary of Astellas. 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 development agreement with CHOP, we may lose our rights under that agreement, which would negatively impact their development capabilities.

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.

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.

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 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 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. Recent 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 recently developed new 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. Accordingly, it is not clear what, if any, impact the America Invents Act will have on the operation of our business. However, 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. In India, unlike the United States, there is no link between regulatory approval of a drug and its patent status. 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. In addition to India, certain countries in Europe and developing countries, including 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 Our Financial Position and Capital Needs

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, 2019, we had $3.6 million in cash and cash equivalents and $12.2 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 include a $15 million loan due in January 2021 minimum monthly and royalty payments of the higher of 15% of net sales or $100,000 through the earlier of February 2026 (the "Deerfield Obligation") or reaching the maximum aggregated royalty payment of $12.5 million. 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 with TRIS Pharma (the "Karbinal Agreement"). 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. We currently do not have cash on hand to permit us to pay the entire amount that could become due under the Deerfield Obligation, and any amount we would be required to pay under the Karbinal Agreement would limit the amount of cash available for development of our clinical pipeline. If we were to become required to pay the Deerfield Obligation, such obligation could significantly impair our ability to continue as a going concern and our ability to continue operations. Even if we were to have sufficient liquidity to pay the TRIS Obligation, or obtain funding to meet the Deerfield Obligation, we might not be able to recover the cost of such a payment and may therefore be exposed 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 private placements of our common and convertible preferred stock and convertible debt. We incurred net loss of $16.1 million for the year ended December 31, 2019. As of December 31, 2019, we had an accumulated deficit of $114.3 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).

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.

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.

We engage in in-licensing, acquisitions or other strategic transactions that could impact our liquidity, increase our expenses and divert a significant amount of our management's time.

Since inception, we have acquired or in-licensed product candidates, most recently product candidates we acquired from our Merger with Aevi. As a part of the Aevi Merger, we issued approximately 3.9 million shares of our common stock at closing, and payment of contingent value rights, which represent the right to receive contingent payments upon the achievement of certain milestones of up to an additional $6,500,000, payable either in shares of our common stock or in cash. From time to time we may consider additional in-licensing of products and other strategic transactions, such as acquisitions of companies, asset purchases and out-licensing of product candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including strategic partnerships, collaborations, joint ventures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions or to fund the operations;
- higher than expected acquisition and integration costs;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or other counterparties of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

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, 2019, 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 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 often 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, 2019, there were 2,532,162 shares available for future issuance under the Second 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, 2020, on the terms of the 2016 Amended Plan, an additional 1,775,368 shares were made available for issuance for a total of 4,307,530 shares available for issuance. In addition, as of December 31, 2019, there were 1,118,882 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, 2020, the number of shares available for issuance under the ESPP increased by 443,842 for a total of 1,562,724 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 Capital, LLC ("Armistice") beneficially owns approximately 59% 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.

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.

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 an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act") and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our securities less attractive to investors and adversely affect the market price of our securities.

For so long as we remain an "emerging growth company" as defined in the JOBS Act, we may take advantage of certain exemptions from various requirements applicable to public companies that are not "emerging growth companies" including:

- the provisions of Section 404(b) of the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act, requiring that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;

- the "say on pay" provisions (requiring a non-binding stockholder vote to approve compensation of certain executive officers) and the "say on golden parachute" provisions (requiring a non-binding stockholder vote to approve golden parachute arrangements for certain executive officers in connection with mergers and certain other business combinations) of the Dodd-Frank Act and some of the disclosure requirements of the Dodd-Frank Act relating to compensation of our chief executive officer.

- the requirement to provide detailed compensation discussion and analysis in proxy statements and reports filed under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and instead provide a reduced level of disclosure concerning executive compensation; and

- any rules that the Public Company Accounting Oversight Board may adopt requiring mandatory audit firm rotation or a supplement to the auditor's report on the financial statements.

We may take advantage of these exemptions until we are no longer an "emerging growth company." We would cease to be an "emerging growth company" upon the earliest of: (i) the first fiscal year following the fifth anniversary of our initial public offering; (ii) the first fiscal year after our annual gross revenues are $1.07 billion or more; (iii) the date on which we have, during the previous three-year period, issued more than $1.07 billion in non-convertible debt securities; or (iv) as of the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded $700 million as of the end of the second quarter of that fiscal year.

We have determined to take advantage of some, but not all, of the reduced regulatory and reporting requirements that will be available to us so long as we qualify as an "emerging growth company." For example, we have irrevocably elected not to take advantage of the extension of time to comply with new or revised financial accounting standards available under Section 102(b) of the JOBS Act. Our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an "emerging growth company," which may increase the risk that material weaknesses or significant deficiencies in our internal control over financial reporting go undetected. Likewise, so long as we qualify as an "emerging growth company," we may elect not to provide you with certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the SEC which may make it more difficult for investors and securities analysts to evaluate us. Even after we "no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, 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 if investors will find our securities less attractive because we may rely on these exemptions. If some investors find our securities less attractive as a result, there may be a less active trading market for our securities, and the securities prices may be more volatile and may decline.

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.

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 demand and net of sales our products, that could result in our reported revenues and earnings being lower than the so-called "market consensus" of our projected revenues, which could negatively affect our stock price. Additionally, if the securities and industry analysts are unable to predict accurately the cost of advancing our pipeline, which could result in our reported costs being different than expectations and 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.

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, and these expenses may increase even more after we are no longer an "emerging growth company." 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 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 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.

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.

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 term of the headquarters' lease expires January 31, 2030. We have the ability to expand this office space based on our growth and employee headcount.

Upon consummation of the Aevi Merger on February 3, 2020, the Company also occupies approximately 5,800 square feet of administrative office space in Wayne, Pennsylvania. The lease expires April 2020 and goes month-to-month thereafter, however both the Company and the landlord have the right to terminate the lease 60 days after written notice is provided.

Item 3. Legal Proceedings.

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"). A portion of the consideration for TRx Acquisition included shares of Cerecor common stock. The TRx Acquisition also included certain earn-outs for the former TRx owners for Cerecor achieving gross profit targets in the sales of the TRx acquired products. Currently, the former TRx owners beneficially own more than 10% of Cerecor's outstanding common stock.

On December 19, 2019, Cerecor, through its law firm, received a letter from an attorney on behalf of the former TRx owners dated December 18, 2019, which enclosed a draft complaint seeking relief against Cerecor and one of the members of its board of directors. The letter further threatened that if an immediate discussion regarding a settlement did not occur, that the lawsuit would be filed on December 24, 2019. However, as of the date of this filing, no lawsuit has been filed, and the parties have agreed to a pre-lawsuit mediation tentatively set for April 30, 2020. The proposed complaint indicates that the former TRx owners would seek the following relief: (a) $3,000,000 on the grounds that commercially reasonable efforts to sell the acquired TRx products would have resulted in the gross profit earn-out target being reached; (b) that the $3,000,000 amount be trebled as a result of Cerecor's alleged improper conduct; (c) $9,200,000 as a result of alleged losses resulting from the alleged improper treatment of the former TRx owners as affiliates; and (d) the removal of any restrictions on the former TRx owners' shares of common stock in Cerecor. Cerecor disputes that the former TRx owners are entitled to the relief sought and intends to vigorously defend against any lawsuit filed on behalf of the former TRx owners.

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." Our Class A warrants ("CERCW") expired in October 2018 and our Class B warrants ("CERCZ") expired in April 2017.

Holders

As of March 9, 2020, there were approximately 64 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.

Results of Operations

During the fourth quarter of 2019, the Company sold its 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"), retaining as our only commercial product, Millipred, an oral prednisolone indicated across a wide variety of inflammatory conditions. As a result of the Aytu Divestiture, the Pediatric Portfolio met all conditions required in order to be classified as discontinued operations as of December 31, 2019. Accordingly, operating results from the Pediatric Portfolio are reported separately within income (loss) from discontinued operations, net of tax (inclusive of gain on sale) for all periods presented. Unless otherwise noted, the following section focuses on results of operations from continuing operations only.

Comparison of the Years Ended December 31, 2019 and 2018

The following table summarizes our revenue from continuing operations for the years ended December 31, 2019 and 2018:

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Product revenue, net	$ 6,650	$ 6,572
Sales force revenue	—	456
License and other revenue	100	—
Total revenues, net	$ 6,750	$ 7,028

Product revenue, net

Product revenue, net increased $0.1 million for the year ended December 31, 2019 as compared to the year ended December 31, 2018.

Sales force revenue

As part of the acquisition of TRx Pharmaceuticals, LLC ("TRx") in November 2017, the Company acquired a sales and marketing agreement with Pharmaceutical Associates, Inc. ("PAI") under which the Company received a monthly marketing fee to promote, market and sell certain products on behalf of PAI, as well as a share of PAI's profits, which we collectively categorized as sales force revenue. For the year ended December 31, 2018, sales force revenue was $0.5 million. The PAI contract was canceled during the second quarter of 2018 and therefore there is no sales force revenue for the year ended December 31, 2019.

License and other revenue

In August 2019, the Company assigned and transferred its rights, title, interest, and obligations with respect to CERC-611 to ES Therapeutics in exchange for gross proceeds of $0.1 million, which was recognized as license and other revenue for the year ended December 31, 2019. Under the Assignment Agreement, the Company is also eligible for the following potential milestone payments: (a) a $7.5 million payment to the Company upon cumulative net sales of licensed products reaching $750.0 million; and (b) a $12.5 million payment to the Company upon cumulative net sales of licensed products reaching $1.25 billion. There was no license and other revenue for the year ended December 31, 2018.

Cost of product sales

Cost of product sales of continuing operations was $(0.6) million for the year ended December 31, 2019, compared to $3.3 million for the year ended December 31, 2018.

The $(0.6) million of cost of product sales of continuing operations recognized in the current year is driven by the Settlement Agreement the Company entered into related to the Ulesfia product during the second quarter of 2019. The Settlement Agreement fully released the Company of all current and future liabilities related to the Lachlan Agreement, which contained minimum purchase obligations and minimum royalty provisions that the Company had accrued for in the amount of $2.4 million in the year ended December 31, 2018. Pursuant to the Settlement Agreement, during the second quarter of 2019, the Company made a $2.3 million cash payment for a full release of all current and future liabilities related to the Lachlan Agreement as of June 30, 2019. As a result, the Company reversed the $8.7 million liability for the minimum obligations and $0.4 million royalty payable in accrued liabilities during the second quarter of 2019. The Settlement Agreement also released the former TRx owners of their requirement to indemnify the Company for the losses discussed above. As a result, the Company reversed the $5.2 million indemnity receivable in other receivables during the second quarter of 2019. The Settlement Agreement resulted in a net reversal of $1.6 million in previously recognized expense to cost of product sales for the year ended December 31, 2019. This reversal is partially offset by cost of product sales of approximately $1.0 million, which is primarily composed of royalties, cost of inventory sold and licenses.

The $3.3 million of cost of product sales for the year ended December 31, 2018 primarily consists of the Ulesfia minimum royalty obligations described above.

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2019 and 2018:

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Preclinical expenses	$ 2,789	$ 1,886
Clinical expenses	4,079	1,693
CMC expenses	3,728	389
Internal expenses not allocated to programs:		
Salaries, benefits and related costs	1,909	1,223
Stock-based compensation expense	464	101
Other	(1,205)	495
	$ 11,764	$ 5,787

Research and development expenses increased $6.0 million for the year ended December 31, 2019 compared to the prior year. The overall increase was driven by an increase in research and development activities during the current year as the Company continues to develop its pipeline assets. Clinical expenses increased $2.4 million primarily due to increased development costs related to CERC-801, CERC-802, and CERC-803, which were acquired as part of the Ichorion Acquisition in September 2018, and increased activities related to the CERC-301 clinical study in nOH during the first half of 2019. Chemistry, Manufacturing, and Controls ("CMC") expenses increased $3.3 million for the year ended December 31, 2019 compared to the same period in 2018 due to additional spending on manufacturing to support clinical development. Salaries, benefits and related costs increased by $0.7 million compared to the same period in 2018 due to an increase in headcount and salary-related costs needed to maintain and grow our research and development activities as we continue to invest in our pipeline assets. Additionally, stock-based compensation increased by $0.4 million due to an increase in the amount of stock option grants in 2019 driven by an increased headcount, as well as the additional expense related to the annual stock option award that was granted on April 1, 2019.

These increases were partially offset by a $1.3 million reversal of research and development expense related to the Company's assignment of its license agreement with respect to CERC-611 to ES Therapeutics in the third quarter of 2019. Pursuant to the Assignment Agreement, the Company assigned and transferred its rights, interest and obligations related to the compound, thus releasing the Company's contingent payment of $1.3 million to 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 elimination of the license obligation resulted in an offset of research and development expense for the year ended December 31, 2019.

The Company expects research and development expenses to increase in 2020 as the Company advances its newly acquired pipeline assets and also continues to advance the CERC-800 assets.

Acquired In-Process Research and Development Expenses

As part of the Ichorion acquisition in September 2018, the Company acquired $18.7 million of in-process research and development ("IPR&D") for three preclinical therapies (CERC-801, CERC-802 and CERC-803) for CDGs. The fair value of the IPR&D was immediately recognized as acquired IPR&D expense as the IPR&D asset has no other alternate use due to the stage of development. There was no acquired IPR&D 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, 2019 and 2018:

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Salaries, benefits and related costs	$ 4,196	$ 3,607
Legal, consulting and other professional expenses	3,943	4,426
Stock-based compensation expense	1,550	2,136
Other	434	342
	$ 10,123	$ 10,511

General and administrative expenses decreased $0.4 million for the year ended December 31, 2019 compared to 2018. The overall decrease was driven by a $0.5 million decrease in legal, consulting and other professional fees and a $0.6 million decrease in stock-based compensation, largely offset by a $0.6 million increase in salaries, benefits and related costs.

Legal, consulting and other professional expenses decreased $0.5 million, which was driven by a substantial decrease in consulting fees in the current year. The consulting fees incurred in the prior year were related to the integration of the acquisitions of TRx and Avadel Pharmaceuticals PLC's ("Avadel") pediatric products. The Company has since increased corporate headcount and therefore uses less consulting services to meet accounting and reporting requirements. Further, stock-based compensation expense decreased $0.6 million for the year ended December 31, 2019 as compared to the same period in 2018 mainly due to the reversal of expense recognition of $0.3 million of stock-based compensation expense related to the modification of a separated executive's awards in 2018, and due to the current year reversal of the expense recognized of $0.5 million related to the former CEO's unvested market-based options that were forfeited during the second quarter of 2019. These decreases to stock-based compensation were partially offset by expense recognized for stock options granted to executives and the Company's annual stock option awards. The decreases to general and administrative expenses were partially offset by a $0.6 million increase in salaries, benefits and related costs due to an increase in headcount and salary-related costs.

The Company expects general and administrative expenses to increase in 2020 due to expected increases to legal, consulting and other professional expenses as a result of integration costs related to the Merger, in addition to increased salaries and stock-based compensation as a result of additional headcount as a result of the Merger.

Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses of continuing operations for the years ended December 31, 2019 and 2018:

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Salaries, benefits and related costs	$ 628	$ 367
Stock-based compensation expense	191	57
Advertising and marketing expense	606	60
Other	59	61
	$ 1,484	$ 545

Sales and marketing expenses of continuing operations consist of expenses related to advertising and marketing initiatives to support the go-to-market strategy of the CERC-800 compounds and the respective salaries and stock-based compensation to support such initiatives. The increase was primarily driven by a $0.5 million increase in advertising and marketing expense related to developing the go-to-market strategy in the current year in preparation to quickly and effectively market, launch, and distribute each of our pipeline assets, if any, that receive marketing approval in the future. Additionally, during the second quarter of 2018, a sales and marketing executive was hired. As a result, salaries, benefits and related costs and stock-based compensation expense increased $0.3 million and $0.1 million, respectively, due to a full year of such amounts in 2019, as opposed to only three quarters in 2018.

Amortization expense

The following table summarizes our amortization expense of continuing operations for the years ended December 31, 2019 and 2018:

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Amortization of intangible assets	$ 1,339	$ 1,829

Amortization expense of the continuing operations for the year ended December 31, 2019 relates to the amortization of the Company's acquired Millipred product marketing rights and amortization of the assembled workforce acquired as part of the Ichorion Acquisition. Amortization expense decreased $0.5 million from the previous year because the expense for the year ended December 31, 2018 includes $0.5 million of amortization related to the sales and marketing agreement with PAI, which was terminated in the second quarter of 2018.

