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, 2018
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	**Name of each exchange on which registered**
Common Stock, $0.001 par value	NASDAQ Stock 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 and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§299.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See 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, 2018 (based on the closing price of $4.34 on June 29, 2018, the last business day of the registrant's most recently completed second fiscal quarter) was $40,821,693. 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 11, 2019, there were 42,653,659 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, 2018, 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 results of operations, cash flows, market position, sales efforts, the development of product candidates or products, the timing and results of clinical trials, the potential attributes and benefits of our product candidates, the use and sufficiency of capital resources 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 fully integrated biopharmaceutical company with commercial operations and research and development capabilities. The Company is building a robust pipeline of innovative therapies in neurology, pediatric healthcare, and orphan rare diseases.

The Company's neurology pipeline is led by CERC-301, which is currently in a Phase I safety study for Neurogenic Orthostatic Hypotension ("nOH"). The Company is also developing two other neurological clinical and preclinical stage compounds. The Company's pediatric orphan rare disease pipeline is led by CERC-801, CERC-802 and CERC-803. All three of these compounds are preclinical therapies for inherited metabolic disorders known as Congenital Disorders of Glycosylation ("CDGs") by means of substrate replacement therapy. The U.S. Food and Drug Administration ("FDA") has granted Rare Pediatric Disease designation ("RPDD") and Orphan Drug Designation ("ODD") to all three compounds. Under the FDA's Rare Pediatric Disease Priority Review Voucher ("PRV") program, upon the approval of a new drug application ("NDA") for the treatment of a rare pediatric disease, the sponsor of such application would be eligible for a PRV that can be used to obtain priority review for a subsequent new drug application or biologics license application. The 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. The Company is also in the process of developing one other preclinical pediatric orphan rare disease compound, CERC-913.

The Company also has a diverse portfolio of marketed products. Our marketed products are led by our prescribed dietary supplements and prescribed drugs. Our prescribed dietary supplements include Poly-Vi-Flor and Tri-Vi-Flor which are prescription vitamin and fluoride supplements used in infants and children to treat or prevent deficiency of essential vitamins and fluoride. The Company also markets a number of prescription drugs that treat a range of pediatric diseases, disorders and conditions. Cerecor's prescription drugs include Millipred®, Ulesfia®, Karbinal™ ER, AcipHex® Sprinkle™ and Cefaclor for Oral Suspension. Finally, the Company has one marketed medical device, Flexichamber™.

Recent Developments

Ichorion Asset Acquisition

On September 24, 2018, we acquired Ichorion Therapeutics, Inc. for approximately 5.8 million shares of the Company's Common Stock, par value $0.001 per share, as adjusted for estimated working capital. Consideration for the Ichorion asset acquisition also includes certain development milestones worth up to an additional $15 million, payable either in shares of the Company's common stock or in cash, at the election of the Company. Substantially all of the value of Ichorion was related to one group of similar identifiable assets, which was the in-process research and development ("IPR&D") for the three preclinical therapies for CDGs (CERC-801, CERC-802 and CERC-803) and as such the Company accounted for this transaction as an asset acquisition.

Acquisition of Avadel Products

On February 16, 2018, we acquired all rights in the Avadel U.S. Holdings, Inc's marketed pediatric products for a nominal cash payment and assumption of certain of Avadel's financial obligations to Deerfield CSF, LLC, which include a $15 million loan due in January 2021 and certain royalty obligations through February 2026. The acquired products consist of Karbinal™ ER, AcipHex® Sprinkle™, Cefaclor for Oral Suspension, and Flexichamber™.

Research and Development Updates

During the third quarter of 2018, the Company enrolled its first patient in the Phase 1 trial for nOH in Parkinson's Disease. The purpose of this study is to evaluate the single-dose safety, tolerability and pharmacokinetics of CERC-301 in the relevant patient population from the study, as well as explore the effects on blood pressure of nOH during an orthostatic challenge at escalating dose levels. Data is expected in the first half of 2019. In early 2019, a patent was issued for CERC-301, which provides Cerecor with intellectual property rights to CERC-301 until 2035.

During the fourth quarter of 2018, the FDA awarded RPDD for CERC-801, CERC-802, and CERC-803. Additionally, the FDA granted ODD to each of the three compounds in early 2019, thus granting eligibility for receipt of a PRV upon approval of an NDA. In addition to PRV eligibility, there are numerous benefits associated with receipt of both ODD and RPDD which include 7-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 ("PDUFA") application fees (filing fees).

The Company also filed an Investigational New Drug ("IND") application with the FDA for CERC-801 in the fourth quarter of 2018 and received a may proceed letter in early 2019. Additionally, the FDA designated Fast Track Designation for CERC-801. Fast Track Designation is granted to drugs being developed for the treatment of serious or life-threatening diseases or conditions where there is an unmet medical need. The purpose of the Fast Track Designation provision is to help facilitate development and expedite the review of drugs to treat serious and life-threatening conditions so that an approved product can reach the market expeditiously. The clinical development program for CERC-801 will commence in 2019 with a Phase 1 study in healthy volunteers. The goals of the study will be to assess the single dose tolerability and pharmacokinetics of CERC-801. Cerecor seeks to leverage existing clinical and nonclinical data in conjunction with sponsor-initiated studies, such as this Phase 1 study, to accelerate development and approval of CERC-801 via the 505(b)(2) pathway.

Additionally, the Company expects to file an IND application with the FDA for CERC-802 in 2019 and expects to file an IND application with the FDA for CERC-803 in 2020.

	Program	Target Indication	Upcoming Milestone
Metabolic Disorders	CERC-801*	PGM1 Deficiency	Phase I Data 1H19
	CERC-802*	MPI Deficiency	IND Filing 1H19
	CERC-803*	CDG-IIc	IND Filing 2020
	CERC-913	DGUOK Deficiency	IND Filing 2020
Neurology Disorders	CERC-301	Neurogenic Orthostatic Hypotension	Phase I Data 1H19
	CERC-406	Parkinson's Disease	IND Filing 1H20
	CERC-611	Partial Onset Seizures	Under Strategic Review

*505(b)(2) Pathway

Recent Financings

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") participated in the offering by purchasing 363,637 shares of common stock of the Company from the underwriter at the public price. The gross proceeds to the Company, before deducting underwriting discounts and commissions and estimated offering expenses and assuming no exercise of the option to purchase additional shares of common stock, were approximately $10.0 million. The net proceeds were approximately $9.0 million.

During the fourth quarter of 2018, Armistice exercised warrants and acquired an aggregate of 2,857,143 shares of the Series B Convertible Preferred Stock, which can be converted to 14,285,715 shares of common stock, for net proceeds of approximately $5.7 million. Additionally, as part of this transaction, the Company issued warrants for 4,000,000 shares of common stock (see "December 2018 Armistice Private Placement" in Note 13 below for a description of this transaction).

During the third quarter of 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 for net proceeds of approximately $3.9 million (see "Armistice Private Placements" in Note 13 below for a description of this transaction).

Lachlan Pharmaceuticals

In November 2017, the Company acquired TRx and its wholly-owned subsidiaries, including Zylera. The previous owners of TRx beneficially own more than 10% of our outstanding common stock. Zylera, which is our wholly owned subsidiary, entered into the First Amended and Restated Distribution Agreement with Lachlan, effective December 18, 2015. 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.

Zylera is obligated to purchase a minimum of 20,000 units per year, or approximately $1.2 million worth of product, from Lachlan, subject to certain termination rights. Zylera must pay Lachlan $58.84 per unit and handling fees that are equal to $3.66 per unit of fully packaged Ulesfia in 2018, and escalate at a rate of 10% annually, as well as reimburse Lachlan for all product liability insurance fees incurred by Lachlan. The Lachlan Agreement also requires 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 has been a “Market Change” involving a new successful competitive product. Lachlan is obligated to pay identical amounts to an unrelated third party from which it obtained rights to Ulesfia, with the payments ultimately flowing to Summers Laboratories, Inc. (“Summers Labs”). Because of the dispute described below, the Company has 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. The second interim award rejected Summers Labs' request to accelerate future minimum royalties, however, it ruled 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 as contemplated in the second interim ruling. The final award has no direct bearing on the Company as 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 is 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 the Company’s agreement with Lachlan. However, the Company has interpreted this ruling's impact on the Lachlan agreement to mean that a market change has not occurred, and the minimum purchase obligation and minimum royalty provisions of the contract are active and due for any prior periods as well as going forward for any future periods.

The Company has recognized a $7.8 million liability for these minimum obligations in accrued liabilities as of December 31, 2018. Under the terms of the TRx Purchase Agreement, the former TRx owners are required to indemnify the Company for 100% of all pre-acquisition losses related this arbitration, including legal costs, and possible minimum payments in excess of $1 million. Furthermore, the former TRx owners are required to indemnify the Company for 50% of post-acquisition Ulesfia losses, which would include losses resulting from having to fund these minimum obligations. The Company has recorded an indemnity receivable of $4.9 million in other receivables as of December 31, 2018, which the Company believes is fully collectible. The receivable is net of $1.9 million collection made in the fourth quarter of 2018 from a full cash escrow release with the former TRx owners from the escrow that was established as a part of the TRx acquisition. The post-acquisition minimum obligations net of amounts recorded within the indemnity receivable of $2.2 million has been recorded in cost of product sales for the year ended December 31, 2018. If the Company fails to make these minimum obligations timely then the Lachlan Agreement may be terminated by Lachlan, in which case the Company would no longer be able to sell the Ulesfia product, but it would also not be subject to future minimum obligations. Lachlan has not requested payment for the minimum obligations.

Our Strategy

The Company is building a robust pipeline of innovative therapies in neurology, pediatric healthcare, and orphan rare diseases. We plan to use the proceeds generated from the profits of our portfolio of pediatric products toward the development of drug candidates that have unique mechanisms of action and can change the lives of patients with rare orphan diseases in pediatrics and neurology. 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 shareholder value includes:

- Advancing our pipeline of compounds through development and to regulatory approval;

- Pursuing targeted, differentiated preclinical and clinical stage product candidates;

- Acquiring or licensing rights to clinically meaningful and differentiated products that are already on the market for pediatric use or in late-stage development for pediatric indications; and

- Growing sales of the existing commercial products in our portfolio, including by identifying and investing in growth opportunities such as new treatment indications and new geographic markets.

Product Pipeline Assets

The following table summarizes key information about our product candidates and further detail regarding each product candidate follows:

	Program	Mechanism of Action	Target Indication	Development Stage
Pediatric Division	CERC-801	D-Galactose replacement	PGM1 Deficiency	Phase 1 505(b)(2)
	CERC-802	D-Mannose replacement	MPI Deficiency	IND-Enabling 505(b)(2)
	CERC-803	L-Fucose replacement	CDG-IIc	IND-Enabling 505(b)(2)
	CERC-913	Nucleoside replacement	DGUOK Deficiency	IND-Enabling
Neurology Division	CERC-301	GluN2B selective, NMDA Receptor antagonist	Neurogenic Orthostatic Hypotension	Phase 1 POC
	CERC-406	CNS-targeted, COMT inhibitor (2nd Gen)	Parkinson's Disease	IND-Enabling
	CERC-611	TARP-γ8 dependent AMPA Receptor antagonist	Partial Onset Seizures	Phase 1 Ready

Neurology Pipeline Assets

- **CERC-301:** ***Orphan Neurological Indication.*** CERC-301 is currently being developed as an adjunct therapy in Parkinson's Disease patients suffering from nOH, which is a condition that is part of a larger category called orthostatic hypotension ("OH") also known as postural hypotension. nOH is caused by dysfunction in the autonomic nervous system and causes people to feel faint when they stand or sit up. CERC-301 belongs to a class of compounds known as antagonists of the N-methyl-D-aspartate ("NMDA") receptor, 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 has been shown to be safe and well tolerated in over 350 patients and healthy volunteers during several clinical investigations. Throughout various trials, CERC-301 produced consistent and robust increases in blood pressure, which we believe will provide long-term clinical benefit of reducing the frequency and severity of symptoms associated with nOH. We anticipate progressing development into Phase 2 efficacy and dose ranging studies in nOH with the goal of obtaining the first chronic use label with symptomatic benefit. Currently approved therapies for nOH, Nothera (droxidopa) and Midodrine, have conditional approval (Sub-part H) and have not demonstrated and are not labeled for long-term

clinical benefits. As such, we believe CERC-301 may be well suited to address unmet medical needs in neurologic indications.

While listed as an orphan condition affecting less than 200,000 patients in the United States, nOH results from failure of the autonomic nervous system to regulate blood pressure in response to postural change, due to an inadequate release of norepinephrine. This leads to both orthostatic hypotension upon standing and supine hypertension when lying. nOH is a hallmark of several neurodegenerative diseases, including multiple systems atrophy, Parkinson's disease, and primary autonomic failure.

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

  Similarly, CERC-425 is an orally active small molecule, COMT inhibitor. The Company has de-prioritized the development of CERC-425 in order to focus on CERC-406, as described above.

- **CERC-611:** ***Adjunctive Treatment of Partial-Onset Seizures in Epilepsy.*** CERC-611 is a potent and selective antagonist of transmembrane alpha-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid ("AMPA") receptor regulatory protein ("TARP")-γ8-dependent AMPA currently in development as an adjunct therapy for refractory partial-onset seizures. TARPs are a recently discovered family of proteins that have been found to associate with, and modulate the activity of, AMPA receptors. TARP γ8-dependent AMPA receptors are localized primarily in the hippocampus, a region of the brain with importance in complex partial seizures and particularly relevant to seizure origination and/or propagation.

  We believe CERC-611 is the first drug candidate to selectively target and functionally block region-specific AMPA receptors after oral dosing, which we believe may improve the efficacy and side effect profile of CERC-611 over current anti-epileptics. Research also suggests that selectively targeting individual TARPs may enable selective modulation of specific brain circuits without globally affecting synaptic transmission. The clinical strategy for CERC-611 is currently being reevaluated due to a partial clinical hold. The exposure limits imposed by the agency currently allows for subtherapeutic dosing. We are investigating opportunities to broaden the exposure limits. We intend to develop CERC-611 as an adjunctive therapy for the treatment of partial-onset seizures in patients with epilepsy.

Pediatric Rare Orphan Disease Pipeline Assets

- **CERC-800 Series (CERC-801, CERC-802, and CERC-803):** ***Substrate Replacement Therapies for CDGs.*** CERC-801, CERC-802 and CERC-803 represent genetically-targeted, small molecule, substrate replacement therapies with established therapeutic utility for the treatment of CDGs. CDGs are a rapidly expanding group of rare Inborn Errors of Metabolism ("IEMs") due to defects in glycosylation. Glycosylation is the process by which carbohydrate complexes are created, modified and attached to proteins and lipids, creating glycoconjugates that are essential for cell structure and function in all tissues and organs. CDG is caused by a specific inherited mutation and more than 100 CDGs have been identified to date. CDGs typically present in infancy and can be associated with a broad spectrum of symptoms that include severe, disabling or life-threatening cases. Oral administration of CERC-801, CERC-802 or CERC-803 can replenish critical metabolic intermediates that are reduced or absent due to genetic mutation, overcoming single enzyme

defects to support glycoprotein synthesis, maintenance and function. CERC-801 utilizes D-galactose as the active pharmaceutical ingredient to treat Phosphoglucomutase 1 (PGM1) Deficiency; CERC-802 utilizes D-mannose as the active pharmaceutical ingredient to treat Mannose-Phosphate Isomerase (MPI) Deficiency; and CERC-803 utilizes L-fucose as the active pharmaceutical ingredient to treat Leukocyte Adhesion Deficiency Type II (LADII).

The FDA has granted Rare Pediatric Disease Designation and Orphan Drug Designation to CERC-801, CERC-802 and CERC-803. Under the FDA's PRV program, upon the approval of an NDA for the treatment of a rare pediatric disease, the sponsor of such application would be eligible for a PRV that can be used to obtain priority review for a subsequent new drug application or biologics license application. The PRV may be sold or transferred an unlimited number of times. Furthermore, we plan to leverage the 505(b)(2) NDA pathway for all three compounds to accelerate development and approval.

The below chart depicts the benefits associated with ODD and RPDD for each of the CERC-800 series compounds:

Eligibility	CERC-801	CERC-802	CERC-803
505(b)(2) NDA Pathway	✓	✓	✓
NCE 5-yrs Exclusivity	✓	✓	✓
ODD 7-yrs Exclusivity	✓	✓	✓
Priority Review Voucher	✓	✓	✓
EMA ODD 10-yrs Exclusivity	✓	✓	✓

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

Commercially Marketed Products

- **Poly-Vi-Flor:** This medication is a combination product of vitamins and fluoride. It is used in infants and children to treat or prevent deficiency due to poor diet or low levels of fluoride in drinking water and other sources. Vitamins are important building blocks of the body and help keep you in good health. Fluoride is used to prevent dental cavities.

- **Tri-Vi-Flor:** Multivitamins provide essential vitamins and minerals that are not taken in to the body through diet. Fluoride strengthens tooth enamel, which helps prevent dental cavities. In most major U.S. communities, fluoride is put into the water supply. Tri-Vi-Flor are used as a supplement to the diet of infants and children who do not receive adequate fluoride through drinking water. Tri-Vi-Flor are also used to prevent tooth decay in people treated with radiation, which may cause dryness of the mouth and increased risk of tooth decay.

- **Millipred®:** 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 problems, immune system disorders, skin and eye conditions, breathing problems, cancer, and severe allergies. It decreases your immune system's response to various diseases to reduce symptoms such as pain, swelling and allergic-type reactions. Supplied in 5mg tablets and 10mg in oral solution.

- **Ulesfia®:** Ulesfia® Lotion is indicated for the topical treatment of head lice infestation in patients six months of age and older. This product is not toxic to lice but kills them by depriving them of oxygen.

- **Karbinal™ ER:** Carbinoxamine is an antihistamine used to relieve symptoms of allergy, hay fever, and the common cold. These symptoms include rash, watery eyes, itchy eyes/nose/throat/skin, cough, runny nose, and sneezing. This medication works by blocking a certain natural substance (histamine) that your body makes during an allergic reaction. By blocking another natural substance made by your body (acetylcholine), it helps dry up some body fluids to relieve symptoms such as watery eyes and runny nose.

- **AcipHex® Sprinkle™:** AcipHex® Sprinkle™ or Rabeprazole is used to treat certain stomach and esophagus problems (such as acid reflux, ulcers). It works by decreasing the amount of acid your stomach makes. It relieves symptoms such as heartburn, difficulty swallowing, and persistent cough. This medication helps heal acid damage to the stomach and esophagus, helps prevent ulcers, and may help prevent cancer of the esophagus. Rabeprazole belongs to a class of drugs known as proton pump inhibitors ("PPIs").

