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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, 2017
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.)

400 E. Pratt Street, Suite 606
Baltimore, Maryland 21202
(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 Class A Warrants, consisting of the right to purchase one share of common stock at an exercise price of $4.55 per share Class B Warrants, consisting of the right to purchase one-half share of common stock at an exercise price of $3.90 per share	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 ☐ (Do not check if a smaller reporting company)	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, 2017 (based on the closing price of $0.573 on that date) was $5,882,756. 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 16, 2018, there were 31,379,778 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, 2017, 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

We are a biopharmaceutical company with the near-term goal of becoming a self-sustained, integrated pharmaceutical company that is focused on pediatric health care. In November 2017 we acquired TRx Pharmaceuticals, LLC and it wholly-owned subsidiaries (see "Acquisition of TRx Pharmaceuticals") and in February 2018 we purchased and acquired all rights to Avadel Pharmaceuticals PLC's ("Avadel's") marketed pediatric products (see "Acquisition of Avadel Products").

We have a diversified portfolio of products and product candidates in development with a focus on patients with rare neurological disorders or orphan diseases. Our lead marketed products are:

Prescribed Dietary Supplements: Poly-Vi-Flor and Tri-Vi-Flor are prescribed vitamin and fluoride supplements used in infants and children to treat or prevent deficiency of essential vitamins and fluoride, often caused by poor diet or low levels of fluoride in drinking water and other sources. Poly-Vi-Flor and Tri-Vi-Flor are available in various formulations, including an oral suspension and chewable tablets.

Prescription Drugs: The Company has three prescription drugs,. Millipred®, Veripred® and Ulesfia®. Millipred and Veripred are branded prescription formulations for prednisolone, which is a corticosteroid and is commonly used to treat inflammation of the skin, joints, lungs and other organs. It can also be prescribed for treatments including asthma, allergies and arthritis. Ulesfia (benzyl alcohol) 5% Lotion is indicated for the topical treatment of head lice infestation in patients 6 months of age and older. Our prescription portfolio was expanded in February 2018 (see “Acquisition of Avadel Products) and further consiste of Karbinal™ ER, AcipHex® Sprinkle™, Cefaclor for Oral Suspension, and Flexichamber™

Our strategy is to enhance shareholder value by:

- Growing sales of the existing products in our portfolio, including by identifying and investing in growth opportunities such as new treatment indications and new geographic markets;
- Acquiring or licensing rights to clinically meaningful and differentiated products that are already on the market for pediatric use or product candidates that are in late-stage development for pediatric indications that are near market launch; and
- Pursuing targeted clinical-stage development assets that are differentiated product candidates for rare neurological disorders or orphan diseases.

We apply a disciplined decision making methodology as we evaluate the optimal allocation of our resources between investing in our current commercial product line, our development portfolio and acquisitions or in-licensing of new assets.

Our research and development activities currently include development of new product candidates, activities related to new indications for existing products and the generation of additional clinical data for existing product candidates. A summary of our ongoing development activities is provided below:

CERC-301: Orphan Neurological Indications. CERC-301 belongs to a class of compounds known as antagonists of the N-methyl-D-aspartate, or 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, or NR2B (also called GluN2B). We intend to initiate a Phase I study in 2018 for neurogenic orthostatic hypotension (“nOH”), a condition that is part of a larger category called orthostatic hypotension (OH), which is 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. We will continue to explore the use of CERC-301 in orphan neurologic conditions in preclinical and clinical studies.

- ***CERC-611: Adjunctive Treatment of Partial-Onset Seizures in Epilepsy.*** CERC-611, is a preclinical asset that 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 receptor. 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. We intend to develop CERC-611 as an adjunctive therapy for the treatment of partial-onset seizures, with or without secondarily generalized seizures, in patients with epilepsy.

The Company has two preclinical stage development candidates that are selective catechol-O-methyltransferase or COMT inhibitors:

- ***CERC-406 and CERC-425:*** We believe these compounds have potential for treatments associated with motoric and non-motoric symptoms of Parkinson's Disease as well as other psychiatric and neurological conditions frequently impacted by impaired cognition.

We plan both to evaluate our current portfolio for potential new indications and to identify new product candidates for development.

Members of our management team have extensive pharmaceutical product development and commercialization experience and they have played key roles in development or commercialization. Collectively, our officers and directors have contributed to the submission of numerous Investigational New Drug Applications ("INDs") and New Drug Applications (NDAs") to the FDA, and commercial launch post FDA approval.

Acquisition of TRx Pharmaceuticals

On November 17, 2017, we acquired TRx, including its wholly-owned subsidiary Zylera Pharmaceuticals, LLC and its franchise of commercial medications led by Poly-Vi-Flor® (multivitamin and fluoride supplement tablet, chewable) and Tri-Vi-Flor® (multivitamin and fluoride supplement suspension/drops). Under the terms of the transaction, we paid $18.9 million in cash and $8.1 million in Cerecor common stock. TRx shareholders will be eligible to receive up to an additional $7 million in contingent payments upon achievement of certain commercial and regulatory milestones.

The acquisition of TRx and its subsidiaries is a pivotal move in our strategic shift towards an integrated pediatric pharmaceutical company. Operationally, we believe the transaction adds a highly-effective commercial unit that will drive a solid revenue stream to help us advance our pipeline of drug candidates for rare neurologic or orphan diseases.

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™. Additionally, Avadel Ireland will develop and provide Cerecor with four stable product formulations of Cerecor's choosing utilizing its proprietary LiquiTime™ and Micropump® technology. Three of these development projects are already underway.

Related Party Arrangements

Lachlan Pharmaceuticals

In November 2017, we acquired Zylera Pharmaceuticals, LLC (Zylera) as part of the acquisition of TRx. Each of the previous owners of TRx beneficially own more than 5% of our outstanding common stock. Zylera, which is now our wholly owned subsidiary, entered into the First Amended and Restated Distribution Agreement (the "Lachlan Agreement") with Lachlan Pharmaceuticals, an Irish company controlled by the previous owners ("Lachlan"), effective December 18, 2015. Pursuant to the Lachlan Agreement, Lachlan named Zylera as its exclusive distributor of Ulesfia in the U.S. and agreed to supply Ulesfia to Zylera exclusively for marketing and sale in the U.S. The Lachlan Agreement provides that all trademark rights used in connection with Ulesfia will remain the intellectual property of Lachlan, and all goodwill associated with the use of the trademarks for the marketing and sale of Ulesfia in the territory will inure to the sole benefit of Lachlan. The Lachlan Agreement term continues as long as (i) there exists an issued and unexpired patent right for the product in the United States, or (ii) no generic version of the product is being sold in the United States. The Lachlan Agreement can be terminated by Zylera upon the introduction of a generic product in the territory or upon the expiration or invalidity of all patent rights for the product in the territory.

Pursuant to an amended and restated distribution agreement entered into between Zylera and Lachlan dated, December 18, 2015. Zylera is obligated to purchase a minimum of 20,000 units per year, or approximately $1,177,000 worth of product, from Lachlan, subject to certain termination rights. Zylera must pay Lachlan management 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 distribution agreement also requires that Zylera make certain cumulative net sales milestone payments and royalty payments to Lachlan with a $3,000,000 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.

On December 10, 2016, Zylera informed Lachlan that a market change had occurred due to the introduction of Arbor Pharmaceutical's lice product, Sklice®. According to the terms of the distribution agreement if there is a market change, the minimum purchase obligation is void. On June 5, 2017, Lachlan and Zylera entered into joint legal representation along with other unrelated third parties in negotiation and arbitration of dispute with Summers Laboratory, Inc. regarding the ongoing arbitration proceeding with the ultimate recipient of the royalties over whether a Market Change has occurred. The Company has not made any payments to Lachlan in 2017 under the Lachlan Agreement (from the acquisition date through year-end).

Our Strategy

Our goal is to become an integrated pediatric specialty pharmaceutical company that commercializes pediatric nutritional supplements and prescription medicines. We plan to use the proceeds generated from the profits of our portfolio of pediatric products towards the development of drug candidates that have unique mechanisms of action and can be applied towards patients with rare neurological and orphan diseases. We systematically identify 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 key strategic objectives include:

- Generate revenue through sales of marketed pediatric products acquired from TRx and Avadel.
- Develop other products, including CERC-301 as an adjunctive therapy for Neurogenic orthostatic hypotension ("nOH"), and the product candidates under our development arrangement with Avadel.
- Pursue opportunistic acquisitions of additional complementary marketed products and development stage companies. We will identify, along with Avadel Ireland, four stable product formulations of Cerecor's choosing utilizing its proprietary LiquiTime™ and Micropump® technology. Cerecor has chosen three of these development projects which are already underway.

Product Pipeline

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

Product Candidate / Platform	Potential Indication(s)	Stage of Development	Anticipated Milestones
CERC-301	*Neurogenic orthostatic hypotension (nOH).*	Phase 1 Safety Study	Initiate clinical study in 2018
CERC-611	Adjunctive treatment of partial-onset seizures in epilepsy	Preclinical	IND acceptance (timing dependent on further evaluation of the molecule)
COMT Inhibitors **CERC-406** **CERC-425**	Residual motoric and non-motoric cognitive impairment symptoms as well as other psychiatric and neurological diseases	Preclinical	IND submission (timing dependent on further evaluation of the molecule)

Disease Overview

Neurogenic orthostatic hypotension

Disease Overview and Treatment Limitations

While listed as an orphan condition affecting less than 200,000 patients in the U.S., neurogenic orthostatic hypotension (nOH) results from failure of the autonomic nervous system (ANS) to regulate blood pressure in response to postural change, due to an inadequate release of norepinephrine (NE). 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 (PD), and primary autonomic failure. PD is the second most common neurodegenerative disease, and nOH is a commonly encountered clinical problem in patients with PD, perhaps affecting up to 40%-60% of patients throughout the multi-decade disease course. nOH constitutes and area in which there is still significant unmet medical need.

Current treatment options for nOH are targeted towards reduced symptom burdens to increase quality of life such as correcting aggravating factors (i.e. discontinuation of hypotension drugs and correction of anemia and vitamin deficiencies); implementing nonpharmacologic measures such as intravascular volume expansion, increased physical activity, reduction of meal size, compression stocking/abdominal binder, and sleeping arrangement; and drug therapies (i.e. droxidopa, midrodrine, fludrocortisone, pyridostigmine, atomoxetine).

Unmet Needs

Northera (droxidopa), the most recently approved product, has the following clinical profile, from their product insert, which shows efficacy in patients with a 0.9 unit improvement in an 11 point dizziness scale. The effect of Northera did not persist beyond Week 1 and it had the lowest standing systolic blood pressure within 3 minutes after standing also increased by 5.6 mm Hg. Twenty-eight percent (28%) of patients on Northera discontinued treatment prematurely versus 20% on placebo due to headache, dizziness, nausea and hypertension.

CERC-301

Neurogenic orthostatic hypotension (nOH)

We acquired MK-0657, which is now known as CERC-301, from Merck & Co., Inc., or Merck, in 2013 through an exclusive worldwide license. CERC-301 is an oral and selective NR2B antagonist that we are developing as a novel oral medication for patients with neurogenic orthostatic hypertension ("nOH"). We believe CERC-301 may have efficacy with greater tolerability and have fewer side effects than the treatments currently available. We expect that a drug with these attributes would lead to improved compliance and outcomes. We believe CERC-301 may have rapid effects and my reduce the hypertension side effects of other treatments.

Our Program

Our plan is to develop, register and commercialize CERC-301 as a therapy for the treatment of nOH. We plan to initiate a Phase 1 safety study for nOH in 2018. If we are successful in demonstrating continued safety and tolerability in these studies we anticipate progressing development into Phase 2 efficacy and dose ranging studies in nOH.

Epilepsy

Disease Overview and Treatment Limitations

It is estimated the epilepsy patient population in the US, Japan, and five major EU markets (France, Germany, Italy, Spain, and the UK) will increase from 4.6 million cases in 2012 to 5.1 million cases by 2020, representing an increase of 10.7%. The US will have the largest number of diagnosed epilepsy cases across the aforementioned markets, with approximately 2.35 million patients by 2020. It has been reported that there are approximately 150,000 new cases of epilepsy diagnosed annually in the US

alone. Epilepsy constitutes an area in which there is still significant unmet medical need, with up to 40% of patients not achieving seizure freedom despite therapy with currently available antiepileptic drugs, or AEDs.

Epilepsy is broadly classified according to whether the contributing seizures are partial-onset or generalized. While the two subtypes produce seizures with different characteristics, the differentiation is most important when deciding upon the appropriate course of treatment. Certain therapies are more effective in partial-onset or generalized seizures, and drugs only gain approval for the seizure subtype in which there is proven efficacy.

Current AED therapies target a variety of mechanisms, including gamma-aminobutyric acid, or GABA, receptor agonism, T-type calcium channel blockers, sodium channel modulators, synaptic vesicle glycoprotein 2A, or SV2A, modulation, and inhibition of GABA transaminase. More recently, AMPA receptor antagonists have been investigated and approved for treatment of epilepsy as well. The chosen AEDs are very similar for partial-onset seizures, irrespective of whether patients respond to treatment or remain refractory. The sum of all drugs patient shares in the Datamonitor Healthcare survey is over 200%, suggesting that the typical patient receives two AEDs on average to control their treatment-refractory partial-onset seizures. This trend is apparent in each of the US, Japan, and the five major EU markets.