Impairment of Intangible Assets

The following table summarizes our expense related to impairment of intangible assets of continuing operations for the years ended December 31, 2019 and 2018:

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Impairment of intangible assets	$ —	$ 1,862

The Company recorded impairment of intangible asset expense of $1.9 million for the year ended December 31, 2018 due to the impairment of the PAI sales and marketing agreement upon termination of that agreement. The Company recorded impairment of intangible assets of $1.4 million for the year ended December 31, 2019 due to the impairment of the Flexichamber asset. However, as Flexichamber was part of the Aytu Divestiture, this expense was included in income (loss) from discontinued operations, net of tax (inclusive of gain on sale) for the year ended December 31, 2019. There was no impairment recognized on intangible assets from continuing operations for the year ended December 31, 2019.

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, 2019 and 2018:

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Change in fair value of contingent consideration	$ (1,256)	$ (111)

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 as compared to a gain of $0.1 million for the same period in 2018. The contingent consideration from continuing operations was related to the potential for future payment of consideration that is 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.

The fair value of contingent consideration was determined at the acquisition date. Subsequent to the acquisition date, at each reporting period, the contingent consideration liability was remeasured at the current fair value with changes recorded in operating expenses in the condensed consolidated statement of operations. The gain recognized in 2019 was related to the Company entering into the Lachlan Settlement Agreement during the second quarter of 2019, which released the Company from the potential contingent payments related to the TRx acquisition, reducing the fair value down to $0 as of June 30, 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.

Other income, net

The following table summarizes our other income, net from continuing operations for the years ended December 31, 2019 and 2018:

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Change in fair value of Investment in Aytu	$ 54	$ —
Change in fair value of warrant liability and unit purchase option liability	(4)	25
Other (expense) income, net	(24)	14
Interest income, net	121	16
	$ 147	$ 55

Other income, net increased $0.1 million for the year ended December 31, 2019 as compared to the prior year. The increase is driven by a $0.1 million increase in interest income, net in the current year which is the result of the Company opening a money market account during 2019 and having a higher average cash balance year over year. Additionally, for the year ended December 31, 2019, the Company recognized a $0.1 million gain on change in the fair value of the investment related to the Company's Investment in Aytu. As part of the Aytu Divestiture, the Company received 9,805,845 shares of Aytu Series G Preferred Stock. The fair value of the Investment was determined on November 1, 2019, the closing date of the Aytu Divestiture. Subsequent to this date, at each reporting period, the Investment will be remeasured at current fair value with changes recorded in other income in the condensed consolidated statement of operations. Subsequent to December 31, 2019, Aytu's common stock price has been volatile and therefore Cerecor may recognize a significant gain or loss on the change in fair value of the Investment in Aytu for the three months ending March 31, 2020 and any future reporting period based on actual movements in the underlying stock price.

Income tax expense (benefit)

The income tax expense from continuing operations was $0.3 million for the year ended December 31, 2019. The provision for income taxes for the year ended December 31, 2019 is primarily composed of interest on the income tax liability. The Company recognized an immaterial income tax benefit for the year ended December 31, 2018, which was composed of an adjustment benefit from the return to provision true up of a prior year tax liability, offset by state income tax of one subsidiary, and deferred income tax

expense, all of which were not significant. The annual effective tax rate was (1.75)% and 0.14% for the years ended December 31, 2019 and 2018, respectively.

Liquidity, Capital Resources and Expenditure Requirements

During the first quarter of 2019, the Company closed on an underwritten public offering of common stock for 1,818,182 shares of common stock of the Company, at a price to the public of $5.50 per share ("public price"). Armistice Capital Master Fund Ltd. ("Armistice"), the Company's largest stockholder, participated in the offering by purchasing 363,637 shares of common stock of the Company at the public price. Cerecor director, Steven J. Boyd, is Armistice's Chief Investment Officer. The net proceeds of the offering were approximately $9.0 million. During the third quarter of 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 a purchase price of $3.132 per share. Net proceeds of the private placement were approximately $3.7 million. During the fourth quarter of 2019, the Company entered into, and subsequently closed on, the Aytu Purchase Agreement to sell the Company's rights, title and interest in, assets relating to its Pediatric Portfolio and related commercial infrastructure for a combination of cash and preferred stock ($4.5 million in cash, and approximately 9.8 million shares of Aytu convertible preferred stock) and the assumption of certain of the Company's liabilities including the Company's payment obligations payable to Deerfield of $15.1 million and certain other liabilities of approximately $11.0 million. During the first quarter of 2020, the Company closed on a registered direct offering with institutional investors of 1,306,282 shares of the Company's common stock at a purchase price of $3.98 per share. Armistice participated in the offering by purchasing 1,256,282 shares of common stock from the Company. The net proceeds of the offering were approximately $5.0 million.

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, 2019, Cerecor generated a net loss of $16.1 million and negative cash flow from operations of $19.1 million. As of December 31, 2019, Cerecor had an accumulated deficit of $114.3 million and $3.6 million in cash and cash equivalents.

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern; however, the Company expects to incur additional losses in the future in connection with research and development activities and will require additional financing to fund its operations and to continue to execute its strategy. The Company plans to use its current cash on hand and the anticipated cash flows from the Company's profits from Millipred product sales and/or the potential proceeds from the out-license or sale of Millipred to a third party to offset costs related to its orphan disease pipeline assets, business development, and costs associated with its organizational infrastructure; however, Cerecor expects to continue to incur significant expenses and operating losses for the immediate future as it continues to invest in the Company's pipeline assets. The Company's ability to continue as a going concern through 2020 is dependent upon the Company's ability to raise additional equity and/or debt capital; however, there can be no assurance that such capital will be available in sufficient amounts or on terms acceptable to the Company.

Over the long term, the Company's ultimate ability to achieve and maintain profitability is dependent on, among other things, the development, regulatory approval, and commercialization of its pipeline assets, and the potential sale of any PRVs it receives, all being adequate to support its cost structure and pipeline asset development.

These conditions raise substantial doubt about its ability to continue as a going concern within one year after the date that the financial statements are issued. To alleviate these conditions, the Company is evaluating the potential out-licensing or sale of Millipred to a third party and some combination of rights to future PRV sales, equity or debt financings, collaborations, out-licensing arrangements, strategic alliances, federal and private grants, marketing, distribution or licensing arrangements, the sale of current or future assets or possible monetization of the Company's holdings of Aytu equity. 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 is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible or suspend or curtail planned programs. Due to the uncertainty regarding future financings and/or 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 are issued.

Uses of Liquidity

The Company uses cash to fund research and development expenses related to its rare pediatric and orphan disease pipeline, business development and costs associated with its organizational infrastructure.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2019 and 2018:

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (19,134)	$ (3,128)
Investing activities	(443)	865
Financing activities	12,559	10,404
Net (decrease) increase in cash and cash equivalents	$ (7,018)	$ 8,141

Net cash used in operating activities

Total 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 increased research and development activities as the Company continued to fund its pipeline of development assets. Adjustments to reconcile net loss to net cash used in net operating activities included $8.0 million gain recognized on the Aytu Divestiture and a $1.0 million non-cash gain on the change of fair value of contingent consideration liability, partially offset by $3.9 million of non-cash depreciation and amortization and non-cash stock-based compensation of $2.5 million. Additionally, changes in assets and liabilities, net of Aytu Divestiture decreased by a net $2.0 million, mainly driven by decreases in accrued expenses and other liabilities of $6.8 million, license obligations of $1.3 million and income taxes payable of $1.5 million, partially offset increases in accounts receivable of $1.7 million, net, and other receivables, excluding the Aevi loan, of $5.1 million.

The Company expects a significant and likely increase in net cash used in operating activities in 2020 due to our continued investment in the CERC-800 compounds and our increased investment in the pipeline assets recently acquired as part of the Aevi Merger.

Net cash used in operating activities was $3.1 million for the year ended December 31, 2018 and consisted primarily of a net loss of $40.1 million, offset by non-cash acquired IPR&D of $18.7 million, depreciation and amortization of $4.6 million, non-cash stock-based compensation expense of $2.4 million, impairment of intangible assets of $1.9 million and changes in working capital, primarily, an increase in accrued expenses of $7.8 million, largely related to the Lachlan minimum obligations (prior to entering into the Lachlan Settlement in 2019) and a decrease in escrowed cash receivable of $3.8 million.

Net cash (used in) provided by investing activities

Total 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 (which is discussed in detail in Note 7 to the audited consolidated financial statements) and purchase of property and equipment of $0.3 million, largely offset by $4.0 million net cash received from the Aytu Divestiture.

Net cash used in investing activities was $0.9 million for the year ended December 31, 2018 and consisted primarily of $1.4 million of cash acquired from the acquisition of Ichorion partially offset by purchase of property, plant and equipment of $0.6 million, which includes leasehold improvement costs incurred as part of our lease for the Company's corporate headquarters.

Net cash provided by financing activities

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, at a price to the public of $5.50 per share, which the Company 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. Additionally, for the year ended December 31, 2019, the Company received $0.8 million of proceeds from the exercise of stock options and warrants and $0.2 million of proceeds from sales of common stock under the employee stock purchase plan. This increase was partially offset by $0.9 million of contingent consideration payments related to the Avadel acquisition made prior to the Aytu Divestiture.

Net cash provided by financing activities was $10.4 million for the year ended December 31, 2018, which consisted primarily of proceeds of $5.7 million from the warrant exercise by Armistice Capital in December 2018, net proceeds of $3.9 million from a private placement of equity securities to Armistice Capital in August 2018, and $1.1 million of proceeds from option and warrant exercises throughout the year. This increase was partially offset by $0.3 million payment in contingent consideration payments related to the Avadel 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.

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 risk-free interest rate, the expected volatility of a peer group of similar companies, the expected term of the awards and the expected dividend yield. The expected term for market-based stock option awards is based on the expected term calculated using a Monte-Carlo simulation. 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.

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	**2019**			**2018**		
Risk-free interest rate	1.47%	—	2.59%	2.51%	—	3.01%
Expected term of options (in years)	5.0	—	6.25	5.0	—	6.25
Expected stock price volatility	55%			55%	—	65%
Expected annual dividend yield	0%			0%		
Market-based options						
Risk-free interest rate	2.32%			2.84%		
Expected term of options (in years)	10.0			10.0		
Expected stock price volatility	60%			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.

Estimated Fair Value and Change in Fair Value of Contingent Consideration

The Company's business acquisitions of Avadel's pediatric products and TRx involved the potential for future payment of consideration that is contingent upon the achievement of operation and commercial milestones and royalty payments on future product sales. 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 statements of operations.

As part of the Aytu Divestiture, Aytu assumed the Company's contingent consideration liability related to future royalties on Avadel's pediatric products. Additionally, 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 TRx. Therefore, the Company's contingent consideration liability was $0 as of December 31, 2019.

There is no change in fair value of contingent consideration included in cost of product sales or research and development costs. For the year ended December 31, 2019 and 2018, the change in fair value of contingent consideration related to royalties on Avadel's pediatric products was included within net income (loss) from discontinued operations, net of tax (inclusive of gain on sale). The change in fair value of contingent consideration related to TRx was included within its own standalone line in operating expenses from continuing operations in the Company's consolidated statements of operations because the contingent consideration was related to a product that was not sold as part of the Aytu Divestiture.

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

As consideration for the Aytu Divestiture, the Company received approximately 9.8 million shares of Aytu Series G Convertible Preferred Stock. Pursuant to ASC 323, the Company accounts 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 our shares being restricted as of December 31, 2019 and subject to a lockup period ending on July 1, 2020. Subsequent to the divestiture date, at each reporting period, the Investment in Aytu will be remeasured at its current fair value with the change in fair value recorded to other income, net in the accompanying statements of operations. The Investment in Aytu is recorded in the consolidated balance sheet as a current asset because it is available for sale within one year of December 31, 2019.

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 and the contingent consideration liability related to future royalties on Avadel's pediatric products. In conjunction with the closing of the Aytu Divestiture in the fourth quarter of 2019, the Company entered into a Guarantee, which guarantees the payment of the assumed debt obligation and contingent consideration. The fair value of the Guarantees were 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 Guarantee will be remeasured at its current fair value with changes recorded in income (loss) from discontinued operations, net of tax within the consolidated statements of operations.

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 (the "IRC"). See Note 15 for further information within the Company's consolidated financial statements. 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, 2019, the Company did not believe any material uncertain tax positions were present.

On December 22, 2017, the "Tax Cuts and Jobs Act" ("TCJA" or the "Act") was enacted, that significantly reforms the IRC. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest and NOL carryforwards, allows for the expensing of capital expenditures, and puts into effect the migration from a "worldwide" system of taxation to a territorial system. See Note 15 within the Company's consolidated financial statements for further discussion related to the tax impact to the Company.

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, 2019, the Company's chief operating decision makers were the Chief Financial Officer and the Executive Chairman of the Board. The CFO and the Executive Chairman of the Board view the Company's operations and manage the business as one operating segment. All long-lived assets of the Company reside in the United States.

Goodwill

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, we assign 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 and is reclassified within discontinued operations.

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.

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.

JOBS Act

The JOBS Act contains provisions that, among other things, reduce reporting requirements for an "emerging growth company." As an emerging growth company, we have elected to not take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards and, as a result, will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

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, 2019, 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. The Dodd-Frank Wall Street Reform and Consumer Protection Act exempts non-accelerated filers 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, 2019.

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, 2019, 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, 2019.

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 Executive Chairman of the Board and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2019, 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, 2019.

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 exemption established by the JOBS Act for emerging growth companies.

Item 9B. Other Information.

On March 11, 2020, Michael F. Cola, the Company's Chief Executive Officer, and the Company entered into an amendment (the "Amendment") to the employment agreement effective February 3, 2020 (the "Cola Employment Agreement"). The Amendment reduces Mr. Cola's base salary in cash from an annual rate of $450,000 to an annual rate of $35,568 (the "Reduction"). In consideration for the Reduction, the Company will grant Mr. Cola stock options, to be approved by the independent Compensation Committee at regularly scheduled Compensation Committee meetings, for the purchase of a number of shares of the Company's outstanding common stock with a total value (based on the Black-Scholes valuation methodology) based on a prorata total annual value of $414,432 since the last Compensation Committee meeting (the "Salary Options"). If the Company's stock price at the time of the applicable meeting of the Compensation Committee is below $2.07/share, then the Salary Options will not be granted, and instead the Company will pay Mr. Cola a cash bonus based on the prorata portion of $414,432 since the last Compensation Committee meeting.

The foregoing description of the Amendment to the Cola Employment Agreement is a summary, is not complete and is qualified in its entirety by reference to the Amendment, which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ending March 31, 2020.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Pursuant to Paragraph G(3) of the General Instructions to the Annual Report on Form 10-K, the information required by Part III (Items 10, 11, 12, 13 and 14) is being incorporated by reference herein from our definitive proxy statement (or an amendment to our Annual Report on Form 10-K) to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2019 in connection with our 2020 Annual Meeting of Stockholders.

Item 11. Executive Compensation.

See Item 10.

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

See Item 10.

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

See Item 10.

Item 14. Principal Accounting Fees and Services.

See Item 10.

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	Form of Warrant to Purchase Shares of Common Stock issued in connection with the issuance of convertible promissory notes from April 2014 through June 2014 (incorporated by reference to Exhibit 4.6 to the Registration Statement on Form S-1 filed on June 12, 2015).
4.3	Warrant Agreement, dated as of August 19, 2014, issued to Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 4.7 to the Registration Statement on Form S-1 filed on June 12, 2015).
4.4	Form of Unit Purchase Option (incorporated by reference to Annex IV of Exhibit 1.1 to the Registration Statement on Form S-1/A filed on October 13, 2015).
4.5	Specimen Unit Certificate (incorporated by reference to Exhibit 4.13 to the Registration Statement on Form S-1/A filed on October 13, 2015).
4.6	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).
4.7	Form of Warrant to Purchase Shares of Common Stock of Cerecor Inc. issued to Armistice Capital Master Fund Ltd. (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed on April 28, 2017).
4.8	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).
4.9	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).
4.10‡	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	List of current directors with a Director Indemnification Agreement in the form provided as Exhibit 10.4 (incorporated by reference to Exhibit 10.13 to the Registration Statement on Form S-1/A filed on September 8, 2015).
10.6	Loan and Security Agreement, dated as of August 19, 2014, by and between Cerecor Inc. and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 10.15 to the Registration Statement on Form S-1 filed on June 12, 2015).
10.7	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).
10.8 +	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).
10.9 **	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).
10.10	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).
10.11	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).
10.12 +	Employment Agreement, dated March 27, 2018, by and between Cerecor Inc. and Peter Greenleaf (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on April 2, 2018).
10.13 **	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).
10.14 +	Employment Agreement, dated January 22, 2018, by and between Cerecor Inc. and Matthew Phillips (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on April 10, 2018).
10.15.1 +	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).
10.15.2 +‡	Amendment to Employment Agreement of James A. Harrell, Jr., dated October 14, 2019.
10.16 +	Employment Agreement, dated July 12, 2018, by and between Cerecor Inc. and Joseph M. Miller (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on July 16, 2018).