- **Cefaclor for Oral Suspension:** This medication is a second-generation cephalosporin-type antibiotic used to treat a wide variety of bacterial infections (e.g., middle ear, skin, urine and respiratory tract infections). It works by stopping the growth of bacteria. This antibiotic only treats bacterial infections. It will not work for viral infections (e.g., common cold, flu). Unnecessary use or overuse of any antibiotic can lead to its decreased effectiveness.

- **Flexichamber™:** When a child is diagnosed with asthma, doctors often prescribe a metered dose inhaler ("MDI") - commonly referred to as an inhaler. Using an inhaler requires refined coordination and inhalation techniques that can be tricky, especially for small children. To ensure the child receives the optimal dose, many doctors prescribe a spacer - such as Flexichamber - to be used with an inhaler. Flexichamber was designed to overcome problems that patients commonly experience when using just an inhaler to administer their asthma medication. When used properly and as prescribed by a doctor, Flexichamber helps deliver asthma medication from the inhaler to tissue deep within the lungs, reduces the amount of medication that settles onto the child's mouth and throat, and allows caregivers to visually monitor breathing techniques and provide additional instructions if needed.

Intellectual Property

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 patent portfolios for our most advanced programs are summarized below:

- **CERC-301:** ***Orphan Neurological Indication.*** 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.*** 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.

- **CERC-611:** ***Adjunctive Treatment of Partial-Onset Seizures in Epilepsy.*** We possess worldwide exclusive rights to manufacture, use, and sell LY3130481, now known as CERC-611. The CERC-611 patent portfolio consists of two patent families. The first family consists of patents that have issued in the United States, Australia, Canada, China, France, Germany, Italy, Spain, Switzerland, United Kingdom, Japan, and a patent application in India with composition of matter and use claims for CERC-611. The expiration date of the United States patent, exclusive of any patent term extension, is November 20, 2033. The second family consists of patents that have issued in the United States, Australia, Canada, and Japan, and international patent applications in China (allowed) and India with composition of matter and use claims of varying scope for additional selective TARP γ8-dependent AMPA receptor antagonists. The expiration date of the U.S. patent, exclusive of any patent term extension, is May 21, 2035.

- **CERC-913:** ***ProTide Nucleotide for Mitochondrial Disorder.*** The CERC-913 patent portfolio consists of patent applications in the United States, Australia, Canada, China, Europe, India, and Japan with claims to compositions of matter and methods of use. Any patents issuing from these applications would expire in November 16, 2036 at the earliest, not including any potential patent term adjustment, patent term extension, or market exclusivity period.

- **Flexichamber.** The Flexichamber patent portfolio consists of patents that have issued in the United States, Australia and Japan, and patent applications in the United States, Australia, Canada, China, Europe, and India with claims to the device, methods for forming the device, and methods of use. The expiration date of the U.S. patent, exclusive of any patent term extension, is June 23, 2034.

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.

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

We promote our commercially marketed products through a sales force of 42 territory managers. During the third quarter of 2018, the Company initiated an expansion of the sales force, which is expected to be largely completed during the first quarter of 2019. Additionally, during the fourth quarter of 2018, we collaborated, on a limited basis, with a third-party sales force to market specific products to health care professionals. In the future, we may collaborate with a third-party sales force to market specific products on a limited basis. Our team is comprised of a complete support staff internally and we also partner with numerous world class vendors to increase our effectiveness and efficiency.

As pediatric specialists, our reach and frequency with key physicians and pharmacies is data driven to maximize our coverage of these important healthcare professionals. With established commercial operations, the Company is poised to be both flexible and scalable based on opportunities within the market.

For our neurology pipeline assets (CERC-301, CERC-406 and CERC-611), we intend to selectively retain commercialization or co-commercialization rights in the United States. We may complement with co-development and or co-promotion agreements with partners. For those product candidates for which we receive marketing approval, we will evaluate expanding our sales force into other specialty markets. We may also collaborate with third parties to market the approved product candidates in 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 pediatric rare orphan disease pipeline assets (CERC-800 series and CERC-913), we intend to retain commercialization in the United States. 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.

Competition—Pipeline Assets

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—Neurology Pipeline Assets

- **CERC-301:** ***Orphan Neurological Indication.*** 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.

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

- **CERC-611:** ***Adjunctive Treatment of Partial-Onset Seizures in Epilepsy.*** The epilepsy market is crowded with current therapies targeting a variety of mechanisms, including gamma-aminobutyric acid ("GABA") receptor agonism, T-type calcium channel blockers, sodium channel modulators, synaptic vesicle protein SV2A modulation, and inhibition of GABA transaminase. More recently, a new class of AMPA receptor antagonists have been approved for the treatment of epilepsy.

  CERC-611, if we are successful in developing it and it gains regulatory approval, would compete with a number of branded and generic anti-epileptic drugs. A few major pharmaceutical companies (GSK (Lamictal/XR), Pfizer (Lyrica)) and specialty players (UCB (Vimpat, Keppra), Lundbeck (Sabril) and Supernus (Trokendi XR)) dominate the anti-epilepsy drug therapy market. New market entrants such as Sage Pharmaceuticals and GW Pharmaceuticals are targeting difficult to treat orphan patient populations such as super-refractory status epilepticus and Dravet Syndrome, respectively. To our knowledge, there are no other TARP γ-8-dependent AMPA receptor antagonist s in development other than CERC-611.

Competition—Pediatric Rare Orphan Disease Pipeline Assets

- **CERC-800 series (CERC-801, CERC-802 and CERC-803):** ***Substrate Replacement Therapy for CDGs.*** Currently there are no FDA or EMEA 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).

- **CERC-913:** ***ProTide Nucleotide for Mitochondrial Disorder.*** Currently there are no FDA or EMEA approved products for the treatment of Mitochondrial Depletion Syndrome MDA using a ProTide Nucleotide therapy for Mitochondrial DNA Depletion Syndrome ("MDS").

Competition—Commercially Marketed Products

Across all our product lines there is over-the-counter ("OTC") branded and generic competition. However, we believe our products do have significant aspects of clinical and competitive differentiation in the marketplace that allows us to effectively market, compete and grow market share in the face of competition.

- **Poly-Vi-Flor / Tri-Vi-Flor:** Poly-Vi-Flor / Tri-Vi-Flor primarily compete against generic prescription multi-vitamin fluoride market and the brands of FLORIVA and QFLORA. Our primary point of differentiation is Metafolin and that our form of Metafolin is a body-ready folate to aid in cell reproduction. As well, we offer formulations that are patient friendly in terms of size of tablet and taste of medication ensuring compliance of their daily fluoride vitamin supplementation.

- **Millipred®:** 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 market place allowing HCPs greater flexibility when dosing a glucocorticoid steroid across a variety of pediatric 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.

- **Ulesfia®:** Ulesfia® competes in a market place that is primarily made up of step-wise therapy utilizing OTC remedies. Once into the prescription marketplace Sklice® is the market leader differentiated primarily by pricing and contracting. However, Ulesfia is the leader in providing a non-neuro toxic / non-pesticide for treating headlice.

- **Karbinal™ ER:** Karbinal™ ER faces competition from OTC products such as non-sedating antihistamines, sedating antihistamines as well as nasal steroids. Karbinal's greatest point of differentiation is our LIQUIDRX Technology that allows for extended release and flexible BID dosing. This feature makes Karbinal ER the only BID first generation antihistamine. Additionally, Karbinal has a significant anticholinergic / drying effect on the symptoms associated with seasonal, perennial, as well as vasomotor allergic rhinitis.

- **AcipHex® Sprinkle™:** AcipHex® Sprinkle™ primarily faces competition from the OTC Proton Pump Inhibitors, however those products (Nexium OTC and Prilosec OTC) are not indicated for children less than 18 years of age. In the branded space the primary competition is from Nexium Packets. We clinically differentiate AcipHex Sprinkle as the only PPI that is proven to demonstrate esophageal mucosal healing as determined by endoscopy in children less than 18 years of age.

- **Cefaclor for Oral Suspension:** Cefaclor for Oral Suspension faces significant competition from the generic antibiotics of amoxicillin as well as Omnicef / Ceftin. We feel our keep point of differentiation is through our clinical positioning for appropriate patients who have failed first line therapies. Cefaclor is the best first choice as a second line treatment for antibiotics that have failed patients suffering from streptococcus, urinary tract infections and otitis media. Cefaclor is a second generation antibiotic indicated against a broad range of pathogens with a broad range of indications.

- **Flexichamber™:** Flexichamber™ is a patented and proprietary design that allows a patient with a necessary spacer that is conveniently portable. There are numerous competitors in the market place with the main competition being AreoChamber. Flexichamber's collapsibility / portability is unique compared to the competition.

Overall Competitive Climate and Risks

In addition, the companies described above and 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 may 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, 2018, we had 64 full-time employees, five of whom were primarily engaged in research and development activities and 47 were engaged in commercialization activities. None of our employees is 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.

Item 1A. Risk Factors.

You should consider carefully the following information about t
he 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

Our success and revenue depend on two portfolios of products; if either is not successfully commercialized or if we do not acquire new products, our revenue might not grow, which could affect our stock price.

We currently have rights to only two portfolios of commercial pharmaceutical products consisting of eight commercial assets, those we acquired with TRx in November 2017 and Avadel's pediatric products, which we acquired in February 2018. Our prospects over the next three to five years are substantially dependent on the successful commercialization and growth of revenue from these products, including their acceptance by the medical community and third-party payers as useful and cost-effective. We might be required to engage in expensive advertising, educational programs, provide discounts or other means to market these products.

Even if our current products generate significant revenue and profits, our ability to increase revenue in the future will depend in part on our success in in-licensing or acquiring, and developing, additional pharmaceutical products. We currently intend to seek to in-license or acquire development stage compounds and commercialized pharmaceutical products, focusing on the pediatric space. These kinds of compounds and pharmaceutical products might not be available to us on attractive terms.

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 or trial termination following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities, or due to concerns about trial design, or a decision by the FDA, other regulatory authorities, IRBs or the company, or recommendation by a data safety monitoring board, to place the trial on hold or otherwise suspend or terminate clinical trials at any time for safety issues or for any other reason;
- delays in reaching agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites;
- deviations from the trial protocol by clinical trial sites and investigators, or failing to conduct the trial in accordance with regulatory requirements;
- failure of our third parties, such as CROs, to satisfy their contractual duties or meet expected deadlines;
- failure to enter into agreements with third parties to obtain the results of clinical trials;
- delays in the importation and manufacture of clinical supply;
- delays in the testing, validation and delivery of the clinical supply of the product candidates to the clinical sites;
- for clinical trials in selected subject populations, delays in identification and auditing of central or other laboratories and the transfer and validation of assays or tests to be used to identify selected subjects;
- delays in recruiting suitable subjects to participate in a trial;
- delays in having subjects complete participation in a trial or return for post-treatment follow-up;
- delays caused by subjects dropping out of a trial due to side effects or disease progression;
- delays in adding new investigators and clinical trial sites;
- 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 because of negative publicity from

adverse events in the biotechnology industry or for other reasons, including competitive clinical trials for similar subject populations, 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 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. For example, the clinical trial must be well-designed and conducted and performed by qualified investigators in accordance with ethical principles and current Good Clinical Practice, or GCPs. 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 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 PDUFA NDA application fee 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 do 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. Thus, 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 interrupt, delay or halt clinical trials (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 current GMP regulations and standards. If we or a regulatory agency discover previously unknown problems with the facility where the product is manufactured, we may be subject to reporting obligations and a regulatory agency may impose restrictions on that product, the manufacturing facility, us, or our suppliers, including requesting recalls or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates, our contractors, the manufacturing facilities for our product candidates or others working on our behalf fail to comply with applicable regulatory requirements, either before or after marketing approval, a regulatory agency may:

- issue Warning Letters 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 Foreign Corrupt Practices Act of 1977 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 or 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 (such as Medicare and Medicaid), 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. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we generate from the sale of the product in that particular country. 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.

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.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product

candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively the Affordable Care Act, was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The law has continued the downward pressure on pharmaceutical pricing, especially under the Medicare program, and increased the industry's regulatory burdens and operating costs. Among the provisions of the Affordable Care Act of importance to our potential drug candidates are the following:

- 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 50% (and 70% commencing January 1, 2019) 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.

We cannot predict the full impact of the Affordable Care Act on pharmaceutical companies, as many of the reforms require the promulgation of detailed regulations implementing the statutory provisions, some of which has not yet fully occurred. For example, in January 2016, the Centers for Medicare and Medicaid Services issued a final rule regarding the Medicaid Drug Rebate Program, effective April 1, 2016, that, among other things, revises the manner in which the "average manufacturer price" is to be calculated by manufacturers participating in the program and implements certain amendments to the Medicaid rebate statute created under the Affordable Care Act. Further, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. Since January 2017, the President of the United States has signed two Executive Orders and other directives designed to delay the implementation of any certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Congress will likely consider other legislation to replace elements of the Affordable Care Act. The Affordable Care Act is likely to continue the downward pressure on pharmaceutical pricing and may also increase our regulatory burdens and operating costs. We continue to evaluate the effect that the Affordable Care Act and its possible repeal and replacement has on our business.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This included further reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2025 unless additional Congressional action is taken. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period in which the government may recover overpayments to providers from three to five years.

Further, there have been several recent U.S. 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 for drugs. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to pharmaceutical product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the current administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, on May 11, 2018, the President of the United States laid out his administration's "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" to reduce the cost of prescription drugs while preserving innovation and cures. The Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. Although some of these and other proposals will require authorization through additional legislation to become effective, Congress and the U.S. presidential administration have each indicated that they will continue to seek new legislative and/or administrative 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.

Moreover, the Drug Supply Chain Security Act, which was enacted in 2012 as part of the Food and Drug Administration Safety and Innovation Act, imposes new obligations on manufacturers of pharmaceutical products related to product tracking and tracing. Legislative and regulatory proposals have been made 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.

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 such as Medicare or Medicaid;
- 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. Civil False Claims Act liability may be imposed for Medicare or Medicaid overpayments, for example, overpayments caused by understated rebate amounts, that are not refunded within 60 days of discovering the overpayment, even if the overpayment was not cause by a false or fraudulent act;

- the criminal federal False Claims Act imposes criminal fines or imprisonment against individuals or entities who willfully make or present a claim to the government knowing such claim to be false, fictitious or fraudulent;

- the Veterans Health Care Act requires manufacturers of covered drugs to offer them for sale on the Federal Supply Schedule, which requires compliance with applicable federal procurement laws and regulations and subjects us to contractual remedies as well as administrative, civil and criminal sanctions;

- the federal Health Insurance Portability and Accountability Act and its related regulations, collectively HIPAA, impose criminal liability for, among other actions, knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, or knowingly and willfully making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, also imposes obligations on certain covered entity health care providers, health plans, and health care clearinghouses as well as their business associates that perform certain services involving individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, as well as directly applicable privacy and security standards and requirements

- the civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent;

- the federal Physician Sunshine Act, created under Section 6002 of the Affordable Care Act and its implementing regulations, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare and Medicaid Services, or CMS, information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians (as defined above) and their immediate family members;

- the FCPA prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations; and

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

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations involve substantial costs. For example, we must ensure that all applicable price concessions are included in prices calculated and reported to federal agencies. 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. If our security measures are breached or fail and/or are bypassed because of third-party action, inadvertent disclosures through technological or human error (including employee error), malfeasance, hacking, ransomware, social engineering (including phishing schemes), computer viruses, malware, or otherwise, unauthorized acquisition of or access to sensitive information may occur. As a result, our reputation could be damaged, our business might suffer, information might be lost, and we could face damages for breach of contract, 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 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 U.S., 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 penalties or sanctions. For example, violations of the Health Insurance Portability and Accountability Act ("HIPAA") may result in civil fines of up to $57,051 per violation and a maximum civil penalty of $1,711,533in a calendar year for violations of the same requirement, as well as criminal penalties. Recently, the U.S. Department of Health and Human Services Office for Civil Rights, which enforces HIPAA, appears to have increased its enforcement activities. 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. For example, California recently enacted and amended the California Consumer Protection Act ("CCPA"), which could present implementation challenges and risk of enforcement. There may be additional amendments to the CCPA, and regulations promulgated pursuant to the CCPA may alter how the law applies; therefore, the extent to and manner in which the CCPA would apply to our operations is unclear. 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, the 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 Department of Health and Human Services and, in certain circumstances involving large breaches, to the media. Business Associates must report breaches of unsecured protected health information to Covered Entities within 60 days of discovery of the breach by the Business Associate or its agents. 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 we 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, since May 25, 2018, 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. Under GDPR, for example, fines of $20.0 million or 4% of global turnover may be imposed for violations.

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.

We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. As such, we could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. Many of the other biotechnology and pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than 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.

In addition, we have scientific and clinical advisors who assist us in formulating our development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

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 fail to realize all of the anticipated benefits of recent acquisitions or those benefits may take longer to realize than expected, and our future results of will suffer if we do not effectively manage our expanded operations following the completion of the acquisitions.

In November 2017 we acquired TRx Pharmaceuticals, LLC and its franchise of commercial medications, in February 2018 we acquired pediatric products from Avadel U.S. Holdings, Inc., and in September 2018 we acquired Ichorion's in-process research and development for three preclinical therapies for inherited metabolic disorder. Our ability to realize the anticipated benefits of these acquisitions will depend, to a large extent, on our ability to integrate the acquisitions into our business, which might be particularly challenging because these are our first commercial operations. As a result, our management team will devote a significant amount of attention and resources into integrating these acquisitions into our business practices and operations. This integration process may disrupt our current business.

Our future success depends, in part, upon our ability to integrate and manage these new product lines, pipeline assets, and any future acquisitions, which poses substantial challenges for management, including challenges related to the management and monitoring of new operations and associated increased costs and complexity. If we are unsuccessful in integrating and managing our new product lines, pipeline assets, and any future acquisitions, our operations and financial condition could be adversely affected, and we might not be able to take advantage of business development opportunities anticipated when making the acquisitions.

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

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

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

products effectively. Such third parties may also not comply with the applicable regulatory requirements, which could potentially expose us to regulatory and legal enforcement actions.

Risks Related to Our Dependence on Third Parties

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

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

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

- collaborators have significant discretion in determining the amount and timing of the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- the nonclinical studies and clinical trials conducted as part of these collaborations may not be successful;
- collaborators may 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 may 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 may 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 may 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 complies with GCP requirements. In addition, we must conduct our clinical trials with product produced under applicable GMP requirements. Failure to comply with these regulations may require us to repeat preclinical and clinical trials, which would delay the marketing approval process.

Our CROs and clinical trial sites are not our employees, and, except for remedies available to us under our agreements with such CROs and clinical trial sites, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. These CROs and clinical trial sites may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If CROs or clinical trial sites do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we might not be able to obtain marketing approval for or successfully commercialize our product candidates or we may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be adversely affected.

Switching or adding CROs involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, prospects, financial condition and results of operations.