Unmet Needs

Continuous medication with AEDs is necessary even after the seizures have long been suppressed with treatments. AEDs can prevent seizures from happening but are not effective in stopping seizures once they are underway and do not cure epilepsy; that is, they are anti-seizure, but not anti-epileptogenic. Therefore, currently available AEDs should be classified as symptomatic drugs against ictogenesis.

No marketed or pipeline drugs have yet demonstrated anti-epileptogenic properties in humans. In the past 20 years, many new AEDs have come on to the market with the promise of improved seizure control and minimal side effects. Nevertheless, there remain several key unmet needs in the treatment of epilepsy that pharmaceutical companies can target: effective treatments for refractory epilepsy subtypes, AEDs with safer and more tolerable side-effect profiles, and better treatment options for elderly patients.

CERC-611

Adjunctive Treatment of Partial-Onset Seizures in Epilepsy

We acquired LY3130481, which is now known as CERC-611, from Lilly in June 2016 through an exclusive worldwide license. We believe CERC-611is the first molecule to selectively target and functionally block region-specific AMPA receptors after oral dosing. This selectivity was engineered into CERC-611 by chemical SAR studies to achieve selective blockade of the AMPA receptor regulator protein or TARP γ8 (high density in hippocampus, a region of importance in partial-onset epilepsies) while sparing AMPA receptors associated with TARP γ-2 (high density in cerebellum regulating the ataxia and falling associated with perampanel-Fycompa™). Because of the predominant hippocampal location of TARP γ8-dependent AMPA receptors, we believe that the efficacy and side effect profile of CERC-611 may be improved compared to current antiepileptics.

We believe CERC-611 may:

- Have efficacy in refractory partial-onset seizures as an adjunctive therapy. It may be uniquely qualified to treat temporal lobe seizures, unlike any other current or pipeline therapy, due to its selectivity for the TARP γ8-dependent AMPA receptors
- Lack sedative, ataxic, or falling side effects of global AMPA receptor antagonists such as perampanel-Fycompa™
- Have a reduced or absent requirement for multi-week dose titration
- Potentially mitigate some of the side-effect liabilities associated with other conjointly administered antiepileptic medications.

Emergence of AMPA Receptor Antagonists as Anti-Epileptic Drugs (AEDs)

AMPA receptors are glutamate-sensitive ion channels on postsynaptic membranes of excitatory synapses in the central nervous system and are largely responsible for mediating fast neurotransmission across synaptic gaps. AMPA receptor antagonists are known anticonvulsant agents and their ability to down modulate excitatory neurotransmission is key to their anti-epileptic

therapeutic potential. However, because AMPA receptor activity is so ubiquitous in the central nervous system, or CNS, general antagonism affects most areas of the CNS, resulting in undesired effects, such as ataxia, falls, sedation, and/or dizziness, which are shared by all known general or broad spectrum AMPA receptor antagonists, e.g., parampanel, talampanel. Typically, these general or broad-spectrum antagonists have a very narrow therapeutic dosing window, meaning that typically the doses needed to obtain anticonvulsant activity are close to or overlap with doses at which undesired effects are observed.

TARPs are a fairly recently discovered family of proteins that have been found to associate with and modulate the activity of AMPA receptors. Several TARPs are fairly region-specific in the brain, leading to physiological differentiation of the AMPA receptor activity. As for example, TARP γ8 (stargazing)-dependent AMPA receptors are primarily localized in the cerebellum and cerebral cortex and TARP γ8-dependent AMPA receptors are localized primarily in the hippocampus, a region particularly relevant to seizures origination and/or propagation. It has been theorized that targeting individual TARPs may enable selective modulation of specific brain circuits without globally affecting synaptic transmission.

Our Program

Our plan is to develop, register and commercialize CERC-611 as an adjunctive therapy for the treatment of partial-onset seizures, with or without secondarily generalized seizures, in patients with epilepsy aged 12 years and older. Once an IND has been reviewed and approved we plan to initiate Phase 1 single ascending dose (SAD) and multiple ascending dose (MAD) clinical studies. If we are successful in demonstrating continued safety and tolerability in these studies we anticipate progressing development into Phase 2 efficacy and dose ranging studies in epilepsy.

COMTi Platform

In 2013, we acquired rights to our COMTi platform by means of an exclusive, worldwide license from Merck. 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 MDD, schizophrenia, Parkinson's disease and pathological gambling. We believe compounds from this platform increase dopamine levels in the prefrontal cortex, or PFC, which is the region of the brain that is responsible for working memory, attention tasks and decision making, all of which are human attributes that we collectively refer to as executive function. We have selected CERC-406 as our first preclinical candidate from the COMTi platform. We anticipate establishing the data set necessary to select additional preclinical lead candidates for treatment of various conditions where impaired executive function is a core symptom, subject to the availability of funding. These programs will target the improvement of working memory and executive function, which are key components of cognition.

Entacapone and tolcapone are two commercially available COMT inhibitors used to treat aspects of Parkinson's disease. Both drugs inhibit COMT outside of the nervous system, or peripheral COMT, and may be administered, with levodopa, which is the precursor to the neurotransmitter dopamine, multiple times per day. Tolcapone, which has modest brain penetration and inhibits brain COMT, is hampered by side effects including diarrhea and liver toxicity. Entacapone does not penetrate the brain. Because of these factors, neither drug is used clinically to treat executive function impairment. Nonetheless, pilot studies using tolcapone have repeatedly suggested an improvement in aspects of executive function in normal volunteers and in subjects with various conditions that are associated with cognitive impairment. Improvements in aspects of the underlying conditions were also found.

CERC-406 and CERC-425

CERC-406 and CERC-425 are orally active small, molecules and are selective COMT inhibitors with low inhibitory activity on peripheral COMT. We intend to develop CERC-406 as an oral adjunctive medication for patients with residual cognitive impairment symptoms. We selected CERC-406 as our lead preclinical candidate from our COMTi platform because in preclinical testing we observed that it had lower potential of peripheral, off target side effects, rapid absorption and bioavailability, good brain penetration and a favorable dose-dependent biomarker profile in rats. We have also observed that CERC-406 has an off-rate on brain COMT that is slower than tolcapone, potentially implying a good duration of effect. In preclinical studies it appears that CERC-406 may have favorable drug distribution and metabolism properties, suggesting that it has the potential to be administered orally on a once or twice daily basis. Similarly, CERC-425 is an orally active small molecule, COMT inhibitor also being explored for neurologic conditions.

We believe that CERC-406 may:

- demonstrate efficacy as it is a brain penetrant COMT inhibitor with selectivity for MB-COMT to target the PFC dopamine deficit in this patient population;

- be more effective in Val homozygotes population, who have higher levels of COMT activity and lower prefrontal dopamine receptor activation; and

- be safer than existing COMT inhibitors- which are associated with adverse events such as liver toxicity and diarrhea.

Our Program

We anticipate developing CERC-406 for the enhancement of executive function and working memory in patients with diseases of impaired motoric functions, where we believe a new therapy with efficacy in residual cognitive symptoms may be associated with improved functional outcomes.

We anticipate advancing the characterization of the safety and efficacy of CERC-406 and CERC-425 in preclinical animal studies, to advance manufacturing of product for potential clinical trials, and to file their IND, subject to the availability of additional funding.

Business Development Activities

We are considering strategic transactions, such as mergers and acquisitions of companies, asset purchases and in-licensing of products, 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. We believe we have the ability to identify, evaluate and procure valuable product programs that are consistent with our goal of becoming a leader in the development of innovative drugs for patients suffering from rare and orphan diseases. We plan to continue to evaluate these opportunities to expand our product candidate portfolio in a fashion that fits within our core strategy and enhances our overall value.

Intellectual Property

We strive to protect the proprietary technologies that we believe are important to our business, including seeking and maintaining patent protection intended to cover the composition of matter of our product candidates, their methods of use, related technology and other inventions that are important to our business. As more fully described below, we have issued patents covering the compounds and compositions of CERC-301, CERC-611, CERC-406 and CERC-425. We also may rely on trade secrets and careful monitoring of our proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, maintain our licenses to use intellectual property owned by third parties, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen, and maintain our proprietary position in the field of central nervous system disorders.

The patent positions of biopharmaceutical companies are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by enforceable patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

Because patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference proceedings declared by the United States Patent and Trademark Office, or USPTO, or a foreign patent office to determine priority of invention or in post-grant challenge proceedings, such as oppositions, that challenge priority of invention or other features of patentability. Such proceedings could result in substantial cost, even if the eventual outcome is favorable to us.

The patent portfolios for our most advanced programs are summarized below.

- ***CERC-301.*** 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 (U.S.), Australia, Canada, Germany, France, United Kingdom, Switzerland, and Japan. The patents in the first family include composition of matter and use claims of varying scope, including picture claims to CERC-301 or a pharmaceutically acceptable salt thereof. The expiration date of the U.S. patent in the first family is August 31, 2026, not including any patent term extension or market exclusivity period which may apply. The second family consists of patents that have issued in U.S., Germany, France, and United Kingdom.The patents in the second family include composition of matter claims (in U.S. patent only) 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 third family consists of patent applications in U.S., Argentina, Australia, Brazil, Canada, China, Europe, India, Japan, Mexico, Russia, South Korea, and Taiwan, with claims to compositions of matter, methods of use, and methods of manufacture. Any patents issuing from these applications would expire in December 2035 at the earliest, not including any potential patent term adjustment, patent term extension, or market exclusivity period.

- ***CERC-611.*** 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 U.S., Australia, Canada, China, Eurasia, Europe, Japan, Singapore, South Africa, South Korea, Ukraine, and Vietnam, and over 20 international patent applications with composition of matter and use claims for CERC-611. The expiration date of the U.S. patent, exclusive of any patent term extension, is November 20, 2033. The second family consists of patents that have issued in U.S., Australia, and South Korea, and international patent applications 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-406, CERC-425 and COMTi Platform.*** 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 U.S., Australia, Canada, China, Japan, South Korea, Mexico, and Russia, and patent applications in Brazil, Europe, and India. The expiration date of the U.S. 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 U.S., Australia, China, Europe, Japan, South Korea, Mexico, and Russia, and patent applications in Brazil, Canada, and India. The expiration date of the U.S. patent in the second family, exclusive of any patent term extension, is February 28, 2031.

The term of any individual patent depends upon the legal term of the patents in the countries in which they are obtained. In most countries where we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application.

In the United States, the patent term of a patent that covers an FDA-approved drug that contains an active ingredient or salt or ester of the active ingredient that has not previously been marketed may also be eligible for patent term extension, which permits patent term restoration to account for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is based upon one half of the time between the IND effective date and a company's initial submission of a marketing application, plus the entire time between the submission of the marketing application and the FDA's approval of the application. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other non-United States jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those product candidates. We intend to seek patent term extensions to any of our issued patents in any jurisdiction where these are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

For all of our product candidates, we intend to explore at each stage of the drug discovery process opportunities for follow-on patent filings to maximize patent terms and market exclusivities. Such follow-on patent filings may be directed to new indications, formulations, combination therapies, manufacturing methods, dosages, routes of administration, patient populations, contraindications, drug interactions (or absence of interactions) or other aspects of drug labels.

We also rely on trade secret protection for our confidential and proprietary information. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to

our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property.

Manufacturing

We do not have any manufacturing facilities or personnel. We rely on contract manufacturing organizations, or CMOs, to produce our drug candidates in accordance with applicable provisions of the FDA's current Good Manufacturing Practice, or 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.

License 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, 2017. 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 License

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 & Cie ("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 also 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. Additionally, the insurance provision in the agreement requires TRx to procure and maintain general comprehensive liability insurance covering each occurrence of bodily injury and property damage in an amount of not less than a $3,000,000 combined single limit**.** 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-ViFlor" trademarks and agreed not to oppose TRx's seeking the marks Poly-Vi-Flor and Tri-ViFlor in the United States and in any other countries where Mead Johnson does not have an active rregistration 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 PolyVi-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. The agreement requires that the TRx products sold under the Poly-Vi-Flor and Tri-ViFlor trademarks adhere to specified quality requirements, and such products are subject to inspection by Mead Johnson on a periodic basis. The agreement also prohibits TRx's ability to sublicense the Poly-Vi-Flor and Tri-Vi-Flor trademarks and provides that TRx will use its best efforts to ensure that its products are not displayed or marketed in association with any Mead Johnson products. 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 and Veripred Related Contracts

Marketing Agreement between Pharmaceutical Associates, Inc. ("PAI"), and TRx and TRx Corp., effective April 1, 2017

TRx entered into a Marketing Agreement with PAI, effective April 1, 2017. Under the agreement, TRx will promote, market and sell PSP 10 and PSP 20 on behalf of PAI. TRx agrees to maintain the size of its current sales force, 16 salespersons, to perform the services under the agreement. Assuming a salesforce of 16 salespeople, PAI will pay a monthly fee of $62,500 to TRx. PAI and TRx also agree to share the net revenues from sales of the products, after reimbursing certain expenditures, in a manner designed to achieve a 50/50 split of net revenues above the "break even" point, calculated in accordance with the terms and inputs set forth in the agreement. The revenue sharing continues for a period of six months after termination of the agreement, unless the agreement is terminated due to a breach. The agreement has an initial six-month term, which automatically renews for additional six-month terms, unless terminated. Either party may terminate at any time with 90 days' written notice.