10.17 +	Employment Agreement, dated July 16, 2018, by and between Cerecor Inc. and Pericles Calias (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed on July 16, 2018).
10.18	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).
10.19	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).
10.20	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).
10.21 +	Employment Agreement, dated April 10, 2019, by and between Cerecor Inc. and Simon Pedder, effective April 15, 2019 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on April 12, 2019).
10.22 +	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).
10.23	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).
10.24	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).
10.25	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).
10.26	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).
10.27	Form of Contingent Value Rights Agreement (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on December 5, 2019).
10.28	Voting Agreement, made and entered into as of December 5, 2019, by and between Cerecor Inc., Aevi Genomic Medicine, Inc. and the undersigned holders (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on December 5, 2019).
10.29	Promissory Note, dated December 5, 2019, issued to Aevi Genomic Medicine, Inc. (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed on December 5, 2019).
10.30	Promissory Note, dated December 5, 2019 issued to Aevi Genomic Medicine, Inc. (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed on December 5, 2019).

10.31	Backstop Agreement, dated December 5, 2019, entered into by and between Cerecor Inc. and Armistice Capital Master Fund Ltd. (incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K filed on December 5, 2019).
10.32 ‡	Assignment of License Agreement, dated August 8, 2019, entered into by and between Cerecor Inc., ES Therapeutics, LLC, and Armistice Capital Master Fund Ltd.
21.1 ‡	List of Subsidiaries of the Registrant.
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 Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

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* The schedules to these agreements have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company agrees to furnish a copy of any schedule omitted from the agreements to the SEC upon request.

** Confidential treatment requested under 17 C.F.R. §§ 200.80(b)(4) and 230.406. The confidential portions of this exhibit have been omitted and are marked accordingly. The confidential portions have been filed separately with the Securities and Exchange Commission.

+ 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/ Joseph M. Miller

Joseph M. Miller
Chief Financial Officer

Date: March 11, 2020

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 11, 2020
/s/ Joseph M. Miller **Joseph M. Miller**	Chief Financial Officer (Principal Financial and Accounting Officer)	March 11, 2020
/s/ Simon Pedder **Simon Pedder**	Executive Chairman of the Board	March 11, 2020
/s/ Sol J. Barer **Dr. Sol J. Barer**	Director	March 11, 2020
/s/ Steven J. Boyd **Steven J. Boyd**	Director	March 11, 2020
/s/ Phil Gutry **Phil Gutry**	Director	March 11, 2020
/s/ Uli Hacksell **Uli Hacksell**	Director	March 11, 2020
/s/ Magnus Persson **Magnus Persson**	Director	March 11, 2020
/s/ Keith Schmidt **Keith Schmidt**	Director	March 11, 2020

CERECOR INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders 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, 2019 and 2018, the related consolidated statements of operations, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, 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.

/s/ Ernst & Young LLP
We have served as the Company's auditor since 2013.
Baltimore, Maryland
March 11, 2020

CERECOR INC. and SUBSIDIARIES

Consolidated Balance Sheets

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 3,609,438	$ 10,646,301
Accounts receivable, net	1,001,645	822,327
Other receivables	4,240,572	5,262,213
Inventory, net	21,334	317,923
Prepaid expenses and other current assets	706,968	731,954
Restricted cash, current portion	17,535	18,730
Investment in Aytu	7,628,947	—
Current assets of discontinued operations	497,577	4,132,445
Total current assets	17,724,016	21,931,893
Property and equipment, net	1,447,663	586,512
Intangibles assets, net	2,426,258	3,765,254
Goodwill	14,409,088	14,409,088
Restricted cash, net of current portion	101,945	81,725
Long-term assets of discontinued operations	—	29,476,249
Total assets	$ 36,108,970	$ 70,250,721
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,077,524	$ 1,446,141
Accrued expenses and other current liabilities	5,640,252	14,328,879
Income taxes payable	551,671	2,032,258
Contingent consideration, current portion	—	859,670
Current liabilities of discontinued operations	3,891,012	7,549,631
Total current liabilities	12,160,459	26,216,579
Contingent consideration, net of current portion	—	396,540
Deferred tax liability, net	85,981	69,238
License obligations	—	1,250,000
Other long-term liabilities	1,111,965	385,517
Long-term liabilities of discontinued operations	1,755,000	21,025,099
Total liabilities	15,113,405	49,342,973
Stockholders' equity:		
Common Stock—$0.001 par value; 200,000,000 shares authorized at December 31, 2019 and 2018; 44,384,222 and 40,804,189 shares issued and outstanding at December 31, 2019 and 2018, respectively	44,384	40,804
Preferred Stock—$0.001 par value; 5,000,000 shares authorized at December 31, 2019 and 2018; 2,857,143 shares issued and outstanding at December 31, 2019 and 2018, respectively	2,857	2,857
Additional paid-in capital	135,238,941	119,082,157
Accumulated deficit	(114,290,617)	(98,218,070)
Total stockholders' equity	20,995,565	20,907,748
Total liabilities and stockholders' equity	$ 36,108,970	$ 70,250,721

See accompanying notes to the consolidated financial statements.

CERECOR INC. and SUBSIDIARIES

Consolidated Statements of Operations

	Year Ended December 31,	
	2019	**2018**
Revenues		
Product revenue, net	$ 6,650,351	$ 6,572,322
Sales force revenue	—	456,056
License and other revenue	100,000	—
Total revenues, net	6,750,351	7,028,378
Operating expenses:		
Cost of product sales	(566,523)	3,260,668
Research and development	11,764,133	5,786,635
Acquired in-process research and development	—	18,723,952
General and administrative	10,123,320	10,511,207
Sales and marketing	1,484,044	545,218
Amortization expense	1,338,996	1,828,552
Impairment of intangible assets	—	1,861,562
Change in fair value of contingent consideration	(1,256,211)	(110,923)
Total operating expenses	22,887,759	42,406,871
Loss from continuing operations	(16,137,408)	(35,378,493)
Other (expense) income:		
Change in fair value of Investment in Aytu	53,932	—
Change in fair value of warrant liability and unit purchase option liability	(3,888)	25,010
Other (expense) income, net	(24,399)	13,657
Interest income, net	121,326	16,261
Total other income, net from continuing operations	146,971	54,928
Loss from continuing operations before taxes	(15,990,437)	(35,323,565)
Income tax expense (benefit)	280,316	(49,466)
Loss from continuing operations	$ (16,270,753)	$ (35,274,099)
Income (loss) from discontinued operations, net of tax (inclusive of gain on sale)	198,206	(4,778,711)
Net loss	$ (16,072,547)	$ (40,052,810)
Net (loss) income per share of common stock, basic and diluted:		
Continuing operations	$ (0.28)	$ (1.06)
Discontinued operations	0.00	$ (0.14)
Net loss per share of common stock, basic and diluted	$ (0.28)	$ (1.20)
Net (loss) income per share of preferred stock, basic and diluted:		
Continuing operations	$ (1.42)	
Discontinued operations	0.01	
Net loss per share of preferred stock, basic and diluted	$ (1.41)	

See accompanying notes to the consolidated financial statements.

CERECOR INC. and SUBSIDIARIES

Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2019	**2018**
Operating activities		
Net loss	$ (16,072,547)	$ (40,052,810)
Adjustments to reconcile net loss used in operating activities:		
Depreciation and amortization	3,883,567	4,554,963
Impairment of intangible assets	1,449,121	1,861,562
Stock-based compensation, excluding amount included within gain on sale of Pediatric Portfolio	2,532,257	2,431,063
Acquired in-process research and development, including transaction costs	—	18,723,952
Deferred taxes	16,743	(16,745)
Amortization of inventory fair value adjustment associated with acquisition of TRx and Avadel pediatric products	107,271	300,573
Non-cash interest expense	—	302,882
Gain on Aytu Divestiture	(7,964,924)	—
Change in fair value of Investment in Aytu	(53,932)	—
Change in fair value of contingent consideration liability	(1,009,169)	58,366
Change in fair value of warrant liability and unit purchase option liability	3,888	(25,010)
Changes in assets and liabilities, net of Aytu Divestiture:		
Accounts receivable, net	1,658,333	(222,530)
Other receivables (excluding Aevi Loan)	5,120,247	(2,277,255)
Inventory, net	532,947	(311,199)
Prepaid expenses and other assets	(917,016)	(241,641)
Escrowed cash receivable	—	3,752,390
Accounts payable	1,019,358	82,451
Income taxes payable	(1,480,587)	(226,890)
Accrued expenses and other liabilities	(6,835,395)	7,792,259
License obligations	(1,250,000)	—
Lease liability, net	125,506	—
Other long term liabilities	—	385,517
Net cash used in operating activities	(19,134,332)	(3,128,102)
Investing activities		
Net cash received from Aytu Divestiture	3,958,412	—
Loan to Aevi	(4,139,401)	
Avadel pediatric products acquisition	—	(1)
Net cash acquired from acquisition of Ichorion Therapeutics, Inc.	—	1,429,877
Purchase of property and equipment	(262,013)	(564,415)
Net cash (used in) provided by investing activities	(443,002)	865,461
Financing activities		
Proceeds from exercise of stock options and warrants	836,188	1,083,953
Proceeds from shares purchased through employee stock purchase plan	210,777	72,236
Restricted Stock Units withheld for taxes	(33,959)	
Proceeds from sale of shares pursuant to common stock private placement, net	3,708,602	3,857,106
Proceeds from sale of shares of common stock in underwritten public offering, net of offering costs	8,975,960	
Proceeds from issuance of Series B convertible preferred stock upon warrant exercise, net	—	5,685,038
Payment of contingent consideration	(881,932)	(294,435)
Payment of long-term debt	(256,140)	—
Net cash provided by financing activities	12,559,496	10,403,898

(Decrease) increase in cash and cash equivalents	(7,017,838)	8,141,257
Cash, cash equivalents, and restricted cash at beginning of period	10,746,756	2,605,499
Cash, cash equivalents, and restricted cash at end of period	$ 3,728,918	$ 10,746,756
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 1,050,000	$ 525,000
Cash paid for taxes	$ 1,803,665	$ 354,000
Supplemental disclosures of non-cash investing and financing activities		
Leased asset obtained in exchange for new operating lease liability	$ 743,025	$ —
Debt assumed in Avadel Pediatric Products acquisition	$ —	$ (15,075,000)

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,	
	2019	**2018**
Cash and cash equivalents	$ 3,609,438	$ 10,646,301
Restricted cash, current portion	17,535	18,730
Restricted cash, net of current portion	101,945	81,725
Total cash, cash equivalents and restricted cash	$ 3,728,918	$ 10,746,756

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	Contingently issuable stock	Accumulated	Total stockholders'
	Shares	Amount	Shares	Amount	capital	Amount	deficit	equity
Balance, December 31, 2017	31,266,989	$ 31,268	—	$ —	$ 83,338,136	$ 2,655,464	$ (58,165,260)	$ 27,859,608
Issuance of contingently issuable shares in acquisition of TRx	2,349,968	2,350		—	2,653,114	(2,655,464)	—	—
Issuance of shares pursuant to common stock private placement, net of offering costs	1,000,000	1,000		—	3,856,106	—	—	3,857,106
Issuance of shares in acquisition of Ichorion assets	5,774,464	5,774		—	19,965,780	—	—	19,971,554
Issuance of Series B convertible preferred stock upon warrant exercise, net of offering costs		—	2,857,143	2,857	5,682,181	—	—	5,685,038
Exercise of stock options and warrants	370,361	370		—	1,083,583	—	—	1,083,953
Shares purchased through employee stock purchase plan	42,407	42		—	72,194	—	—	72,236
Stock-based compensation		—		—	2,431,063	—	—	2,431,063
Net loss		—		—	—	—	(40,052,810)	(40,052,810)
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

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, 2019 and 2018

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 pediatric and orphan diseases. The Company is advancing an emerging clinical-stage pipeline of innovative therapies that address unmet patient needs within rare pediatric and orphan diseases. The Company's pediatric rare disease pipeline is led by CERC-801, CERC-802 and CERC-803 ("CERC-800 compounds"), which are therapies for inherited metabolic disorders known as Congenital Disorders of Glycosylation ("CDGs"). The U.S. Food and Drug Administration ("FDA") granted Rare Pediatric Disease designation ("RPDD") and Orphan Drug Designation ("ODD") to all three CERC-800 compounds, thus potentially qualifying the Company to receive a Priority Review Voucher ("PRV") upon approval of each New Drug Application ("NDA"). Each PRV may be sold or transferred an unlimited number of times. The Company plans to leverage the 505(b)(2) NDA pathway for all three compounds to accelerate development and approval. Additionally, CERC-801 and CERC-802 were granted Fast Track Designation ("FTD") from the FDA, which can help facilitate and potentially expedite development of each compound.

The Company is also developing CERC-002, CERC-006 and CERC-007. CERC-007 is an anti-IL-18 monoclonal antibody being developed for the treatment of autoimmune inflammatory diseases such as Adult Onset Stills Disease ("AOSD") and Multiple Myeloma. CERC-006 is a dual mTOR inhibitor being developed for the treatment of complex Lymphatic Malformations. CERC-002 is an anti-LIGHT (**L**ymphotoxin-like, exhibits **I**nducible expression, and competes with HSV **G**lycoprotein D for **H**VEM, a receptor expressed by **T** lymphocytes) monoclonal antibody being developed for the treatment of Pediatric-onset Crohn's Disease.

The Company continues to explore strategic alternatives for its non-core assets, including CERC-301, as well as its sole commercialized product, Millipred®, an oral prednisolone indicated across a wide variety of inflammatory conditions.

On February 3, 2020, the Company consummated its two-step merger (the "Merger") with Aevi Genomic Medicine, Inc. ("Aevi") in accordance with the terms of the Agreement and Plan of Merger and Reorganization (the "Merger Agreement") dated December 5, 2019. The Merger consideration included stock valued at approximately $15.6 million, resulting in the issuance of approximately 3.9 million shares of Cerecor common stock to Aevi stockholders, forgiveness of a $4.1 million loan that Cerecor loaned Aevi in December 2019 (the "Aevi Loan"), and contingent value rights ("CVRs") for up to an additional $6.5 million in subsequent payments based on clinical and/or regulatory milestones. As part of the Merger, Cerecor acquired CERC-002, CERC-006 and CERC-007, expanding Cerecor's pipeline to six clinical stage assets being developed for rare pediatric and orphan diseases. Effective upon the consummation of the Merger, Cerecor entered into an employment agreement with Mike Cola for him to serve as Cerecor's Chief Executive Officer, an employment agreement with Dr. Garry Neil for him to serve as Cerecor's Chief Medical Officer and appointed Mike Cola and Sol J. Barer, Ph.D. to the Company's Board of Directors. See Note 17 for more information.

During the fourth quarter of 2019, the Company entered into, and closed on, an asset purchase agreement (the "Aytu Purchase Agreement") with Aytu BioScience, Inc. (“Aytu”) 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"). Aytu paid consideration of $4.5 million in cash and approximately 9.8 million shares of Aytu convertible preferred stock (the "Investment"), and assumed certain of the Company’s liabilities, including the Company’s payment obligations payable to Deerfield CSF, LLC of $15.1 million and other liabilities of $11.0 million. The Company recognized a gain of $8.0 million upon the closing of the Aytu Divestiture. As a result of the sale of the Pediatric Portfolio, the Pediatric Portfolio met all conditions required in order to be classified as discontinued operations. Therefore, operating results from the Pediatric Portfolio are reported within income (loss) from discontinued operations, net of tax (inclusive of gain on sale) for all periods presented and the gain recognized as a result of the sale is reported within income from discontinued operations, net of tax (inclusive of gain on sale) for the year ended December 31, 2019. In addition, 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, 2019 and 2018. See Note 3 for more information regarding the Aytu Divestiture and its accounting treatment.

Cerecor was incorporated in 2011, commenced operations in the second quarter of 2011 and completed an initial public offering in October 2015.

Liquidity

During the first quarter of 2019, the Company closed on an underwritten public offering of common stock for 1,818,182 shares of common stock of the Company, at a price to the public of $5.50 per share ("public price"). Armistice Capital Master Fund Ltd. ("Armistice"), the Company's largest stockholder, participated in the offering by purchasing 363,637 shares of common stock of the Company at the public price. Cerecor director, Steven J. Boyd, is Armistice's Chief Investment Officer. The net proceeds of the offering were approximately $9.0 million. During the third quarter of 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 a purchase price of $3.132 per share. Net proceeds of the private placement were approximately $3.7 million. During the fourth quarter of 2019, the Company entered into, and subsequently closed on, the Aytu Purchase Agreement to sell the Company's rights, title and interest in, assets relating to its Pediatric Portfolio and related commercial infrastructure for a combination of cash and preferred stock ($4.5 million in cash, and approximately 9.8 million shares of Aytu convertible preferred stock) and the assumption of certain of the Company's liabilities including the Company's payment obligations payable to Deerfield of $15.1 million and certain other liabilities of approximately $11.0 million. During the first quarter of 2020, the Company closed on a registered direct offering with institutional investors of 1,306,282 shares of the Company's common stock at a purchase price of $3.98 per share. Armistice participated in the offering by purchasing 1,256,282 shares of common stock from the Company. The net proceeds of the offering were approximately $5.0 million.