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

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

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

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

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

- reliance on the third parties for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreements by the third parties because of factors beyond our control;
- the possible misappropriation of our proprietary information, including trade secrets and know-how;
- the possibility of termination or nonrenewal of the agreements by the third parties because of our breach of the manufacturing agreement or based on their own business priorities;
- the disruption and costs associated with changing suppliers, including additional regulatory filings.
- failure to satisfy their 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 GMP 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.

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 ours. 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 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 have entered into exclusive license agreements with Merck & Co., Inc. and its affiliates ("Merck") pursuant to which Merck has granted us rights to the compounds used in CERC-301 and the COMTi platform, including CERC-406. We have also entered into an exclusive

license, development and commercialization agreement with Eli Lilly and Company ("Lilly") pursuant to which we received exclusive global rights to develop and commercialize CERC-611. If we fail to comply with the obligations under these agreements, including payment terms, Merck and Lilly 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 our 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.

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 United States Patent and Trademark Office, or 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 infringe 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 our 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 preissuance submission of prior art to the USPTO, or opposition, derivation, reexamination, inter partes review or interference proceedings, or other preissuance 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 Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith 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 Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith 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 Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith 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, 2018, we had $10.6 million in cash and cash equivalents and $26.2 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 until our November 2017 acquisition of TRx, our operations have consumed substantial amounts of cash since inception. Research and development remain an important part of our business, and our new commercial operations might not be profitable or generate enough funds to support our operations. 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.

Additionally, as part of the Avadel acquisition, we assumed financial obligations to Deerfield CSF, LLC, which include a $15 million loan due in January 2021. Depending on the Company's cash position in January 2021, we may need to raise additional capital to repay the loan obligation.

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 ourselves.

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

- the integration and profitability of our recently acquired commercial businesses (TRx in November 2017 and Avadel's pediatric business in February 2018);
- 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 expanding 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.

Failure to comply with the financial covenants under the debt agreement assumed during the acquisition of Avadel's pediatric products could allow Deerfield CSF to call for immediate repayment of the outstanding borrowings.

As part of the Avadel acquisition, we assumed financial obligations to Deerfield CSF, LLC, which include a $15 million loan due in January 2021 ("Deerfield Obligation"), fixed quarterly payments of $262,500 through January 2020 and contingent consideration of $12,500,000 paid quarterly as 15% of acquired Avadel pediatric product sales. The Deerfield Obligation is governed an agreement containing certain covenants. There can be no assurance that we will be in compliance with all of these covenants in the future and that Deerfield will not immediately call for repayment of the outstanding borrowings in the event we are not in compliance with any of the covenants.

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

Until our acquisition of TRx in November 2017, we were a clinical-stage biotechnology company with a limited operating history. 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 $40.1 million for the year ended December 31, 2018. As of December 31, 2018, we had an accumulated deficit of $98.2 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.

Even though we now have approved products and commercial operations, we might continue to incur losses in the future. Even if we do generate product sales, we might never achieve or sustain 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 significant 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.

The Company had a significant amount of gross net operating losses ("NOLs") for federal and state purposes that will begin to expire in 2031.

Unused losses 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 losses generated after December 31, 2017, under new tax legislation signed into law on December 22, 2017, known as the Tax Cuts and Jobs Act of 2017, or the Tax Act, 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 our current and our future unused losses 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, as defined (in general, an "ownership change" is defined as a greater than 50% change (by value) in equity ownership over a three-year period).

U.S. federal income tax reform could adversely affect our business and financial condition.

The Tax Act significantly revised the IRC. The revised federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for NOLs to 80% of current year taxable income and elimination of NOL carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits (including reduction of tax credits under the Orphan Drug Act). Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our

business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law.

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 limited commercial operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We commenced commercial operations upon our acquisition of TRx in November 2017. Prior to that, our operations consisted of organizing and staffing our company, business planning, raising capital and developing our product candidates and platform. We have not yet demonstrated our ability to successfully develop any product candidate, obtain marketing approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability might not be as accurate as they could be if we had a longer commercial operating history.

In addition, as an early-stage business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. Our transition from a company with a research and development focus to a company capable of supporting commercial activities might not be successful.

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 each of our product candidates, including pediatric products from Avadel and TRx, and most recently product candidates we acquired Ichorion. As a part of the Ichorion acquisition, we issued approximately 5,798,735 shares of our common stock, and payment of certain development milestones of up to an additional $15,000,000, payable either in shares of our common stock or in cash. As part of the Avadel acquisition, we assumed financial obligations to Deerfield CSF, LLC, which include a $15 million loan due in January 2021 and royalty payments of 15% of net sales through February 2026. As a part of the TRx acquisition, we issued 7,534,884 shares of our common stock to the sellers and the potential to pay Lachlan Pharmaceuticals up to $4.0 million in milestone payments. 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 Capital Market, NASDAQ could delist our common stock.

Our common stock is currently listed on the NASDAQ Capital Market ("NASDAQ"). 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 NASDAQ 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 NASDAQ'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 minimum bid price requirement or prevent future non-compliance with NASDAQ's listing requirements.

An active trading market for our securities might not be sustained.

Although our common shares are listed on the NASDAQ we cannot assure you that an active trading market for our common shares will continue to develop or be sustained, particularly because one investor, Armistice Capital, now holds a significant amount of our outstanding stock. If an active market for our common shares is not sustained it may impair your ability to sell your warrants or shares of our common stock at the time you wish to sell them or at a price that you consider reasonable, you may not be able to sell your shares quickly or at the market price. An inactive market may also impair our ability to raise capital to continue to fund operations by selling common shares and may impair our ability enter into strategic collaborations or acquire companies or products by using our by using our common shares as consideration.

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, 2018, the per share trading price of our common stock has been as high as $6.65 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 us 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, 2018, there were 602,657 shares available for future issuance under the 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 common stock of the Company on the last trading day in December of the prior calendar year. On January 1, 2019, on the terms of the 2016 Amended Plan an additional 1,632,167 shares were made available for issuance for a total of 2,234,824 shares available for issuance. In addition, as of December 31, 2018, there were 783,983 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 shall automatically increase 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. Future issuances, as well as the possibility of future issuances, under our 2016 Plan or 2016 ESPP or other equity incentive plans could cause the market price of our common stock to decrease.

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

Armistice Capital beneficially own approximately 60% of our outstanding common stock. As a consequence, Armistice Capital 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 Capital 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 Capital makes investments in companies and may, from time to time, acquire and hold interests in businesses that compete directly or indirectly with us. Armistice Capital 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 Capital may supersede ours, causing Armistice Capital 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 Capital and inaction on our part could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Armistice Capital controls a seat on our board of directors. Since Armistice Capital could invest in entities that directly or indirectly compete with us, when conflicts arise between the interests of Armistice Capital 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 shareholder vote to approve compensation of certain executive officers) and the "say on golden parachute" provisions (requiring a non-binding shareholder 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, or 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 our company. 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 our company, 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, that could result in our reported costs being different than expectations, which could negatively affect our stock price. If we do obtain securities or industry analyst coverage and if one or more of the analysts who covers us downgrades our securities or publishes inaccurate or unfavorable research about our business, our securities prices would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our securities could decrease, which could cause our securities prices and trading volume to decline.

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, NASDAQ 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 NASDAQ 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 the Court of Chancery of the State of Delaware is the sole and exclusive forum for certain litigation that may be initiated by 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 the Court of Chancery of the State of Delaware is the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the company; (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the company to the company or the company's stockholders; (iii) any action asserting a claim against the company arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our second amended and restated bylaws; or (iv) any action asserting a claim against the company governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in our securities shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation described above. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, 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 adversely affect our business, financial condition and results of operations.

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 Delaware General Corporation Law (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 has 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.

Item 3. Legal Proceedings.

Lachlan Pharmaceuticals

In November 2017, the Company acquired TRx and its wholly-owned subsidiaries, including Zylera. The previous owners of TRx beneficially own more than 10% of our outstanding common stock. Zylera, which is our wholly owned subsidiary, entered into the First Amended and Restated Distribution Agreement with Lachlan, effective December 18, 2015. 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.

Zylera is obligated to purchase a minimum of 20,000 units per year, or approximately $1.2 million worth of product, from Lachlan, subject to certain termination rights. Zylera must pay Lachlan $58.84 per unit and handling fees that are equal to $3.66 per unit of fully packaged Ulesfia in 2018, and escalate at a rate of 10% annually, as well as reimburse Lachlan for all product liability insurance fees incurred by Lachlan. The Lachlan Agreement also requires that Zylera make certain cumulative net sales milestone payments and royalty payments to Lachlan with a $3 million annual minimum payment unless and until there has been a “Market Change” involving a new successful competitive product. Lachlan is obligated to pay identical amounts to an unrelated third party from which it obtained rights to Ulesfia, with the payments ultimately flowing to Summers Laboratories, Inc. (“Summers Labs”). Because of the dispute described below, the Company has 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. The second interim award rejected Summers Labs' request to accelerate future minimum royalties, however, it ruled 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 as contemplated in the second interim ruling. The final award has no direct bearing on the Company as 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 is 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 the Company’s agreement with Lachlan. However, the Company has interpreted this ruling's impact on the Lachlan agreement to mean that a market change has not occurred, and the minimum purchase obligation and minimum royalty provisions of the contract are active and due for any prior periods as well as going forward for any future periods.

The Company has recognized a $7.8 million liability for these minimum obligations in accrued liabilities as of December 31, 2018. Under the terms of the TRx Purchase Agreement, the former TRx owners are required to indemnify the Company for 100% of all pre-acquisition losses related this arbitration, including legal costs, and possible minimum payments in excess of $1 million. Furthermore, the former TRx owners are required to indemnify the Company for 50% of post-acquisition Ulesfia losses, which would include losses resulting from having to fund these minimum obligations. The Company has recorded an indemnity receivable of $4.9 million in other receivables as of December 31, 2018, which the Company believes is fully collectible. The receivable is net of $1.9 million collection made in the fourth quarter of 2018 from a full cash escrow release with the former TRx owners from the escrow that was established as a part of the TRx acquisition. The post-acquisition minimum obligations net of amounts recorded within the indemnity receivable of $2.2 million has been recorded in cost of product sales for the year ended December 31, 2018. If the Company fails to make these minimum obligations timely then the Lachlan Agreement may be terminated by Lachlan, in which case the Company would no longer be able to sell the Ulesfia product, but it would also not be subject to future minimum obligations. Lachlan has not requested payment for the minimum obligations.

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 11, 2019, there were approximately 56 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.

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

Comparison of the Years Ended December 31, 2018 and 2017

The following table summarizes our revenue for the years ended December 31, 2018 and 2017

	Year Ended December 31,	
	2018	2017
	(in thousands)	
Product revenue, net	$ 17,871	$ 1,910
Sales force revenue	456	278
License and other revenue	—	25,000
Grant revenue	—	625
	$ 18,327	$ 27,813

Product revenue, net

Product revenue, net was $17.9 million for the year ended December 31, 2018, compared to $1.9 million for the year ended December 31, 2017. The net product revenue for the year ended December 31, 2018 represents a full year of revenues from the sale of products acquired in the acquisition of TRx on November 17, 2017 and nearly a full year of sales of products acquired from the acquisition of Avadel's pediatric products on February 16, 2018. The net product revenue for the year ended December 31, 2017 represents revenues from the sale of our pediatric products following the acquisition of TRx on November 17, 2017.

Sales force revenue

As part of the acquisition of TRx in November 2017, the Company acquired a sales and marketing agreement with Pharmaceutical Associates, Inc. ("PAI") in which 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. Sales force revenue was $0.5 million for the year ended December 31, 2018 as compared to $0.3 million for the year ended December 31, 2017. The increase was due to 1.5 months of revenue in 2017 as compared to four months of revenue in 2018. The PAI contract was canceled during the second quarter of 2018.

License and other revenue

There was no license and other revenue for the year ended December 31, 2018, compared to $25.0 million for the year ended December 31, 2017. In the third quarter of 2017, the Company sold CERC-501 to Janssen in exchange for initial gross proceeds of $25.0 million. Under this agreement, we are also eligible for a potential future $20.0 million regulatory milestone payment. 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.

Grant revenue

There was no grant revenue for the year ended December 31, 2018, compared to $0.6 million for the year ended December 31, 2017. The grant revenues for the year ended December 31, 2017 related to CERC-501 and were dependent upon the timing and progress of the underlying studies and development activities. The grant revenue and study costs related to these grants were discontinued with the sale of CERC-501 to Janssen in August 2017.

Cost of product sales

Cost of product sales was $7.5 million for the year ended December 31, 2018, compared to $0.6 million for the year ended December 31, 2017. Cost of product sales related to sales of products from our pediatric products that we recently acquired. The increase of $6.9 million in cost of product sales in the current year is due to the Company having a full year of sales of products acquired from the TRx acquisition in 2017 and nearly a full year of sales of products acquired from the acquisition of Avadel's pediatric products on February 16, 2018, while in the previous year the Company had approximately one month of sales since TRx was acquired on November 17, 2017.

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2018 and 2017:

	Year Ended December 31,	
	2018	2017
	(in thousands)	
Preclinical expenses	$ 1,886	$ 1,162
Clinical expenses	1,693	607
CMC expenses	389	677
Internal expenses not allocated to programs:		
Salaries, benefits and related costs	1,223	1,476
Stock-based compensation expense	101	152
Other	495	299
	$ 5,787	$ 4,373

Research and development expenses were $5.8 million for the year ended December 31, 2018, an increase of $1.4 million compared to the same period in 2017. Preclinical expenses increased by $0.7 million primarily due to toxicology studies performed during 2018 in support of clinical development. Clinical expenses increased by $1.1 million compared to the same period in 2017 primarily due to activities related to the CERC-301 clinical study in nOH and activities related to CERC-801, CERC-802, and CERC-803, which were acquired as part of the Ichorion acquisition in September 2018. Chemistry, Manufacturing, and Controls ("CMC") expenses decreased $0.3 million for the year ended December 31, 2018 compared to the same period in 2017 due to higher prior year spending on clinical trial material stability and drug product to support clinical development.

Acquired In-Process Research and Development Expenses

The following table summarizes our acquired in-process research and development ("IPR&D") expenses for years ended December 31, 2018 and 2017:

	Year Ended December 31,	
	2018	2017
	(in thousands)	
Acquired in-process research and development	$ 18,724	$ —

As part of the asset acquisition of Ichorion, the Company acquired $18.7 million of IPR&D expenses for three preclinical therapies for inherited metabolic disorders known as CDGs (CERC-801, CERC-802 and CERC-803). The fair value of the IPR&D was immediately recognized as acquired in-process research and development expense as the IPR&D asset has no other alternate use due to the stage of development. There was no acquired in-process research and development expense for the year ended December 31, 2017.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the years ended December 31, 2018 and 2017:

	Year Ended December 31,	
	2018	2017
	(in thousands)	
Salaries, benefits and related costs	$ 3,607	$ 2,433
Legal, consulting and other professional expenses	4,426	3,944
Stock-based compensation expense	2,136	1,001
Other	508	564
	$ 10,677	$ 7,942

General and administrative expenses were $10.7 million for the year ended December 31, 2018, an increase of $2.7 million compared to the period in 2017. Salaries, benefits and related costs increased by $1.2 million for the year ended December 31, 2018 compared to the same period of 2017 due to an increase in salary related costs. Legal, consulting and other professional expenses increased by $0.5 million compared to the same period of 2017 primarily as a result of the legal, compliance and integration costs associated with our acquisitions. Stock-based compensation expense increased by $1.1 million over the same period comparison primarily as a result of the acceleration of the vesting of stock options of a senior executive who was separated in the period and the subsequent recognition of the additional expense, in addition to stock compensation expense related to awards granted to new senior executives.

Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses for the years ended December 31, 2018 and 2017:

	Year Ended December 31,	
	2018	2017
	(in thousands)	
Salaries, benefits and related costs	$ 5,571	$ 303
Consulting and other professional expenses	1,458	140
Stock-based compensation expense	194	4
Advertising and marketing expense	1,161	71
Other	138	52
	$ 8,522	$ 570

The Company began to incur sales and marketing expenses after the TRx acquisition on November 17, 2017. Sales and marketing expenses were $8.5 million for the year ended December 31, 2018 as compared to $0.6 million for the year ended December 31, 2017. Salaries, benefits and related costs increased as a result of increasing sales and sales support personnel needed to maintain and grow our commercial sales activities in connection with the acquired TRx and Avadel's pediatric products. Logistics, insurance and other commercial operations expenses were incurred in order to support commercial operations. Advertising and marketing expenses were incurred to support the portfolio of pediatric drug products for sale. During the third quarter of 2018, the Company initiated an expansion of the sales force which is expected to be largely completed by the end of the first quarter of 2019.

Amortization expense

The following table summarizes our amortization expense for the years ended December 31, 2018 and 2017:

	Year Ended December 31,	
	2018	2017
	(in thousands)	
Amortization of intangible assets	$ 4,532	$ 404

Amortization expense was $4.5 million for the year ended December 31, 2018 as compared to $0.4 million for the year ended December 31, 2017. The amortization expense relates to the acquisition of intangible assets as part of the acquisitions of TRx in November

2017 and Avadel's pediatric products in February 2018. The increase of amortization expense of $4.1 million for the year ended December 31, 2018 as compared to 2017 is driven by a full year of amortization for the intangible assets acquired as part of the TRx acquisition and amortization from February 16, 2018 through December 31, 2018 for the intangible assets acquired as part of Avadel's pediatric products in 2018. In 2017, the amortization relates only to the intangible assets acquired as part of the TRx acquisition for the period between the TRx acquisition date on November 17, 2017 and December 31, 2017.

Impairment of Intangible Assets

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 intangible asset upon termination of the corresponding agreement. No expense related to impairment of intangible assets was recognized for the year ended December 31, 2017.

Change in fair value of contingent consideration

The Company recognized a loss on the change in fair value of contingent consideration of $58,366 for the year ended December 31, 2018 as compared to $0 for the same period in 2017. The contingent consideration is related to 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 as part of the Company's acquisitions of Avadel's pediatric products and TRx. The fair value of contingent consideration was determined at the acquisition date (see Note 5 for more information). Subsequent to the acquisition date, at each reporting period, the contingent consideration liability is remeasured at the current fair value with changes recorded to its own standalone line in operating expenses in the consolidated statement of operations.

Other expense, net

The following table summarizes our other expense, net for the years ended December 31, 2018 and 2017:

	Year Ended December 31,	
	2018	2017
	(in thousands)	
Change in fair value of warrant liability and unit purchase option liability	$ 25	$ (30)
Other income, net	14	—
Interest expense, net	(812)	(24)
	$ (773)	$ (54)

Other expense, net was $0.8 million for the year ended December 31, 2018 as compared to $0.1 million for the same period in 2017. Interest expense increased $0.8 million for the year ended December 31, 2018 as compared to the same period in 2017. The interest expense recognized in the year ended December 31, 2018 relates to interest for the Deerfield obligation assumed as part of the Avadel Pediatric Products Acquisition, which took place in the first quarter of 2018. Interest expense was minimal for the year ended December 31, 2017 due to the reduction in the principal balance of the secured term loan facility which was paid off in August 2017.