License and Supply Agreement, dated May 19, 2008, by and between TRx and Watson Laboratories, Inc., as amended

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. If neither party terminates the agreement prior to April 1, 2021, then the agreement will automatically renew for successive one year periods. The April 1, 2016 amendment terminated the royalty provisions and instead 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 TRx and Lachlan Pharmaceuticals ("Lachlan")

TRx entered into the First Amended and Restated Distribution Agreement with Lachlan, effective December 18, 2015. The agreement amends, restates and supersedes all previous agreements between the parties with respect to the Ulesfia® (benzyl alcohol) lotion 5%. Pursuant to the agreement, Lachlan named TRx as its exclusive distributor of Ulesfia in the U.S. and agreed to supply Ulesfia® to TRx exclusively for marketing and sale in the U.S. The agreement provides that all trademark rights used in connection with Ulesfia® will remain the intellectual property of Lachlan, and all goodwill associated with the use of the trademarks for the marketing and sale of Ulesfia® in the territory will inure to the sole benefit of Lachlan. The agreement provides that TRx will retain all trademarks it develops for the distribution and commercialization of Ulesfia®, including promotional and educational materials. The agreement term continues through the end of the "Exclusivity Period", defined as any period where (i) there exists an issued and unexpired patent right for the product in the United States, or (ii) no generic version of the product is being sold in the United States. The agreement can be terminated by TRx upon the introduction of a generic product in the territory or upon the expiration or invalidity of all patent rights for the product in the territory. Forty days prior to the beginning of each calendar quarter TRx is required to provide written forecasts of its expected Ulesfia® purchases for each of the five subsequent calendar quarters. The first two calendar quarters of each such forecast will constitute a binding purchase obligation of TRx. The remaining three calendar quarters are non-binding. The agreement also requires that TRx make a royalty payment to Lachlan in the amount of 15% of net sales so long as net sales remain below $50 million annually. For annual net sales above $50 million, TRx will owe Lachlan a royalty payment of 20% of net sales, and for annual net sales over $100 million, TRx will owe Lachlan a royalty payment of 25% of net sales. Additionally, in the event TRx's annual net sales of the product are less than $20 million, other than as a result of a "Market Change," TRx shall pay Lachlan an amount sufficient to make total product payments equal to the amount that would have been paid if the net sales had been equal to $20 million. The practical effect of this provision is that there is a minimum annual royalty payment of $3,000,000. TRx has asserted that a "Market Change" has occurred pursuant to the terms of this agreement and litigation is pending with respect to that assertion). There are also certain milestone payments which become payable upon the achievement of certain cumulative net sales milestones. Upon the achievement of cumulative net sales amounting to $90,000,000; $180,000,000; $270,000,000; and $400,000,000, TRx will owe Lachlan payments of $3,000,000; $3,500,000; $4,000,000; and $5,000,000, respectively. TRx is obligated to purchase a minimum of 20,000 units per year, or approximately $1,177,000 worth of product; however, the minimum purchase requirements are void upon the earliest of: (i) Lachlan's failure to fulfill TRx's purchase orders for two consecutive quarters or any three quarters in a 12-month period; (ii) the first commercial sale of a generic version of the product, or (iii) termination of the agreement. The purchase price for fully packaged product is the greater of a contractually agree upon price (subject to de minimis annual increases) or 20% of the prior year's net sales divided by the number of units sold in the prior year. The agreement includes provisions for retroactively adjusting the purchase price for the previous year if the price determined at the end of the year differs from what was actually paid. If Lachlan launches a generic product during the term, TRx will have a right of first refusal to act as the exclusive distributor for such product. TRx will have 30 days' notice before the launch of the product to negotiate the terms of an agreement with Lachlan. Lachlan entered into a First Amended and Restated Exclusive Distribution Agreement with Concordia on January 1, 2014, and the agreement is substantively similar to the First Amended and Restated Exclusive Distribution Agreement between Lachlan and TRx discussed above (with the exception of the parties thereto, the agreements are substantially identical.

On December 10, 2016, Zylera informed Lachlan that a market change had occurred due to the introduction of Arbor Pharmaceutical's lice product, Sklice®. According to the terms of the distribution agreement if there is a market change, the minimum purchase obligation is void. On June 5, 2017, Lachlan and Zylera entered into joint legal representation along with other unrelated third parties in negotiation and arbitration of dispute with Summers Laboratory, Inc regarding the ongoing arbitration proceeding with the ultimate recipient of the royalties over whether a Market Change has occurred. The Company has not made any payments to Lachlan in 2017 under the Lachlan Agreement (from the acquisition date through year-end).

Avadel Pharmaceuticals

In February 2018, entered into an Asset Purchase Agreement (the "Purchase Agreement") with Avadel US Holdings, Inc. ("Avadel") to purchase and acquire all rights in Avadel's pediatric products for a nominal cash payment for the acquired assets, and an 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.

In connection with closing the Purchase Agreement, we entered into a licensing and development agreement with Flamel Ireland Limited ("Avadel Ireland"), a subsidiary of Avadel (the "Development Agreement"), under which Avadel Ireland will develop and provide us with four stable product formulations utilizing its proprietary LiquiTime® and Micropump® technology. We will reimburse Avadel Ireland for any costs associated with the development of these products in excess of $1.0 million in the aggregate. Upon transfer of the product formulations, we will assume all remaining development and regulatory costs. Once approved and marketed, we will pay Avadel Ireland royalties on net sales of such products.

Sales and Marketing

In November 2017, we purchased TRx which included a sales, marketing or product distribution infrastructure in pediatric health care with plans to build a premier pediatric sales and marketing team in the United States. We promote Poly-Vi-Flor®, Tri-Vi-Flor®, Millipred®, Veripred®, Ulesfia®, Cefaclor®, Karbinal®, Aciphex Sprinkles™ and Flexichamber® through a highly skilled sales force of 30 representatives and four Territory Managers. 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. Our primary goal is to make a positive difference in the lives of pediatric patients across the country. With established commercial operations, Cerecor is poised to be both flexible and scalable based on opportunities within the market.

Because our drug candidates are still in preclinical or early clinical development, we intend to selectively retain commercialization or co-commercialization rights in the United States for CERC-301, CERC-611 and certain indications of our COMTi platform, which we may complement with 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, although we only plan to do so with one or more collaborators.

Competition

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. Even if we and our potential collaborators are successful in developing our product candidates, the resulting products would compete with a variety of established drugs in the areas of depression, bipolar depression, schizophrenia, epilepsy, Parkinson's disease, substance use disorders and pain and impulse control disorders, or ICDs.

There are several generic prednisolone and prednisone preparations available in the market. However, these preparations have a very bitter taste and are of different strengths. Millipred® and Veripred® OS are the only two oral solutions that utilize the proprietary double taste-masking technology to provide a pleasant grape taste with no bitterness. Parents typically prefer Millipred and Veripred OS to other products as it is easier to administer to their children, thereby increasing treatment compliance.

The main competitor for Millipred® and Veripred® OS is Mission Pharmacal Company's branded prednisolone, which has the same active ingredient, but at a higher concentration (25mg/5ml). Ballentyne believes the current market leader in oral solids (where TRx competes with its Millipred tablet) is Concordia Healthcare's Ovapred ODT.

CERC-301

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]), an oral prodrug converted by decarboxylation to NE in both the central and the peripheral nervous systems.

CERC-611

The epilepsy market is crowded with current therapies targeting a variety of mechanisms, including 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 AEDs. 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.

CERC-406 / CERC-425

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.

COMT Inhibitor Platform

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., or 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.

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 on Form 10-K.

Government Regulation and Product Approval

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

United States Government Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or 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.

The process required by the FDA before a new drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin;
- approval by local or central independent institutional review boards, or IRB, before each clinical trial may be initiated;
- performance of human clinical trials, including adequate and well-controlled clinical trials, in accordance with good clinical practices, or GCP, and regulations to establish the safety and efficacy of the proposed drug product for each indication;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practice, or GMP, regulations and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, as well as satisfactory completion of an FDA inspection of selected clinical sites to determine GCP compliance; and
- FDA review and approval of the NDA.

Additionally, if a drug is considered a controlled substance, prior to the commencement of marketing, the DEA must also determine the controlled substance schedule, taking into account the recommendation of the FDA.

Preclinical Studies and IND Submission

Preclinical studies include laboratory evaluation of product chemistry, pharmacology, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical testing may continue even after the IND is submitted. Once the IND is submitted, the sponsor must wait 30 calendar days before initiating any clinical trials. During this time, among other things, the FDA has an opportunity to review the IND for safety to assure that research subjects will not be subjected to unreasonable risk. The FDA may raise concerns or questions related to one or more proposed clinical trials and place the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical Trials

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial, and review and approval by an IRB. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the trial procedures, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated, and a statistical analysis plan. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, a central IRB or local IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must continue to oversee the clinical trial, including any changes, while it is being conducted. Information about certain clinical trials, including a description of the study and study results, must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their ClinicalTrials.gov website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined. In Phase 1, the drug is initially introduced into healthy human subjects or subjects with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness. In Phase 2, the drug typically is administered through well-controlled studies to a limited subject population with the target disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. In Phase 3, the drug is administered to an expanded subject population, generally at geographically dispersed clinical trial sites, in two adequate and well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

The manufacture of investigational drugs for the conduct of human clinical trials is subject to GMP requirements. Investigational drugs and active pharmaceutical ingredients imported into the United States are also subject to regulation by the FDA relating to their labeling and distribution. Further, the export of investigational drug products outside of the United States is subject to regulatory requirements of the receiving country as well as United States export requirements under the FDCA.

Progress reports and other summary information detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if certain serious adverse events occur or other significant safety information is found. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk or the trial is not being conducted in accordance with the applicable regulatory requirements or the protocol. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to subjects. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group regularly reviews accumulated data and advises the study sponsor regarding the continuing safety of trial subjects, potential trial subjects, and the continuing validity and scientific merit of the clinical trial. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. These user fees must be filed at the time of the first submission of the application, even if the application is being submitted on a rolling basis. A waiver from the application user fee may be sought by an applicant. One basis for a waiver of the application user fee is if the applicant employs fewer than 500 employees, including employees of affiliates, the applicant does not have a drug product that has been approved under a human drug application and introduced or delivered for introduction into interstate commerce, and the applicant, including its affiliates, is submitting its first human drug application. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has agreed to certain performance goals regarding the timing of its review of an application. The FDA aims to review 90% of all standard review applications within ten months of acceptance for filing and six months of acceptance for filing for priority review applications.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA for a new active ingredient, indication, dosage form, dosage regimen or route of administration must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and

administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

The FDA also may require submission of a risk evaluation and mitigation strategy, or REMS, either during the application process or after the approval of the drug to ensure the benefits of the drug outweigh the risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

Under the FDCA, before approving a drug for which no active ingredient (including any ester or salt of active ingredients) has previously been approved by the FDA, the FDA must either refer that drug to an external advisory committee or provide in an action letter, a summary of the reasons why the FDA did not refer the drug to an advisory committee. The external advisory committee review may also be required for other drugs because of certain other issues, including clinical trial design, safety and effectiveness, and public health questions. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with GMP requirements and adequate to assure consistent production of the product within required specifications by the manufacturer and all of its subcontractors and contract manufacturers. Additionally, before approving an NDA, the FDA will inspect one or more clinical trial sites to assure compliance with GCP regulations.

The testing and approval process for an NDA requires substantial time, effort and financial resources, and each may take several years to complete. Data obtained from preclinical and clinical testing are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent marketing approval. The FDA may not grant approval of an NDA on a timely basis, or at all.

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.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, including a black boxed warning, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms under a REMS which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, certain circumstances may require FDA notification, review, or approval, as well as further testing. These may include some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, or new safety information

Special FDA Expedited Review and Approval Programs

The FDA has various programs, including fast track designation, accelerated approval, priority review and breakthrough designation, that are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions, and demonstrate the potential to address unmet medical needs or present a significant improvement over existing therapy. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if the product will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy, safety, or public health factors. If fast track designation is obtained, drug sponsors may be eligible for more frequent development meetings and correspondence with the FDA. In addition, the FDA may initiate review of sections of an NDA before the application is complete. This "rolling review" is available if the applicant provides and the FDA approves a schedule for the remaining information. In some cases, a fast track product may be eligible for accelerated approval or priority review.

The FDA may give a priority review designation to drugs that are intended to treat serious conditions and provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions. A priority review means that the goal for the FDA is to review an application in six months, rather than the standard review of ten months under current PDUFA guidelines. These six and ten month review periods are measured from the "filing" date rather than the receipt date for NDAs, which typically adds approximately two months to the timeline for review and decision from the date of submission. Products that are eligible for fast track designation may also be considered appropriate to receive a priority review.

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses or conditions and that fill an unmet medical need may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoints, and the drug may be subject to accelerated withdrawal procedures.

Moreover, under the provisions of the new Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are eligible for the fast track designation features as described above, intensive guidance on an efficient drug development program beginning as early as Phase 1 trials, and a commitment from the FDA to involve senior managers and experienced review staff in a proactive collaborative, cross-disciplinary review.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and 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 the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

The FDA may impose a number of 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.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies and list drugs manufactured at their facilities with the

FDA. These facilities are further subject to periodic announced and unannounced inspections by the FDA and these state agencies for compliance with GMP and other regulatory requirements. Changes to the manufacturing process are strictly regulated and may require prior approval by the FDA or notification to the FDA before or after being implemented. FDA regulations also require investigation and correction of any deviations from GMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain GMP compliance.