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, 2019, Cerecor generated a net loss of $16.1 million and negative cash flow from operations of $19.1 million. As of December 31, 2019, Cerecor had an accumulated deficit of $114.3 million and $3.6 million in cash and cash equivalents.

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern; however, the Company expects to incur additional losses in the future in connection with research and development activities and will require additional financing to fund its operations and to continue to execute its strategy. The Company plans to use its current cash on hand and the anticipated cash flows from the Company's profits from Millipred product sales and/or the potential proceeds from the out-license or sale of Millipred to a third party to offset costs related to its orphan disease pipeline assets, business development, and costs associated with its organizational infrastructure; however, Cerecor expects to continue to incur significant expenses and operating losses for the immediate future as it continues to invest in the Company's pipeline assets. The Company's ability to continue as a going concern through 2020 is dependent upon the Company's ability to raise additional equity and/or debt capital; however, there can be no assurance that such capital will be available in sufficient amounts or on terms acceptable to the Company.

Over the long term, the Company's ultimate ability to achieve and maintain profitability is dependent on, among other things, the development, regulatory approval, and commercialization of its pipeline assets, and the potential sale of any PRVs it receives, all being adequate to support its cost structure and pipeline asset development.

These conditions raise substantial doubt about its ability to continue as a going concern within one year after the date that the financial statements are issued. To alleviate these conditions, the Company is evaluating the potential out-licensing or sale of Millipred to a third party and some combination of rights to future PRV sales, equity or debt financings, collaborations, out-licensing arrangements, strategic alliances, federal and private grants, marketing, distribution or licensing arrangements, the sale of current or future assets or possible monetization of the Company's holdings of Aytu equity. 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 is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible or suspend or curtail planned programs. Due to the uncertainty regarding future financings and/or 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 are issued.

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.

Variable Interest Entities

The primary beneficiary of a variable interest entity ("VIE") must consolidate the related assets and liabilities. Certain disclosures are required by sponsors, significant interest holders in VIEs and potential VIEs. The Company regularly assesses its relationships with contractual third-party and other entities for potential VIEs, including its relationship with Aytu and Aevi. In making this assessment, the Company considers the potential that its contracts or other arrangements provide subordinated financial support, absorb losses or rights to residual returns of the entity and the ability to directly or indirectly make decisions about the entities' activities. Based on the Company's assessments, management concluded that there were no relationships that constitute a VIE for which the Company was determined to be the primary beneficiary at December 31, 2019. If the Company's management makes the determination that it is the primary beneficiary of a VIE, the Company will consolidate the statements of operations and financial condition of the VIE into its consolidated financial statements.

Discontinued Operations

As a result of the sale of the Pediatric Portfolio, as of December 31, 2019, the Pediatric Portfolio met all conditions required in order to be classified as discontinued operations. Accordingly, the operating results of the Pediatric Portfolio are reported as income (loss) from discontinued operations, net of tax (inclusive of gain on sale) in the accompanying consolidated financial statements for the years ended December 31, 2019 and 2018. Additionally, the gain recognized as a result of the sale of the Pediatric Portfolio is reported within income from discontinued operations, net of tax (inclusive of gain on sale) 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, 2019 and 2018. 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 (including those relating to contingent consideration, equity Investment in Aytu, and guaranteed liabilities), 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.

Certain estimates related specifically to the Pediatric Portfolio, such as revenue, cost of product sales, fair value measurement (including those relating to contingent consideration), goodwill, and other intangible assets have been reclassified under discontinued operations and included in assets and liabilities of discontinued operations.

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 "Plan") deposits, security deposit for our corporate headquarters lease and credit card deposits.

The Company adopted ASU No. 2016-18, *Restricted Cash* ("ASU 2016-18") effective January 1, 2018 and now includes restricted cash balances within the cash, cash equivalents and restricted cash balance on the statement of cash flows.

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, 2019, 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.

Inventory

Inventory consists primarily of finished goods stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis. The Company reviews the composition of inventory at each reporting period in order to identify obsolete, slow-moving, quantities in excess of expected demand, or otherwise non-saleable items. If non-saleable items are observed and there are no alternate uses for the inventory, the Company will record a write-down to net realizable value in the period that the decline in value is first recognized. These valuation adjustments are recorded based upon various factors for the Company’s products, including the level of product manufactured by the Company, the level of product in the distribution channel, current and projected product demand, the expected shelf life of the product and firm inventory purchase commitments.

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 one operating lease, which is for its corporate headquarters. 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 condensed 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 condensed consolidated balance sheet 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, 2019, the Company's chief operating decision makers were the Chief Financial Officer and the Executive Chairman of the Board. The CFO and the Executive Chairman of the Board view 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

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, we assign 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 and is reclassified within discontinued operations.

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

As a result of the Aytu Divestiture, all product revenues related to the Pediatric Portfolio (which represented approximately 60% of total product revenues for the year ended December 31, 2019) are included within net income (loss) from discontinued operations, net of tax (inclusive of gain on sale).

The Company generates substantially all of its revenue from sales of prescription pharmaceutical products to its customers and has identified a single product delivery performance obligation, which is the provision of prescription pharmaceutical products 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.

The following table presents net revenues disaggregated by type:

	Year Ended December 31,	
	2019	2018
Prescription drugs	$ 6,650,351	$ 6,572,322
Sales force revenue	—	456,056
License and other revenue	100,000	—
Total revenues, net from continuing operations	$ 6,750,351	$7,028,378

Concentration with Customer

As is typical in the pharmaceutical industry, the Company sells its prescription pharmaceutical products (which include 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, 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 from continuing operations. For the year ended December 31, 2018, the Company's three largest customers accounting for approximately 31%, 29% and 28%, respectively, of the Company's total net product revenues of prescription drugs from continuing operations.

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, but the principal factor relates to the level of inventory in the distribution channel.

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.

Sales Force Revenue

Pursuant to a marketing agreement with Pharmaceutical Associates, Inc. ("PAI"), the Company received a monthly marketing fee to promote, market and sell certain products on behalf of PAI. The Company was also entitled to a share of PAI's profits under the agreement. Marketing fees and profit-sharing was recognized as sales force revenue when all the performance obligations have been satisfied and to the extent that it was probable that a significant revenue reversal would not occur in a future period. The marketing agreement with PAI was terminated in April 2018.

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 re-assess the milestones each reporting period to determine the probability of achievement.

Accounting Policy Elections Related to Adoption of New Revenue Recognition Standard

The Company elected the following practical expedients in applying ASU 2014-09, Revenue from Contracts with Customers ("Topic 606") to its identified revenue streams:

- Portfolio approach - contracts within each revenue stream have similar characteristics and the Company believes this approach would not differ materially than if applying Topic 606 to each individual contract.
- Modified retrospective approach - the Company applied Topic 606 only to contracts with customers that were not completed at the date of initial application, January 1, 2018.
- Significant financing component - the Company does not adjust the promised amount of consideration for the effects of a significant financing component as the Company expects, at contract inception, that the period between when the Company transfers a promised good or service to a customer and when the customer pays for that good or service will be one year or less.
- Shipping and handling activities - the Company considers any shipping and handling costs that are incurred after the customer has obtained control of the product as a cost to fulfill a promise and will account for them as an expense.
- Contract costs - the Company recognizes the incremental costs of obtaining a contract as an expense when incurred if the amortization period of the asset that the Company otherwise would have recognized is one year or less.

The Company does not incur costs to obtain a contract or costs to fulfill a contract that would result in the capitalization of contract costs. Specifically, internal sales commissions are costs to fulfill a contract and are expensed in the same period that revenue is recognized, which is typically within the same quarterly reporting period. Contract costs are expensed or amortized in "Operating expenses" on the accompanying Consolidated Statements of Operations.

The Company has not made significant changes to the judgments made in applying Topic 606 for the year ended December 31, 2019.

Cost of Product Sales

Cost of product sales is comprised of (i) costs to acquire products sold to customers, (ii) royalty, license payments and other agreements granting the Company rights to sell related products, (iii) distribution costs incurred in the sale of products; (iv) the value of any write-offs of obsolete or damaged inventory that cannot be sold, (v) minimum sale obligations and (vi) minimum purchase obligations.

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, employee-related expenses, including salaries, benefits and stock-based compensation of research and development personnel; 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; other supplies; facilities, depreciation and other expenses, such as direct and allocated expenses for rent, utilities and insurance; and costs associated with preclinical activities and regulatory operations, pharmacovigilance, quality and travel.

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.

Estimated Fair Value and Change in Fair Value of Contingent Consideration

The Company's business acquisitions of Avadel Pharmaceuticals PLC's ("Avadel") pediatric products and TRx Pharmaceuticals, LLC ("TRx") involved the potential for future payment of consideration that is contingent upon the achievement of operation and commercial milestones and royalty payments on future product sales. 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 statements of operations.

As part of the Aytu Divestiture, Aytu assumed the Company's contingent consideration liability related to future royalties on Avadel's pediatric products. Additionally, 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 TRx. Therefore, the Company's contingent consideration liability was $0 as of December 31, 2019. Refer to Note 6 for more information.

There is no change in fair value of contingent consideration included in cost of product sales or research and development costs. For the year ended December 31, 2019 and 2018, the change in fair value of contingent consideration related to royalties on Avadel's pediatric products was included within net income (loss) from discontinued operations, net of tax (inclusive of gain on sale). The change in fair value of contingent consideration related to TRx was included within its own standalone line in operating expenses from continuing operations in the Company's consolidated statements of operations because the contingent consideration was related to a product that was not sold as part of the Aytu Divestiture.

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, the Company received approximately 9.8 million shares of Aytu Series G Convertible Preferred Stock. Pursuant to ASC 323, the Company accounts 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 our shares being restricted as of December 31, 2019 and subject to a lockup period ending on July 1, 2020. Subsequent to the divestiture date, at each reporting period, the Investment in Aytu will be remeasured at current fair value with the change in fair value recorded to other income, net in the accompanying statements of operations. The Investment in Aytu is recorded in the consolidated balance sheet as a current asset because it is available for sale within one year of December 31, 2019.

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 and the contingent consideration liability related to future royalties on Avadel's pediatric products. In conjunction with the closing of the Aytu Divestiture in the fourth quarter of 2019, the Company entered into a Guarantee, which guarantees the payment of the assumed debt obligation and contingent consideration. The fair value of the Guarantees were 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 Guarantee will be remeasured at its current fair value with changes recorded in income (loss) from discontinued operations, net of tax within the consolidated statements of operations. Refer to Note 3 for more information.

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.

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 risk-free interest rate, the expected volatility of a peer group of similar companies, the expected term of the awards and the expected dividend yield. The expected term for market-based stock option awards is based on the expected term calculated using a Monte-Carlo simulation. 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 (the "IRC"). See Note 15 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, 2019, the Company did not believe any material uncertain tax positions were present.

Recently Adopted Accounting Pronouncements

Adoption of ASC 842

In February 2016, FASB issued ASU 2016-02, which revises existing practice related to accounting for leases under ASC No. 840, *Leases* (“ASC 840”) for both lessees and lessors. The new guidance in ASU 2016-02 requires lessees to recognize a ROU asset and a lease liability for nearly all leases (other than leases that meet the definition of a short-term lease). The lease liability will be equal to the present value of lease payments and the ROU asset will be based on the lease liability, subject to adjustment such as for initial direct costs. For income statement purposes, the new standard retains a dual model similar to ASC 840, requiring leases to be classified as either operating leases or finance leases. For lessees, operating leases will result in straight-line expense (similar to current accounting by lessees for operating leases under ASC 840) while finance leases will result in a front-loaded expense pattern (similar to current accounting by lessees for capital leases under ASC 840).

The Company adopted the standard using the modified retrospective transition method on its effective date of January 1, 2019 and therefore did not adjust prior comparative periods as permitted by the codification improvements issued by FASB in July 2018. Additionally, the Company elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allows the Company to carryforward the historical lease classification. Additionally, the Company made an accounting policy election to keep leases with an initial term of 12 months or less off the balance sheet. As a result of the standard, the Company recorded a lease liability of $1.2 million and a ROU asset of $0.7 million, which is equal to the initial measurement of the lease liability reduced by the unamortized balance of lease incentive received and deferred rent. There was no material impact to our condensed consolidated income statement. For additional information see Note 9.

Other Adopted Accounting Pronouncements

SEC Simplification

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532 Disclosure Update and Simplification, to eliminate or modify certain disclosure rules that are redundant, outdated, or duplicative of GAAP or other regulatory requirements. Among other changes, the amendments provide that disclosure requirements related to the analysis of stockholders' equity are expanded for interim financial statements. An analysis of the changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The Company began providing this disclosure in the first quarter of 2019 within a separate statement.

New Accounting Pronouncements- Pending Adoption

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. The Company is assessing any potential impacts on its internal controls, business processes, and accounting policies related to both the implementation of, and ongoing compliance with, the new guidance. Upon adoption of the new standard on January 1, 2020, the Company will begin recognizing an allowance using a forward-looking approach to estimate the expected credit loss related to financial assets. The Company is currently evaluating the potential impact of the adoption of this standard, however, does not expect that the adoption of this new standard will have a material 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 will be effective for the Company on January 1, 2020. The Company is currently evaluating the potential impact of the adoption of this standard on its financial statements.

Income Tax Simplification

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740)(ASU 2019-12) 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 is currently evaluating the potential impact of the adoption of this standard on its financial statements.

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, 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™ 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 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 of $15.1 million and certain other liabilities of $11 million primarily related to contingent consideration, Medicaid rebates and sales returns. In addition, Aytu assumed future contractual obligations under existing license agreements associated with the Pediatric Portfolio. Armistice, a significant stockholder of the Company, is also a significant stockholder of Aytu.

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 will manage Millipred® commercial operations for a monthly fee of $12,000 for up to 18 months or until the Company establishes an independent commercial infrastructure for the product.

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 CSF ("Deerfield"), which guarantees the payment by Aytu of the assumed liabilities to Deerfield, which includes 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. Therefore, Cerecor's Fixed Payment Guarantee will end on January 31, 2021, upon the $15.0 million balloon payment being made to Deerfield. The contingent consideration assumed by Aytu consists of quarterly deferred payments equal to 15% of net sales of certain Pediatric Portfolio 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. $3.2 million of the contingent consideration 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 except the monthly Deferred Payment due on January 31, 2020 will be at least $0.2 million. 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 perform 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. As of December 31, 2019, the maximum potential amount of future payments under the Guarantee was $25.2 million, consisting of $16.1 million for the Fixed Payment Guarantee and $9.1 million for the Deferred Payment Guarantee.

As of December 31, 2019, the fair value of the Guarantee was $1.8 million, consisting of $0.9 million for the Fixed Payment Guarantee and $0.9 million for the Deferred Payment Guarantee. The Guarantee is recorded within long-term liabilities of discontinued operations in the accompanying consolidated balance sheet as of December 31, 2019.

The estimated fair value of Cerecor's Fixed Payment Guarantee as of December 31, 2019 was estimated as the difference between (i) the estimated value of the fixed payments using Cerecor's estimated cost of debt, and (ii) the estimated value of fixed payments using Aytu's estimated cost of debt. Specifically, the significant assumptions used in the estimated fair value of the Fixed Payment Guarantee as of December 31, 2019 include (i) future fixed monthly payments of $0.1 million from January 2020 through January 2021 and the additional balloon payment of $15.0 million due to Deerfield on January 31, 2021, (ii) Cerecor's estimated cost of debt, and (iii) Aytu's estimated cost of debt. Cerecor and Aytu's estimated cost of debt was estimated using a synthetic credit rating model, based on each company's financial performance as of December 31, 2019.

The estimated fair value of Cerecor's Deferred Payment Guarantee as of December 31, 2019 was estimated as the difference between (i) the value of the estimated contingent payments using Cerecor's estimated cost of debt, and (ii) the value of the estimated contingent payments using Aytu's cost of debt. Specifically, the significant assumptions used in estimating the fair value of the Deferred

Payment Guarantee as of December 31, 2019 include (i) simulated net sales of the Pediatric Products subject to the deferred payments, (ii) the estimated contingent payments according to the contractual terms based on the simulated net sales, (iii) Cerecor's cost of debt, and (iv) Aytu's cost of debt. Cerecor and Aytu's estimated cost of debt was estimated using a synthetic credit rating model, based on each company's financial performance as of December 31, 2019.