Income tax (benefit) expense

The income tax benefit was $33,910 for the year ended December 31, 2018. The provision for income taxes for the year ended December 31, 2018 is 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 provision for income taxes was $2.0 million for the year ended December 31, 2017 due to the net income generated from the sale of CERC-501 to Janssen during the third quarter of 2017. The annual effective tax rate was 0.09% and 14.21% for the years ended December 31, 2018 and 2017, respectively.

Non-GAAP Financial Metrics

In addition to disclosing financial results that are determined in accordance with U.S. Generally Accepted Accounting Standards ("GAAP"), the Company also uses the following non-GAAP financial metrics to understand and evaluate our operating performance:

EBITDA, which the Company defines as GAAP net income adjusted for (i) taxes, (ii) interest expense, (iii) interest income, (iv) amortization of intangible assets, (v) depreciation, and (vi) inventory step-up adjustment recognized in earnings.

Adjusted EBITDA, which the Company defines as EBITDA as defined above further adjusted for (i) stock-based compensation expense, (ii) change in fair value of contingent consideration, (iii) change in fair value of warrant liability and unit purchase option liability, (iv) restructuring costs, (v) acquisition and integration-related expenses, (vi) impairment of intangible assets, (vii) arbitration costs related to the Lachlan transaction, which is further described in Item 1 Note 7, (viii) acquired IPR&D, which is further described in Item 1 Note 4, and (ix) sale or out-licensing of Company assets.

The Company updated our definition of Adjusted EBITDA during the third quarter of 2018 to further adjust for acquired IPR&D and sale or out-licensing of Company assets. These updates did not impact previous presentation of prior periods.

The Company believes that providing this additional information is useful to the reader to better assess and understand our operating performance, primarily because management typically monitors the business adjusted for these items in addition to GAAP results. These non-GAAP financial metrics should be considered supplemental to and not a substitute for financial information prepared in accordance with GAAP. Our definition of these non-GAAP metrics may differ from similarly titled metrics used by others. The Company views these non-GAAP financial metrics as a means to facilitate our financial and operational decision-making, including evaluation of our historical operating results and comparison to competitors' operating results. These non-GAAP financial metrics reflect an additional way of viewing aspects of our operations that, when viewed with GAAP results may provide a more complete understanding of factors and trends affecting our business. The determination of the amounts that are adjusted from these non-GAAP financial metrics is a matter of management judgment and depends upon, among other factors, the nature of the underlying expense or income amounts. Because non-GAAP financial metrics adjust for the effect of items that will increase or decrease our reported results of operations, we strongly encourage investors to review our consolidated financial statements and periodic reports in their entirety.

The following tables present reconciliations of these non-GAAP financial metrics to the most directly comparable GAAP financial measure for the years ended December 31, 2018 and 2017:

	Year Ended December 31,	
	2018	2017
GAAP Net (loss) income	$ (40,053)	$ 11,870
Non-GAAP Adjustments:		
Income tax expense	(34)	1,967
Interest expense, net	812	24
Amortization of intangible assets	4,532	404
Depreciation	23	22
Inventory step-up adjustment recorded in earnings	301	138
EBITDA	$ (34,419)	$ 14,425
Non-GAAP Adjustments:		
Stock-based compensation	2,431	1,157
Change in fair value of contingent consideration	58	—
Change in fair value of warrant liability and unit purchase option liability	(25)	30
Restructuring costs	533	1,125
Acquisition and integration related expenses	985	247
Impairment of intangible assets	1,862	—
Lachlan legal arbitration costs	(178)	178
Acquired in-process research and development	18,724	—
Sale or out-licensing of Company assets	—	(25,000)
Total Non-GAAP Adjustments	24,390	(22,263)
Adjusted EBITDA	$ (10,029)	$ (7,838)

Liquidity, Capital Resources and Expenditure Requirements

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 current commercial product line, the Company's development portfolio and acquisitions or in-licensing of new assets in order to meet its cash flow needs. For the year ended December 31, 2018, the Company generated a net loss of $40.1 million and negative cash flow from operations of $3.1 million. As of December 31, 2018, the Company had an accumulated deficit of $98.2 million and a balance of $10.6 million in cash and cash equivalents. During the third quarter of 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 that generated net proceeds of approximately $3.9 million (see "Armistice Private Placements" in Note 13 for a description of this transaction). During the fourth quarter of 2018, Armistice exercised warrants for convertible preferred stock that generated net proceeds of approximately $5.7 million (see "December 2018 Armistice Private Placement" in Note 13 for a description of this transaction). Additionally, 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 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 was approximately $9.0 million.

The Company plans to use cash and the anticipated positive net cash flows from the Company's existing product sales to offset costs related to its pediatric rare disease preclinical programs, neurology clinical programs, business development, costs associated with its organizational infrastructure and debt principal and interest payments. The Company expects to continue to incur significant expenses and operating losses for the immediate future as it continues to invest in its pipeline assets. Our ability to achieve and maintain profitability in the future is dependent on, among other things, the development, regulatory approval and commercialization of our new product candidates and achieving a level of revenues from our existing product sales adequate to support our cost structure, which includes significant investment in our pipeline assets.

The Company believes it will require additional financing to continue to execute its clinical development strategy and/or fund future operations. The Company plans to meet its capital requirements through operating cash flows from product sales and some combination of equity or debt financings, collaborations, out-licensing arrangements, strategic alliances, federal and private grants,

marketing, distribution or licensing arrangements or the sale of current or future assets. 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. If the Company raises additional funds through collaborations, strategic alliances or licensing arrangements with third parties, the Company may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates.

Our plan to aggressively develop our pipeline, including our recently acquired pediatric rare disease preclinical programs, will require substantial cash inflows in excess of what the Company expects our current commercial operations to generate. The Company expects that our existing cash and cash equivalents, together with anticipated revenue, will enable us to fund our operating expenses, capital expenditure requirements, and other non-operating cash payments such as fixed quarterly payments on our outstanding debt balances through at least March 2020.

Uses of Liquidity

Ichorion Asset Acquisition

On September 24, 2018, the Company entered into a merger agreement in which we acquired Ichorion Therapeutics, Inc. The consideration for the Ichorion acquisition at closing consisted of 5.8 million shares of the Company's Common Stock, par value $0.001 per share, as adjusted for estimated working capital. The shares are subject to a lockup date of December 31, 2019. Consideration for the Merger included certain development milestones worth up to an additional $15 million, payable either in shares of Company common stock or in cash, at the election of the Company. There will be future cash outflow for research and development costs associated with the development of the assets acquired as part of the Ichorion acquisition (CERC-801, CERC-802, CERC-803 and CERC-913).

Avadel Pediatric Products Acquisition

On February 16, 2018, the Company entered into an asset purchase agreement with Avadel US Holdings, Inc., Avadel Pharmaceuticals (USA), Inc., Avadel Pediatrics, Inc., Avadel Therapeutics, LLC and Avadel Pharmaceuticals PLC (collectively "Avadel") to purchase and acquire all rights in Avadel's pediatric products. The Company made a nominal cash payment for the acquired assets and assumed certain of Avadel's financial obligations to Deerfield CSF, LLC, ("Deerfield") which include a $15 million loan due in January 2021 and certain royalty obligations through February 2026.

TRx Pharmaceuticals, LLC Acquisition

On November 17, 2017, Cerecor and TRx Pharmaceuticals, LLC ("TRx") entered into a purchase agreement in which the Company acquired TRx, including subsidiary Zylera Pharmaceuticals, LLC and its franchise of pediatric medications. The consideration for the acquisition consists of $18.9 million in cash, subject to working capital adjustments, as well as approximately 7.5 million shares of our common stock having a market value of $8.5 million and certain contingent consideration with a fair value of $1.4 million.

Deerfield Debt Obligation

In relation to the Company's acquisition of Avadel's pediatric products on February 16, 2018, the Company assumed an obligation that Avadel had to Deerfield, (the "Deerfield Obligation"). Beginning in July 2018 through October 2020, the Company will pay a quarterly payment of $262,500 to Deerfield. In January 2021, a balloon payment of $15,250,000 is due. The Deerfield Obligation was $15.4 million as of December 31, 2018, of which $1.1 million is recorded as a current liability.

The Deerfield Obligation contains certain covenants, explained below, in which the Company is in compliance with as of December 31, 2018. The Company cannot waive, breach, terminate or materially amend any of the acquired Avadel pediatric products' commercial, supply, and distribution agreements which include the Karbinal Agreement, the AcipHex Agreement, and the Cefaclor Agreement (See Note 11 for a full description of each of these agreements) until the Deerfield Obligation is paid in full. Further, until the obligation is paid in full, each year the Company must complete no fewer than 60,000 P1 product details and no fewer than 50,000 P2 product details. A product detail is a meeting between a sales person and a health care professional where the sales person presents on the Company's products. A P1 is either the first presentation made or is the longest presentation during a meeting, while a P2 is the second longest presentation made during a meeting. The restrictive nature of the Deerfield Obligation may impact the Company's ability to obtain additional financings.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2018 and 2017:

	Year Ended December 31,	
	2018	2017
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (3,128)	$ 12,579
Investing activities	865	(18,912)
Financing activities	10,404	3,737
Net increase (decrease) in cash and cash equivalents	$ 8,141	$ (2,596)

Net cash (used in) provided by operating activities

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 in-process research and development 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 as discussed in Note 11 and an decrease in escrowed cash receivable of $3.8 million.

Net cash provided by operating activities was $12.6 million for the year ended December 31, 2017 and consisted primarily of net income of $11.9 million, adjusted for non-cash stock-based compensation expense of $1.2 million, depreciation and amortization of $0.4 million and changes in deferred tax liabilities of $0.8 million, and changes in working capital, primarily, a change in income tax payable of $2.3 million and accrued expenses and other current liabilities of $2.0 million, offset by a change in escrowed cash receivable of $3.8 million.

Net cash provided by (used in) investing activities

Net cash provided by investing activities was $0.9 million for the year ended December 31, 2018 and consisted 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 new corporate headquarters.

Net cash used in investing activities was $18.9 million for the year ended December 31, 2017 and consisted primarily of the upfront cash payment for the acquisition of TRx of $18.9 million.

Net cash provided by financing activities

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 of non-voting preferred stock 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. The increase was partially offset by $0.3 million payment of contingent consideration related to the Avadel acquisition.

Net cash provided by financing activities was $3.7 million for the year ended December 31, 2017, which consisted primarily of net proceeds from the Armistice Capital transaction of $4.6 million, proceeds from the sale of common stock to Maxim and Aspire Capital of $1.4 million, offset by principal payments on our term loan of $2.4 million.

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.

Product Revenue, Net

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

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. Our 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 our 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 also 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 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, our 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, our 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.

Accounting Policy Elections Related to Adoption of New Revenue Recognition Standard

The Company elected the following practical expedients in applying 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 which 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 ASU 2014-09, *Revenue from Contracts with Customers* (Topic 606) ("ASU 2014-09") for the year ended December 31, 2018.

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.

Stock-Based Compensation

The Company applies the provisions of ASC 718, Compensation—Stock Compensation (“ASC 718”), 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, our 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	**2018**	**2017**
Risk-free interest rate	2.51% — 3.01%	1.85% — 2.38%
Expected term of options (in years)	5.0 — 6.25	5.0 — 6.25
Expected stock price volatility	55% — 65%	55% — 100%
Expected annual dividend yield	0% — 0%	0% — 0%
Market-based options		
Risk-free interest rate	2.84%	
Expected term of options (in years)	2.8	
Expected stock price volatility	60%	
Expected annual dividend yield	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 involve 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 is remeasured at the current fair value with changes recorded to its own standalone line in operating expenses in the consolidated statement of operations.

As part of the acquisition of Avadel's pediatric products, in connection with the Deerfield debt obligation the Company also assumed a 15% annual royalty on net sales of the acquired Avadel pediatric products through February 2026. The fair value of the future royalty is the expected future value of the contingent payments discounted to a present value. The estimated fair value of the royalty payments as of December 31, 2018 was $7.8 million. The significant assumptions used in estimating the fair value of the royalty payment as of December 31, 2018 include (i) the expected net sales of the acquired Avadel pediatric products that are subject to the 15% royalty based on the Company's net sales forecast, and (ii) the risk-adjusted discount rate of 8.1%, which is comprised of the risk-free interest rate of 2.6% and a counterparty risk of 5.5%.

The consideration for the TRx acquisition includes certain potential contingent payments. First, pursuant to the TRx purchase agreement, the Company is required to pay $3.0 million to the 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 will pay $2.0 million upon the transfer of the Ulesfia NDA to the Company ("NDA Transfer Milestone"). Finally, the Company will pay $2.0 million upon FDA approval of a new dosage of Ulesfia ("FDA Approval Milestone"). The main inputs utilized to determine the fair value of each milestone is the probability of the milestone's success, the expected time to successfully reach the milestone, and the risk-adjusted discount rate. The estimated fair value of the NDA Transfer Milestone as of December 31, 2018 was $0.9 million. The significant assumptions used in estimating the fair value of the NDA Transfer Milestone as of December 31, 2018 include (i) probability of milestone success of 45.0%, (ii) expected time to milestone of 0.5 years, and (iii) risk-adjusted discount rate of 7.9%, which is comprised of the risk free rate of 2.4% and a counterparty risk of 5.5%. The estimated fair value of the FDA Approval Milestone as of December 31, 2018 was $0.4 million. The significant assumptions used in estimating the fair value of the FDA Approval Milestone as of December 31, 2018 include (i) probability of milestone success at 22.5%, (ii) expected time to milestone of 1.5 years, and (iii) risk-adjusted discount rate of 8.0%, which is comprised of the risk free rate of 2.5% and a counterparty risk of 5.5%.

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"). 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, 2018, 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. Among its numerous changes to the IRC, the Act reduces U.S. federal corporate tax rate from 35% to 21%. The analysis of the tax effects of the Act was completed in 2018 and there were no material adjustments in 2018.

Inventory Valuation

Inventories are recorded at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis. Cost is determined based on actual cost. An allowance is established when management determines that certain inventories may not be saleable. If inventory costs exceed expected market value due to obsolescence or quantities in excess of expected demand, we record reserves for the difference between the cost and the market value. These reserves are recorded based upon various factors for our 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, demand, the expected shelf life of the product and firm inventory purchase commitments.

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 about 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. The Company’s chief operating decision maker is the Company's Chief Executive Officer ("CEO"). The CEO views the Company’s operations and manages the business as one operating segment. All long-lived assets of the Company reside in the United States.

Goodwill

Goodwill relates to the amount that arose in connection with the acquisitions of TRx and Avadel's pediatric products. 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.

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, 2018, 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, 2018.

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, 2018, 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, 2018.

Management's Annual Report on Internal Control Over Financial Reporting

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

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2018, 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, 2018.

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.

None.

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, 2018 in connection with our 2019 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 as of August 14, 2017, between Cerecor, Inc. and Janssen Pharmaceuticals, Inc. (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed on August 14, 2017).
2.2*	Equity Interest Purchase Agreement, dated as of November 17, 2017, by and among Cerecor, Inc., TRx Pharmaceuticals, LLC, Fremantle Corporation, LRS International LLC, the selling members of TRx Pharmaceuticals, LLC, and solely for limited purposes stated therein, Randal O. Jones and Robert C. Moscato, Jr. (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed on November 17, 2017).
2.3*	Agreement and Plan of Merger and Reorganization, dated as of November 17, 2017, by and among Cerecor, Inc., ZPC Merger Corp., a direct wholly owned subsidiary of Cerecor, Inc., Zylera Pharma Corp., Zylera Pharmaceuticals, LLC, Fremantle Corporation and LRS International LLC (incorporated by reference to Exhibit 2.2 to the Current Report on Form 8-K filed on November 17, 2017).
2.4*#	Asset Purchase Agreement, dated February 12, 2018, by and between Cerecor Inc., Avadel US Holdings, Inc., Avadel Pharmaceuticals (USA), Inc., Avadel Pediatrics, Inc., FSC Therapeutics, LLC and Avadel Pharmaceuticals PLC (incorporated by reference to Exhibit 2.1 to the Quarterly Report on Form 10-Q on May 11, 2018).
2.5*	Agreement and Plan of Merger, dated as of September 24, 2018, among Cerecor, Inc., ITX Merger Sub, Inc., Second ITX Merger Sub, LLC, Ichorion Therapeutics, Inc. and David Maizenberg, as holders' representative (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed on September 26, 2018).

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 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 sale of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form S-1 filed on June 12, 2015).
4.3	Form of Warrant to Purchase Shares of Common Stock issued in connection with the sale of Series A-1 Convertible Preferred Stock, as amended by the Amendment to Common Stock Warrants, dated as of July 11, 2014 (incorporated by reference to Exhibit 4.3 to the Registration Statement on Form S-1 filed on June 12, 2015).
4.4	Form of Warrant to Purchase Shares of Common Stock, issued to CIFCO International Group and its affiliate (incorporated by reference to Exhibit 4.5 to the Registration Statement on Form S-1 filed on June 12, 2015).
4.5	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).
4.6	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).
4.7	Form of Unit Purchase Option (incorporated by reference to Annex IV of Exhibit 1.1 to the Registration Statement on Form S-1 filed on June 12, 2015).
4.8	Form of Class A Warrant Agreement (incorporated by reference to Exhibit 4.9 to the Registration Statement on Form S-1 filed on October 13, 2015).
4.9	Specimen Class A Warrant Certificate (incorporated by reference to Exhibit 4.10 to the Registration Statement on Form S-1 filed on October 13, 2015).
4.1	Form of Class B Warrant Agreement (incorporated by reference to Exhibit 4.11 to the Registration Statement on Form S-1 filed on October 13, 2015).
4.11	Specimen Class B Warrant Certificate (incorporated by reference to Exhibit 4.12 to the Registration Statement on Form S-1 filed on October 13, 2015).
4.12	Specimen Unit Certificate (incorporated by reference to Exhibit 4.13 to the Registration Statement on Form S-1 filed on October 13, 2015).

4.13	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).
4.14	Form of Warrant to Purchase 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).
4.15	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).
4.16	Form of Warrant to Purchase 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).
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 +	Separation and Release Agreement, dated July 13, 2018, by and between Cerecor Inc. and Mariam Morris (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on July 16, 2018).
10.5 +	Form of Director Indemnification Agreement (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form S-1 filed on September 8, 2015).
10.6	List of current directors with a Director Indemnification Agreement in the form provided as Exhibit 10.6 (incorporated by reference to Exhibit 10.13 to the Registration Statement on Form S-1 filed on September 8, 2015).
10.7	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).
10.8	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).
10.9 +	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).
10.10#	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).