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.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, Warning Letters or Untitled Letters, holds or termination of post-approval clinical trials or FDA debarment;
- delay or refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- regulatory authority, including the FDA, issued safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such products;
- mandated modifications to promotional material or issuance of corrective information;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties, including imprisonment, disgorgement and restitution, as well as consent decrees, corporate integrity agreements, deferred prosecution agreements and exclusion from federal healthcare programs.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Although physicians, in the practice of medicine, may prescribe approved drugs for unapproved indications, pharmaceutical companies are prohibited from marketing or promoting their drug products for uses outside of the approved indications in the approved prescribing information. 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.

In addition, the distribution of prescription pharmaceutical products, including samples, is subject to the Prescription Drug Marketing Act, or PDMA, which, among other things, regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Moreover, the recently enacted Drug Quality and Security Act, imposes new obligations on manufacturers of pharmaceutical products related to product tracking and tracing. Among the requirements of this new legislation, manufacturers will be required to provide certain information regarding drug products to individuals and entities to which product ownership is transferred, label drug products with a product identifier, and keep certain records regarding drug products. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers will also be required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this new legislation, manufactures will have drug product investigation, quarantine, disposition, and FDA and trading partner notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products such that they would result in serious adverse health consequences or death, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

DEA Regulation

While we currently do not know whether any of our product candidates will be considered to be controlled substances, we will be required to evaluate the abuse potential of our product candidates. If any of our product candidates are considered controlled substances, we will need to comply with additional regulatory requirements.

Certain drug products may be regulated as "controlled substances" as defined in the Controlled Substances Act of 1970, or CSA, and the United States Drug Enforcement Administration's, or DEA's, implementing regulations. The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use, and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. FDA provides a recommendation to DEA as to whether a drug should be classified as a controlled substance and the appropriate level of control. If DEA scheduling is required, a drug product may not be marketed until the scheduling process is completed, which could delay the launch of the product.

Depending on the Schedule, drug products may be subject to registration, security, recordkeeping, reporting, storage, distribution, importation, exportation, inventory, quota and other requirements administered by the DEA, which are directly applicable to product applicants, contract manufacturers and to distributors, prescribers and dispensers of controlled substances. The DEA regulates the handling of controlled substances through a closed chain of distribution. This control extends to the equipment and raw materials used in their manufacture and packaging in order to prevent loss and diversion into illicit channels of commerce.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized. Similarly, separate registrations are also required for separate facilities.

The DEA typically inspects a facility to review its security measures prior to issuing a registration and on a periodic basis. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Records must be maintained for the handling of all controlled substances, and periodic reports may be required to made to the DEA for the distribution of certain controlled substances. Reports must also be made for thefts or significant losses of any controlled substance. To enforce these requirements, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can 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.

Federal and State Healthcare related, Fraud and Abuse and Data Privacy and Security Laws and Regulations

In addition to FDA restrictions on marketing of pharmaceutical products, federal and state fraud and abuse, and other laws regulations, and requirements restrict business practices in the biopharmaceutical industry. These laws include anti-kickback and false claims laws and regulations, state and federal transparency laws regarding payments or other items of value provided to health care professionals, as well as data privacy and security laws and regulations and other requirements applicable to the healthcare industry, including pharmaceutical manufacturers. There are also laws, regulations, and requirements applicable to the award and performance of federal contracts and grants.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers, and beneficiaries on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are narrowly drawn. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not meet the requirements of a statutory or regulatory exception or safe harbor. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated.

The reach of the Anti-Kickback Statute was also broadened by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively Affordable Care Act, which, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain provisions of the criminal health care fraud statute (discussed below) such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act provides that the government may

assert that a claim for payment for items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. Penalties for violation of the Anti-Kickback Statute include criminal fines, imprisonment, civil penalties and damages, exclusion from participation in federal healthcare programs and corporate integrity agreements or deferred prosecution agreements. Conviction or civil judgments are also grounds for debarment from government contracts.

The federal civil False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, including payments under a federal grant. A claim includes "any request or demand" for money or property presented to the United States government. The False Claims Act also applies to false submissions that cause the government to be paid less than the amount to which it is entitled, such as a rebate. Intent to deceive is not required to establish liability under the civil False Claims Act. Several pharmaceutical and other healthcare companies have been sued under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Companies have also been sued for causing false claims to be submitted because of the companies' marketing of products for unapproved, or off-label, uses. In addition, federal health care programs require drug manufacturers to report drug pricing information, which is used to quantify discounts and establish reimbursement rates. Several pharmaceutical and other healthcare companies have been sued for reporting allegedly false pricing information, which caused the manufacturer to understate rebates owed or, when used to determine reimbursement rates, caused overpayment to providers. Violations of the civil False Claims Act may result in civil penalties and damages as well as exclusion from federal healthcare programs and corporate integrity agreements or deferred prosecution agreements. The government may further prosecute conduct constituting a false claim under the criminal False Claims Act. The criminal False Claims Act prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious, or fraudulent and, unlike the civil False Claims Act, requires proof of intent to submit a false claim. Violations of the criminal False Claims Act can result in criminal fines and/or imprisonment, as well as exclusion from participation in federal healthcare programs. Conviction or civil judgments and other conduct are also grounds for debarment from government contracts and grants.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, also created federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payers, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. As discussed above, the Affordable Care Act amended the intent standard for certain of HIPAA's healthcare fraud provisions such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations of HIPAA's fraud and abuse provisions may result in fines or imprisonment, as well as exclusion from participation in federal healthcare programs, depending on the conduct in question. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

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 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.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other health care providers. The Affordable Care Act created new federal requirements for reporting, by applicable manufacturers of covered drugs, payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members. Certain states also require implementation of commercial compliance programs and compliance with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments or the provision of other items of value that may be made to healthcare providers and other potential referral sources; impose restrictions on marketing practices; and/or require drug manufacturers to track and report information related to payments, gifts and other items of value to physicians and other healthcare providers.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes specified requirements relating to the privacy, security and transmission of

individually identifiable health information. Penalties for violating HIPAA include civil penalties, criminal penalties and imprisonment. Among other things, HITECH, through its implementing regulations, makes HIPAA's privacy and security standards directly applicable to "business associates," defined as a person or organization, other than a member of a covered entity's workforce, that creates, receives, maintains or transmits protected health information on behalf of a covered entity for a function or activity regulated by HIPAA. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, other federal and state laws govern the privacy and security of health and other information in certain circumstances, many of which differ from each other in significant ways and may not have the same requirements, thus complicating compliance efforts.

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.

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, or 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 Foreign Corrupt Practices Act or 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, or 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. If reports of requested pediatric studies are submitted to and accepted by FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or Orange Book listed patent protection cover the drug are extended by six months. 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. This hypothesis must be demonstrated to obtain orphan drug exclusivity. 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. While we have not sought to obtain orphan drug designation for any of our products, we may in the future seek such designation if we determine that the relevant criteria are met.

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 safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. For example, in the European Union, we must obtain authorization of a clinical trial application, or CTA, in each member state in which we intend to conduct a clinical trial. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. 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, or 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 or 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, or the 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, 2017, we had 38 full-time employees, six of whom were primarily engaged in research and development activities and two of whom had a Ph.D. degree, 26 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.

Item 1A. Risk Factors

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

Risks Related to Our Business and Industry

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, 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 or other means to market these products. Virtually all of our product sales revenue to date has come from TRx products. We expect that a significant portion of our potential revenue for the next few years will depend on sales of those products and the pediatric products we recently acquired from Avadel.

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, CERC-301 beyond Phase 1 and our preclinical product candidates, including CERC-611 and CERC-406/425, 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 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 depression, substance use disorders and impaired executive function, 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.

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, CERC-406/425 and CERC-611.

Our continued development of CERC-406, CERC-425 and CERC-611 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 IND for CERC-611, there is no guarantee that we will be successful in our efforts to advance CERC-611 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 substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. 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 requires a payment of a significant NDA user fee upon submission. 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 depression and other 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 trials;

- 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. For example, in a proof of concept study of CERC-301 conducted by the National Institute of Mental Health, CERC-301 failed to provide a significant improvement in subjects receiving the compound as compared to those receiving a placebo, as measured by the Montgomery-Asberg Depression Rating Scale, the primary assessment tool. Further, neither CERC-301 nor CERC-501 met the primary endpoint in its respective Phase 2 clinical trial, and previously our Clin301-201 Phase 2 study for CERC-301 failed to meet its primary endpoint;

- 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 data 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 of our product candidates for fewer or more limited indications than we request, including more limited patient populations, may require that contraindications, warnings or precautions be included in the product labeling, including a black-box warning, may grant approval contingent on the performance 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 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 risk evaluation and mitigation strategy, or 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 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;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate or 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 more narrow 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. For instance, in 2007, the FDA requested that makers of all antidepressant medications update an existing black-box warning about an increased risk of suicidal thought and behavior. 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 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 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 continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current Good Manufacturing Practice, or GMP, regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or 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 or 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 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 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 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;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market (with low or lower prices) rather than buying them locally;
- 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;
- 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;
- 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;
- 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 and launch 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;
- 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 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; and
- acceptance of any of our product candidates that receive marketing approval by physicians and other healthcare providers.

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 commercialize our product candidates and affect the prices we may obtain.

Ongoing legislative and regulatory changes in the United States and in foreign jurisdictions continue to cause flux in the healthcare sector broadly, including the pharmaceutical industry. These changes could hinder or delay product marketing approval, further restrict post-approval activities, and ultimately impact the profitability of our products. For instance, revisions to benefits provided under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or “MMA”, could decrease the coverage and reimbursement rate that we receive for any of our approved products. While the MMA applies only to drug benefits for Medicare beneficiaries, the

Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and other medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Therefore, any reduction in reimbursement that results from healthcare reform impacting government programs may result in a similar reduction in payments from private payors.

The Patient Protection and Affordable Care Act and its related laws and regulations, collectively, the Affordable Care Act, contain multiple provisions impacting our business. Among other things, the Affordable Care Act:

- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs;
- 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;
- extended Medicaid drug rebates, previously due only on fee-for-service utilization, to Medicaid managed care utilization;
- created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the amount of rebates due on those drugs;
- expanded the types of entities eligible to receive discounted 340B pricing, although, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, because 340B pricing is determined based on AMP and Medicaid drug rebate data, the revisions to the Medicaid rebate formula and AMP definition described above can cause the required 340B discounts to increase;
- imposed a significant annual fee on companies that manufacture or import branded prescription drug products;
- required manufacturers to provide a 50% discount off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the "donut hole"; and
- enacted substantial new provisions affecting compliance which may affect our business practices with healthcare practitioners.

The future of the Affordable Care Act is uncertain. The Tax Cut and Jobs Act of 2017 removed the penalty associated with failure to comply with the individual mandate, which may destabilize the insurance markets and erode the gains in the number of insured Americans since 2014. Continued legislative efforts for a wholesale repeal of the Affordable Care Act appear likely.

It is not clear how continued healthcare reform or the potential repeal of the Affordable Care Act will impact our business. However, it is likely that any changes to the law would maintain the goal of slowing the growth of pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. In addition, the recent White House budget calls for more than $3 trillion in spending cuts to Medicare, Medicaid, and related programs over ten years, which could put further downward pressure on program reimbursement. We expect that continued change in healthcare sector regulations may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, which could reduce our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

To qualify for federal coverage of pharmaceuticals under Medicaid and Medicare Part B, companies participating in the Medicaid Drug Rebate Program are also required to participate in the Health Resources and Services Administration's 340B program. Generally, products subject to Medicaid price reporting and rebate liability are also subject to the 340B "ceiling price" calculation and discounting. Participating manufacturers must agree to charge 340B-covered entities no more than the 340B ceiling price for covered outpatient drugs. The ceiling price is based on the average manufacturer price and average rebate amount for the covered outpatient drug under the Medicaid Drug Rebate Program. 340B covered entities include community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. Any changes to the definition of average manufacturer price and the average rebate amount also could affect the 340B ceiling price calculation for our products.

The Drug Quality and Security Act of 2013 imposes obligations on drug manufacturers related to product tracking. Among other requirements, manufacturers must: (1) provide certain product information to individuals and entities to which products are transferred; (2) label drug products with a product identifier; and (3) keep certain records regarding drug products. Manufacturers are also required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, manufacturers have drug product investigation, quarantine, disposition, and FDA and trading partner notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products such that they would result in serious adverse health consequences or death, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

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 is 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 and 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 Foreign Corrupt Practices Act, or 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. For instance, the National Institutes of Mental Health, or NIMH, decided to discontinue the funding of a Phase 1 study of CERC-501 that was to be conducted by a third party as NIMH decided the study would be unlikely to provide new information beyond what a NIMH funded Phase 2 study, conducted by the same third party, would provide. Similarly, in January 2016 NIMH decided to discontinue the funding of a Phase 2 study of CERC-501 for treatment-resistant depression that was to be conducted by the National Institutes of Health and sponsored by Massachusetts General Hospital because of slow study progression.

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 have devoted significant effort and resources to developing systems and processes that are designed to protect sensitive information, but we cannot assure you that these measures will provide absolute security. Because techniques used to obtain unauthorized access or to sabotage systems change frequently and often are not recognized until launched against a target, we might not be able to anticipate these techniques or implement adequate preventive measures.

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 may result in civil fines of up to $55,910 per violation and a maximum civil penalty of $1,677,299 in a calendar year for violations of the same requirement, as well as criminal penalties.