Discontinued Operations

As a result of the sale of the Pediatric Portfolio, as of December 31, 2019, the operating results from the Pediatric Portfolio are reported as income (loss) from discontinued operations, net of tax (inclusive of gain on sale) in the accompanying consolidated statements of operations. Accordingly, the accompanying consolidated financial statements for the years ended December 31, 2019 and 2018 reflect the operations and related assets and liabilities of the Pediatric Portfolio as a discontinued operation. During the quarter and year ended December 31, 2019, the Company recognized a gain of $8.0 million upon the close of the transaction, which is included in income (loss) from discontinued operations, net of tax (inclusive of gain on sale) in the accompanying consolidated statement of operation for the year ended December 31, 2019. The gain is 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 following tables summarizes the assets and liabilities of the discontinued operations as of December 31, 2019 and 2018:

	December 31,	
	2019	2018
Assets		
Current assets:		
Accounts receivable, net	$ 497,577	$ 2,335,228
Other receivables	—	206,798
Inventory, net	—	792,857
Prepaid expenses and other current assets	—	797,562
Total current assets of discontinued operations	497,577	4,132,445
Intangibles assets, net	—	27,474,214
Goodwill	—	2,002,035
Total long-term assets of discontinued operations	—	29,476,249
Liabilities		
Current liabilities:		
Accounts payable	387,975	—
Accrued expenses and other current liabilities	3,503,037	5,402,494
Long-term debt, current portion	—	1,050,000
Contingent consideration, current portion	—	1,097,137
Total current liabilities of discontinued operations	3,891,012	7,549,631
Long term debt, net of current portion	—	14,327,882
Contingent consideration, net of current portion	—	6,697,217
Other long-term liabilities	1,755,000	—
Total long-term liabilities of discontinued operations	1,755,000	21,025,099

Subsequent to the closing of the Aytu Divestiture on November 1, 2019, Cerecor retains continuing involvement with the divested Pediatric Portfolio mainly surrounding collection of accounts receivable associated with sales of Pediatric Portfolio prior to November 1, 2019, future sales returns made after November 1, 2019 relating to sales of the Pediatric Portfolio prior to the close date of the Aytu Divestiture and the Deerfield Guarantee of $1.8 million (discussed in detail above).

As of December 31, 2019, Cerecor is entitled to the $0.5 million of accounts receivable associated with sales of the Pediatric Portfolio prior to November 1, 2019. The Company expects it will collect the accounts receivable in 2020. Additionally, 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. As of December 31, 2019, the Company estimated its sales return reserve from discontinued operations to be $2.3 million, which is included above in accrued expenses and other current liabilities from discontinued operations. 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 as of November 1, 2019, which will be recognized in loss from 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, which, in line with the products' return policies, returns on these products may be accepted through 2023.

The following table summarizes the results of discontinued operations for the year ended December 31, 2019 and 2018:

	Year Ended December 31,	
	2019	2018
Product revenue, net	$ 10,166,611	$ 11,298,423
Operating expenses:		
Cost of product sales	4,288,234	4,217,594
General and administrative	137,911	165,674
Sales and marketing	8,521,190	7,977,243
Amortization expense	2,425,083	2,703,896
Impairment of intangible assets	1,449,121	—
Change in fair value of contingent consideration	247,042	169,289
Total operating expenses	17,068,581	15,233,696
Interest expense, net	(793,860)	(827,882)
Gain on sale of Pediatric Portfolio	7,964,924	—
Income (loss) from discontinued operations before tax	269,094	(4,763,155)
Income tax expense	70,888	15,556
Income (loss) from discontinued operations, net of tax (inclusive of gain on sale)	$ 198,206	$ (4,778,711)

The significant non-cash operating items from the discontinued operations for the years ended December 31, 2019 and 2018 are contained below. There were no non-cash investing items from the discontinued operations for the years ended December 31, 2019 and 2018.

	Year Ended December 31,	
	2019	2018
Operating activities		
Amortization	$ 2,425,083	$ 2,703,896
Impairment of intangible assets	1,449,121	—
Stock-based compensation, excluding amount included within gain on sale of Pediatric Portfolio	327,180	137,082
Amortization of inventory fair value adjustment associated with acquisition of TRx and Avadel Pediatric Product	107,271	170,629
Non-cash interest expense	—	302,882
Gain on Aytu Divestiture	(7,964,924)	—
Change in fair value of contingent consideration liability	247,042	169,289

4. Net (Loss) Income Per Share of Common Stock, Basic and Diluted

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 Series B Convertible Preferred Stock ("convertible preferred stock"). The 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. The convertible preferred stock is considered a separate class of stock for EPS purposes, however basic and diluted EPS was not provided for the convertible preferred stock for the year ended December 31, 2018 because the shares were only outstanding for five days in 2018, and therefore, EPS for the preferred stock is immaterial for the year ended December 31, 2018. EPS for both common stock and preferred stock is disclosed for the year ended December 31, 2019.

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; (ii) common stock to be issued upon the assumed conversion of the Company's unit purchase option (the "UPO") shares, which are included under the "if-converted method" when dilutive; and (iii) 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, 2019 and 2018, which includes both classes of participating securities:

	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 per share	$ (0.28)	$ 0.00	$ (1.42)	$ 0.01

	Year Ended December 31, 2018		
	Common stock		
	Continuing Operations	Discontinued Operations	Total
Numerator:			
Net loss	$ (35,274,099)	$ (4,778,711)	$ (40,052,810)
Deemed distribution to stockholder	1,657,383	—	1,657,383
Allocation of undistributed net loss to common stockholders	$ (36,931,482)	$ (4,778,711)	$ (41,710,193)
Denominator:			
Weighted average shares	34,773,613	34,773,613	34,773,613
Basic and diluted net loss per share	$ (1.06)	$ (0.14)	$ (1.20)

As part of a private placement with Armistice entered into during the fourth quarter of 2018, the Company also entered into a securities purchase agreement with Armistice pursuant to which the Company issued warrants to purchase up to 4,000,000 shares of the Company's common stock with a term of 5.5 years and an exercise price of $12.50 per share (the "incentive warrants"). For accounting purposes, the Company calculated the fair value of the incentive warrants of $1.7 million, which was considered a deemed distribution to Armistice for the year ended December 31, 2018. Therefore, the net loss of $40.1 million for the year ended December 31, 2018 was increased by the deemed distribution of $1.7 million to arrive at the net loss attributable to common stockholders of $41.7 million. While the incentive warrants do have the rights to participate in undistributed earnings, the incentive warrants issued do not share in net losses of the Company. As such, the incentive warrants are excluded from the weighted average shares and warrants outstanding during periods of net loss.

The following outstanding securities at December 31, 2019 and 2018 have been excluded from the computation of diluted weighted shares outstanding, as they could have been anti-dilutive:

	December 31,	
	2019	2018
Stock options	4,480,606	4,246,597
Warrants on common stock	4,024,708	4,024,708
Restricted Stock Units	267,500	445,000
Underwriters' unit purchase option	40,000	40,000

5. Acquisitions

Ichorion Asset Acquisition

On September 24, 2018, the Company entered into, and subsequently consummated the transactions contemplated by, an agreement and plan of merger (the "Ichorion Merger Agreement") by and among the Company and Ichorion Therapeutics, Inc., a Delaware corporation (the “Ichorion Asset Acquisition”), with Ichorion surviving as a wholly owned subsidiary of the Company. The consideration for the Ichorion Asset Acquisition consisted of approximately 5.8 million shares of the Company’s common stock, as adjusted for Estimated Working Capital as defined in the Ichorion Merger Agreement. The shares of common stock issued as part of the acquisition may not be resold until January 2020. Consideration for the Ichorion Asset Acquisition includes certain development milestones worth up to an additional $15.0 million, payable either in shares of the Company's common stock or in cash, at the election of the Company.

The fair value of the common stock shares transferred at closing was approximately $20.0 million using the Company's closing stock price on September 24, 2018 and offset by an estimated discount for lack of marketability calculated using guideline public company volatility for comparable companies. The assets acquired consisted primarily of $18.7 million of IPR&D, $1.6 million of cash and $0.2 million assembled workforce. The Company recorded this transaction as an asset purchase as opposed to a business combination as management concluded that substantially all of the value received was related to one group of similar identifiable assets which was the IPR&D for the three preclinical therapies for inherited metabolic disorders known as CDGs (CERC-801, CERC-802 and CERC-803). The Company considered these assets similar due to similarities in the risks for development, compound type, stage of development, regulatory pathway, patient population and economics of commercialization.

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. The acquired IPR&D expense was not tax deductible for the year ended December 31, 2018. The $0.2 million of transaction costs incurred were recorded to acquire IPR&D expense. The assembled workforce asset recorded to intangible assets will be amortized over an estimated useful life of two years.

The contingent consideration of up to an additional $15.0 million relates to three future development milestones. The first milestone is the first product to be 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, 2019, no contingent consideration related to the development milestone has been recognized. The Company will continue to monitor the development milestones at each reporting period.

Acquisitions of Businesses

Avadel Pediatric Products Acquisition

As part of the Company's Aytu Divestiture, Cerecor sold its rights, title and interest in each of the marketed pediatric products it initially acquired from Avadel in 2018, which included Aciphex® Sprinkle™, Cefaclor for Oral Suspension, Karbinal™ ER, Flexichamber™.

On February 16, 2018, the Company entered into an Asset Purchase Agreement (the “Purchase Agreement”) with Avadel US Holdings, Inc., Avadel Pharmaceuticals (USA), Inc., Avadel Pediatrics, Inc., Avadel Therapeutics, LLC and Avadel Pharmaceuticals PLC (collectively, the “Sellers”) to purchase and acquire all rights to the Sellers’ pediatric products. Total consideration transferred to the Sellers consisted of a cash payment of one dollar. In addition, the Company assumed existing seller debt due in January 2021 with a fair value of $15.1 million and contingent consideration relating to royalty obligations through February 2026 with a fair value at acquisition date of approximately $7.9 million. As a result of the Avadel pediatric products acquisition, the Company recorded goodwill of $3.8 million, which is deductible over 15 years for income tax purposes.

The transaction was accounted for as a business combination under the acquisition method of accounting. Accordingly, the tangible and identifiable intangible assets acquired and liabilities assumed were recorded at fair value as of the date of acquisition, with the remaining purchase price recorded as goodwill. The goodwill recognized is attributable primarily to strategic opportunities related to an expanded commercial footprint and diversified pediatric product portfolio that is expected to provide revenue and cost synergies.

During the second quarter of 2018, the Company identified and recorded measurement period adjustments to the preliminary purchase price allocation. These adjustments are reflected in the tables below. The measurement period adjustments were the result of additional analysis performed and information identified during the second quarter of 2018 based on facts and circumstances that existed as of the purchase date. There were no additional measurement adjustments recorded in 2018.

The following table summarizes the preliminary fair values of the assets acquired and liabilities assumed at the date of acquisition and as adjusted for measurement period adjustments identified during the second quarter of 2018:

	At February 16, 2018 (preliminary)	Measurement Period Adjustments	At February 16, 2018 (as adjusted)
Inventory	$ 2,549,000	$ (1,831,000)	$ 718,000
Prepaid assets	—	570,000	570,000
Intangible assets	16,453,000	1,838,000	18,291,000
Accrued expenses	—	(362,000)	(362,000)
Fair value of debt assumed	(15,272,303)	197,303	(15,075,000)
Fair value of contingent consideration	(7,875,165)	(44,835)	(7,920,000)
Total net liabilities assumed	(4,145,468)	367,468	(3,778,000)
Consideration exchanged	241,000	(240,999)	1
Goodwill	$ 4,386,468	$ (608,467)	$ 3,778,001

The purchase price allocation related to the acquisition of Avadel's pediatric products was finalized in 2018. The fair values of intangible assets, including marketing rights, licenses and developed technology, were determined using variations of the income approach. Varying discount rates were also applied to the projected net cash flows. The Company believes the assumptions are representative of those a market participant would use in estimating fair value. The fair value of intangible assets both as of the date of acquisition and as adjusted by measurement period adjustments identified during the second quarter of 2018 includes the following:

	At February 16, 2018 (preliminary)	Measurement Period Adjustments	At February 16, 2018 (as adjusted)
Acquired Product Marketing Rights - Karbinal	$ 6,221,000	$ (21,000)	$ 6,200,000
Acquired Product Marketing Rights - AcipHex	2,520,000	283,000	2,803,000
Acquired Product Marketing Rights - Cefaclor	6,291,000	1,320,000	7,611,000
Acquired Developed Technology - Flexichamber	1,131,000	546,000	1,677,000
Acquired IPR&D - LiquiTime formulations	290,000	(290,000)	—
Total	$ 16,453,000	$ 1,838,000	$ 18,291,000

During the second quarter of 2019, the Company made a strategic decision to eliminate sales force efforts related to selling Flexichamber (other than the limited inventory currently on hand). As a result of this decision, paired with significant deviations from forecasted sales, management identified an impairment indicator for Flexichamber. Accordingly, during the second quarter of 2019, the Company performed a test for recoverability and concluded that the sum of its estimated future undiscounted cash flows was less than its carrying value of $1.4 million. Management then measured the impairment loss by calculating the excess of Flexichamber's carrying amount over its fair value. Management determined that due to the absence of future material cash flows the fair value of Flexichamber as of June 30, 2019, which is considered a Level 3 nonrecurring fair value measurement, was $0. Accordingly, a full impairment in the amount of $1.4 million was recognized within income (loss) from discontinued operations, net of tax (inclusive of gain on sale) for the year ended December 31, 2019 because Flexichamber was part of the Aytu Divestiture. In addition, because the Company expected the sale of remaining inventory on hand will not generate material cash flows, the Company wrote down the existing inventory on hand as of June 30, 2019 to $0, which resulted in $0.2 million charge to cost of product sales of discontinued operations during the year ended December 31, 2019.

TRx Acquisition

As part of the Company's Aytu Divestiture, Cerecor sold its rights, title and interest in Metafolin (also referred to as Poly-Vi-Flor/Tri-Vi-Flor) which it initially acquired as part of the TRx acquisition.

On November 17, 2017, the Company entered into, and consummated the transactions contemplated by, an equity interest purchase agreement (the “TRx Purchase Agreement”) by and among the Company, TRx, Fremantle Corporation and LRS International LLC, the selling members of TRx (collectively, the “TRx Sellers”), which provided for the purchase of all of the equity and ownership interests of TRx by the Company (the "TRx Acquisition"). The consideration for the TRx Acquisition consisted of $18.9 million in cash, as adjusted for estimated working capital, estimated cash on hand, estimated indebtedness and estimated transaction expenses, as well as 7,534,884 shares of the Company’s common stock having an aggregate value on the closing date of $8.5 million (the "Equity Consideration") and certain potential contingent payments. Upon closing, the Company issued 5,184,920 shares of its common stock to the TRx Sellers. Pursuant to the TRx Purchase Agreement, the issuance of the remaining 2,349,968 shares were subject to the Company's stockholder approval. In May 2018, stockholder approval was obtained and the remaining shares were issued to the TRx Sellers. The contingent shares were initially recorded to contingently issuable shares, which is recorded within stockholder's equity and were reclassed to common stock and additional paid in capital upon issuance, on the consolidating balance sheet date. As a result of the TRx Acquisition, the Company recorded goodwill of $12.6 million, of which $8.7 million was deductible for income taxes.

During the third quarter of 2018, the Company identified and recorded measurement period adjustments to its preliminary purchase price allocation that was disclosed in prior periods. These adjustments are reflected in the tables below. If the measurement period adjustments were reflected in the consolidated statement of operations for the year ended December 31, 2017 its impact would have been immaterial. The measurement period adjustments were the result of an arbitration ruling discussed in further detail in Note 16, the facts and circumstances of which existed as of the acquisition date.

The following table summarizes the preliminary acquisition-date fair value of the consideration transferred at the date of acquisition both as disclosed in prior periods prior to the third quarter of 2018 and as adjusted for measurement period adjustments identified during the third quarter of 2018:

	At November 17, 2017 (preliminary)	Measurement Period Adjustments	At November 17, 2017 (as adjusted)
Cash	$ 18,900,000	$ —	$ 18,900,000
Common stock (including contingently issuable shares)	8,514,419	—	8,514,419
Contingent payments	2,576,633	(1,210,000)	1,366,633
Total consideration transferred	$ 29,991,052	(1,210,000)	28,781,052

The TRx Acquisition was accounted for as a business combination under the acquisition method of accounting. Accordingly, the tangible and identifiable intangible assets acquired, and liabilities assumed, were recorded at fair value as of the date of acquisition, with the remaining purchase price recorded as goodwill. The goodwill recognized is attributable primarily to strategic opportunities related to leveraging TRx’s research and development, intellectual property, and processes.