10.11	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).
10.12#	Securities Purchase Agreement, dated as of April 27, 2017, by and between 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 April 28, 2017).
10.13	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).
10.14.1+	Employment Agreement by and between Cerecor Inc. and Robert C. Moscato, Jr., effective November 20, 2017 (incorporated by reference to Exhibit 10.25 to the Annual Report on Form 10-K on April 2, 2018).
10.14.2+	Separation and Release Agreement, dated April 23, 2018, by and between Cerecor, Inc. and Robert Moscato (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on April 27, 2018).
10.15+	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).
10.16#	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 on May 11, 2018).
10.17+	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).
10.18+	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).
10.19+	Cerecor Inc. Amended and Restated 2016 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on May 17, 2018).
10.20+	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).
10.21+	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).
10.22	Securities Purchase Agreement, dated as of August 17, 2018, by and among Cerecor Inc. and each of the investors (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on August 20, 2018).
10.23	Registration Rights Agreement, dated 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).

10.24	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).
10.25	Securities Purchase Agreement, dated as of December 27, 2018, 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 December 27, 2018).
10.26	Registration Rights Agreement, dated 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).
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.

* 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.

** 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/ Peter Greenleaf

Peter Greenleaf
Chief Executive Officer

Date: March 18, 2019

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/ Peter Greenleaf **Peter Greenleaf**	Chief Executive Officer and Director (Principal Executive Officer)	March 18, 2019
/s/ Joseph M. Miller **Joseph M. Miller**	Chief Financial Officer (Principal Financial and Accounting Officer)	March 18, 2019
/s/ Uli Hacksell **Uli Hacksell**	Chairman of the Board	March 18, 2019
/s/ Isaac Blech **Isaac Blech**	Director	March 18, 2019
/s/ Steven J. Boyd **Steven J. Boyd**	Director	March 18, 2019
/s/ Phil Gutry **Phil Gutry**	Director	March 18, 2019
/s/ Simon C. Pedder **Simon C. Pedder**	Director	March 18, 2019
/s/ Magnus Persson **Magnus Persson**	Director	March 18, 2019

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, 2018 and 2017, 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, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the 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 18, 2019

CERECOR INC. and SUBSIDIARIES

Consolidated Balance Sheets

	December 31,	
	2018	**2017**
Assets		
Current assets:		
Cash and cash equivalents	$ 10,646,301	$ 2,472,187
Accounts receivable, net	3,157,555	2,935,025
Other receivables	5,469,011	427,241
Escrowed cash receivable	—	3,752,390
Inventory, net	1,110,780	382,153
Prepaid expenses and other current assets	1,529,516	703,225
Restricted cash, current portion	18,730	1,959
Total current assets	21,931,893	10,674,180
Property and equipment, net	586,512	44,612
Intangibles assets, net	31,239,468	17,664,480
Goodwill	16,411,123	14,292,282
Restricted cash, net of current portion	81,725	131,353
Total assets	$ 70,250,721	$ 42,806,907
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,446,141	$ 1,298,980
Accrued expenses and other current liabilities	19,731,373	7,531,122
Income taxes payable	2,032,258	2,259,148
Long-term debt, current portion	1,050,000	—
Contingent consideration, current portion	1,956,807	—
Total current liabilities	26,216,579	11,089,250
Long term debt, net of current portion	14,327,882	—
Contingent consideration, net of current portion	7,093,757	2,576,633
Deferred tax liability, net	69,238	7,144
License obligations	1,250,000	1,250,000
Other long-term liabilities	385,517	24,272
Total liabilities	49,342,973	14,947,299
Stockholders' equity:		
Common Stock—$0.001 par value; 200,000,000 shares authorized at December 31, 2018 and 2017; 40,804,189 and 31,266,989 shares issued and outstanding at December 31, 2018 and 2017, respectively	40,804	31,268
Preferred Stock—$0.001 par value; 5,000,000 shares authorized at December 31, 2018 and 2017; 2,857,143 and zero shares issued and outstanding at December 31, 2018 and 2017, respectively	2,857	—
Additional paid-in capital	119,082,157	83,338,136
Contingently issuable shares	—	2,655,464
Accumulated deficit	(98,218,070)	(58,165,260)
Total stockholders' equity	20,907,748	27,859,608
Total liabilities and stockholders' equity	$ 70,250,721	$ 42,806,907

See accompanying notes to the consolidated financial statements.

CERECOR INC. and SUBSIDIARIES

Consolidated Statements of Operations

	Year Ended December 31,	
	2018	**2017**
Revenues		
Product revenue, net	$ 17,870,745	$ 1,910,403
Sales force revenue	456,056	278,165
License and other revenue	—	25,000,000
Grant revenue	—	624,569
Total revenues, net	18,326,801	27,813,137
Operating expenses:		
Cost of product sales	7,478,262	635,648
Research and development	5,786,635	4,372,578
Acquired in-process research and development	18,723,952	—
General and administrative	10,676,881	7,941,584
Sales and marketing	8,522,461	569,825
Amortization expense	4,532,448	403,520
Impairment of intangible assets	1,861,562	—
Change in fair value of contingent consideration	58,366	—
Total operating expenses	57,640,567	13,923,155
(Loss) income from operations	(39,313,766)	13,889,982
Other (expense) income:		
Change in fair value of warrant liability and unit purchase option liability	25,010	(29,624)
Other income, net	13,657	—
Interest expense, net	(811,621)	(24,016)
Total other expense, net	(772,954)	(53,640)
Net (loss) income before taxes	(40,086,720)	13,836,342
Income tax (benefit) expense	(33,910)	1,966,519
Net (loss) income after taxes	$ (40,052,810)	$ 11,869,823
Net (loss) income	$ (40,052,810)	$ 11,869,823
Net (loss) income attributable to common shareholders	$ (41,710,193)	$ 7,772,084
Net (loss) income per share of common stock, basic	$ (1.20)	$ 0.42
Net (loss) income per share of common stock, diluted	$ (1.20)	$ 0.42
Weighted-average shares of common stock outstanding, basic	34,773,613	18,410,005
Weighted-average shares of common stock outstanding, diluted	34,773,613	18,754,799

See accompanying notes to the consolidated financial statements.

CERECOR INC. and SUBSIDIARIES

Consolidated Statements of Changes in Stockholders' Equity

	Stockholders' Equity							
	Common stock		Preferred Stock		Additional paid-in capital	Contingently issuable stock	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount		Amount		
Balance, December 31, 2016	9,434,141	$ 9,434	—	$ —	$ 70,232,651	$ —	$(70,035,083)	$ 207,002
Issuance of common stock from sale of shares under common stock purchase agreement, net of offering costs	2,301,598	2,302	—	—	1,500,291			1,502,593
Issuance of preferred and common stock to Armistice Capital, net of offering costs	2,345,714	2,346	—	4	4,559,308			4,561,658
Issuance of shares in acquisition of TRx	5,184,920	5,185	—		5,853,770			5,858,955
Contingently issuable stock in acquisition of TRx	—	—	—	—	—	2,655,464		2,655,464
Shares purchased through employee stock purchase plan	60,616	61	—	—	46,800			46,861
Stock-based compensation	—	—	—	—	1,157,252			1,157,252
Conversion of Armistice Capital preferred to common stock	11,940,000	11,940	—	(4)	(11,936)	—	—	—
Net income	—	—	—	—	—		11,869,823	11,869,823
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

See accompanying notes to the consolidated financial statements.

CERECOR INC. and SUBSIDIARIES

Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2018	**2017**
Operating activities		
Net (loss) income	$ (40,052,810)	$ 11,869,823
Adjustments to reconcile net (loss) income (used in) provided by to net cash (used in) provided by operating activities:		
Depreciation and amortization	4,554,963	425,476
Impairment of intangible assets	1,861,562	—
Stock-based compensation	2,431,063	1,157,252
Acquired in-process research and development, including transaction costs	18,723,952	—
Deferred taxes	(16,745)	(832,629)
Amortization of inventory fair value adjustment associated with acquisition of TRx and Avadel Pediatric Product	300,573	137,900
Non-cash interest expense	302,882	20,364
Change in fair value of contingent consideration liability	58,366	—
Change in fair value of warrant liability and unit purchase option liability	(25,010)	29,624
Changes in assets and liabilities:		
Accounts receivable, net	(222,530)	(247,195)
Other receivables	(2,277,255)	(427,241)
Inventory, net	(311,199)	(24,276)
Prepaid expenses and other assets	(241,641)	(177,691)
Escrowed cash receivable	3,752,390	(3,752,390)
Accounts payable	82,451	96,065
Income taxes payable	(226,890)	2,259,148
Accrued expenses and other liabilities	7,792,259	2,044,548
Other long term liabilities	385,517	—
Net cash (used in) provided by operating activities	(3,128,102)	12,578,778
Investing activities		
Acquisition of TRx, net of cash acquired	—	(18,888,932)
Acquisition of Avadel Pediatric Products	(1)	—
Net cash acquired from acquisition of Ichorion Therapeutics, Inc.	1,429,877	—
Purchase of property and equipment	(564,415)	(23,325)
Net cash provided by (used in) investing activities	865,461	(18,912,257)
Financing activities		
Proceeds from exercise of stock options and warrants	1,083,953	—
Proceeds from issuance of Series B convertible preferred stock upon warrant exercise, net	5,685,038	—
Proceeds from sale of shares pursuant to common stock private placement, net	3,857,106	4,649,996
Proceeds from sales of common stock purchased through employee stock purchase plan	72,236	46,861
Proceeds from sale of shares under common stock purchase agreement	—	1,693,498
Payment of contingent consideration	(294,435)	—
Principal payments on term debt	—	(2,374,031)
Payment of fractional shares upon conversion of preferred stock to common stock	—	4
Payment of offering costs	—	(279,247)
Net cash provided by financing activities	10,403,898	3,737,081
Increase (decrease) in cash and cash equivalents	8,141,257	(2,596,398)
Cash and cash equivalents at beginning of period	2,605,499	5,201,897

Cash and cash equivalents at end of period	$ 10,746,756	$ 2,605,499
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 525,000	$ 72,526
Cash paid for taxes	$ 354,000	$ 540,000
Supplemental disclosures of non-cash investing and financing activities		
Debt assumed in Avadel Pediatric Products acquisition	$ (15,075,000)	$ —
Issuance of common stock in TRx acquisition	$ —	$ 5,858,955
Contingently issuable shares in TRx acquisition	$ —	$ 2,655,464

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,	
	2018	**2017**
Cash and cash equivalents	$ 10,646,301	$ 2,472,187
Restricted cash, current	18,730	1,959
Restricted cash, non-current	81,725	131,353
Total cash, cash equivalents and restricted cash	$ 10,746,756	$ 2,605,499

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, 2018 and 2017

1. Business

Cerecor Inc. (the "Company" or “Cerecor”) is a fully integrated biopharmaceutical company with commercial operations and research and development capabilities. The Company is building a robust pipeline of innovative therapies in pediatric healthcare, neurology, and orphan rare diseases. The Company's neurology pipeline is led by CERC-301, which is currently in a Phase I safety study for Neurogenic Orthostatic Hypotension ("nOH"). The Company is also developing two other neurological clinical and preclinical stage compounds. The Company's pediatric orphan rare disease pipeline is led by CERC-801, CERC-802 and CERC-803. All three of these compounds are preclinical therapies for inherited metabolic disorders known as Congenital Disorders of Glycosylation ("CDGs") by means of substrate replacement therapy. The U.S. Food and Drug Administration ("FDA") has granted Rare Pediatric Disease designation ("RPDD") and Orphan Drug Designation ("ODD") to all three compounds. Under the FDA’s Rare Pediatric Disease Priority Review Voucher ("PRV") program, upon the approval of a new drug application ("NDA") for the treatment of a rare pediatric disease, the sponsor of such application would be eligible for a PRV that can be used to obtain priority review for a subsequent new drug application or biologics license application. The 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. The Company is also in the process of developing one other preclinical pediatric orphan rare disease compound, CERC-913.

The Company also has a diverse portfolio of marketed products. Our marketed products are led by our prescribed dietary supplements and prescribed drugs. Our prescribed dietary supplements include Poly-Vi-Flor and Tri-Vi-Flor which are prescription vitamin and fluoride supplements used in infants and children to treat or prevent deficiency of essential vitamins and fluoride. The Company also markets a number of prescription drugs that treat a range of pediatric diseases, disorders and conditions. Cerecor's prescription drugs include Millipred®, Ulesfia®, Karbinal™ ER, AcipHex® Sprinkle™ and Cefaclor for Oral Suspension. Finally, the Company has one marketed medical device, Flexichamber™.

Cerecor was incorporated in 2011, commenced operations in the second quarter of 2011 and completed an initial public offering in October 2015. 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 million, of which $3.75 million was deposited into a twelve-month escrow to secure indemnification obligations to Janssen. The Company collected the full amount of the escrow in August of 2018. Additionally, there is a potential future $20 million regulatory milestone payment to the Company. 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.

On November 17, 2017, the Company acquired TRx Pharmaceuticals, LLC (“TRx”) and its wholly-owned subsidiaries (see "TRx Acquisition" in Note 4 below for a description of the transaction).

On February 16, 2018, Cerecor acquired all rights to Avadel Pharmaceuticals PLC’s (“Avadel”) marketed pediatric products (the “Acquired Products”) for the assumption of certain of Avadel's financial obligations (see "Avadel Pediatric Products Acquisition" in Note 4 below for a description of the transaction).

On September 25, 2018, the Company acquired Ichorion Therapeutics, Inc., a privately-held biopharmaceutical company focused on developing treatments and increasing awareness of inherited metabolic disorders known as CDGs (see "Ichorion Asset Acquisition" in Note 4 below for a description of the transaction).

Liquidity

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 current commercial product line, the Company's development portfolio and acquisitions or in-licensing of new assets in order to meet its cash flow needs. For the year ended December 31, 2018, Cerecor generated a net loss of $40.1 million and negative cash flow from operations of $3.1 million. As of December 31, 2018, Cerecor had an accumulated deficit of $98.2 million and a balance of $10.6 million in cash and cash equivalents. During the third quarter of 2018, the Company entered into a securities purchase agreement with Armistice Capital Master Fund Ltd. ("Armistice"), pursuant to which the Company sold 1,000,000 shares of the Company's common stock that generated net proceeds of approximately $3.9 million (see "Armistice Private Placements" in Note 13 below for a description of the transaction). During the fourth quarter of 2018, Armistice exercised warrants for convertible preferred stock that generated net proceeds of approximately $5.7 million (see "December 2018 Armistice

Private Placement" in Note 13 below for a description of the transaction). Additionally, 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 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 of the offering was approximately $9.0 million.

The Company plans to use cash and the anticipated positive net cash flows from the Company's existing product sales to offset costs related to its pediatric rare disease programs, neurology clinical programs, business development, costs associated with its organizational infrastructure and debt principal and interest payments. 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. Our ability to achieve and maintain profitability in the future is dependent on, among other things, the development, regulatory approval and commercialization of our new product candidates and achieving a level of revenues from our existing product sales adequate to support our cost structure, which includes significant investment in our pipeline assets.

The Company believes it will require additional financing to continue to execute its clinical development strategy and/or fund future operations. The Company plans to meet its capital requirements through operating cash flows from product sales and some combination of equity or debt financings, collaborations, out-licensing arrangements, strategic alliances, federal and private grants, marketing, distribution or licensing arrangements or the sale of current or future assets. 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. If the Company raises additional funds through collaborations, strategic alliances or licensing arrangements with third parties, the Company may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates.

Our plan to aggressively develop our pipeline, including our recently acquired pediatric rare disease preclinical programs, will require substantial cash inflows in excess of what the Company expects our current commercial operations to generate. The Company expects that our existing cash and cash equivalents, together with anticipated revenue, will enable us to fund our operating expenses, capital expenditure requirements, and other non-operating cash payments such as fixed quarterly payments on our outstanding debt balances through at least March 2020.

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”).

Reclassification

During 2018, the Company concluded that going forward it would net amounts due to distributors against open receivable balances. The Company has reclassified $0.3 million from accrued expenses and other current liabilities to accounts receivable, net in the December 31, 2017 balance sheet to conform with current period presentation.

During 2018, the Company concluded that going forward it would include amortization expense within its own standalone line in operating expenses in the Company's consolidated statements of operations. The Company has reclassified $0.4 million from sales and marketing expenses in the December 31, 2017 statements of operations to conform with current period presentation.

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.

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), cash flows used in management's going concern assessment, income taxes, goodwill and other intangible assets, and clinical trial accruals. The Company bases its estimates

on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

Cash and Cash Equivalents

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

Escrowed Cash Receivable

On August 14, 2017, the Company sold all of its rights to CERC-501 to Janssen in exchange for initial gross proceeds of $25 million, of which $3.75 million was deposited into a twelve-month escrow to secure certain indemnification obligations to Janssen. The Company collected the full escrow amount in August 2018.

Restricted Cash

Restricted cash consists of the 2016 Employee Stock Purchase Plan (the "Plan") deposits and credit card deposits. In exchange for receiving business credit card services from Silicon Valley Bank, the Company deposited $50,000 as collateral with Silicon Valley Bank. These deposits are recorded as restricted cash, net of current portion on the balance sheet at December 31, 2018. Additionally, deposits made by employees for future stock purchases as part of the Plan is recorded as restricted cash. As part of the Plan, eligible employees can purchase common stock through accumulated payroll deductions at such times as are established by the Plan administrator.

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. All prior periods were retrospectively adjusted to conform to the current period presentation.

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, 2018, 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.

Property and Equipment

Property and equipment consists of computers, office equipment, furniture, 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 a life of 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 about 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. The Company’s chief operating decision maker is the Company's Chief Executive Officer. The CEO views the Company’s operations and manages the business as one operating segment. All long-lived assets of the Company reside in the United States.

Goodwill

Goodwill relates to the amount that arose in connection with the acquisitions of TRx and Avadel's pediatric products. 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.

Intangible Assets

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

Product Revenues, net

The Company generates substantially all of its revenue from sales of prescription 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,	
	2018	2017
Prescribed dietary supplements	$ 7,678,003	$ 1,092,271
Prescription drugs	10,192,742	818,132
Sales force revenue	456,056	278,165
License and other revenue	—	25,000,000
Grant revenue	—	624,569
Total revenues, net	$ 18,326,801	$27,813,137

Concentration with Customer

As is typical in the pharmaceutical industry, the Company sells its prescription pharmaceutical products (which include prescribed dietary supplements and 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, 2018, the Company's three largest customers accounted for approximately 30%, 30%, and 25%, respectively, of the Company's total net product revenues from sale of prescription pharmaceutical products. For the year ended December 31, 2017, the Company's three largest customers accounted for approximately 40%, 25% and 22%, respectively, of the Company's total net product revenues from sale of prescription pharmaceutical products.

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 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 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, our 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 sale 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.

Grant Revenue

Grant revenues are derived from government grants that support the Company's efforts on specific research projects. The Company determined that the government agencies providing grants to the Company are not our customers. The Company recognizes grant revenue when there is reasonable assurance of compliance with the conditions of the grant and reasonable assurance that the grant revenue will be received.