Numerous other countries have, or are developing, laws governing the collection, use, and transmission of personal information. These laws often impose significant compliance obligations. For example, the European Data Protection Directive (the "Directive") is a robust data protection regime that currently regulates personal information pertaining to residents of the European Economic Area ("EEA"). In May 2018, the General Data Protection Regulation ("GDPR"), will replace the Directive. GDPR imposes more stringent obligations and restrictions on the ability to collect, analyze, and transfer personal information, including health data from clinical trials. We expect that there will be discrepancies in how data protection authorities from the different EEA member states interpret GDPR. This lack of uniformity adds to the complexity of processing personal information in and received from the European Union. To the extent that our activities are or become subject to the Directive or 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 Directive and related national laws of European Union Member States, or GDPR when it takes effect, could lead to government enforcement actions and significant penalties against us and adversely impact our operating results. Under GDPR, for example, fines of $20 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. Our Chief Executive Officer, Peter Greenleaf, and our Chief Commercial Officer, Matthew V. Phillips, have only been with us since the November 2017 acquisition of TRx. 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 Policy, but despite the adoption of such policy, we might not be able to prevent a director, executive or 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.

As discussed above, in November 2017 we acquired TRx Pharmaceuticals, LLC and its franchise of commercial medications, and in February 2018, we acquired pediatric products from Avadel U.S. Holdings, Inc. 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 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 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;
- 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. For example, Avadel has agreed to develop four products for us, so we depend on them. 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, such as Avadel. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a development collaboration regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the development collaboration. These disagreements can be difficult to resolve if neither of the parties has final decision making authority.

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 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; and
- the disruption and costs associated with changing suppliers, including additional regulatory filings.

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, or Merck, pursuant to which Merck has granted us rights to the compounds used in CERC-301 and the COMTi platform, including CERC-406 and CERC-425. We have also entered into an exclusive license, development and commercialization agreement with Eli Lilly and Company, or Lilly, pursuant to which we received exclusive global rights to develop and commercialize CERC-611. We have also entered into an exclusive license, development and commercialization agreement with Flamel Ireland Limited (operating under the trade name of Avadel Ireland), or Avadel, pursuant to which we received exclusive global rights to develop certain products incorporating LiquiTime® and/or Micropump® technology. If we fail to comply with the obligations under these agreements, including payment terms, Merck, Lilly and Avadel 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 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, 2017, we had $2.5 million in cash and cash equivalents and $11.4 million in current liabilities. We expect our cash reserves to be bolstered in the third quarter of 2018 by the release to us of $3.75 million held in escrow by Janssen, but we cannot assure we will get those funds. 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 remains 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.

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.

We have incurred significant net losses in every period 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 income (loss) of $11.9 million, $(16.5) million and $(10.5) million for the years ended December 31, 2017, 2016 and 2015, respectively. As of December 31, 2017, we had an accumulated deficit of $58.2 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.

As of December 31, 2017, the Company had approximately $3.0 million of gross net operating losses for Federal and State purposes that will begin to expire in 2031.

Sections 382 and 383 of the Internal Revenue Code of 1986 subject the future utilization of net operating losses and certain other tax attributes, such as research and experimental tax credits, to an annual limitation in the event of certain ownership changes, as defined. The Company has undergone an ownership change study and has determined that a "change in ownership" as defined by IRC Section 382 of the Internal Revenue Code of 1986, as amended, and the rules and regulations promulgated thereunder, did occur in February 2012, July 2014, and April 2017. Accordingly, about $52,170,000 of the Company's NOL carryforwards are limited. Based on the company having undergone multiple ownership changes throughout their history these NOLs will free up at varying rates each year. Approximately, $2,800,000 of these NOLs can utilized before the 2017 ownership change and $46,000,000 of NOLs and R&D Credits are expected to expire unused which has been adjusted in the table above. At December 31, 2017 there are $107,702 of NOLs available for immediate use and an additional $158,513 will become available in 2018.

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 contract research organizations, or 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 most recently Avadel's pediatric products and TRx. As a part of the Avadel acquisition, we assumed financial obligations to Deerfield CSF, LLC, which include a $15 million loan due in January 2021 and certain royalty obligations through February 2026. As a part of the TRx acquisition, we agreed to issue 2,349,968 shares of our common stock to the sellers upon shareholder approval at our 2018 annual stockholder meeting, and the potential to pay Lachlan Pharmaceuticals up to $4.0 million in milestone payments and royalty payments of 15% of net sales over the next several years. 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;
- 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. 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.

An active trading market for our common stock and warrants might not continue to develop or be sustained.

Prior to our initial public offering, there was no public market for our common stock and our warrants. Although our common stock and warrants are listed on The NASDAQ Capital Market, we cannot assure you that an active trading market for our shares or warrants will continue to develop or be sustained, particularly because one investor, Armistice Capital, now holds a majority of our outstanding stock. As a result of this and other factors, you may be unable to resell your warrants or shares of our common stock. The lack of an active market 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. The lack of an active market may also reduce the fair market value of your warrants or shares of our common stock. Furthermore, an inactive market may also impair our ability to raise capital by selling the warrants or shares of

our common stock and may impair our ability to enter into strategic collaborations or acquire companies or products by using our warrants or shares of common stock 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, 2017, 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. 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 contract research organizations 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;
- 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;
- 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 warrants or shares of common stock;
- future sales of our warrants or 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 warrants or 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 warrants or shares of common stock.

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 the holders of our warrants or shares of common stock.

We expect to offer stock options, restricted stock and other forms of stock-based compensation to our directors, officers and employees in the future. If any options that we issue are exercised, or any restricted stock that we may issue vests, and those shares are sold into the public market, the market price of our common stock may decline. In addition, the availability of shares of common stock for award under our equity incentive plan, or the grant of stock options, restricted stock or other forms of stock-based compensation, may adversely affect the market price of our common stock.

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. On May 26, 2017, we filed a registration statement on Form S-3 under the Securities Act to register an aggregate of 29,166,864 shares of our common stock owned directly, or underlying convertible securities held by, our shareholders. We also have an effective registration statement for 4,000,000 shares of our common stock issuable upon the exercise of our outstanding warrants. All of these shares of our common stock are currently freely tradable. 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. 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, or the JOBS Act, and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our warrants or shares of common stock less attractive to investors and adversely affect the market price of our warrants or shares of common stock.

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 billion or more; (iii) the date on which we have, during the previous three-year period, issued more than $1 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 common stock less attractive because we may rely on these exemptions. If some investors find our warrants or shares of common stock less attractive as a result, there may be a less active trading market for our warrants or shares of common stock, 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 warrants and shares of common stock 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 warrants and shares of common stock 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 our warrants and shares of common stock would be negatively impacted. If we obtain securities or industry analyst coverage and if one or more of the analysts who covers us downgrades our warrants and shares of common stock 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 warrants and shares of common stock 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 that we did not incur as a private company, and these expenses may increase even more after we are no longer an "emerging growth company." We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC, The NASDAQ Capital Market and other applicable securities rules and regulations imposed on public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. The increased costs will increase our net loss. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

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

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

We are subject to the periodic reporting requirements of the Exchange Act. 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.

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 amended and restated bylaws; or (iv) any action asserting a claim against the company governed by the internal affairs doctrine. 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 and financial condition.

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 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, or 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 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 Baltimore, Maryland, where we occupy approximately 6,000 square feet of administrative office space. The term of the headquarters' lease expires January 31, 2019. 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, we acquired TRx and its wholly-owned subsidiaries which included Zylera. The previous owners of TRx beneficially own more than 5% of our outstanding common stock. Zylera, which is now our wholly owned subsidiary, entered into the First Amended and Restated Distribution Agreement (the "Lachlan Agreement") with Lachlan Pharmaceuticals, an Irish company controlled 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 U.S. and agreed to supply Ulesfia to Zylera exclusively for marketing and sale in the U.S.

Pursuant to an amended and restated distribution agreement entered into between Zylera and Lachlan dated, December 18, 2015. Zylera is obligated to purchase a minimum of 20,000 units per year, or approximately $1,177,000 worth of product, from Lachlan, subject to certain termination rights. Zylera must pay Lachlan management 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 distribution agreement also requires that Zylera make certain cumulative net sales milestone payments and royalty payments to Lachlan with a $3,000,000 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.

On December 10, 2016, Zylera informed Lachlan that a market change had occurred due to the introduction of Arbor Pharmaceutical's lice product, Sklice®. According to the terms of the distribution agreement if there is a market change, the minimum purchase obligation is void. On June 5, 2017, Lachlan and Zylera entered into joint legal representation along with other unrelated third parties in negotiation and arbitration of dispute with Summers Laboratory, Inc regarding the ongoing arbitration proceeding with the ultimate recipient of the royalties over whether a Market Change has occurred. The Company has not made any payments to Lachlan in 2017 under the Lachlan Agreement (from the acquisition date through year-end).

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 are also listed and publicly traded on the NASDAQ Capital Market under the symbol "CERCW." Our Class B warrants ("CERCZ") expired in April 2017. The following table sets forth the high and low closing trading prices of our common stock and warrants as reported on the NASDAQ Capital Market for each quarter our common stock and warrants were traded in the years ended December 31, 2017 and 2016.

Year Ended December 31, 2017

First Quarter	High	Low
Common stock	$ 1.24	$ 0.66
Class A warrants	$ 0.19	$ 0.01
Class B warrants	$ —	$ —
Second Quarter		
Common stock	$ 0.89	$ 0.34
Class A warrants	$ 0.12	$ 0.01
Class B warrants	$ —	$ —
Third Quarter		
Common stock	$ 1.42	$ 0.52
Class A warrants	$ 0.18	$ 0.02
Class B warrants	$ —	$ —
Fourth Quarter		
Common stock	$ 4.25	$ 0.83
Class A warrants	$ 0.60	$ 0.02
Class B warrants	$ —	$ —

Year Ended December 31, 2016

First Quarter	High	Low
Common stock	$ 4.92	$ 2.90
Class A warrants	$ 1.50	$ 0.64
Class B warrants	$ 1.08	$ 0.65
Second Quarter		
Common stock	$ 4.01	$ 1.94
Class A warrants	$ 1.20	$ 0.63
Class B warrants	$ 0.98	$ 0.40
Third Quarter		
Common stock	$ 4.91	$ 2.21
Class A warrants	$ 1.61	$ 0.45
Class B warrants	$ 0.85	$ 0.35
Fourth Quarter		
Common stock	$ 5.23	$ 0.88
Class A warrants	$ 1.99	$ 0.11
Class B warrants	$ 1.00	$ 0.02

Holders

As of March 16, 2018, there were approximately 58 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

On April 27, 2017, we entered into a securities purchase agreement with Armistice Capital Master Fund Ltd, or Armistice, pursuant to which Armistice purchased $5.0 million of our securities, consisting of 2,345,714 shares of our common stock at a purchase price of $0.35 per share and 4,179 shares of our newly-created Series A Convertible Preferred Stock, or Series A Preferred Stock, which shares of preferred stock were convertible into 11,940,000 shares of common stock at a conversion price of $0.35 per share and have a stated value of $1,000 per share. The number of shares of common stock that were purchased in the private placement constituted approximately 19.99% of our outstanding shares of common stock immediately prior to the closing of the private placement. As part of this private placement, Armistice also received warrants to purchase up to 14,285,714 shares of our common stock at an exercise price of $0.40 per share. Under the terms of the agreement, the Series A Preferred Stock were not convertible into common stock, and the warrants were not exercisable until we received approval of the private placement by our stockholders as required by the rules and regulations of NASDAQ. We received stockholder approval for this transaction on June 30, 2017. The Company received $4.65 million in net proceeds from the private placement. The securities issued pursuant to the agreement were issued under the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder, including Regulation D. On July 6, 2017, Armistice converted all of its outstanding shares of Series A Preferred Stock into 11,940,000 shares of common stock.

Item 6. Selected Financial Data

The following data has been derived from our audited consolidated financial statements, including the balance sheets at December 31, 2017, 2016 and 2015 and the related statements of operations for each of the three years ended December 31, 2017 and related notes appearing elsewhere in this Annual Report on Form 10-K or as previously filed with the Securities and Exchange Commission. You should read the selected financial data set forth below in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,				
	2017	2016	2015	2014	2013
Consolidated Statement of Operations Data:					
License and other revenue	$ 25,000,000	$ —	$ —	$ —	$ —
Product revenue, net	1,910,403	—	—	—	—
Sales force revenue	278,165	—	—	—	—
Grant revenue	624,569	1,152,987	—	—	—
Total revenues	27,813,137	1,152,987	—	—	—
Gross profit	1,274,755	—	—	—	—
Research and development	4,372,578	10,149,879	6,587,183	12,240,535	8,914,084
General and administrative	7,941,584	7,083,155	4,422,764	4,875,030	4,020,364
Sales and marketing	973,345	—	—	—	—
Income (loss) from operations	13,889,982	(16,080,047)	(11,009,947)	(17,115,565)	(12,934,448)
Change in fair value of warrant liability, unit purchase option liability and investor rights obligation	(29,624)	72,625	1,313,049	2,266,161	(121,115)
Interest expense, net	(24,016)	(464,181)	(793,205)	(1,206,187)	10,555
Total income (loss) before taxes	13,836,342	(16,471,603)	(10,490,103)	(16,055,591)	(13,045,008)
Income taxes expense	1,966,519	—	—	—	—
Net income (loss) after taxes	$ 11,869,823	$(16,471,603)	$(10,490,103)	$(16,055,591)	$(13,045,008)
Net income (loss)	$ 11,869,823	$(16,471,603)	$(10,490,103)	$ (3,521,153)	$(13,126,972)
Net income (loss) attributable to common stockholders	$ 7,772,084	$(16,471,603) —	$(10,490,103)	$ (3,521,153)	$(13,126,972)
Net income (loss) per share of common stock, basic	$ 0.42	$ (1.87)	$ (4.71)	$ (5.48)	$ (20.72)
Net income (loss) per share of common stock, diluted	$ 0.42	$ (1.87)	$ (4.71)	$ (5.48)	$ (20.72)
Weighted-average shares of common stock outstanding, basic	18,410,005	8,830,396	2,226,023	642,052	633,669
Weighted-average shares of common stock outstanding, diluted	18,754,799	8,830,396	2,226,023	642,052	633,669