The following table summarizes the preliminary fair values of the assets acquired and liabilities assumed at the date of acquisition both as disclosed in prior periods prior to the third quarter of 2018 and as adjusted for measurement period adjustments identified during the third quarter of 2018:

	At November 17, 2017 (preliminary)	Measurement Period Adjustments	At November 17, 2017 (as adjusted)
Fair value of assets acquired:			
Cash and cash equivalents	$ 11,068	$ —	$ 11,068
Accounts receivable, net	2,872,545	—	2,872,545
Inventory	495,777	—	495,777
Prepaid expenses and other current assets	134,281	—	134,281
Other receivables	—	2,764,515	2,764,515
Identifiable Intangible Assets:			—
Acquired product marketing rights - Metafolin (Poly-Vi-Flor/Tri-Vi-Flor)	10,465,000	1,522,000	11,987,000
PAI sales and marketing agreement	2,334,000	219,000	2,553,000
Acquired product marketing rights - Millipred	4,714,000	342,000	5,056,000
Acquired product marketing rights - Ulesfia	555,000	(555,000)	—
Total assets acquired	21,581,671	4,292,515	25,874,186
Fair value of liabilities assumed:			
Accounts payable	192,706	—	192,706
Accrued expenses and other current liabilities	4,850,422	3,764,515	8,614,937
Deferred tax liability	839,773	78,840	918,613
Total liabilities assumed	5,882,901	3,843,355	9,726,256
Total identifiable net assets	15,698,770	449,160	16,147,930
Fair value of consideration transferred	29,991,052	(1,210,000)	28,781,052
Goodwill	$ 14,292,282	$ (1,659,160)	$ 12,633,122

The purchase price allocation related to the TRx Acquisition was finalized in 2018. The fair values of intangible assets, including marketing rights, licenses and developed technology, were determined using variations of the income approach, specifically the multi-period excess earnings method. Varying discount rates were also applied to the projected net cash flows. The Company believes the assumptions are representative of those a market participant would use in estimating fair value. The final fair value of intangible assets both as disclosed in prior periods and as adjusted by measurement period adjustments identified during the third quarter of 2018 includes the following:

	At November 17, 2017 (preliminary)	Measurement Period Adjustments	At November 17, 2017 (as adjusted)
Acquired product marketing rights - Metafolin (Poly-Vi-Flor/Tri-Vi-Flor)	$ 10,465,000	$ 1,522,000	$ 11,987,000
PAI sales and marketing agreement	2,334,000	219,000	2,553,000
Acquired product marketing rights - Millipred	4,714,000	342,000	5,056,000
Acquired product marketing rights - Ulesfia	555,000	(555,000)	—
Total	$ 18,068,000	$ 1,528,000	$ 19,596,000

The Company received written notice to terminate the PAI sales and marketing agreement in the second quarter of 2018. As a result, the Company reassessed the fair value of the PAI sales and marketing agreement on that date (a level III non-recurring fair value measurement) and concluded due to the absence of future cash flows beyond the date of termination that the fair value was $0. An impairment charge was recognized in the year ended December 31, 2018 in the amount of $1.9 million, representing the remaining net book value of the PAI sales and marketing agreement intangible asset.

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 table presents, 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, 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	$ —
Liabilities			
Warrant liability**	$ —	$ —	$ 3,460
Unit purchase option liability**	$ —	$ —	$ 10,594

	December 31, 2018 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*	$ 7,324,932	$ —	$ —
Liabilities			
Contingent consideration	$ —	$ —	$ 1,256,210
Warrant liability**	$ —	$ —	$ 2,950
Unit purchase option liability**	$ —	$ —	$ 7,216

*Investments in money market funds are reflected in cash and cash equivalents on the accompanying consolidated balance sheets.

**Warrant liability and unit purchase option liability are reflected in accrued expenses and other current liabilities on the accompanying consolidated balance sheets.

As of December 31, 2019 and 2018, the Company's financial instruments included cash and cash equivalents, restricted cash, accounts receivable, other receivables, accounts payable, accrued expenses and other current liabilities, warrant liability, the underwriters' unit purchase option liability and contingent consideration. The carrying amounts reported in the accompanying consolidated financial statements for cash and cash equivalents, restricted cash, accounts receivable, other receivables, 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

The table presented below is a summary of changes in fair value of the Company's Level 2 valuation for the Investment in Aytu for the year ended December 31, 2019:

	Investment in Aytu
Balance at December 31, 2018	$ —
Initial valuation of Investment in Aytu upon issuance of Aytu Preferred Stock	7,575,015
Change in fair value of Investment in Aytu	53,932
Balance at December 31, 2019	$ 7,628,947

As part of the consideration for the Aytu Divestiture, Aytu issued to Cerecor 9,805,845 shares of Aytu Series G Convertible Preferred Stock (the "Aytu Series G Preferred Stock" or "Aytu Preferred Stock") at a price of $1.2747 per share, which, pursuant to the Aytu Purchase Agreement, represents a formula averaging the volume weighted average price of Aytu's common stock for the 30-day period ending immediately prior to August 30, 2019 and the 30-day period ending on October 28, 2019. The Aytu Series G Preferred Stock is not transferable until July 1, 2020. Further, the Aytu Series G Preferred Stock becomes convertible at the option of Cerecor and solely in connection with either (i) the distribution of the underlying shares of common stock issuable upon conversion to Cerecor's stockholders; or (ii) the sale of the underlying shares of common stock issuable upon conversion in open market broker transactions or private sales to unaffiliated third parties. The Aytu Series G Preferred Stock is similar to Aytu's common stock other than it has no voting rights, is subject to a lock-up period and is only convertible to common stock in certain circumstances. Additionally, the Aytu Series G Preferred Stock was restricted as of December 31, 2019.

Upon closing of the Aytu Divestiture on November 1, 2019, the Company recognized $7.6 million as the estimated fair value of the Aytu Series G Preferred Stock on that date. The fair value as of November 1, 2019 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 of 25% calculated using guideline public company volatility for comparable companies.

Subsequent to the initial measurement, at each reporting period, the Investment in Aytu will be remeasured at the current fair value with the change in fair value recorded to other income, net in the accompanying statements of operations. As of December 31, 2019, the Investment of Aytu was $7.6 million, representing an immaterial change from the initial measurement on November 1, 2019. The fair value as of December 31, 2019 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% calculated using guideline public company volatility for comparable companies. The Investment in Aytu is recorded in the consolidated balance sheet as a current asset because the Aytu Series G Preferred Stock is available for sale within one year of December 31, 2019. Subsequent to December 31, 2019, Aytu's common stock price has been volatile and therefore Cerecor may recognize a significant gain or loss on the change in fair value of the Investment in Aytu for the three months ending March 31, 2020 and any future reporting period based on actual movements in the underlying stock price.

Level 3 Valuation

The tables presented below are a summary of changes in the fair value of the Company's Level 3 valuations for the warrant liability, unit purchase option liability and contingent consideration from continuing operations for the years ended December 31, 2019 and 2018:

	Warrant liability	Unit purchase option liability	Contingent consideration	Total
Balance at December 31, 2018	$ 2,950	$ 7,216	$ 1,256,211	$ 1,266,377
Change in fair value due to Lachlan Settlement	—	—	(1,277,150)	(1,277,150)
Change in fair value	510	3,378	20,939	24,827
Balance at December 31, 2019	$ 3,460	$ 10,594	$ —	$ 14,054

	Warrant liability	Unit purchase option liability	Contingent consideration	Total
Balance at December 31, 2017	$ 8,185	$ 26,991	$ 2,577,134	$ 2,612,310
Purchase price allocation measurement period adjustment of contingent consideration	—	—	(1,210,000)	(1,210,000)
Change in fair value	(5,235)	(19,775)	(110,923)	(135,933)
Balance at December 31, 2018	$ 2,950	$ 7,216	$ 1,256,211	$ 1,266,377

In 2014, the Company issued warrants to purchase 625,208 shares of convertible preferred stock. Upon the closing of the Company's initial public offering ("IPO") in October 2015, these warrants became warrants to purchase 22,328 shares of common stock, in accordance with their terms. The warrants expire in October 2020. The warrants represent a freestanding financial instrument that is indexed to an obligation, which the Company refers to as the warrant liability. The warrant liability is marked-to-market each reporting period with the change in fair value recorded to other income, net in the accompanying statements of operations until the warrants are exercised, expire or other facts and circumstances lead the warrant liability to be reclassified to stockholders' equity. The fair value of the warrant liability is estimated using a Black-Scholes option-pricing model. The significant assumptions used in preparing the option pricing model for valuing the warrant liability as of December 31, 2019, include (i) volatility of 42%, (ii) risk-free interest rate of 1.59%, (iii) strike price of $8.40, (iv) fair value of common stock of $5.39, and (v) expected life of 0.8 years.

The underwriters' unit purchase option (the "UPO") was issued to the underwriters of the Company's IPO in 2015 and provides the underwriters the option to purchase up to a total of 40,000 units. The units underlying the UPO will be, immediately upon exercise, separated into shares of common stock, underwriters' Class A warrants and underwriters' Class B warrants (such warrants together referred to as the Underwriters' Warrants). The Underwriters' Warrants are warrants to purchase shares of common stock. The Class B warrants expired in April 2017 and the Class A warrants expired in October 2018, while the UPO expires in October 2020. The Company classifies the UPO as a liability as it is a freestanding marked-to-market derivative instrument that is precluded from being classified in stockholders' equity. The UPO liability is marked-to-market each reporting period with the change in fair value recorded to other income, net in the accompanying statements of operations until the UPO is exercised, expires or other facts and circumstances lead the UPO to be reclassified to stockholders' equity. The fair value of the UPO liability is estimated using a Black-Scholes option-pricing model. The significant assumptions used in preparing the simulation model for valuing the UPO as of December 31, 2019, include (i) volatility of 42%, (ii) risk-free interest rate of 1.59%, (iii) unit strike price of $7.47, (iv) fair value of underlying equity of $5.39, and (v) expected life of 0.8 years.

The Company's business acquisitions of Avadel's pediatric products and TRx (see Note 5) involved the potential for future payment of consideration that is contingent upon the achievement of operational and commercial milestones and royalty payments on future product sales. 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 liabilities are remeasured at the current fair value with changes recorded in the consolidated statement of operations.

Prior to the close of the Aytu Divestiture on November 1, 2019, the Company was required to pay a 15% annual royalty on net sales of the acquired Avadel pediatric products through February 2026 up to an aggregate amount of $12.5 million. The fair value of the future royalty was the expected future value of the contingent payments discounted to a present value. As detailed in Note 3, in connection with the close of the Aytu Divestiture on November 1, 2019, the contingent consideration related to Avadel's pediatric products was assumed by Aytu. Therefore, as of December 31, 2019, no value was assigned to the contingent consideration as of December 31, 2019. On November 1, 2019, in conjunction with the closing of the Aytu Divestiture, the Company entered into a Guarantee which guarantees the payment by Aytu of the contingent consideration related to future potential royalties on Avadel's pediatric products. For additional information regarding the Guarantee, which is recorded within discontinued operations, see Note 3.

The consideration for the TRx Acquisition included certain potential contingent payments. First, pursuant to the TRx Purchase Agreement, the Company was required to pay $3.0 million to the TRx Sellers upon the gross profit related to TRx products achieving or exceeding a gross profit of $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 for the year ended December 31, 2018. Additionally, the Company was required to pay the following: (1) $2.0 million upon the transfer of the Ulesfia NDA to the Company ("NDA Transfer Milestone"), and (2) $2.0 million upon FDA approval of a new dosage of Ulesfia ("FDA Approval Milestone"). However, as part of the settlement the Company entered into during the second quarter of 2019 with Lachlan Pharmaceuticals, an Irish company controlled by the previous owners of TRx, among additional terms discussed in Note 16, the Company gave up its right to sell Ulesfia, except for a limited amount of inventory on hand until that inventory is sold or expired. As a result, the settlement released the Company from the potential contingent payments related to the NDA Transfer Milestone and FDA Approval Milestone and therefore, no value was assigned to the two milestones as of December 31, 2019 resulting in the Company recognizing a gain on the change of fair value of contingent consideration of $1.3 million for the year ended December 31, 2019.

Additionally, as a result of the Aytu Divestiture, the Company performed a non-recurring Level 3 valuation to assign goodwill to the disposed Pediatric Portfolio using the relative fair value approach (see Note 3 and Note 10 for more detail). The Company also recognized impairment of $1.4 million for the year ended December 31,2019 due to the impairment of the Flexichamber asset, which is considered a non-recurring Level 3 valuation. As Flexichamber was a part of the Aytu Divestiture, the impairment expense was included in income (loss) from discontinued operations, net of tax (inclusive of gain on sale) for the year ended December 31, 2019 (see Note 3 and Note 5 for more detail).

No other changes in valuation techniques or inputs occurred during the years ended December 31, 2019 and 2018. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the years ended December 31, 2019 and 2018.

7. Aevi Loan

As discussed in detail in Note 17, on December 5, 2019, the Company entered into a Merger Agreement with Aevi that was subsequently consummated during the first quarter of 2020. In connection with the Merger Agreement, Cerecor agreed to fund certain expenses of Aevi 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 interleukin 18, or IL-18, AEVI-007 (the "AZ Option"), as well as fund the operating expenses of Aevi from December 5, 2019 through the earlier of the termination of the Merger Agreement or the closing of the Merger. Cerecor received from Aevi two promissory notes in consideration for the loans for such expenses. In December 2019, Aevi requested and Cerecor funded a $4.1 million advance under the note specific to the AZ Option. Aevi did not request any advances under the note specific to general operating expenses.

Pursuant to the Aevi Loan, the maximum loan amount was $5.0 million, together with interest on the outstanding principal amount of all such advances at an annual rate of 5%. The use of proceeds was limited to fund obligations related to the AZ Option. All unpaid principal and unpaid accrued interest on the Aevi Loan was due and payable in full on December 5, 2020 (unless the Merger Agreement was terminated or upon consummation of the Merger). Upon termination of the Merger Agreement for any reason, Aevi would be required to repay the amount borrowed under the Aevi Loan in full. Upon consummation of the Merger, the Aevi Loan was to be forgiven.

As of December 31, 2019, it was unknown if the Merger would be consummated. Accordingly, as of December 31, 2019, the Company recognized the $4.1 million loaned to Aevi as an other receivable within its accompanying consolidated balance sheet.

As discussed in detail in Note 17, on February 3, 2020, the Merger was consummated in accordance with the terms of the Merger Agreement and the $4.1 million loan that Cerecor advanced to Aevi in December 2019 was forgiven. The Company is in the process of determining the financial effect of the Merger, including whether the Merger will be recorded as an asset purchase or a business combination and will perform preliminary purchase accounting during the first quarter of 2020, however the Company preliminarily plans to treat the Aevi Loan as purchase price consideration.

8. Inventory

Inventory consists of finished goods stated at the lower of cost or net realizable value with cost determined on a first-in, first-out basis. The Company reviews the composition of inventory at each reporting period in order to identify obsolete, slow-moving, quantities in excess of expected demand, or otherwise non-saleable items.

Inventory consisted of the following as of December 31, 2019 and 2018:

	December 31,	
	2019	2018
Raw materials	$ —	$ 11,392
Finished goods	46,705	497,949
Inventory reserve	(25,371)	(191,418)
Inventory, net of continuing operations	$ 21,334	$ 317,923

During the years ended December 31, 2019 and 2018, the Company recorded a related charge to cost of goods sold for obsolete inventory of continuing operations of $36,577 and $174,944, respectively.

9. Property and Equipment

Property and equipment as of December 31, 2019 and 2018 consisted of the following:

	December 31,	
	2019	2018
Furniture and equipment	$ 143,168	$ 133,229
Computers and software	6,708	122,065
Right-of-use asset (Corporate Headquarters' Lease)	718,628	—
Leasehold improvements	657,328	463,381
Total property and equipment	1,525,832	718,675
Less accumulated depreciation	(78,169)	(132,163)
Property and equipment, net	$ 1,447,663	$ 586,512

Depreciation expense was $119,488 and $22,515 for the years ended December 31, 2019 and December 31, 2018, respectively.

Corporate Headquarters' Lease

The Company identified one operating lease, which is for its corporate headquarters located in Rockville, Maryland. The annual base rent for the office space is $161,671, subject to annual 2.5% increases over the term of the lease. The lease provides 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 remaining term of the lease at December 31, 2019 was 10.1 years.