Accounting Policy Elections Related to Adoption of New Revenue Recognition Standard

The Company elected the following practical expedients in applying 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 ASU 2014-09, *Revenue from Contracts with Customers* (Topic 606) for the year ended December 31, 2018.

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.

Shipping, Handling, and Freight

The Company includes the cost of shipping, handling, and freight associated with product sales as part of cost of product sales.

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's pediatric products and TRx involve 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 is remeasured at the current fair value with changes recorded in the consolidated statement of operations.

There is no change in fair value of contingent consideration included in cost of product sales or research and development costs as the change in fair value of contingent consideration is included within its own standalone line in operating expenses in the Company's consolidated statements of operations.

Stock-Based Compensation

The Company applies the provisions of ASC 718, Compensation—Stock Compensation (“ASC 718”), 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, our 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, 2018, 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 below for further discussion related to the tax impact to the Company.

Recently Adopted Accounting Pronouncements

Adoption of ASC 606

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers* (Topic 606) ("ASU 2014-09"). Topic 606, along with amendments issued in 2015, 2016 and 2017, supersedes the revenue recognition requirements in Topic 605, *Revenue Recognition*, including most industry-specific revenue recognition guidance throughout the Industry Topics of the Accounting Standards Codification. ASU 2014-09 provides a comprehensive new revenue recognition model that requires a company to recognize revenue to depict the transfer of goods or services to a customer in an amount that reflects the consideration it expects to receive in exchange for those goods or services. On January 1, 2018, the Company adopted the new revenue recognition standard for all contracts not completed as of the adoption date using the modified retrospective method. The implementation of the new revenue recognition standard did not have a material quantitative impact on the Company's consolidated financial statements as the timing of revenue recognition for product sales did not significantly change. In addition, the Company did not have a material cumulative effect adjustment to accumulated deficit upon adoption of the new revenue recognition standard on January 1, 2018. The information presented for the periods prior to January 1, 2018 has not been restated and is reported under Topic 605.

The Company recognizes revenue when its performance obligations with its customers have been satisfied. At contract inception, the Company determines if a contract is within the scope of Topic 606 and then evaluates the contract using the following five steps: (1) identify the contract with the customer; (2) identify the performance obligations; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations; and (5) recognize revenue when (or as) the entity satisfies a performance obligation.

Other Adopted Accounting Pronouncements

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business* ("ASU 2017-01"). The standard provides guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. If substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single asset or a group of similar assets, the assets acquired (or disposed of) are not considered a business. ASU 2017-01 is effective for fiscal periods beginning after December 15, 2017 (including interim periods within those periods) with early adoption permitted. The Company adopted this standard on January 1, 2018.

In January 2017, the FASB issued ASU No. 2017-04 "*Intangibles-Goodwill and Other (Topic 350)*: *Simplifying the Test for Goodwill Impairment*" ("ASU 2017-04"). ASU 2017-04 eliminates step two of the goodwill impairment test and specifies that goodwill impairment should be measured by comparing the fair value of a reporting unit with its carrying amount. ASU 2017-04 is effective for annual or interim goodwill impairment tests performed in fiscal years beginning after December 15, 2019 and early adoption is permitted. The Company early adopted this standard on January 1, 2018. The standard was applied prospectively and the adoption of this standard did not have an impact on the Company's financial statements.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718) - Scope of Modification Accounting* (“ASU 2017-09”) to clarify when to account for a change to the terms or conditions of a stock-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The guidance is effective prospectively for all companies for annual periods and interim periods within those annual periods, beginning on or after December 15, 2017. The adoption of this standard on January 1, 2018 did not have a significant impact on the Company’s financial statements.

In November 2016, the FASB issued ASU No. 2016-18, *Restricted Cash ("*ASU 2016-18"*)*. The guidance is intended to address the diversity that currently exists in the classification and presentation of changes in restricted cash on the statement of cash flows. The new standard requires that entities show the changes in the total of cash and cash equivalents, restricted cash and restricted cash equivalents on the statement of cash flows and no longer present transfers between cash and cash equivalents, restricted cash and restricted cash equivalents on the statement of cash flows. The new standard is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The Company adopted this standard on January 1, 2018. Upon adoption of ASU 2016-18, the Company applied the retrospective transition method for each period presented and included $0.1 million of restricted cash in the beginning period cash, cash equivalents and restricted cash balance as of January 1, 2017.

In October 2016, the FASB issued ASU No. 2016-16, “*Income Taxes (Topic 740), Intra-Entity Transfers of Assets Other Than Inventory*” ("ASU 2016-16"), which requires companies to recognize the income tax consequences of an intra-entity transfer of an asset other than inventory when the transfer occurs. ASU 2016-16 is effective for annual reporting periods, and interim periods therein, beginning after December 15, 2017. The adoption of this standard on January 1, 2018 did not have a significant impact on the Company’s financial statements.

In August 2016, the FASB issued ASU No. 2016-15 *Statement of Cash Flows, Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"), which reduces existing diversity in the classification of certain cash receipts and cash payments on the statements of cash flows. ASU 2016-15 is effective for fiscal years beginning after December 15, 2017, and for interim periods within those fiscal years. The adoption of this standard on January 1, 2018 did not have a significant impact on the Company’s financial statements.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (Topic 842) ("ASU 2016-02"). This guidance 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 right-of-use 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 right-of-use 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 capital leases. For lessees, operating leases will result in straight-line expense (similar to current accounting by lessees for operating leases under ASC 840) while capital leases will result in a front-loaded expense pattern (similar to current accounting by lessees for capital leases under ASC 840). The new standard is effective for the Company beginning January 1, 2019. In July 2018, the FASB issued both codification improvements, which clarify how to apply certain aspects of the standard, and an update to the transition methods allowable. Companies can either adopt the new standard at the earliest period presented using a modified retrospective approach or continue to apply the guidance under the current lease standard in the comparative periods presented. Companies that elect this option would record a cumulative-effect adjustment to the opening balance of retained earnings on the date of adoption, if necessary. The Company expects to apply the new guidance at the effective date, without adjusting the comparative periods. The Company anticipates that ASU 2016-02 will have an impact to the consolidated balance sheet, as the Company will record an asset and a liability in connection with the leased office space. The Company will elect 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. The Company is not electing the hindsight practical expedient.

The Company has performed a preliminary assessment on the impact to the consolidated balance sheet and preliminarily expects that we will record a right-of-use liability and corresponding of approximately $1 million and a corresponding right-of-use asset (with certain adjustments for the accrued rent and unamortized lease incentive balance at January 1, 2019) related to the leased office space. This expectation is subject to change as management refines the inputs utilized in the calculation. The Company does not expect an impact to the statement of operations or liquidity. The Company is in the process of identifying its other lease agreements that will be impacted by the new standard to arrive at the overall impact to the consolidated financial statements, however anticipates the overall balance sheet impact to be less than 5% of the total liabilities balance as of December 31, 2018.

3. 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. Under the two-class method, EPS for the common stock, preferred stock and participating warrants are computed by dividing the sum of distributed earnings to common shareholders and undistributed earnings allocated to common shareholders by the weighted average number of shares of common stock and participating warrants outstanding for the period. In applying the two-class method, undistributed earnings are allocated to common stock, preferred stock and participating warrants based on the weighted average shares outstanding during the period. 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.

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 awards 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 shares, which are included under the "if-converted method" when dilutive; (iii) prior to issuance, the contingently issuable shares in the TRx acquisition if contingencies would have been satisfied if the end of the contingency period were as of the balance sheet date under the "if converted method" when dilutive; and (iv) 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 addition, as stated above, net losses are not allocated to the participating securities unless the participating security has a contractual obligation to share in both earnings and losses of the Company.

The following table sets forth the computation of basic and diluted net loss per share of common stock for the years ended December 31, 2018 and 2017, which includes both classes of participating securities:

Net (loss) income per share, basic and diluted calculation:	Year ended December 31, 2018	2017
Basic (loss) income per share		
Net (loss) income	$ (40,052,810)	$ 11,869,823
Deemed distribution to shareholder	1,657,383	—
Undistributable (loss) earnings allocable to common shares	$ (41,710,193)	$ 7,772,084
Undistributable (loss) earnings allocable to participating warrants	$ —	$ 4,097,739
Weighted average shares, basic		
Common stock	34,773,613	18,410,005
Participating warrants	—	9,706,458
	34,773,613	28,116,463
Basic (loss) income per share:		
Common stock	$ (1.20)	$ 0.42
Participating warrants	$ —	$ 0.42
Diluted (loss) income per share:		
Net (loss) income attributable to common shares	$ (41,710,193)	$ 7,772,084
Net (loss) income reallocated	—	49,642
Undistributed (loss) earnings allocable to common shares	$ (41,710,193)	$ 7,821,726
Weighted average number of shares attributable to common shareholders - basic	34,773,613	18,410,005
Effect of dilutive securities:		
Stock options	—	61,510
Contingently issuable shares	—	283,284
Potentially dilutive shares	—	344,794
Weighted average number of shares - diluted	34,773,613	18,754,799
Diluted (loss) income per share	$ (1.20)	$ 0.42

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 our 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 as a part of the Armistice private placement in 2017 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 (the "Series B Convertible Preferred Stock" or "convertible preferred stock") with an exercise price of $2.00 per share (the "exchanged warrants"). The convertible preferred stock has the same rights and preferences as common stock other than it is non-voting and converts to shares of common stock on a 1 for 5 ratio. Armistice immediately exercised the exchanged warrants and acquired an aggregate of 2,857,143 shares of the Series B Convertible Preferred Stock to generate net proceeds of approximately $5.7 million. The convertible preferred stock is considered a separate class of stock for EPS purposes, however basic and diluted EPS is not provided for the preferred stock for the year ended December 31, 2018 because the shares were only outstanding for five days for the year. Therefore, EPS for the preferred stock is immaterial for the year ended December 31, 2018, however will be disclosed going forward.

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 fair value of the incentive warrants was considered a deemed distribution to Armistice of $1.7 million. The deemed distribution is calculated as the difference between the fair value of the incentive warrants on the date of the transaction of $2.2 million and the value that Armistice forwent by exchanging the original warrants of $0.5 million. The fair value of the incentive warrant is estimated using a Black-Scholes option-pricing model. The significant assumptions used in the model for valuing the incentive warrant on December 27, 2018 include:

(i) volatility of 55%, (ii) risk-free interest rate of 2.62%, (iii) unit strike price of $12.50, (iv) fair value of underlying equity of $3.02, and (v) expected life of 5.5 years.

The net loss of $40.1 million for the year ended December 31, 2018 is increased by the deemed distribution of $1.7 million to arrive at the net loss attributable to common shareholders 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. For the 2017 EPS calculation, the shares of unexercised original warrants issued in the Armistice private placement transaction in 2017 are considered participating securities because these warrants contain a non-forfeitable right to dividends irrespective of whether the warrants are ultimately exercised.

The following outstanding securities at December 31, 2018 and 2017 have been excluded from the computation of diluted weighted shares outstanding, as they could have been anti-dilutive:

	December 31,	
	2018	2017
Stock options	4,246,597	2,812,006
Warrants on common stock	4,024,708	4,661,145
Restricted Stock Awards	445,000	—
Underwriters' unit purchase option	40,000	40,000

4. Acquisition

Ichorion Asset Acquisition

On September 24, 2018, the Company entered into, and subsequently consummated the transactions contemplated by, an agreement and plan of merger 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, par value $0.001 per share, as adjusted for Estimated Working Capital as defined in the Merger Agreement. The shares are subject to a lockup date through December 31, 2019, which restricts the resale of the common stock issued as part of the acquisition until the lockup period is complete. Consideration for the Ichorion Asset Acquisition includes certain development milestones worth up to an additional $15 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 million using the Company's stock price close 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 has 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 is related to three future development milestones and if met the Company may be required to pay out an additional $15 million. The first milestone is contingent on 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 million, payable either in shares of the Company's common stock or in cash, at the election of the Company. The second milestone is contingent on 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 million, payable in either shares of the Company's common stock or cash, at the election of the Company. The third milestone is contingent on 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 million, 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, 2018, 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

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 has currently 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. Transaction costs of $0.1 million were included as general and administrative expense in the consolidated statements of operations for the year ended December 31, 2018.

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:

	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

Based on valuation estimates utilizing the estimated sales price of inventory less sales and marketing costs and an allowance for profit, a step-up in the value of inventory of $0.3 million was recorded in the opening balance sheet, of which approximately $0.1 million was charged to cost of goods sold during the post-acquisition period, February 16, 2018 through December 31, 2018.

The purchase price allocation related to the acquisition of Avadel's pediatric products has been finalized. 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 preliminary fair value of intangible assets both as of the date of acquisition and as adjusted by measurement period adjustments identified during the second quarter includes the following:

	At February 16, 2018 (preliminary)	Measurement Period Adjustments	At February 16, 2018 (as adjusted)	Useful Life
Acquired Product Marketing Rights - Karbinal	$ 6,221,000	$ (21,000)	$ 6,200,000	10 years
Acquired Product Marketing Rights - AcipHex	2,520,000	283,000	2,803,000	10 years
Acquired Product Marketing Rights - Cefaclor	6,291,000	1,320,000	7,611,000	7 years
Acquired Developed Technology - Flexichamber	1,131,000	546,000	1,677,000	10 years
Acquired IPR&D - LiquiTime formulations	290,000	(290,000)	—	Indefinite
Total	$ 16,453,000	$ 1,838,000	$ 18,291,000	

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 consists 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 has currently 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 our 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 11, 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	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

Based on valuation estimates utilizing the estimated selling price of inventory less sales and marketing costs and an allowance for profit, a step-up in the value of inventory of $0.2 million was recorded in the opening balance sheet, of which approximately $0.2 million was charged to cost of product sales during the year ended December 31, 2018.

The purchase price allocation related to the TRx Acquisition has been finalized. 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)	Useful Life
Acquired product marketing rights - Metafolin	$ 10,465,000	$ 1,522,000	$ 11,987,000	15 years
PAI sales and marketing agreement	2,334,000	219,000	2,553,000	2 years
Acquired product marketing rights - Millipred	4,714,000	342,000	5,056,000	4 years
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.

Pro Forma Impact of Business Combinations

The following supplemental unaudited pro forma information presents Cerecor's financial results as if the acquisitions of Avadel Pediatric Products, which was completed on February 16, 2018, and of TRx, which was completed on November 17, 2017, had each occurred on January 1, 2017:

	Year Ended December 31,	
	2018	2017
	Pro forma	Pro forma
Total revenues, net	$ 20,031,801	$ 51,288,212
Net loss	$ (40,919,015)	$ 5,963,853
Basic and diluted net (loss) income per share	$ (1.18)	$ 0.21

The above unaudited pro forma information was determined based on the historical GAAP results of Cerecor, Avadel's pediatric products and TRx. The unaudited pro forma consolidated results are provided for informational purposes only and are not necessarily indicative of what Cerecor's consolidated results of operations would have been had the acquisitions of Avadel's pediatric products and TRx been completed on the dates indicated or what the consolidated results of operations will be in the future.

5. 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 that are measured at fair value on a recurring basis:

	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	$ —	$ —	$ 9,050,564
Warrant liability**	$ —	$ —	$ 2,950
Unit purchase option liability**	$ —	$ —	$ 7,216

	December 31, 2017 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*	$ 471,183	$ —	$ —
Liabilities			
Contingent consideration	$ —	$ —	$ 2,576,633
Warrant liability**	$ —	$ —	$ 8,185
Unit purchase option liability**	$ —	$ —	$ 26,991

*Investments in money market funds are reflected in cash and cash equivalents on the accompanying Balance Sheets.

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

At December 31, 2018 and 2017, the Company's financial instruments included cash and cash equivalents, restricted cash, accounts receivable, accounts payable, accrued expenses and other current liabilities, short term and long-term debt, 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, accounts payable, accrued expenses and other current liabilities approximate their respective fair values because of the short-term nature of these accounts. The estimated fair value of the Company's long-term debt of $14.9 million as of December 31, 2018 was based on current interest rates for similar types of borrowings and is in Level 2 of the fair value hierarchy.

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 for the years ended December 31, 2018 and 2017:

	Warrant liability	Unit purchase option liability	Contingent consideration	Total
Balance at December 31, 2017	$ 8,185	$ 26,991	$ 2,576,633	$ 2,611,809
Issuance of contingent consideration	—	—	7,920,000	7,920,000
Payment of contingent consideration	—	—	(294,435)	(294,435)
Purchase price allocation measurement period adjustment of contingent consideration	—	—	(1,210,000)	(1,210,000)
Change in fair value	(5,235)	(19,775)	58,366	33,356
Balance at December 31, 2018	$ 2,950	$ 7,216	$ 9,050,564	$ 9,060,730

	Warrant liability	Unit purchase option liability	Contingent consideration	Total
Balance at December 31, 2016	$ 5,501	$ 51	$ —	$ 5,552
Issuance of contingent consideration	—	—	2,576,633	2,576,633
Change in fair value	2,684	26,940	—	29,624
Balance at December 31, 2017	$ 8,185	$ 26,991	$ 2,576,633	$ 2,611,809

In 2014, the Company issued warrants to purchase 625,208 shares of convertible preferred stock. Upon the closing of our 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, 2018, include (i) volatility of 50%, (ii) risk-free interest rate of 2.51%, (iii) strike price of $8.40, (iv) fair value of common stock of $3.23, and (v) expected life of 1.8 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, 2018, include (i) volatility of 50%, (ii) risk-free interest rate of 2.51%, (iii) unit strike price of $7.47, (iv) fair value of underlying equity of $3.23, and (v) expected life of 1.8 years.

The Company's business acquisitions of Avadel's pediatric products and TRx (see Note 4) involve 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 liabilities are remeasured at the current fair value with changes recorded in the consolidated statement of operations.

As part of the acquisition of Avadel's pediatric products, the Company will 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 is the expected future value of the contingent payments discounted to a present value. The estimated fair value of the royalty payments as of December 31, 2018 was $7.8 million. The significant assumptions used in estimating the fair value of the royalty payment as of December 31, 2018 include (i) the expected net sales of the acquired Avadel pediatric products that are subject to the 15% royalty based on the Company's net sales forecast, and (ii) the risk-adjusted discount rate of 8.1%, which is comprised of the risk-free interest rate of 2.6% and a counterparty risk of 5.5%. The liability is reduced by periodic payments.