	As of December 31,				
Consolidated Balance Sheet Data:	**2017**	**2016**	**2015**	**2014**	**2013**
Cash and cash equivalents	$ 2,472,187	$ 5,127,958	$ 21,161,967	$ 11,742,349	$ 3,421,480
Total assets	43,124,094	5,768,865	21,657,565	12,316,894	5,075,600
Long term debt, net of current portion and discount	—	—	2,353,482	5,308,211	—
Total current liabilities	11,406,437	4,311,863	5,849,818	4,993,816	3,065,642
Total liabilities	15,264,486	5,561,863	8,573,838	10,302,027	3,065,642
Convertible preferred stock	—	—	—	28,345,531	19,856,633
Common stock	31,268	9,434	8,650	650	643
Additional paid-in capital	83,338,136	70,232,651	66,638,557	16,742,063	9,170,468
Contingently issuable shares	2,655,464	—	—	—	—
Total stockholders' equity (deficit)	27,859,608	207,002	13,083,727	(26,330,664)	(17,846,675)

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 of this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are an integrated biopharmaceutical company dedicated to making a difference in the lives of patients. Our goal is to become a self-sustained, integrated pharmaceutical company focused on pediatric healthcare. We apply a disciplined decision making methodology as we evaluate the optimal allocation of our resources between investing in our current commercial product line, our development portfolio and acquisitions or in-licensing of new assets. We have a diverse portfolio of commercial products we sell and product candidates in development. We were incorporated in 2011 and commenced operations in the second quarter of 2011. On November 17, 2017, we acquired TRx Pharmaceuticals, LLC ("TRx") and its wholly-owned subsidiaries (see Acquisition of TRx Pharmaceuticals for a description of the transaction).

Prior to the TRx acquisition, we were a biopharmaceutical company focused exclusively on the development of innovative drug candidates for neurologic and psychiatric disorders. The Company's operations, since inception, had been focused on organizing and staffing the Company, acquiring rights to and developing certain product candidates, business planning and raising capital. We currently have a portfolio of novel clinical and preclinical compounds that we are developing for a variety of indications. Our lead clinical development program is CERC-301, which Cerecor currently intends to explore as a novel treatment for neurogenic orthostatic hypotension (nOH). The Company is also developing three preclinical stage compounds, CERC-611, CERC-406 and CERC-425.

In August 2017, we sold our 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 certain indemnification obligations to Janssen, as well as a potential future $20 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.

In February 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™. Additionally, Avadel Ireland will develop and provide Cerecor with four stable product formulations of Cerecor's choosing utilizing its proprietary LiquiTime™ and Micropump® technology. Three of these development projects are already underway.

Our portfolio of product candidates is summarized below:

- **CERC-301:** ***Orphan Neurological Indication***. CERC-301 belongs to a class of compounds known as antagonists of the N-methyl-D-aspartate, or 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, or NR2B (also called GluN2B). Given its specific mechanism of action and demonstrated tolerability profile, we believe CERC-301 may be well suited to address unmet medical needs in neurologic indications. We intend to initiate a Phase I study in 2018 for neurogenic orthostatic hypotension ("nOH"), a condition that is part of a larger category called orthostatic hypotension (OH), which is 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. We will continue to explore the use of CERC-301 in orphan neurologic conditions in preclinical and clinical studies.
- **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")-ã8-dependent AMPA receptor in preclinical development. TARPs are a recently discovered family of proteins that have been found to associate with, and modulate the activity of, AMPA receptors. TARP ã8-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. We intend to develop CERC-611 as an adjunctive therapy for the treatment of partial-onset seizures, with or without secondarily generalized seizures, in patients with epilepsy.

- **CERC-406 and CERC-425:** ***Residual Motoric and Cognitive Impairment.*** CERC-406 is a preclinical candidate from our proprietary platform of compounds that inhibit catechol-O-methyltransferase, or COMT, within the brain, which we refer to as our COMTi platform. We believe CERC 406 may have the potential to be developed for the treatment of residual cognitive impairment symptoms such as Parkinson's disease.

Our strategy for increasing shareholder value includes:

- 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;
- 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 that are near market launch; and
- Pursuing targeted, differentiated clinical stage product candidates for rare disorders or orphan diseases.

For the year ended December 31, 2017, the Company generated net income of $11.9 million and positive cash flows from operations of $12.5 million. Prior to the year ended December 31, 2017, the Company had incurred recurring operating losses since inception. As a result of the TRx and Avadel acquisitions, our commercial operations are expected to continue to generate positive cash flows from product sales. We apply a disciplined decision making methodology as we evaluate the optimal allocation of our resources between investing in our current commercial product line, our development portfolio and acquisitions or in-licensing of new assets.
We may seek future funding for our development programs and operations from further offerings of equity or debt securities, non-dilutive financing arrangements such as federal grants, collaboration agreements or out-licensing arrangements. However, we may be unable to raise additional funds or enter into such other agreements or transactions on favorable terms, or at all.

Since inception, our operations have included organizing and staffing our company, acquiring strategic companies and commercial products, raising capital and developing our product candidates. We have incurred losses in each period since our inception, until the year ended December 31, 2017. As of December 31, 2017 we had an accumulated deficit of $58.2 million. We expect to use the profits from our commercial products for the expansion of our portfolio of commercial products, development of our product candidates, and operating expenses.

We have financed our operations primarily through a public offering, private placements of our common stock and convertible preferred stock, the issuance of debt and the sale of our rights to CERC-501. Our ability to remain profitable depends on our ability to continue to generate product revenue and control the spending related to research and development and the administrative and compliance costs associated with being a public company.

Recent Developments

Avadel Acquisition

On February 16, 2018, we purchased and acquired all rights to Avadel Pharmaceuticals PLC's ("Advadel(s)") marketed pediatric products (the "Acquired Products") for the assumption of certain of Avadel's financial obligations to Deerfield CSF, LLC, which includes a $15 million loan due in January 2021 and its related interest payments as well as a 15% annual royalty on net sales of the Acquired Products through February 2026 (the "Avadel Acquisition").

Avadel is specialty pharmaceutical company, which identifies, develops, and commercializes pharmaceutical products for primary care and sterile injectable markets in the United States, France, and Ireland. Avadel markets products in the hospital and primary care spaces. The Acquired Products consist of Karbinal™ ER, AcipHex® Sprinkle™, Cefaclor for Oral Suspension, and Flexichamber™. Trailing twelve-month net sales for the Acquired Products were approximately $8 million.

Additionally, under the terms of the Avadel Acquisition, Avadel will develop and provide us with four stable product formulations of our choosing, utilizing its proprietary LiquiTime™ and Micropump® technology. Three of these development projects are already underway. We will reimburse Avadel for any costs associated with the development of the Acquired Products in excess of $1.0 million in aggregate. Upon transfer of the Acquiried Products formulations, we will assume all remaining development and regulatory costs.

The Avadel Acquisition aligns with our strategy to become a leading U.S. pediatric pharmaceutical company.

TRx acquisition

On November 17, 2017, we acquired TRx, including its wholly-owned subsidiary Zylera Pharmaceuticals, LLC and its franchise of commercial medications led by Poly-Vi-Flor® (multivitamin and fluoride supplement tablet, chewable) and Tri-Vi-Flor® (multivitamin and fluoride supplement suspension/drops), Zylera Pharma Corp, and Princeton, LLC. Under the terms of the transaction, we paid $18.9 million in cash and $8.1 million in Cerecor common stock. TRx shareholders will be eligible to receive up to an additional $7 million in contingent payments upon achievement of certain commercial and regulatory milestones.

TRx is a specialty pharmaceutical company that develops, acquires, and commercializes prescription pharmaceutical products and dietary supplements and markets those products in the U.S. TRx has a diversified portfolio of products prescribed by pediatricians to treat an array of conditions.

The acquisition of TRx and its subsidiaries is a pivotal move in our strategic shift towards becoming an integrated pediatric pharmaceutical company. Operationally, we believe the transaction adds a highly-effective commercial unit that will drive a solid, profitable revenue stream to help us advance our pipeline of drug candidates for rare neurologic diseases.

Components of Operating Results

License, other and grant revenue

Prior to the acquisition of TRx, we have primarily derived revenue from the sale of CERC-501 to Janssen Pharmaceuticals, Inc. ("Janssen") in August 2017 and research grants from the National Institutes of Health.

In April 2016, we received a research and development grant from the National Institute on Drug Abuse, or NIDA, at the National Institutes of Health to provide additional resources for the period from May 2016 through April 2017 for a Phase 2 clinical trial for CERC501. Additionally, in July 2016, we received a research and development grant from the National Institute on Alcohol Abuse and Alcoholism, or NIAAA, at the National Institutes of Health to provide additional resources for the period of July 2016 through August 2017 to progress the development of CERC-501 for the treatment of alcohol use disorder. We recognize revenue under grants in earnings on a systemic basis in the period the related expenditures for which the grants are intended to compensate are incurred.

In August 2017, we sold all of our rights to a prior product candidate, CERC-501, to Janssen in exchange for initial gross proceeds of $25.0 million, of which $3.75 million was deposited into a twelve-month escrow to secure indemnification obligations. 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.

Product revenue, net

We sell our prescription pharmaceuticals to our primary customers, which are wholesale distributors and other direct customers. Revenue from prescription pharmaceuticals sales is recognized when ownership of the product is transferred to our customers, the sales price is fixed and determinable, and collectability is reasonably assured. Sales are generally recognized when title to the product has transferred to our customers in accordance with the terms of the sale, FOB Destination and to a lesser extent FOB shipping point, since title to the product passes and our customers have assumed the risks and rewards of ownership.

We account for sales to some of our direct customers on a consignment basis and do not recognize revenue for these customers until product is sold into the retail market. We defer the recognition of revenue related to these shipments until we confirm that the product has been sold into the retail market and all other revenue recognition criteria have been met.

We record allowances for product returns, and wholesaler rebates, chargebacks, fees and discounts (“allowances”) at the time of sale, and report revenue net of these allowances. We make significant judgments and estimates when determining these allowances. For example, we estimate demand, buying patterns, historical product return rates from wholesalers and the levels of inventory held by wholesalers. The Company periodically adjusts these allowances based on actual experience.

Sales force revenue

Pursuant to our Marketing Agreement with Pharmaceutical Associates, Inc***. (“PAI”)*** we receive a monthly marketing fee to promote, market and sell certain of our products behalf of PAI. The Company also receives a matching fee payment for each month of

the term of the Marketing Agreement if certain provisions calculated in accordance with the terms and inputs set forth in the Marketing Agreement are met. Marketing fees and any matching payments are recognized as sale force revenue when all performance obligations have been satisfied and earned.

We and PAI also share the net revenues from sales of certain products, after reimbursing certain expenditures, in a manner designed to achieve a 50/50 split of net revenues above a "break even" point, calculated in accordance with the terms and inputs set forth in the agreement. We recognize these revenue sharing payments as earned under the terms of the agreement when collectability is reasonably assured.

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.

Inventory valuation

We state inventories at the lower of cost and net realizable value. 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.

Research and Development Expenses

Our research and development expenses consist primarily of costs incurred developing, testing and seeking marketing approval for our product candidates. These costs include both external costs, which are study-specific costs, and internal research and development costs, which are not directly allocated to our product candidates.

External costs include:

- expenses incurred under agreements with third-party contract research organizations and investigative sites that conduct our clinical trials, preclinical studies and regulatory activities;
- payments made to contract manufacturers for drug substance and acquiring, developing and manufacturing clinical trial materials; and
- payments related to acquisitions of our product candidates and preclinical platform and
- milestone payments, and fees associated with the prosecution and maintenance of patents.

Internal costs include:

- personnel-related expenses, including salaries, benefits and stock-based compensation expense;
- consulting costs related to our internal research and development programs; allocated facilities, depreciation and other expenses, which include rent and utilities, as well as other supplies; and
- product liability insurance.

Research and development costs are expensed as incurred. We record costs for some development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or information provided to us by our vendors.

We track external costs by program and subsequently by product candidate once a product candidate has been selected for development. Product candidates in later stage clinical development generally have higher research and development expenses than those in earlier stages of development, primarily due to the increased size and duration of the clinical trials.

As of December 31, 2017, we had six full-time employees who were primarily engaged in research and development.

General and Administrative Expenses

General and administrative expenses consist primarily of professional fees, patent costs and salaries, benefits and related costs for executive and other personnel, including stock-based compensation and travel expenses. Other general and administrative expenses include facility-related costs, communication expenses and professional fees for legal, including patent-related expenses, consulting, tax and accounting services, insurance, depreciation and general corporate expenses.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of professional fees, advertising and marketing cost and salaries, benefits and related costs for sales and sales support personnel, including stock-based compensation and travel expenses. Sales and marketing expense also includes amortization of marketing rights intangible assets acquired in the acquisition of TRx.