Supplemental balance sheet information related to the lease are as follows:

	December 31, 2019
Property and equipment, net	$ 718,626
Other current liabilities	$ 155,815
Other long-term liabilities	$ 1,111,965

The operating lease ROU asset is included in property and equipment and the lease liability is included in accrued expenses and other current liabilities and other long-term liabilities in our condensed consolidated balance sheets. In order to determine the present value of lease payments, the Company utilized a discount rate of 7.7%. This rate was determined based on available information of the rate of interest the Company would pay to borrow on a collateralized basis at an amount equal to the lease payments in a similar economic environment over a similar term on the transition date.

The components of lease expense for the year ended December 31, 2019:

	Year Ended December 31,	
	2019	2018
Operating lease cost*	$ 160,767	$ 239,259

*Includes short-term leases, which are immaterial.

Because the corporate headquarters lease provides for a 12-month lease abatement, the cash paid for amounts included in the measurement of lease liabilities was $0 as of December 31, 2019.

The following table shows a maturity analysis of the operating lease liability as of December 31, 2019:

	Undiscounted Cash Flows
2020	$ 155,815
2021	169,510
2022	173,748
2023	178,092
2024	182,544
Thereafter	1,000,746
Total lease payments	$ 1,860,455
Less implied interest	(592,675)
Total	$ 1,267,780

Upon consummation of the Aevi Merger on February 3, 2020, the Company also occupies an office in Wayne, Pennsylvania, which is an operating lease. The lease expires April 2020 and goes month-to-month thereafter, however both the Company and the landlord have the right to terminate the lease 60 days after written notice is provided. The monthly rent payment for this lease is $12,050.

10. Goodwill

The changes in the carrying amount of goodwill for the years ended December 31, 2019 and 2018 were as follows:

Balance as of December 31, 2017	$ 12,290,247
Goodwill from acquisition of Avadel's pediatric products	3,778,001
Goodwill purchase price allocation measurement period adjustment from acquisition of TRx Pharmaceuticals	(1,659,160)
Balance as of December 31, 2018 and as of December 31, 2019	$ 14,409,088

The Company consists of one reporting unit. A portion of the Company's reporting unit was disposed of as part of the Aytu Divestiture, which closed on November 1, 2019. To determine the amount of goodwill allocated to the discontinued operation, the Company assigned goodwill based on the relative fair values of the portion of the reporting unit disposed and the portion of the reporting unit remaining (relative to the total estimated enterprise fair value of Cerecor on the closing date of the Aytu Divestiture on November 1, 2019). The estimated fair value of the reporting unit disposed was determined based on the estimated purchase consideration received as part of the Aytu Divestiture. The estimated fair value of the reporting unit remaining was determined based on the estimated enterprise fair value of Cerecor on the closing date of the Aytu Divestiture, which was based on the Company's market capitalization on November 1, 2019 and increased by an estimated enterprise value control premium of 20% calculated using historical market data of similar transactions at comparable companies. Based on the relative fair value approach, the Company assigned 12.2% or $2.0 million of its total goodwill balance to the Pediatric Portfolio and therefore the goodwill balance from continuing operations was $14.4 million as of December 31, 2018 and December 31, 2019.

There were no accumulated impairment losses to goodwill at December 31, 2019 or December 31, 2018.

11. Intangible Assets

The changes in intangible assets for the years ended December 31, 2019 and 2018 were as follows:

Balance as of December 31, 2017	$ 7,286,688
Additions	150,000
Purchase price allocation measurement period adjustments	6,000
Amortization	(1,815,872)
Impairment	(1,861,562)
Balance as of December 31, 2018	$ 3,765,254
Amortization	(1,338,996)
Balance as of December 31, 2019	$ 2,426,258

The Company received written notice to terminate the PAI sales and marketing agreement in the second quarter of 2018. As a result the Company reassessed the fair value of the PAI sales and marketing agreement on that date (a level III non-recurring fair value measurement) and concluded due to the absence of future cash flows beyond the date of termination that the fair value was $0. An impairment charge was recognized in the year ended December 31, 2018 in the amount of $1.9 million, representing the remaining net book value of the PAI sales and marketing agreement intangible asset on the date of assessment. No impairment for intangible assets from continuing operations was recognized as of December 31, 2019.

The following is a summary of intangible assets held by the Company at December 31, 2019 and December 31, 2018, respectively:

	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	1.92
Acquired Assembled Workforce	150,000	(93,750)	56,250	0.75
Total Intangible Assets	$ 5,206,000	$ (2,779,742)	$ 2,426,258	1.89

	December 31, 2018				
	Gross Carrying Amount	Accumulated Amortization	Impairment Loss	Net Carrying Amount	Weighted-Average Remaining Life
					(in years)
Acquired Product Marketing Rights	$ 5,056,000	$ (1,421,996)	$ —	$ 3,634,004	2.92
Sales and Marketing Agreement	2,553,000	(691,438)	(1,861,562)	—	—
Acquired Assembled Workforce	150,000	(18,750)	—	131,250	1.75
Total Intangible Assets	$ 7,759,000	$ (2,132,184)	$ (1,861,562)	$ 3,765,254	2.88

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
2020	$ 1,320,246
2021	1,106,012
2022	—
2023	—
2024	—
Thereafter	—
Total future amortization expense	$ 2,426,258

12. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities as of December 31, 2019 and 2018 consisted of the following:

	December 31,	
	2019	2018
Sales returns and allowances	$ 2,284,175	$ 1,465,419
Medicaid rebates	118,271	50,246
Minimum sales commitments, royalties payable, and purchase obligations	75,000	8,954,521
Compensation and benefits	1,591,964	1,953,065
Research and development expenses	920,901	278,132
General and administrative	360,016	1,112,378
Sales and marketing	120,056	235,721
Other	169,869	279,397
Accrued expenses and other current liabilities	$ 5,640,252	$ 14,328,879

13. Capital Structure

Pursuant to the Company's amended and restated certificate of incorporation, the Company is authorized to issue two classes of stock; common stock and preferred stock. At December 31, 2019, 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" or "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 Convertible 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 holds no voting rights.

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 Armistice 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 up to 14,285,714 shares of the Company’s common stock at an exercise price of $0.40 per share (the "original warrants") for like-kind warrants to purchase up to 2,857,143 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.

In order to provide Armistice an incentive to exercise the exchanged warrants, the Company also entered into a securities purchase agreement with Armistice pursuant to which the Company issued warrants for 4,000,000 shares of common stock of the Company with a term of 5.5 years and an exercise price of $12.50 per share (the "incentive warrants"). For accounting purposes, the Company calculated the fair value of the incentive warrants at $1.7 million, which was considered a deemed distribution to Armistice for the year ended December 31, 2018.

During the first quarter of 2020, Armistice converted 1.6 million of Series B Convertible Preferred Stock (of its approximate 2.9 million shares of convertible preferred stock) into 8.0 million shares of Cerecor's common 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.

Common Stock

February 2020 Financing

On February 6, 2020, the Company closed on a registered direct offering with certain institutional investors for the sale by the Company of 1,306,282 shares of the Company's common stock at a purchase price of $3.98 per share, which represents the closing stock price the day prior to entering into the agreement. Armistice participated in the offering by purchasing 1,256,282 shares of common stock from the Company. The net proceeds of the offering were approximately $5 million.

Aevi Merger

On February 3, 2020, under the terms of the Aevi Merger noted below in Note 17, the Company issued 3.9 million shares of common stock.

September 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 the Company’s common stock for a purchase price of $3.132 per share, which represents the average closing price of the Common Stock on Nasdaq for the five trading days immediately preceding September 4, 2019. Net proceeds of the private placement were approximately $3.7 million.

March 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, at a price to the public of $5.50 per share. Armistice participated in the offering by purchasing

363,637 shares of common stock of the Company from the underwriter at the public price. The net proceeds to the Company from the offering were approximately $9.0 million.

December 2018 Armistice Private Placement

As discussed in detail above (see "December 2018 Armistice Private Placement"), on December 27, 2018, the Company exchanged with Armistice previously outstanding warrants for like-kind warrants to purchase up to 2,857,143 shares of the Company's convertible preferred stock with an exercise price of $2.00 per share which Armistice immediately exercised thus acquiring 2,857,143 shares of convertible preferred stock for net proceeds of $5.7 million. The convertible preferred stock is convertible into shares of common stock on a 1-for-5 ratio (or to 14,285,714 shares of common stock in total, subject to adjustment). Additionally, on December 27, 2018, in order to provide Armistice an incentive to exercise the exchanged warrants, the Company entered into a securities purchase agreement with Armistice pursuant to which the Company issued warrants for 4,000,000 shares of common stock of the Company with a term of 5.5 years and an exercise price of $12.50 per share.

August 2018 Armistice Private Placement

On August 17, 2018, the Company entered into a securities purchase agreement with Armistice, pursuant to which the Company sold 1,000,000 shares of the Company’s common stock, $0.001 par value per share for a purchase price of $3.91 per share, which was the closing price of shares of the common stock on August 16, 2018. Net proceeds of this securities purchase agreement were approximately $3.9 million.

Ichorion Asset Acquisition

On September 25, 2018, under the terms of the Ichorion Asset Acquisition noted above in Note 5, the Company issued 5.8 million common stock shares upon closing.

Contingently Issuable Shares

Under the terms of the TRx Acquisition noted above in Note 5, the Company was required to issue common stock having an aggregate value as calculated in the TRx Purchase Agreement on the closing date of $8.1 million (the “Equity Consideration”). Upon closing, the Company issued 5,184,920 shares of its common stock. Pursuant to the TRx Purchase Agreement, the issuance of the remaining 2,349,968 shares as a part of the equity consideration was subject to stockholder approval at the Company's 2018 Annual Stockholder's Meeting. This approval was obtained in May 2018 and the remaining shares were issued to the TRx Sellers.

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 have no 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, 2019, the following common stock warrants were outstanding:

Number of shares underlying warrants	Exercise price per share	Expiration date
22,328*	$ 8.40	October 2020
2,380*	$ 8.68	May 2022
4,000,000	$ 12.50	June 2024
4,024,708		

*Accounted for as a liability instrument (see Note 6)

14. 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 as 464,476 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. During the term of the 2016 Second 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 common stock of the Company on the last trading day in December of the prior calendar year. As of December 31, 2019, there were 2,532,162 shares available for future issuance under the 2016 Second Amended Plan. On January 1, 2020, pursuant to the terms of the 2016 Second Amended Plan an additional 1,775,368 shares were made available for issuance for a total of 4,307,530 shares available for issuance.

Option grants expire after ten years. Employee options typically vest over three or four years. 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 ending December 31, 2019 and 2018 was as follows:

	Year Ended December 31,	
	2019	2018
Research and development	$ 464,382	$ 101,000
General and administrative	1,549,844	2,135,710
Sales and marketing	190,851	57,271
Total stock-based compensation, continuing operations	2,205,077	2,293,981
Total stock-based compensation, discontinued operations	257,719	137,082
Total stock-based compensation	$ 2,462,796	$ 2,431,063

In April 2019, the Company's former CEO resigned, however he remained on the Company's board of directors as of December 31, 2019. Subsequent to his resignation, during the second quarter of 2019, the former CEO agreed to forfeit the unvested portion of his equity awards granted to him during his service as CEO. As a result, he forfeited a total of 1,489,583 equity awards, which included 689,583 unvested service-based vesting options, 500,000 unvested market-based options and 300,000 unvested restricted stock units. The Company accounts for forfeitures as they occur. Because the requisite service period of 2.8 years was not rendered for the market-based options, the forfeiture of the market-based options resulted in the reversal in the second quarter of 2019 of the full expense recognized to date of $0.5 million, which was recorded as a reduction to general and administrative expense. Stock-based compensation during the year ended December 31, 2018 includes $0.3 million of expense related to modifications of awards related to a separated executive.

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. A summary of option activity with service-based vesting conditions for the year ended December 31, 2019 is as follows:

	Options Outstanding			
	Number of shares	Weighted average exercise price	Grant date fair value of options	Weighted average remaining contractual term (in years)
Balance at December 31, 2018	3,746,597	$ 4.16		7.8
Granted	2,631,927	$ 5.70	$ 8,106,310	
Exercised	(323,403)	$ 2.59		
Forfeited	(1,445,554)	$ 5.22	$ 4,218,136	
Expired	(428,961)	$ 4.99	$ 1,062,853	
Balance at December 31, 2019	4,180,606	$ 4.80		7.9
Exercisable at December 31, 2019	2,228,748	$ 4.58		6.8

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, 2019, the aggregate intrinsic value of options outstanding and options currently exercisable was $4.9 million and $3.5 million, respectively. The total intrinsic value of options exercised during the year ended December 31, 2019 was $1.0 million. The total grant date fair value of shares which vested during the years ended December 31, 2019 and 2018 was $2.2 million and $1.2 million, respectively. The per-share weighted-average grant date fair value of the options granted during 2019 and 2018 was estimated at $3.08 and $2.28, respectively. There were 983,644 options that vested during the year ended December 31, 2019 with a weighted average grant date fair value of $2.21 per share.

The Company recognized stock-based compensation expense of $2.0 million related to stock options with service-based vesting conditions for the year ended December 31, 2019. At December 31, 2019, there was $4.5 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 2.7 years.

Stock options with market-based vesting conditions

The Company has granted awards that contain market-based vesting conditions. A summary of option activity with market-based vesting conditions for the year ended December 31, 2019 is as follows:

	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, 2018	500,000	$ 4.24	9.2	
Granted	300,000	$ 4.98		
Exercised	—			
Forfeited	(500,000)	$ 4.24		
Balance at December 31, 2019	300,000	$ 4.98	9.4	$ 123,000
Exercisable at December 31, 2019	—			

(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 2019, the Company granted the Executive Chairman of the Board an option to purchase 300,000 shares of Company common stock with market-based vesting conditions at an exercise price of $4.98 per share. One-third of the shares vest upon the Company's common stock closing at or above $8.00 per share for three consecutive days, one-third of the shares vest upon the Company's stock closing at or above $10.50 per share for three consecutive days, and one-third of the shares vest upon the Company's stock closing at or above $13.00 per share for three consecutive days. 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 Company recognized $(0.1) million related to stock options with market-based vesting conditions for the year ended December 31, 2019, which includes the reversal of expense for the former CEO's forfeited options and the expense related to the market-based options granted to the Executive Chairman of the Board.

The weighted-average grant-date fair value of stock options with market-based vesting conditions granted during 2019 was $3.42 per share or $1.0 million. The weighted-average grant-date fair value of stock options with market-based vesting conditions forfeited during 2019 was $2.52 per share or $1.3 million.

At December 31, 2019, there was $0.8 million of total unrecognized compensation cost related to unvested market-based vesting conditions awards. This compensation cost is expected to be recognized over a weighted-average period of 2.0 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	**2019**			**2018**		
Risk-free interest rate	1.47%	—	2.59%	2.51%	—	3.01%
Expected term of options (in years)	5.0	—	6.25	5.0	—	6.25
Expected stock price volatility	55%			55%	—	65%
Expected annual dividend yield	0%			0%		
Market-based options						
Risk-free interest rate	2.32%			2.84%		
Expected term of options (in years)	10			10		
Expected stock price volatility	60%			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. The expected life of stock options with market-based vesting is derived from a Monte Carlo simulation which is the valuation technique used to value such awards.

- Expected stock price volatility: The Company estimated the expected volatility based on actual historical volatility of the stock price of other publicly-traded biotechnology companies engaged in lines of business that are the same or similar to the Company’s. The Company calculated the historical volatility of the selected companies by using daily 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 has granted restricted stock units ("RSU") to certain employees. The Company measures the fair value of the restricted awards 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, 2019:

	RSUs Outstanding	
	Number of shares	Weighted average grant date fair value
Unvested RSUs at December 31, 2018	445,000	$ 4.27
Granted	295,000	$ 4.98
Vested	(172,500)	$ 4.52
Forfeited	(300,000)	$ 4.24
Unvested RSUs at December 31, 2019	267,500	

During the second quarter of 2019, the Company granted its newly appointed Executive Chairman of the Board 250,000 RSUs, of which 50,000 shares vested immediately on the grant date and the remainder are to vest in three equal annual increments based on continued service.

The Company recognized stock-based compensation expense of $0.5 million related to RSUs for the year ended December 31, 2019. At December 31, 2019, there was $1.3 million of total unrecognized compensation cost related to the RSU grants. This compensation cost is expected to be recognized over a weighted-average period of 2.3 years.

Employee Stock Purchase Plan

On April 5, 2016, the Company's board of directors approved the 2016 Employee Stock Purchase Plan (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 $0.03 million 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, 2019, 1,118,882 shares remained available for issuance. On January 1, 2020, the number of shares available for issuance under the ESPP increased by 443,842 for a total of 1,562,724 shares available for issuance.

In accordance with the guidance in ASC 718-50, 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 $0.2 million and $0.05 million for the years ended December 31, 2019 and December 31, 2018, respectively, which are

included in the table above with stock-based compensation from stock options.