The consideration for the TRx acquisition includes certain potential contingent payments. First, pursuant to the TRx Purchase Agreement, the Company is required to pay $3.0 million to the 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 will pay $2.0 million upon the transfer of the Ulesfia NDA to the Company ("NDA Transfer Milestone"). Finally, the Company will pay $2.0 million upon FDA approval of a new dosage of Ulesfia ("FDA Approval Milestone"). The main inputs utilized to determine the fair value of each milestone is the probability of the milestone's success, the expected time to successfully reach the milestone, and the risk-adjusted discount rate. The estimated fair value of the NDA Transfer Milestone as of December 31, 2018 was $0.9 million and the significant assumptions used in estimating the fair value include (i) probability of milestone success of 45.0%, (ii) expected time to milestone of 0.5 years, and (iii) risk-adjusted discount rate of 7.9%, which is comprised of the risk-free rate of 2.4% and a counterparty risk of 5.5%. The estimated fair value of the FDA Approval Milestone as of December 31, 2018 was $0.4 million. The significant assumptions used in estimating the fair value of the FDA Approval Milestone as of December 31, 2018 include (i) probability of milestone success at 22.5%, (ii) expected time to milestone of 1.5 years, and (iii) risk-adjusted discount rate of 8.0%, which is comprised of the risk-free rate of 2.5% and a counterparty risk of 5.5%.

No other changes in valuation techniques or inputs occurred during the years ended December 31, 2018 and 2017. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the years ended December 31, 2018 and 2017.

6. 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, 2018 and 2017:

	December 31,	
	2018	2017
Raw materials	$ 11,392	$ —
Finished goods	1,427,935	560,499
Inventory reserve	(328,547)	(178,346)
Inventory, net	$ 1,110,780	$ 382,153

During the years ended December 31, 2018 and 2017, the Company recorded a related charge to cost of goods sold for obsolete inventory of $150,201 and $178,346, respectively.

7. Property and Equipment

Property and equipment as of December 31, 2018 and 2017 consisted of the following:

	December 31,	
	2018	2017
Furniture and equipment	$ 133,229	$ 58,126
Computers and software	122,065	96,133
Leasehold improvements	463,381	—
Total property and equipment	718,675	154,259
Less accumulated depreciation	(132,163)	(109,647)
Property and equipment, net	$ 586,512	$ 44,612

Depreciation expense was $22,515 and $21,956 for the years ended December 31, 2018 and December 31, 2017, respectively.

8. Goodwill

The changes in the carrying amount of goodwill for the years ended December 31, 2018 and 2017 were as follows:

Balance at December 31, 2016	$ —
Goodwill from acquisition of TRx Pharmaceuticals	14,292,282
Balance at December 31, 2017	$ 14,292,282
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 at December 31, 2018	$ 16,411,123

There were no accumulated impairment losses to goodwill at December 31, 2018 or December 31, 2017.

9. Intangible Assets

The changes in intangible assets for the years ended December 31, 2018 and 2017 were as follows:

Balance at December 31, 2016	$ —
Additions	18,068,000
Amortization	(403,520)
Balance at December 31, 2017	$ 17,664,480
Additions	18,441,000
Purchase price allocation measurement period adjustments	1,527,998
Amortization	(4,532,448)
Impairment	(1,861,562)
Balance at December 31, 2018	$ 31,239,468

The following is a summary of intangible assets held by the Company at December 31, 2018 and December 31, 2017, respectively:

	December 31, 2018				
	Gross Carrying Amount	Accumulated Amortization	Impairment Loss	Net Carrying Amount	Weighted-Average Remaining Life
					(in years)
Acquired Product Marketing Rights	$ 33,656,998	$ (4,080,767)	$ —	$ 29,576,231	9.45
Sales and Marketing Agreement	2,553,000	(691,438)	(1,861,562)	—	—
Acquired Developed Technology	1,677,000	(145,013)	—	1,531,987	9.25
Acquired Assembled Workforce	150,000	(18,750)	—	131,250	1.75
Total Intangible Assets	$ 38,036,998	$ (4,935,968)	$ (1,861,562)	$ 31,239,468	9.41

	December 31, 2017				
	Gross Carrying Amount	Accumulated Amortization	Impairment Loss	Net Carrying Amount	Weighted-Average Remaining Life
					(in years)
Acquired Product Marketing Rights	$ 15,734,000	$ (257,645)	$ —	$ 15,476,355	11.20
Sales and Marketing Agreement	2,334,000	(145,875)	—	2,188,125	1.90
Total Intangible Assets	$ 18,068,000	$ (403,520)	$ —	$ 17,664,480	10.05

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.

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
2019	$ 4,315,318
2020	4,296,568
2021	4,082,334
2022	2,976,322
2023	2,976,322
Thereafter	12,592,604
Total future amortization expense	$ 31,239,468

10. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities as of December 31, 2018 and 2017 consisted of the following:

	December 31,	
	2018	2017
Sales returns	$ 3,972,510	$ 3,478,349
Medicaid rebates	2,237,269	350,681
Minimum sales commitments, royalties payable, and purchase obligations	9,662,901	743,010
Compensation and benefits	1,953,065	1,401,514
Research and development expenses	278,132	299,480
General and administrative	1,112,378	1,001,454
Sales and marketing	235,721	—
Other	279,397	256,634
Total accrued expenses and other current liabilities	$ 19,731,373	$ 7,531,122

11. Agreements

Lilly CERC-611 License

On September 22, 2016, the Company entered into an exclusive license agreement with Eli Lilly and Company (“Lilly”) pursuant to which the Company received exclusive, global rights to develop and commercialize CERC-611, previously referred to as LY3130481, a potent and selective Transmembrane AMPA Receptor Regulatory Proteins (“TARP”) ã-8-dependent á-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid (“AMPA”) receptor antagonist. The terms of the license agreement provide for an upfront payment of $2.0 million, of which $750,000 was due within 30 days of the effective date of the license agreement, and the remaining balance of $1.25 million is due after the first subject is dosed with CERC-611 in a multiple ascending dose study and is recorded as license obligations on the balance sheet at December 31, 2018. Additional payments may be due upon achievement of development and commercialization milestones, including the first commercial sale. Upon commercialization, the Company is obligated to pay Lilly milestone payments and a royalty on net sales.

Merck CERC-301 License

In 2013, the Company entered into an exclusive license agreement with Merck & Co., Inc. (“Merck”) pursuant to which Merck granted the Company rights relating to certain small molecule compounds. In consideration of the license, the Company paid an initial

payment of $750,000, and upon achievement of acceptance by the United States Food and Drug Administration, or FDA, of Merck pre-clinical data and FDA approval of a Phase 3 clinical trial the Company will pay an additional $750,000. Additional payments may be due upon achievement of development and regulatory milestones, including the first commercial sale. Upon commercialization, the Company is obligated to pay Merck milestone payments and royalties on net sales.

Merck CERC-406

In 2013, the Company entered into a separate exclusive license agreement with Merck pursuant to which Merck granted the Company certain rights in small molecule compounds which are known to inhibit the activity of COMT. In consideration of the license, the Company made a $200,000 upfront payment to Merck. Additional payments may be due upon the achievement of development and regulatory milestones. Upon commercialization of a COMT product, the Company is required to pay Merck royalties on net sales.

Poly-Vi-Flor and Tri-Vi-Flor Related Contracts

Supply and License Agreement, effective December 1, 2014, by and between TRx and Merck & Co. ("Merck")

On December 1, 2014 TRx entered into a Supply and License Agreement with Merck. The initial term of the agreement expires on December 31, 2020, and the agreement will automatically continue for subsequent one-year terms thereafter until terminated in accordance with its terms. Pursuant to the agreement, Merck agrees to supply a specific compound called Metafolin® to TRx for use in dietary supplements within a defined market, and TRx agrees to purchase 100% of its Metafolin requirements from Merck. Under the agreement, TRx has an exclusive license under a number of U.S. and international patents, as well as related trade secrets, know-how and trademark rights, to make and sell TRx products positioned in the pediatric market (i.e., targeted for children 0-3 years of age) in the U.S. Under the agreement, TRx also has a non-exclusive license under the same intellectual property rights to make and sell TRx dietary supplement products within the U.S. outside of certain specified fields, including products containing Metafolin in combination with folic acid or any other folate, products positioned for type II diabetes, pharmaceutical drugs, and medical, fortified, and special dietary foods. TRx must pay Merck a royalty of two-percent (2%) of net sales from TRx products in the pediatric field that contain Metafolin. The royalty payment does not apply to net sales of TRx products marketed as pre-or postnatal vitamins. The royalty payment will continue to apply throughout the initial term and any automatic renewal periods. The minimum annual order quantity for the compound is 1kg. Payments of royalties are made by TRx within 45 days following the end of each calendar quarter.

Settlement and License Agreement, dated February 28, 2011, by and between TRx and Mead Johnson and Company LLC, as amended

TRx entered into a Settlement and License Agreement with Mead Johnson and Company LLC, and the parties subsequently entered into an amendment to such agreement on October 6, 2011. Pursuant to the agreement, Mead Johnson granted TRx an exclusive license to the "Poly-Vi-Flor" and "Tri-Vi-Flor" trademarks and agreed not to oppose TRx's seeking the marks Poly-Vi-Flor and Tri-Vi-Flor in the United States and in any other countries where Mead Johnson does not have an active registration for such marks. As consideration for such licenses, TRx agreed to pay a royalty to Mead Johnson in the amount of 10% of net revenues received by TRx with respect to products sold under the Poly-Vi-Flor and Tri-Vi-Flor trademarks during the term of the agreement. The term of the agreement is indefinite and will continue unless terminated pursuant to the provisions of the agreement. Payments are made by TRx in arrears on a quarterly basis within 45 days after the end of a given calendar quarter.

Redemption Agreement with Additional Poly-Vi-Flor Royalty Obligation

TRx and the Selling Members entered into an Agreement to Redeem Membership Interest on May 31, 2011 with a former Member, Presmar Associates, Inc. Pursuant to the agreement, TRx and the Selling Members agreed to pay to Presmar Associates a royalty payment of 5% of gross sales for Poly-Vi-Flor branded or authorized generic product and, upon the sale of the Poly-Vi-Flor trademark to a third party, to pay to Presmar Associates 5% of the cash proceeds from such sale transaction. Any future sale of the Poly-Vi-Flor trademark to a third party would require that 5% of the sale proceeds be paid to Presmar Associates. Payments are made by TRx in arrears on a quarterly basis within 45 days after the end of a given calendar quarter.

Millipred Related Contracts

License and Supply Agreement between TRx and Watson Laboratories, Inc.

TRx entered into a License and Supply Agreement with Watson Laboratories, Inc. on May 19, 2008, and the parties subsequently entered into amendments of the agreement on July 19, 2013 and April 1, 2016. Pursuant to the most recent amendment, the term of the agreement was extended for an additional five-year period expiring on April 1, 2021. However, TRx has the option to terminate the agreement following the first commercial sale of a generic product which occurred in April of 2017. If neither party terminates the agreement prior to April 1, 2021, then the agreement will automatically renew for successive one-year periods. The amended agreement provides that the company make license payments of $75,000 in February and August of each year through April 2021.

Ulesfia Related Contracts

First Amended and Restated Exclusive Ulesfia Distribution Agreement, dated December 18, 2015, by and between Zylera and Lachlan Pharmaceuticals ("Lachlan")

In November 2017, the Company acquired TRx and its wholly-owned subsidiaries, including Zylera. The previous owners of TRx beneficially own more than 10% of our outstanding common stock. Zylera, which is our wholly owned subsidiary, entered into the First Amended and Restated Distribution Agreement with Lachlan, effective December 18, 2015. 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.

Zylera is obligated to purchase a minimum of 20,000 units per year, or approximately $1.2 million worth of product, from Lachlan, subject to certain termination rights. Zylera must pay Lachlan $58.84 per unit and handling fees that are equal to $3.66 per unit of fully packaged Ulesfia in 2018, and escalate at a rate of 10% annually, as well as reimburse Lachlan for all product liability insurance fees incurred by Lachlan. The Lachlan Agreement also requires that Zylera make certain cumulative net sales milestone payments and royalty payments to Lachlan with a $3 million annual minimum payment unless and until there has been a "Market Change" involving a new successful competitive product. Lachlan is obligated to pay identical amounts to an unrelated third party from which it obtained rights to Ulesfia, with the payments ultimately flowing to Summers Laboratories, Inc. ("Summers Labs"). Because of the dispute described below, the Company has 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. The second interim award rejected Summers Labs' request to accelerate future minimum royalties, however, it ruled 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 as contemplated in the second interim ruling. The final award has no direct bearing on the Company as 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 is 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 the Company's agreement with Lachlan. However, the Company has interpreted this ruling's impact on the Lachlan agreement to mean that a market change has not occurred, and the minimum purchase obligation and minimum royalty provisions of the contract are active and due for any prior periods as well as going forward for any future periods.

The Company has recognized a $7.8 million liability for these minimum obligations in accrued liabilities as of December 31, 2018. Under the terms of the TRx Purchase Agreement, the former TRx owners are required to indemnify the Company for 100% of all pre-acquisition losses related this arbitration, including legal costs, and possible minimum payments in excess of $1 million. Furthermore, the former TRx owners are required to indemnify the Company for 50% of post-acquisition Ulesfia losses, which would include losses resulting from having to fund these minimum obligations. The Company has recorded an indemnity receivable of $4.9 million in other receivables as of December 31, 2018, which the Company believes is fully collectible. The receivable is net of $1.9 million collection made in the fourth quarter of 2018 from a full cash escrow release with the former TRx owners from the escrow that was established as a part of the TRx acquisition. The post-acquisition minimum obligations net of amounts recorded within the indemnity receivable of $2.2 million has been recorded in cost of product sales for the year ended December 31, 2018. If the Company fails to make these minimum obligations timely then the Lachlan Agreement may be terminated by Lachlan, in which case the Company would no longer be able to sell the Ulesfia product, but it would also not be subject to future minimum obligations. Lachlan has not requested payment for the minimum obligations.

Commercial, Supply, and Distribution Agreements

Acquired Product Marketing Rights - Karbinal

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"), under which the Company is granted the exclusive right to distribute and sell the product in the United States. The initial term of the Karbinal Agreement is 20 years. The Company will pay

TRIS a royalty equal to 23.5% of net sales. Avadel has agreed to offset the 23.5% royalty payable by 8.5%, for a net royalty equal to 15%, in fiscal year 2018 and 2019 for net sales of Karbinal. The make-whole payment is capped at $750,000 each year. The Karbinal Agreement also contains minimum unit sales commitments, which is based on a commercial year that spans from August 1 through July 31, of 70,000 units through 2033. The Company is required to pay TRIS a royalty make whole payment of $30 for each unit under the 70,000 units annual minimum sales commitment through 2033. The annual payment is due in August of each year. The Karbinal Agreement also has multiple commercial milestone obligations that aggregate up to $3.0 million based on cumulative net sales, the first of which is triggered at $40.0 million.

Acquired Product Marketing Rights - AcipHex

On February 16, 2018, in connection with the acquisition of Avadel's pediatric products, the Company assumed the License and Assignment Agreement for AcipHex (“AcipHex Agreement”) between Eisai, Inc. and FSC Therapeutics, LLC dated June 2014 and the Supply Agreement between Eisai, Inc. and FSC Laboratories, Inc. dated June 2014. Per the AcipHex Agreement, the Company is granted the exclusive license to exploit the products in the territory (U.S.) and an exclusive license to use Eisai trademarks to sell the products. Eisai will manufacture and supply the requirements for supply of the products. The term of the AcipHex Agreement is perpetual unless terminated per the agreement. Eisai will receive (a) a royalty with respect to the sales of AcipHex equal to 15.0% of Net Sales. The royalties are payable until the first commercial sale of an unauthorized generic product in the territory or the date that is five years from the effective date of the agreement. A maximum $8.0 million of sales-based milestone payments is possible should AcipHex accumulated net sales exceed $50.0 million in any twelve-month period

Acquired Product Marketing Rights- Cefaclor

On February 16, 2018, in connection with the acquisition of Avadel's pediatric products, the Company assumed the License, Supply and Distribution Agreement for Cefaclor between Yung Shin Pharm. Ind, Co., Ltd. and FSC Therapeutics, LLC dated March 2015 (“Cefaclor Agreement”). The initial term of the Cefaclor Agreement runs through December 31, 2024 and will automatically renew for additional, successive twelve-month periods unless terminated by either party. Yung Shin will receive a royalty equal to 15.0% of Net Sales of Cefaclor. A maximum $6.5 million of sales-based milestone payments is possible should Cefaclor accumulated net sales exceed $40.0 million in any twelve-month period.

12. Deerfield Debt Obligation

In relation to the Company's acquisition of Avadel's pediatric products on February 16, 2018, the Company assumed an obligation that Avadel had to Deerfield (the "Deerfield Obligation"). Beginning in July 2018 through October 2020, the Company will pay a quarterly payment of $262,500 to Deerfield. In January 2021, a balloon payment of $15,250,000 is due. On the acquisition date, the Company determined the fair value of these payments to be $15,075,000 using a market participant's estimated cost of debt. Management performed a credit risk analysis that determined the Company's credit rating to be B to BB plus the yield on a ten-year treasury security. The difference between the gross value and fair value of these payments will be recorded as interest expense in the Company's consolidated statements of operations through January 2021 using the effective interest method. Interest expense for the year ended December 31, 2018 was $0.8 million and is included in interest expense, net on the accompanying statements of operations. The amounts due within the next year are included in current portion of long-term debt on the Company's consolidated balance sheets. The amounts due in greater than one year are included in long-term debt, net of current portion, on the Company's consolidated balance sheets. The Deerfield Obligation was $15.4 million as of December 31, 2018, of which $1.1 million is recorded as a current liability. The Deerfield Obligation contains certain covenants in which the Company is in compliance with as of December 31, 2018.

13. Capital Structure

According 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, 2018, 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 April 27, 2017, the Company further amended its certificate of incorporation in connection with the closing of the Armistice Private Placement (as defined below) with the filing of a Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (“Series A Preferred Stock”) of Cerecor Inc. (the “Certificate of Designation of the Series A Preferred Stock”). The Certificate of Designation of the Series A Preferred Stock authorized the issuance of 4,179 shares of Series A Preferred Stock to Armistice with a stated value of $1,000 per share, convertible into 11,940,000 shares of the Company’s common stock at a conversion price of $0.35 per share and was approved by its shareholders on June 30, 2017. On July 6, 2017, Armistice converted all of its outstanding shares of Series A Preferred Stock into common stock.

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 converts to 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 our 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 this was considered a deemed distribution to Armistice of $1.7 million. The deemed distribution is calculated as the difference between the fair value of the incentive warrants on the date of the transaction of $2.2 million and the value that Armistice forwent by exchanging the original warrants of $0.5 million. The fair value of the incentive warrant is estimated using a Black-Scholes option-pricing model. The significant assumptions used in the model for valuing the incentive warrant on December 27, 2018 include (i) volatility of 55%, (ii) risk free interest rate of 2.62%, (iii) unit strike price of $12.50, (iv) fair value of underlying equity of $3.02, and (v) expected life of 5.5 years.

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 converts 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

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 was approximately $9.0 million.

Armistice Private Placements

As discussed in detail above (see "December 2018 Armistice Private Placement"), on December 27, 2018 the Company exchanged previously outstanding warrants for like-kind warrants for 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 converts to common stock on a 1 to 5 ratio (or to 14,285,714 shares of common stock in total). 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 (the "incentive warrants"). See "December 2018 Armistice Private Placement" above for more details.