Change in Fair Value of Warrant Liability and Unit Purchase Option Liability

In connection with the issuance of our term debt facility in August 2014, we issued warrants to purchase 625,208 shares of Series B convertible preferred stock. Upon the closing of our initial public offering, or IPO, in October 2015 these warrants became warrants to purchase 22,328 shares of common stock, in accordance with their terms. These warrants represent a freestanding financial instrument that is indexed to an obligation, which we refer to as the Warrant Liability. These warrants are classified as a liability at fair value. This liability is remeasured at each balance sheet date and the change in fair value is recorded within our statement of operations.

As part of our IPO, the underwriter received a unit purchase option, or UPO, to purchase up to 40,000 units, whereby a unit is comprised of one share of our common stock, one Class A warrant to purchase one share of our common stock and one Class B warrant to purchase one-half share of our common stock. The UPO is classified as a liability at its respective fair value. This liability is remeasured at each balance sheet date and the change in fair value is recorded within our statement of operations.

Interest Expense, net

Net interest expense is primarily related to interest payments pursuant to the terms of our term debt facility entered into in August 2014, as well as the amortization of the debt discounts and premiums and deferred financing fees in connection with such term debt facility. We made the final payment under this facility on August 1, 2017.

Critical Accounting Policies and Significant Judgments and Estimates

This discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States of America, or GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reported period. In accordance with GAAP, we base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances. On an ongoing basis, we evaluate our estimates and assumptions, including those related to clinical and preclinical trial expenses and stock-based compensation. Actual results may differ from these estimates under different assumptions or conditions.

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 portrayal of our financial condition and results. We have reviewed these critical accounting policies and estimates with the audit committee of our board of directors.

License and Other Revenue

We recognize revenues from collaboration, license or other research or sale arrangements when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collectability is reasonably assured.

Product Revenue

Product sales revenue is recognized when title has transferred to the customer and the customer has assumed the risks and rewards of ownership, which is typically on delivery to the customer. Revenue from sales transactions where the buyer has the right to return the product is recognized at the time of sale only if (i) the seller's price to the buyer is substantially fixed or determinable at the date of sale, (ii) the buyer has paid the seller, or the buyer is obligated to pay the seller and the obligation is not contingent on resale of the product, (iii) the buyer's obligation to the seller would not be changed in the event of theft or physical destruction or damage of the product, (iv) the buyer acquiring the product for resale has economic substance apart from that provided by the seller, (v) the seller does not have significant obligations for future performance to directly bring about resale of the product by the buyer, and (vi) the amount of future returns can be reasonably estimated.

We have entered into distribution service agreements ("DSAs") with certain of our significant wholesaler customers that obligate the wholesalers, in exchange for fees paid by us, to: (i) manage the variability of their purchases and inventory levels within specified limits based on product demand and (ii) provide us with specific services, including the provision of periodic retail demand information and current inventory levels for our pharmaceutical products held at their warehouse locations.

Sales Deductions

Revenues from sales of products are recorded net of estimated allowances for returns, wholesaler fees, prompt payment discounts, government rebates at the time of sale. Provisions for returns, wholesaler fees and government rebates are included within current liabilities in the consolidated balance sheet. Provisions for prompt payment discounts are generally shown as a reduction in 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.

Where available, we have relied on information received from our wholesaler customers about the quantities of inventory held, including the information received pursuant to DSAs. For other customers, we have estimated inventory held based on buying patterns and other historical information. In addition, we have evaluated market conditions for products primarily through the analysis of wholesaler and other third party sell through, as well as internally-generated information, to assess factors that could impact expected product demand at December 31, 2017. We believe that the estimated level of inventory held by our customers is within a reasonable range as compared to both: (i) historical amounts and (ii) expected demand for each respective product at December 31, 2017.

Returns and Allowances

Consistent with industry practice, we maintain a return policy that allows our customers to return product within a specified period of time both subsequent to and, in certain cases, prior 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. Our provision for returns and allowances consists of our estimates for future product returns, pricing adjustments and delivery errors. The primary factors we consider in estimating our potential product returns include:

- the shelf life or expiration date of each product;
- historical levels of expired product re turns;
- 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.

Our 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. When we are aware of an increase in the level of inventory of our products in the distribution channel, we consider the reasons for the increase to determine whether we believe the increase is temporary or other-than-temporary. Increases in inventory levels assessed as temporary will not result in an adjustment to our provision for returns and allowances. Conversely, other-than-temporary increases in inventory levels may be an indication that future product returns could be higher than originally anticipated and, accordingly, we may need to adjust our provision for returns and allowances. Some of the factors that may be an indication that an increase in inventory levels will be other-than-temporary include:

- declining sales trends based on prescription demand;

- regulatory approvals that could shorten the shelf life of our products, which could result in a period of higher returns related to older product still in the distribution channel;
- introduction of new product or generic competition;
- increasing price competition from generic competitors

Distribution Fees and Rebates

Consistent with pharmaceutical industry practices, we establish contracts with wholesalers that provide for fees under our wholesaler DSAs ("DSA fees"). Settlement of DSA fees may generally occur on a monthly or quarterly basis based on net sales for the period. DSA fee accruals are based on contractual fees to be paid to the wholesale distributor for services provided. Assumptions used to establish the provision include level of wholesaler inventories, contract sales volumes and average contract pricing. We regularly review the information related to these estimates and adjust the provision accordingly.

We are 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 us age, 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, but 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 s ales are subject to rebates and the amount of such rebates. Periodically, we adjust 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 our estimates for rebates, we consider the terms of our contracts, relevant statutes, historical relationships of rebates to revenues, past payment experience, estimated inventory levels of our customers and estimated future trends.

Chargebacks and Sales Discounts

Chargeback accruals are based on the differentials between product acquisition prices paid by wholesalers and lower government contract pricing paid by eligible customers covered under federally qualified programs. Sales discounts accruals are based on payment terms extended to customers.

Sales force revenue

Pursuant to our Marketing Agreement with Pharmaceutical Associates, Inc. ("PAI") we receive a monthly marketing fee to promote, market and sell certain products on behalf of PAI. The Company also receives a matching fee payment for each month of the term of the Marketing Agreement if certain provisions calculated in accordance with the terms and inputs set forth in the Marketing Agreement are met. Marketing fees and any matching payments are recognized as sale force revenue when all performance obligations have been satisfied and earned.

We and PAI also share the net revenues from sales of certain products, after reimbursing certain expenditures, in a manner designed to achieve a 50/50 split of net revenues above a "break even" point, calculated in accordance with the terms and inputs set forth in the agreement. We recognize these revenue sharing payments as earned under the terms of the agreement when collectability is reasonably assured.

Grant Revenue

We recognize grant revenue when there is (i) reasonable assurance of compliance with the conditions of the grant and (ii) reasonable assurance that the grant will be received. We recognize revenue under grants in earnings on a systemic basis in the period the related expenditures for which the grants are intended to compensate are incurred.

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.

Inventory valuation

Inventories are recorded at the lower of cost or net realizable value, with cost determined on a first-in, firstout 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.

Research and Development Expenses

Research and development costs are expensed as incurred. We rely heavily on third parties to conduct preclinical and clinical trials, as well as for the manufacture of our clinical trial supplies. 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 subject enrollment, clinical site activations or information provided to us by our vendors 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.

Income Taxes

As of December 31, 2017, the Company had approximately $3.0 million of gross net operating losses for Federal and State purposes that will begin to expire in 2031.

Sections 382 and 383 of the Internal Revenue Code of 1986 subject the future utilization of net operating losses and certain other tax attributes, such as research and experimental tax credits, to an annual limitation in the event of certain ownership changes, as defined. The Company has undergone an ownership change study and has determined that a "change in ownership" as defined by IRC Section 382 of the Internal Revenue Code of 1986, as amended, and the rules and regulations promulgated thereunder, did occur in February 2012, July 2014, and April 2017. Accordingly, about $52,170,000 of the Company's NOL carryforwards are limited. Based on the company having undergone multiple ownership changes throughout their history these NOLs will free up at varying rates each year. Approximately, $2,800,000 of these NOLs are available to be utilized before the 2017 ownership change and $46,000,000 of NOLs and R&D Credits are expected to expire unused which has been adjusted. At December 31, 2017 there are $107,702 of NOLs available for immediate use and an additional $158,513 will become available in 2018.

On December 22, 2017, H.R. 1 (also, known as the Tax Cuts and Jobs Act (the “Act”)) was signed into law. Among its numerous changes to the Internal Revenue Code, the Act reduces U.S. federal corporate tax rate from 35% to 21%. As a result, we believe that the most significant impact on the Company's consolidated financial statements is the reduction of approximately $2,200,000 of net deferred tax assets and liabilities primarily related to net operating losses and other assets. Such reduction is largely offset by changes to our valuation allowance. We are reporting the impacts of the Act provisionally based upon reasonable estimates.

Estimated Fair Value of Warrants and Unit Purchase Option

Warrants for shares that are contingently redeemable are accounted for as freestanding financial instruments. These warrants are classified as liabilities on our balance sheet and are recorded at their estimated fair value. At the end of each reporting period, changes in the estimated fair value during the period are recorded as a component of other income (expense), net. We will continue to adjust these liabilities for changes in fair value until the earlier of the expiration or the exercise of the warrants. We estimate the fair value of these warrants using a Black-Scholes option-pricing model. The significant assumptions used in preparing the option-pricing model for valuing the warrants as of December 31, 2017, included (i) volatility of 55%, (ii) risk free interest rate of 1.96%, (iii) strike price ($8.40), (iv) fair value of common stock ($3.20), and (v) expected life of 2.8 years. Significant decreases in our stock price volatility will significantly decrease the overall valuation of the warrants, while significant increases in our stock price volatility will significantly increase the overall valuation.

As part of our IPO we offered our underwriters the UPO to purchase up to an additional 40,000 units. The UPO is accounted for as a freestanding financial instrument and is recorded a liability on our balance sheet at its estimated fair value. At the end of each reporting period, the change in the estimated fair value during the period is recorded as component of other income (expense), net. We will continue to adjust this liability for changes in fair value until the earlier of expiration or the exercise of the UPO. We estimate the fair value of the UPO using a Black-Scholes option-pricing model within a Monte Carlo simulation model framework. The significant assumptions used in preparing the simulation model for valuing the UPO as of December 31, 2017, include (i) volatility range of 40% to 50%, (ii) risk free interest rate range of 1.28% to 2.17%, (iii) unit strike price ($7.48), (iv) underwriters' Class A warrant strike price ($5.23), (v) underwriters' Class B warrant strike price ($4.49), (vi) fair value of underlying equity ($3.20), and (vii) optimal exercise point of immediately prior to the expiration of the underwriters' Class B warrants, which occurred on April 20, 2017.

Contingent consideration

Our TRx acquisition involves the potential for future payment of consideration that is contingent upon the achievement of operational and commercial milestones. The fair value of contingent consideration liabilities is determined at the acquisition date using unobservable inputs. These inputs include 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 current fair value with changes recorded in our consolidated statements of operations. Changes in any of the inputs may result in a significantly different fair value adjustment.

Stock-Based Compensation

We measure stock-based awards granted to our employees and nonemployee directors at fair value on the date of grant and recognize the corresponding compensation expense of those awards, net of estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award. Generally, we issue stock options and restricted stock with only service-based vesting conditions and record the expense for these awards using the straight-line method.

We measure stock-based awards granted to nonemployee consultants at the fair value of the award on the date at which the related service is complete. Expense is recognized over the period during which services are rendered by such nonemployee consultants until completed. At the end of each financial reporting period prior to the completion of the service, the fair value of these awards is re-measured using the then-current fair market value of our common stock and updated assumptions in the Black-Scholes option-pricing model.

The fair value of each stock option grant is estimated using the Black-Scholes option-pricing model. We estimate our expected volatility based on the historical volatility of our publicly traded peer companies and expect to continue to do so until such time as we have adequate historical data regarding the volatility of our traded stock price. Due to the lack of sufficient historical data for the term of our options, the expected term of our options granted to employees and non-employee directors has been estimated as the arithmetic average of the vesting term and the original contractual term of the option, while the expected term of our options granted to consultants and nonemployees has been determined based on the contractual term of the options. The risk-free interest rate is determined by reference to the United States Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that we have never paid cash dividends and do not expect to pay any cash dividends in the foreseeable future.

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

	Year Ended December 31,		
	2017	2016	2015
Risk-free interest rate	1.85% — 2.38%	1.01% — 1.93%	1.64% — 1.97%
Expected term of options (in years)	5.0 — 6.25	5.0 — 6.25	5.0 — 6.25
Expected stock price volatility	55% — 100.0%	80% — 100.0%	70.0%
Expected annual dividend yield	—%	—%	—%

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. In developing a forfeiture rate estimate for pre-vesting forfeitures, we have considered our historical experience of actual forfeitures. If our future actual

forfeiture rate is materially different from our estimate, our stock-based compensation expense could be significantly different from what we have recorded in the current period.

Results of Operations

Comparison of the Years Ended December 31, 2017 and 2016

The following table summarizes our revenue for the years ended December 31, 2017 and 2016

	Year Ended December 31,	
	2017	2016
	(in thousands)	
License and other revenue	$ 25,000	$ —
Product revenue, net	$ 1,911	$ —
Sales force revenue	$ 278	$ —
Grant revenue	$ 625	$ 1,153

License and other revenue

In August 2017, we sold all of our rights to a prior product candidate, CERC-501, to Janssen in exchange for initial gross proceeds of $25.0 million, of which $3.75 million was deposited into a twelve-month escrow to secure indemnification obligations. 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.

Product revenue, net

Product revenue, net was $1.9 million for the year ended December 31, 2017, and represents revenues from the pediatric products we acquired in the acquisition of TRx on November 17, 2017. There are no product revenues reported for 2016 as the acquisition did not take place until 2017.