Subsequent Equity Grants

In February 2020, the Company granted options to purchase 2.4 million shares of common stock as inducement option grants, pursuant to NASDAQ Listing Rule 5635(c)(4), to certain employees who joined the Company in connection with the Aevi Merger. Each inducement option grant will vest over four years, with the first 25% of such option vesting on the first anniversary of the date of grant, and the remainder vesting in equal monthly installments, subject to the continued service of the employees, respectively, through the applicable vesting date. Additionally, on February 3, 2020, the Company granted 500,000 options with service-based vesting conditions at an exercise price of $3.98 per share to Sol J. Barer, Ph.D., who was appointed to Cerecor's Board of Directors upon the consummation of the Aevi Merger. The options were granted under the 2016 Second Amended Plan and will vest over three years, with one-third of such option vesting on each of the first, second and third anniversaries of the date of grant. Finally, on February 3, 2020, the Company granted 514,400 options with service-based vesting conditions at an exercise price of $3.98 per share to other employees who joined the Company in connection with the Aevi Merger. The options were granted under the 2016 Second 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.

15. 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, 2019. Tax years beginning in 2016 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. The Company accrued interest and penalties as components of income expense for tax liability generated for the year ended December 31, 2017. There was no interest or penalties related to income taxes arising in the years ended December 31, 2019 and 2018.

The income tax provision from continuing operations consisted of the following for the years ending December 31, 2019 and 2018:

	December 31,	
	2019	2018
Current:		
Federal	$ 209,001	$ (53,281)
State	54,572	20,560
Total Current	263,573	(32,721)
Deferred:		
Federal	24,458	(52,235)
State	(7,715)	35,490
Total Deferred	16,743	(16,745)
Net income tax expense (benefit)	$ 280,316	$ (49,466)

The net deferred tax liabilities consisted of the following for the years ending December 31, 2019 and 2018:

	December 31,	
	2019	2018
Deferred tax assets (liabilities):		
Net operating losses	$ 7,596,955	$ 4,421,423
Accrued compensation	321,748	465,430
Investment in Aytu	577,490	—
Tax credits	1,070,738	252,095
Stock-based compensation	1,872,442	1,922,736
Installment sale	441,305	508,291
Other reserves	399,885	277,633
Prepaid expenses	(120,863)	(160,474)
Right-of-use asset	(167,943)	—
Lease liability	296,259	—
Basis difference in tangible and intangible assets, net	1,968,008	2,968,764
Total deferred tax assets, net	14,256,024	10,655,898
Less valuation allowance	(14,342,005)	(10,725,136)
Net deferred taxes	$ (85,981)	$ (69,238)

As of December 31, 2019, the Company has roughly $32.5 million of gross NOLs for federal and state tax purposes that will begin to expire in 2031, including $27 million of gross NOLs for federal and state tax purposes that carry forward indefinitely. As of December 31, 2019, the Company has research and experimental tax credits of $1.1 million that will begin to expire in 2038.

The income tax benefit for the years ended December 31, 2019 and 2018 differed from the amounts computed by applying the U.S. federal income tax rate of 21% as follows:

	December 31,	
	2019	2018
Federal statutory rate	21.00 %	21.00 %
Stock compensation	(0.47)%	(0.10)%
State taxes	(0.13)%	4.98 %
Research and development credit	5.13 %	0.70 %
Acquired in-process research and development	— %	(11.17)%
Fair value adjustment to contingent consideration	1.65 %	— %
Other	(1.86)%	(0.74)%
Valuation allowance	(27.07)%	(14.53)%
Effective income tax rate	(1.75)%	0.14 %

The valuation allowance recorded by the Company as of December 31, 2019 and December 31, 2018 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 2018 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, 2019 and December 31, 2018.

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 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. Accordingly, approximately $52.2 million of the Company's NOL carryforwards are limited. Based on the Company having undergone multiple ownership changes throughout their history these NOLs will free up at varying rates each year.

On December 22, 2017, H.R. 1 (also, known as the Tax Cuts and Jobs Act (the “Act”)) was signed into law. Among its numerous changes to the Internal Revenue Code, the Act reduces U.S. federal corporate tax rate from 35% to 21%. As a result, the Company concluded that the most significant impact on its 2017 consolidated financial statements is the reduction of approximately $2,200,000 in deferred tax assets and liabilities related to net operating losses and other assets. Such reduction is largely offset by changes to the Company’s valuation allowance. The Company is reported the impacts of the Act provisionally in the 2017 financial statements based upon reasonable estimates. The analysis of the tax effects of the Act has now been complete and there were not adjustments in 2018.

In addition, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Act ("SAB 118") which allowed the Company to record provisional amounts during a measurement period not to extend beyond one year from the enactment date. Since the Tax Act was passed late in the fourth quarter of 2017, ongoing guidance and accounting interpretation was expected over the past year, and significant data and analysis was required to finalize amounts recorded pursuant to the Tax Act, the Company considered the accounting for the deferred tax remeasurements and other items to be incomplete at December 31, 2017 due to the forthcoming guidance and its ongoing analysis of final year-end data and tax positions. The Company completed its analysis within the measurement period in accordance with SAB 118 and there were no additional adjustments necessary.

16. 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 document.

TRx 2018 Target Gross Profit Dispute

As part of the TRx Acquisition, pursuant to the TRx Purchase Agreement, the Company was required to pay $3.0 million to the TRx Sellers (or "former TRx owners") if the gross profit, as defined in the TRx Purchase Agreement, related to TRx products equaled or exceeded $12.6 million in 2018. The Company believes it did not achieve this contingent event in 2018 and therefore, no amount is due to the former TRx owners. However, during the second quarter of 2019, the former TRx owners disputed the Company's calculation of gross profit under the TRx Purchase Agreement, arguing the Company met the $12.6 million target in 2018. Pursuant to the TRx Purchase Agreement, the dispute was submitted to an independent accounting firm for resolution during the third quarter of 2019. The dispute was resolved on October 8, 2019, with the independent accounting firm ruling in favor of the Company.

However, on December 19, 2019, Cerecor received a letter from an attorney on behalf of the former TRx owners dated December 18, 2019 that enclosed a draft complaint seeking relief against Cerecor and one of the members of its board of directors. The letter further threatened that if an immediate discussion regarding a settlement did not occur, that the lawsuit would be filed on December 24, 2019. However, as of the date of this filing, no lawsuit has been filed, and the parties have agreed to a pre-lawsuit mediation tentatively set for April 30, 2020. The proposed complaint indicates that the former TRx owners would seek the following relief: (a) $3.0 million on the grounds that commercially reasonable efforts to sell the acquired former TRx owners would have resulted in the gross profit earn-out target being reached; (b) that the $3.0 million amount be trebled as a result of Cerecor's alleged improper conduct; (c) $9.2 million as a result of alleged losses resulting from the alleged improper treatment of the former TRx

owners as affiliates; and (d) the removal of any restrictions on the former TRx owners shares of common stock in Cerecor. Cerecor disputes that the former TRx owners are entitled to the relief sought and intends to vigorously defend against any lawsuit filed on behalf of the former TRx owners. A loss in this matter is possible in a range of $0 to $18.2 million. As a loss in this matter is not considered probable, there has been no accrual recorded as of December 31, 2019.

Lachlan Pharmaceuticals Settlement

As discussed in Note 5, in November 2017, the Company acquired TRx and its wholly-owned subsidiaries, including Zylera. The former TRx owners beneficially own more than 10% of our outstanding common stock. Zylera, which is now our wholly owned subsidiary, 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. 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, as discussed in more detail below (the Settlement Agreement and related side letter collectively the "Settlement").

The Lachlan Agreement required Zylera to purchase a minimum of 20,000 units per year, or approximately $1.2 million worth of product, from Lachlan, unless and until there was a "Market Change" involving a new successful competitive product. Zylera was required to pay Lachlan $58.84 per unit and handling fees equal to $4.03 per unit of fully packaged Ulesfia in 2019, escalating 10% annually. The Lachlan Agreement also required that Zylera make certain cumulative net sales milestone payments and royalty payments to Lachlan with a $3.0 million annual minimum payment unless and until there was a Market Change. Lachlan was obligated to pay identical amounts to the unrelated third party from which it obtained rights to Ulesfia, with the payments ultimately flowing through Shionogi, Inc. to Summers Laboratories, Inc. ("Summers Labs"). Because of the dispute described below, the Company had not made any payments to Lachlan under the Lachlan Agreement subsequent to the acquisition date.

On December 10, 2016, Zylera informed Lachlan that a Market Change had occurred due to the introduction of Arbor Pharmaceuticals' lice product, Sklice®. On June 5, 2017, Lachlan and Zylera entered into joint legal representation along with other unrelated third parties in negotiation and arbitration of a dispute with Summers Labs regarding the existence of a Market Change and the concomitant obligations of the parties. The arbitration panel issued an interim ruling on October 23, 2018 that no Market Change had occurred up to and including the date of the hearing. The arbitration panel issued a second interim ruling on December 26, 2018, rejecting Summers Labs' request to accelerate future minimum royalties, but ruling in favor of Summers Labs that it is owed reimbursement for all reasonable costs and expenses, including legal fees, by Shionogi, as well as interest, as stipulated in the contract. The arbitration panel issued a final award on March 1, 2019 that dictated the final amount of reimbursable costs and interest. The rulings and final award had no direct bearing on the Company because the Company was not a named defendant to the original claim by Summers Labs and a federal court denied Zylera's ability to be a counterclaimant in the matter. Furthermore, the Company was not subject to the guarantee or interest provisions identified in the second ruling as these elements of the contractual relationship were not passed down to or through Lachlan. However, the Company interpreted the rulings' impact on the Lachlan Agreement to mean that the minimum purchase obligation and minimum royalty provisions of the contract were active and due for any prior periods as well as future periods.

Prior to the Settlement, the Company had recognized an $8.7 million liability for these minimum obligations and $0.4 million for the royalty payable in accrued liabilities as of March 31, 2019. Additionally, prior to settlement, under the terms of the TRx Purchase Agreement, the former TRx owners were required to indemnify the Company for 100% of all "Pre-Acquisition Ulesfia Losses," as defined in the TRx Purchase Agreement, related to this arbitration, including legal costs, in excess of $1.0 million. Furthermore, the former TRx owners were required to indemnify the Company for 50% of "Post-Acquisition Ulesfia Losses," as defined in the TRx Purchase Agreement, which would include losses resulting from having to fund these minimum obligations post-acquisition. The Company had recorded an indemnity receivable of $5.2 million in other receivables as of March 31, 2019, which the Company believed was fully collectible.

Pursuant to the Settlement, during the second quarter of 2019, the Company made a $2.3 million cash payment to Concordia for a full release of all current and future liabilities related to the Lachlan Agreement as of June 30, 2019. As a result, the Company reversed the $8.7 million liability for the minimum obligations and $0.4 million royalty payable in accrued liabilities during the second quarter of 2019. The Settlement also released the former TRx owners of their requirement to indemnify the Company for the losses discussed above. As a result, the Company reversed the $5.2 million indemnity receivable in other receivables during the second quarter of 2019. The Settlement resulted in a net reversal of $1.6 million in previously recognized expense to cost of product sales, which lead to the overall negative cost of product sales for the year ended December 31, 2019.

Additionally, with the termination of the Lachlan Agreement, the Company gave up its right to sell Ulesfia, except for a limited amount of inventory on hand until that inventory is all sold or expired. Finally, as discussed in detail in Note 6, the Settlement released the Company from having to make any acquisition milestone payout for the NDA transfer of Ulesfia and the FDA approval of an alternate dosing. Therefore, no value is assigned to the two milestones as of December 31, 2019, which resulted in the recognition of a gain on the change in fair value of contingent consideration of $1.3 million for the year ended December 31, 2019.

Karbinal Royalty Make-Whole Provision

As discussed in Note 5, 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 (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. The License and Supply Agreement expires on April 1, 2021, however if neither party terminates the agreement prior to April 1, 2021, then the agreement will automatically renew for successive one-year periods. As detailed in Note 17, on December 5, 2019, the Company entered into a Merger Agreement with Aevi that was subsequently consummated during the first quarter of 2020. Effective upon the consummation of the Merger, Cerecor appointed Sol J. Barer, Ph.D. to the Company's Board of Directors. Mr. Barer serves as Teva's Chairman of the Board.

Possible future milestone proceeds for out-licensed compounds

CERC-611 License Assignment

On August 8, 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 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, which was recorded as a license obligation on the balance sheet as of June 30, 2019. The decrease of this license obligation to $0 resulted in an offset of research and development expense of $1.3 million for the year ended December 31, 2019. The Assignment Agreement also releases the Company from additional potential future payments due to Lilly upon achievement of certain development and commercialization milestones, including the first commercial sale, and milestone payments and royalty on net sales upon commercialization of the compound.

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.

Possible future milestone payments

Ichorion Acquisition possible future milestone payments

As detailed in Note 5, on September 24, 2018, the Company acquired Ichorion Therapeutics, Inc., acquiring three compounds for inherited metabolic disorders known as CDGs (CERC-801, CERC-802 and CERC-803) and one other preclinical orphan disease compound, CERC-913, for the treatment of mitochondrial DNA Depletion Syndrome. Consideration for the transaction included approximately 5.8 million shares of the Company's common stock (adjusted for estimated working capital) and certain contingent development milestones worth up to an additional $15.0 million.

The contingent consideration of up to an additional $15.0 million relates to three future development milestones for the acquired compounds. 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, 2019, no contingent consideration related to the development milestone has been recognized. The Company will continue to monitor the development milestones at each reporting period.

OSI Products Royalty Agreement

As discussed in detail in Note 17, on December 5, 2019, the Company entered into a Merger Agreement with Aevi that was subsequently consummated during the first quarter of 2020. Effective upon the consummation of the Merger, Cerecor entered into an employment agreement with Mike Cola for him to serve as Cerecor's Chief Executive Officer and with Dr. Garry Neil for him to serve as Cerecor's Chief Medical Officer.

Prior to Cerecor entering into the Merger Agreement, in July 2019, Aevi entered into a royalty agreement with Mike Cola, our 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 Garry A. Neil, our current Chief Medical Officer, 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' second generation mTORC1/2 inhibitor, CERC-006 (the "OSI Products"). At any time beginning three years after the date of the first public launch of an OSI Product, 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.

17. Subsequent Events

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 overall 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.

The Merger was consummated in accordance with the terms of the Merger Agreement and each outstanding shares of common stock of Aevi, par value of $0.0001 per share, was converted into the right to receive (i) the fraction of a share of Cerecor common stock, par value of $0.001 per share, at a ratio equal to 0.0334, which in the aggregate totaled approximately 3.9 million shares of Cerecor common stock issued to Aevi stockholders (valued at approximately $15.6 million); (ii) forgiveness of a $4.1 million loan that Cerecor loaned Aevi in December 2019 (see Note 7 for more details for its treatment as of December 31, 2019), (iii) one contingent value right, which represents the right to receive the pro rata portion of contingent payments of up to $6.5 million, to be paid in cash or Cerecor common stock in the sole discretion of Cerecor, upon the achievement of certain milestones in accordance with the CVR Agreement; and (iv) cash in lieu of fractional shares of Cerecor common stock, which in the aggregate totaled

approximately $1,000. Additionally, each outstanding Aevi stock option was canceled and each outstanding Aevi warrant was exercised on a cashless basis prior to the Effective Time.

Effective upon the consummation of the Merger, Cerecor entered into an employment agreement with Mike Cola for him to serve as Cerecor's Chief Executive Officer, an employment agreement with Dr. Garry Neil for him to serve as Cerecor's Chief Medical Officer and appointed Mike Cola and Sol J. Barer, Ph.D. to the Company's Board of Directors.

Cerecor is in-process of determining the financial effect of the Merger, including whether the Merger will be recorded as an asset purchase or a business combination and will perform preliminary purchase accounting during the first quarter of 2020.

CORPORATE INFORMATION

Directors

Simon C. Pedder, Ph.D., *Executive Chairman*
Chief Business and Strategy Officer, Proprietary Products, Athenex, Inc

Sol J. Barer

Steven J. Boyd
Chief Investment Officer, Armistice Capital

Michael Cola, *Chief Executive Officer*

Phil Gutry
Chief Business Officer, Kronos Bio

Uli Hacksell, Ph.D.

Magnus Persson, M.D., Ph.D.
Associate Professor in Physiology, Karolinska Institutet
Pediatrician, CityAkuten

Keith Schmidt

Officers

Michael Cola, *Chief Executive Officer*

Joseph Miller, *Chief Financial Officer*

James A. Harrell, Jr., *Chief Commercial Officer*

Garry Neil, M.D., *Chief Scientific Officer*

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Stock Listing

Cerecor, Inc. common stock is listed on the Nasdaq Capital Market and quoted under the symbol “CERC”.

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