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.

On April 27, 2017, the Company entered into a securities purchase agreement with Armistice, pursuant to which Armistice purchased $5.0 million of the Company's securities, consisting of 2,345,714 shares of the Company's common stock at a purchase price of $0.35 per share and 4,179 shares of Series A Preferred Stock at a price of $1,000 per share. The Company received $4.65 million in net proceeds from the Armistice Private Placement. The number of shares of common stock that were purchased in the private placement constituted approximately 19.99% of the Company's outstanding shares of common stock immediately prior to the closing of the Armistice Private Placement. Armistice also received warrants to purchase up to 14,285,714 shares of the Company's common stock at an exercise price of $0.40 per share. Under the terms of the securities purchase agreement, the Series A Preferred Stock were not convertible into common stock, and the warrants were not exercisable until the Company received approval of the private placement by the Company's shareholders as required by the rules and regulations of the NASDAQ Capital Market. The Company received shareholder approval for this transaction on June 30, 2017, at which time the warrants became exercisable and the Series A Preferred Stock became convertible into common stock.

As multiple instruments were issued in a single transaction, the Company initially allocated the issuance proceeds among the preferred stock, common stock and warrants using the relative allocation method. As the warrants were determined to be indexed to the Company's stock, and would only be settled in common shares, entirely in the control of the Company, the warrant instrument was accounted for as an equity instrument. Fair value of the warrants was initially determined upon issuance using the Black-Scholes Model (level 3 fair value measurement). Armistice converted all of the Series A Preferred Stock into 11,940,000 shares of common stock on July 6, 2017.

Ichorion Asset Acquisition

On September 25, 2018, under the terms of the Ichorion Asset Acquisition noted above in Note 4, the Company issued 5.8 million common stock shares upon closing.

Contingently Issuable Shares

Under the terms of TRx acquisition noted above in Note 4, 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 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, 2018, 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 5)

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").

As of the 2016 Plan Effective Date, no additional grants will be made under the 2015 Plan or the 2011 Stock Incentive Plan (the "2011 Plan"), which was previously succeeded by the 2015 Plan effective October 13, 2015. Outstanding grants under the 2015 Plan and 2011 Plan will continue according to their terms as in effect under the applicable plan.

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. 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 common stock of the Company on the last trading day in December of the prior calendar year. As of December 31, 2018, there were 602,657 shares available for future issuance under the 2016 Plan. On January 1, 2019, on the terms of the 2016 Amended Plan an additional 1,632,167 shares were made available for issuance for a total of 2,234,824 shares available for issuance.

Option grants to employees and directors expire after ten years. Employee options typically vest over four years. Options granted to directors typically vest over 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 awards and ESPP shares. The amount of stock-based compensation expense recognized for the years ending December 31, 2018 and 2017 was as follows:

	Year Ended December 31,	
	2018	2017
Research and development	$ 101,000	$ 156,047
General and administrative	2,135,710	1,001,205
Sales and marketing	194,353	—
Total stock-based compensation	$ 2,431,063	$ 1,157,252

During the third quarter of 2018, the Company modified stock options of a senior executive who was separated in the period. This modification resulted in the recognition of approximately $322,000 of compensation expense, which is included in general and administrative expenses for the year ended December 31, 2018 in the accompanying statement of operations.

Stock options with service-based vesting conditions

The Company has granted awards 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, 2018 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, 2017	2,823,489	$ 3.93		7.29
Granted	1,639,860	$ 3.85	$ 3,737,728	
Exercised	(243,115)			
Forfeited	(473,637)	$ 2.77	$ 1,109,083	
Balance at December 31, 2018	3,746,597	$ 4.16		7.79
Exercisable at December 31, 2018	1,997,468	$ 4.71		6.62

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, 2018, the aggregate intrinsic value of options outstanding and options currently exercisable was $1.5 million and $1.0 million, respectively. The total intrinsic value of options exercised during the year ended December 31, 2018 was $0.5 million. The total grant date fair value of shares which vested during the years ended December 31, 2018 and 2017 was $1.2 million and $2.9 million, respectively. The per-share weighted-average grant date fair value of the options granted during 2018 and 2017 was estimated at $2.28 and $0.66, respectively. There were 641,286 options that vested during the year ended December 31, 2018 with a weighted average grant date fair value of $1.87 per share. At December 31, 2018, there was $3,062,257 of total unrecognized compensation cost related to nonvested service-based vesting conditions awards. This unrecognized compensation cost is expected to be recognized over a weighted-average period of 3.1 years.

Stock options with market-based vesting conditions

During 2018 the Company granted awards that contain market-based vesting conditions. A summary of option activity with market-based vesting conditions for the year ended December 31, 2018 is as follows:

	Options Outstanding			
	Number of shares	Weighted average exercise price	Weighted average remaining contractual term (in years)	Aggregate intrinsic value (1)
Balance at December 31, 2017	—			
Granted	500,000	$ 4.24		
Balance at December 31, 2018	500,000	$ 4.24	9.24	$ —
Exercisable at December 31, 2018	—			

(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.

The weighted-average grant-date fair value of stock options with market-based vesting conditions granted during 2018 was $2.52 per share or $1,260,000. At December 31, 2018, there was $917,568 of total unrecognized compensation cost related to nonvested market-based vesting conditions awards. This compensation cost is expected to be recognized over a weighted-average period of 2.05 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	2018			2017		
Risk-free interest rate	2.51%	—	3.01%	1.85%	—	2.38%
Expected term of options (in years)	5.0	—	6.25	5.0	—	6.25
Expected stock price volatility	55%	—	65%	55%	—	100%
Expected annual dividend yield	0%	—	0%	0%	—	0%
Market-based options						
Risk-free interest rate	2.84%					
Expected term of options (in years)	2.8					
Expected stock price volatility	60%					
Expected annual dividend yield	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 and expected dividend yield of 0.0%.

Restricted Stock Award

During 2018, the Company granted restricted stock awards ("RSA") to certain employees. The Company measures the fair value of the restricted awards using the stock price at the date of the grant. The restricted shares vest annually over a four year period beginning on the first anniversary of the award. A summary of RSA grants activity for the year ended December 31, 2018 is as follows:

	Non-vested RSAs Outstanding	
	Number of shares	Weighted average grant date fair value
Non-vested RSAs at December 31, 2017	—	
Granted	445,000	$ 4.27
Non-vested RSAs at December 31, 2018	445,000	

The stock compensation expense on this award for the year ended December 31, 2018 was $346,514. At December 31, 2018, there was $1,551,986 of total unrecognized compensation cost related to the RSA grants. This compensation cost is expected to be recognized over a weighted-average period of 3.3 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 $25,000 of the fair market value of the Company's common stock for each calendar year in which such right is outstanding.

Upon the ESPP Effective Date, the Company reserved and authorized up to 500,000 shares of common stock for issuance under the ESPP. On January 1 of each calendar year, the aggregate number of shares that may be issued under the ESPP shall automatically increase 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, 2018, 783,983 shares remained 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 $49,863 and $76,305 for the years ended December 31, 2018 and December 31, 2017, respectively, which are included in the table above with stock-based compensation from stock options.

15. Income Taxes

The Company accounts for income taxes in accordance with ASC 740 (Topic 740, Income Taxes). ASC Topic 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 the financial statements 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 calendar year 2018. Tax years beginning in 2015 are generally subject to examination by taxing authorities, although NOLs 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. There were $0.2 million of interest and penalties related to unrecognized tax benefits for income taxes that have been accrued or recognized as of and for the year ended December 31, 2018. It is the Company's policy to treat interest and penalties, to the extent they arise, as a component of income taxes.

The income tax provision consisted of the following for the years ending December 31, 2018 and 2017:

	December 31,	
	2018	2017
Current:		
Federal	$ (53,281)	$ 2,309,285
State	36,116	489,863
Total Current:	(17,165)	2,799,148
Deferred:		
Federal	(52,235)	(789,274)
State	35,490	(43,355)
Total Deferred	(16,745)	(832,629)
Net income tax (benefit) expense	$ (33,910)	$ 1,966,519

The net deferred tax liabilities consisted of the following for the years ending December 31, 2018 and 2017:

	December 31,	
	2018	2017
Deferred tax assets:		
Net operating losses	$ 4,421,423	$ 716,819
Accrued compensation	465,430	271,437
Deferred rent	15,373	4,051
Tax credits	252,095	—
Stock-based compensation	1,922,736	1,291,230
Installment sale	508,291	—
Other reserves	262,260	72,881
Basis difference in tangible and intangible assets, net	2,968,764	2,019,272
Total deferred tax assets	10,816,372	4,375,690
Deferred tax liabilities:		
Prepaid expenses	(160,474)	—
Installment sales	—	(358,844)
Total deferred tax liabilities	(160,474)	(358,844)
Deferred tax asset, net	10,655,898	4,016,846
Less valuation allowance	(10,725,136)	(4,023,990)
Net deferred taxes	$ (69,238)	$ (7,144)

As of December 31, 2018, the Company has roughly $16,426,000 of gross NOLs for federal and state tax purposes of which approximately $3,580,000 will begin to expire in 2031, while the remaining amount of $12,846,000 will carryforward indefinitely.

The income tax benefit for the years ended December 31, 2018 and 2017 differed from the amounts computed by applying the U.S. federal income tax rate as follows:

	December 31,	
	2018	2017
Federal statutory rate	21.00 %	34.00 %
Permanent Adjustments	(0.37)%	0.17 %
Built-in-loss	(0.33)%	1.52 %
State taxes	4.43 %	27.91 %
Research and development credit	0.61 %	(1.04)%
Change in statutory rate due to Tax Cuts and Job Act	— %	15.82 %
NOL adjustment per § 382	— %	126.82 %
Non-deductible IPR&D expense	(9.84)%	— %
Other	(0.04)%	0.04 %
Change in valuation allowance	(15.37)%	(191.03)%
Effective income tax rate	0.09 %	14.21 %

The valuation allowance recorded by the Company as of December 31, 2018 and December 31, 2017 resulted from the uncertainties of the future utilization of deferred tax assets relating from NOL carry forwards for federal and state income tax purposes. Realization of the NOL carry forwards is contingent on future taxable earnings. The deferred tax asset was reviewed for expected utilization using a “more likely than not” approach by assessing the available positive and negative evidence surrounding its recoverability. Accordingly, a partial valuation allowance continues to be recorded against the Company’s deferred tax asset as of December 31, 2018 and December 31, 2017, as it was determined based upon past and projected future losses that it was “more likely than not” that the Company’s deferred tax assets would not be realized. As of December 31, 2018 and December 31, 2017, the Company has a net deferred tax liability due to having an indefinite life asset, referred to as a “naked credit.” The naked credit can be offset up to 80% by NOLs generated after January 1, 2018, the remaining 20% remains as a liability. In future years, if the deferred tax assets are determined by management to be “more likely than not” to be realized, the recognized tax benefits relating to the reversal of the valuation allowance as of December 31, 2018 and December 31, 2017 will be recorded. 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.

The Company's current and future unused losses may be subject to limitation under Sections 382 and 383 of 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, as defined (in general, an “ownership change” is defined as a greater than 50% change (by value) in equity ownership over a three-year period).

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 IRC, the Act reduces U.S. federal corporate tax rate from 35% to 21%. 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 has completed its analysis within the measurement period in accordance with SAB 118 and there were no material additional adjustments necessary.

16. Commitments and Contingencies

Litigation

The Company is party in various contractual disputes, litigation, and potential claims arising in the ordinary course of business. The Company does not believe that the resolution of these matters will have a material adverse effect on our financial position or results of operations except as otherwise disclosed in this document. See Note 11 for further discussion of the Lachlan legal arbitration.

Purchase obligations

The Company has unconditional purchase obligations as a result of recent acquisitions that include agreements to purchase goods that are enforceable and legally binding and that specify all significant terms including: fixed or minimum quantities to be purchased; fixed, minimum or variable price provisions; and the approximate timing of the transaction. Purchase obligations exclude agreements that are cancelable at any time without penalty. The unconditional purchase obligations outstanding as of December 31, 2018 include the following:

Lachlan Pharmaceuticals Minimum Purchase and Minimum Royalties Obligations

As discussed in Note 4, in November 2017, the Company acquired TRx and its wholly-owned subsidiaries, including Zylera. The previous owners of TRx 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. 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.

The Lachlan agreement requires 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 has been a "Market Change" involving a new successful competitive product. Zylera must pay Lachlan $58.84 per unit and handling fees that are equal to $3.66 per unit of fully packaged Ulesfia in 2018 and escalate at a rate of 10% annually. The Lachlan Agreement also requires 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 has been a "Market Change" involving a new successful competitive product. The Company expects a successful competitive product will enter the market in early 2021 and therefore the future minimum purchase obligations and royalty payments are expected through 2020.

As of December 31, 2018, future minimum purchase obligations and future minimum royalty payments to Lachlan are as follows:

	2019*	2020*	2021	2022	Total*
Minimum Purchase Obligations	1,257,326	1,265,378	—	—	$2,522,704
Minimum Royalties	3,000,000	3,000,000	—	—	6,000,000
Total	4,257,326	4,265,378	—	—	$8,522,704

*Per the TRx Purchase Agreement, the previous owners of TRx are required to indemnify the Company for 50% of post-acquisition Ulesfia losses, which include the future minimum purchase obligations and future minimum royalties disclosed above. Thus, the Company's future net payouts related to the Ulesfia product will be significantly reduced as a result of the indemnification.

Karbinal Royalty Make Whole Provision

As discussed in Note 4, 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 has 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 is required to pay TRIS a royalty make whole payment of $30 for each unit under the 70,000 units annual minimum sales commitment through 2033. The annual payment is due in August of each year.

The Company paid $0.9 million to TRIS in August 2018 related to the make whole payment for the commercial year ended July 31, 2018. For the year ended December 31, 2018, the Company has accrued $0.7 million in accrued expenses and other current liabilities related to the Karbinal royalty make whole for the commercial year ending July 31, 2019. The post-acquisition make whole provision of $1.3 million has been recorded in cost of product sales for the year ended December 31, 2018. The future royalty make whole payments is unknown as the amount owed to TRIS is dependent on the number of units sold.

Office Lease

During the third quarter of 2018, the Company entered into a lease for the Company's new corporate headquarters in Rockville, Maryland. The Company obtained access to the building in September 2018 to perform leasehold improvements, which resulted in the lease commencement date for accounting purposes. The Company occupied the building in January 2019. The landlord provided a lease incentive related for leasehold improvements in the amount of $381,900, which the Company may requisition the landlord for payment on a monthly basis for the work incurred-to-date. As of December 31, 2018, the Company incurred leasehold improvements for the full amount of the incentive which the Company has recognized within other receivables. The Company recognized a corresponding lease incentive obligation within other long-term liabilities. The lease incentive obligation is reduced and recognized in income as a reduction to straight-line rental expense.

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 is expected to occur 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 is not reasonably certain that the Company will exercise the renewal periods or early terminate the lease and therefore the end date of the lease for accounting purposes is January 31, 2030.

The Company analyzed the lease agreement and determined the lease classification is operating. The Company recognizes operating lease rent expense on a straight-line basis over the expected term of each lease. The Company recognized rent expense for this property of $41,749 in general and administrative expense on the statement of operations for the year ended December 31, 2018.

As of December 31, 2018, minimum operating lease obligations for the new office space are as follows:

	Minimum Lease Payments
2019	$ —
2020	155,815
2021	169,510
2022	173,748
2023	178,092
Thereafter	1,183,290
Total	$ 1,860,455

Exhibit 21.1

List of Subsidiaries of Cerecor Inc.

Entity Name	**Jurisdiction**
Ichorion Therapeutics, LLC	Delaware
TRx Pharmaceuticals, LLC	North Carolina
Zylera Pharmaceuticals, LLC	North Carolina
Zylera Pharma Corp.	North Carolina

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

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

(1) Registration Statement (Form S-1 No. 333-204905) as filed on June 12, 2015, and amended on September 8, 2015, September 22, 2015, October 1, 2015, and October 13, 2015,

(2) Registration Statement (Form S-8 No. 333-207949) pertaining to the 2015 Omnibus Incentive Compensation Plan,

(3) Registration Statement (Form S-8 No. 333-211490) pertaining to the 2016 Equity Incentive Plan,

(4) Registration Statement (Form S-8 No. 333-211491) pertaining to the 2016 Employee Stock Purchase Plan,

(5) Registration Statement (Form S-1 No. 333-213676) as filed on September 16, 2016,

(6) Registration Statement (Form S-3 No. 333-214507) as filed on November 8, 2016, and amended on December 1, 2016,

(7) Registration Statement (Form S-3 No. 333-218252) as filed on May 26, 2017,

(8) Registration Statement (Form S-8 No. 333-226767) pertaining to the Amended and Restated 2016 Equity Incentive Plan,

(9) Registration Statement (Form S-3 No. 333-227227) as filed on September 7, 2018, and amended on October 2, 2018, and

(10) Registration Statement (Form S-3 No. 333-229283) as filed on January 17, 2019;

of our report dated March 18, 2019, with respect to the consolidated financial statements of Cerecor Inc. included in this Annual Report (Form 10-K) of Cerecor Inc. for the year ended December 31, 2018.

/s/ Ernst & Young LLP
Baltimore, Maryland
March 18, 2019

Exhibit 31.1

CERTIFICATION
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Peter Greenleaf, certify that:

1. I have reviewed this Annual Report on Form 10-K of Cerecor Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 18, 2019

/s/ Peter Greenleaf
Peter Greenleaf
Chief Executive Officer
(Registrant's Principal Executive Officer)

Exhibit 31.2

CERTIFICATION
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Joseph M. Miller, certify that:

1. I have reviewed this Annual Report on Form 10-K of Cerecor Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 18, 2019

/s/ Joseph M. Miller
Joseph M. Miller
Chief Financial Officer
(Registrant's Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Cerecor Inc. (the "Registrant") on Form 10-K for the year ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Peter Greenleaf, Chief Executive Officer (principal executive officer) of the Registrant, and I, Joseph M. Miller, Chief Financial Officer (principal financial and accounting officer) of the Registrant, each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition at the end of the period covered by the Report and the results of operations of the Registrant for the periods covered by the Report.

Date: March 18, 2019	By:	/s/ Peter Greenleaf
	Name:	**Peter Greenleaf**
	Title:	**Chief Executive Officer** **(Registrant's Principal Executive Officer)**
Date: March 18, 2019	By:	/s/ Joseph M. Miller
	Name:	**Joseph M. Miller**
	Title:	**Chief Financial Officer** **(Registrant's Principal Financial and Accounting Officer)**

The foregoing certifications are not deemed filed with the Securities and Exchange Commission for purposes of section 18 of the Securities Exchange Act of 1934, as amended (Exchange Act), and are not to be incorporated by reference into any filing of Cerecor Inc. under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.