Sales force revenue

Sales force revenue was $0.3 million for the year ended December 31, 2017. There are no sales force revenues reported for 2016 as the acquisition did not take place until 2017.

Grant revenue

Grant revenue was $0.6 million for the year ended December 31, 2017, compared to $1.2 million for the year ended December 31, 2016. Our grant revenues related to CERC-501 and were dependent upon the timing and progress of the underlying studies and development activities. We had a reduced level of research and development activities in the current year compared to the on-going clinical trial work in the prior year, which resulted in a reduction of grant revenue under the current NIAAA grant compared to the NIDA grant in 2016. The studies related to these grants were discontinued with the sale of CERC-501 to Janssen in 2017.

Cost of product sales

Cost of product sales was $0.6 million for the year ended December 31, 2017, and represents cost of product sales from the acquisition of TRx on November 17, 2017. There are no costs of product sales reported for 2016 as the acquisition did not take place until 2017.

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2017 and 2016:

	Year Ended December 31,	
	2017	2016
	(in thousands)	
CERC-301	$ 1,215	$ 2,890
CERC-501	661	3,122
CERC-611	494	2,103
COMTi	62	124
Internal expenses not allocated to programs:		
Salaries, benefits and related costs	1,433	1,534
Stock-based compensation expense	152	141
Other	356	236
	$ 4,373	$ 10,150

Research and development expenses were $4.4 million for the year ended December 31, 2017, a decrease of $5.8 million compared to the 2016 period. Costs for CERC-301 decreased by $1.7 million from the prior year period, primarily due to the completion of enrollment during the Phase 2 clinical trial for the adjunctive treatment of MDD in 2016. We did not perform any clinical trials for CERC-301 in 2017, however costs were incurred to analyze potential other indications for CERC-301. Costs for CERC-501 decreased by $2.5 million from the prior year period as our Phase 2 clinical trial with CERC-501 was completed in the fourth quarter of 2016 and activities in 2017 up to the date of sale primarily consisted of completing work related to the NIAAA grant. We sold all of our rights to CERC-501 to Janssen in August 2017. We purchased CERC-611 in September 2016 for $2.0 million which was recorded as Research and Development Expense. Costs incurred in 2017 relate to preparing the CERC-611 compound for additional development.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the years ended December 31, 2017 and 2016:

	Year Ended December 31,	
	2017	2016
	(in thousands)	
Salaries, benefits and related costs	$ 2,433	$ 1,922
Legal, consulting and other professional expenses	3,944	2,806
Stock-based compensation expense	1,001	1,554
Amortization of intangible assets	—	—
Other	564	801
	$ 7,942	$ 7,083

General and administrative expenses were $7.9 million for the year ended December 31, 2017, an increase of $0.9 million compared to the 2016 period. Salaries, benefits and related costs increased by $511,000 due to the current year recognition of severance costs of senior executives that resigned in 2017. Legal, consulting and other professional expenses increased by $1.1 million primarily as a result of the legal and financial due diligence related to the acquisition of TRx and it's wholly-owned subsidiaries and investment in the company's accounting and IT infrastructure for compliance purposes. Stock-based compensation expense decreased by $553,000, which was primarily driven by a large modification of grants made to our former chief executive officer in the first quarter of 2016. Modifications to awards in 2017 did not result in a material impact on stock-based compensation. Other general and administrative expenses decreased by $237,000 due to efforts to reduce certain other operating costs in order to preserve cash throughout 2017 until the sale of CERC 501 to Janssen and the acquisition of TRx in November.

Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses for the years ended December 31, 2017 and 2016:

	Year Ended December 31,	
	2017	2016
	(in thousands)	
Salaries, benefits and related costs	$ 303	$ —
Consulting and other professional expenses	140	—
Stock-based compensation expense	4	—
Advertising and marketing expense	71	
Amortization of intangible assets	404	—
Other	51	—
	$ 973	$ —

The Company began to incur sales and marketing expenses after the TRx acquisition on November 17, 2017. These costs were $1.0 million for the period between the acquisition date and December 31, 2017. Salaries, benefits and related costs were $303,000 as a result of obtaining sales and sales support personnel. Legal, consulting and other professional expenses were $140,000 primarily as a result of the legal and financial due diligence related to the acquisition of TRx. Advertising and marketing expenses were incurred to support the Company's recently acquired portfolio of drug products for sale. Amortization of intangible assets results from the Company's acquisition of $18.1 million of intangible assets as part of the TRx acquisition.

Change in Fair Value of Warrant Liability and Unit Purchase Option Liability

We recognized a loss on the change in fair value of our warrant liability and UPO liability of approximately $30,000 during the year ended December 31, 2017 compared to a gain of $73,000 during the 2016 period. The $30,000 loss on the change in fair value during the year ended December 31, 2017 was due to the increase in fair value of our warrant liability and UPO liability, both attributable to the increase in our common stock price at December 31, 2017 compared to December 31, 2016.

Interest Expense, Net

Net interest expense decreased by $440,000 for the year ended December 31, 2017 compared to the year ended December 31, 2016. The decrease was primarily due to a decrease in interest associated with a reduction in the principal balance of our secured term loan facility. We made the final payment under this term loan on August 1, 2017.

Income tax expense

The provision for income taxes was $2.0 million for the year ended December 31, 2017 due to net income generated from operations in 2017. Our annual effective tax rate as of December 31, 2017 was approximately 14.2 percent. Our effective tax rate differs from the federal statutory rate due to the change in statutory rates, §382 limitations, and the Company’s ability to utilize a portion of its prior net operating losses, which were previously subject to a valuation allowance, to offset current period income.

Comparison of the Years Ended December 31, 2016 and 2015

Grant Revenue

The following table summarizes our grant revenue for the years ended December 31, 2016 and 2015:

	Year Ended December 31,	
	2016	2015
	(in thousands)	
Grant revenue	$ 1,153	$ —

Grant revenue was $1.2 million for the year ended December 31, 2016 and was comprised of revenue from two research and development grants awarded during the year. In April 2016, we were awarded a research and development grant of $1.02 million from

the National Institute on Drug Abuse at the National Institutes of Health, or the NIDA Grant. This grant provided additional resources for the completed Phase 2 clinical trial of CERC-501. In July 2016, we were awarded a research and development grant of approximately $1.0 million from the National Institute on Alcohol Abuse and Alcoholism at the National Institutes of Health, or the NIAAA Grant. This grant provides additional resources to progress the development of CERC-501 for the treatment of alcohol use disorder. For the year ended December 31, 2016, grant revenue recognized from the NIDA Grant was $1.02 million and grant revenue recognized from the NIAAA Grant was $132,000. We did not have grant revenue in the 2015 period.

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2016 and 2015:

	Year Ended December 31,	
	2016	2015
	(in thousands)	
CERC-301	$ 2,890	$ 3,110
CERC-501	3,122	1,481
CERC-611	2,103	—
COMTi	124	260
Internal expenses not allocated to programs:		
Salaries, benefits and related costs	1,534	1,367
Stock-based compensation expense	141	67
Other	236	302
	$ 10,150	$ 6,587

Research and development expenses were $10.2 million for the year ended December 31, 2016, an increase of $3.6 million compared to the 2015 period. This increase was largely due to the $2.0 million total upfront payment recorded in connection with the license of CERC-611 in September 2016, of which $750,000 was due and paid within 30 days of the effective date of the license agreement. 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 other long term liabilities on the balance sheet at December 31, 2016. Additionally, costs for CERC-501 increased by $1.6 million, driven by the costs incurred in 2016 related to the enrollment activity and costs to complete our Phase 2 clinical trial for smoking cessation, which was completed in December. These costs were offset by $1.0 million of costs incurred in the 2015 period related to the in-licensing of CERC-501. Costs for CERC-301 decreased by $220,000 due to start-up costs incurred in 2015 to initiate our Phase 2 clinical trial for the adjunctive treatment of MDD, offset by 2016 costs related to the enrollment activity and costs to complete the trial, which was completed in November.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the years ended December 31, 2016 and 2015:

	Year Ended December 31,	
	2016	2015
	(in thousands)	
Salaries, benefits and related costs	$ 1,922	$ 2,326
Legal, consulting and other professional expenses	2,806	1,289
Stock-based compensation expense	1,554	328
Other	801	480
	$ 7,083	$ 4,423

General and administrative expenses were $7.1 million for the year ended December 31, 2016, an increase of $2.7 million compared to the 2015 period. Legal, consulting and other professional expenses increased by $1.5 million, attributable primarily to audit,

legal and other costs resulting from becoming a public company in October 2015, as well as certain financing expenses. Stock-based compensation expense increased by $1.2 million, driven by the modification of grants made to our former chief executive officer in the first quarter of 2016 in which the exercise term was extended, as well as the grant of additional awards in 2016 to our directors, executive officers and other employees. Further, other general and administrative expenses increased by $321,000 due to business development expenses and other costs. These increases were offset by a $404,000 decrease in salaries, benefits and related costs, driven by the $528,000 of severance expense recorded in 2015 due to the resignation of our former chief executive officer, offset by salary increases effected at the close of our initial public offering in October 2015.

Change in Fair Value of Warrant Liability, Unit Purchase Option Liability and Investor Rights Obligation

We recognized a gain on the change in fair value of our warrant liability, UPO liability and investor rights obligation of $73,000 during the year ended December 31, 2016 compared to a gain of $1.3 million during the 2015 period. The $73,000 gain on the change in fair value during the year ended December 31, 2016 was due to the decrease in fair value of our warrant liability and UPO liability, both attributable to the decrease in our common stock price at December 31, 2016 compared to December 31, 2015.

The $1.3 million gain on the change in fair value during the 2015 period resulted from the expiration of the investor rights obligation in October 2015 upon the closing of our initial public offering.

Interest Expense, Net

Net interest expense decreased by $329,000 for the year ended December 31, 2016 compared to the year ended December 31, 2015. The decrease was primarily due to a decrease in interest associated with a reduction in the principal balance of our secured term loan facility.

Liquidity and Capital Resources

Historically, we have devoted most of our cash resources to research and development, general and administrative activities and our acquisitions. Since our inception through the third quarter of 2017, when we sold CERC-501 to Janssen for $25.0 million, we have incurred net losses and negative cash flows from our operations. We plan to fund our drug development and clinical trials from profits generated by sales of our marketed pediatric products acquired in the TRx and Avadel transactions. We apply a disciplined decision making methodology as we evaluate the optimal allocation of our resources between investing in our current commercial product line, our development portfolio and acquisitions or in-licensing of new assets.

We incurred net income (loss) of $11.9 million, $(16.5) million and $(10.5) million for the years ended December 31, 2017, 2016 and 2015, respectively. At December 31, 2017, we had an accumulated deficit of $58.2 million, net working capital of ($0.4) million and cash and cash equivalents of $2.5 million. Historically, we have financed our operations principally through private and public placements of common stock, private placements of convertible preferred stock and convertible and nonconvertible debt. In April 2017, we raised gross proceeds of $5.0 million from a private placement of our equity securities. On August 14, 2017, we sold all of our rights to CERC-501 to Janssen in exchange for initial gross proceeds of $25.0 million, of which $3.75 million was deposited into a twelve month escrow to secure indemnification obligations to Janssen. Under this agreement, we are also eligible for a potential future $20 million regulatory milestone payment. If our revenue does not grow at expected levels, we may require substantial additional financing to fund our operations to continue to execute our strategy. We may have to seek funding for our operations from further offerings of equity or debt securities, non-dilutive financing arrangements such as federal grants, collaboration agreements or out-licensing arrangements, and to explore strategic alternatives such as an acquisition, merger, or business combination. Based on our current research and development plans we expect that our existing cash and cash equivalents, together with the initial proceeds from the Janssen sale and anticipated revenue, will enable us to fund our operating expenses and capital expenditure requirements through March 2019.

The Aspire Capital Transaction

On September 8, 2016, we entered into a common stock purchase agreement, or the Purchase Agreement, with Aspire Capital Fund, LLC, or Aspire Capital, pursuant to which Aspire Capital committed to purchase up to an aggregate of $15.0 million of shares of our common stock over the 30-month term of the Purchase Agreement. Upon execution of the Purchase Agreement, we issued and sold to Aspire Capital 250,000 shares of common stock at a price per share of $4.00, for gross proceeds of $1.0 million. Additionally, as consideration for Aspire Capital entering into the Purchase Agreement, we issued 175,000 shares of common stock as a commitment fee. The net proceeds of the Aspire Capital transaction, after offering expenses, were approximately $1.9 million for the year ended December 31, 2016. As of December 31, 2016, we had sold 763,998 shares of common stock to Aspire Capital. During the twelve months ended

December 31, 2017, the Company sold an additional 965,165 shares of common stock to Aspire Capital under the terms of the Purchase Agreement for gross proceeds of approximately $789,000. As of the date of this Annual Report on Form 10-K, the Company does not have any remaining shares available to issue under the purchase agreement. The Company may not issue any additional shares of common stock to Aspire Capital under the Purchase Agreement unless shareholder approval is obtained.
On January 20, 2018 the Board of Directors resolved to terminate this agreement.

The Maxim Group Equity Distribution Agreement

On January 27, 2017, we entered into an equity distribution agreement, or the Equity Distribution Agreement, with Maxim Group LLC, or Maxim, as sales agent, pursuant to which we may offer and sell shares of our common stock through Maxim from time to time. We have no obligation to sell any of the shares, and may at any time suspend offers under the Equity Distribution Agreement.

As of the December 31, 2017, the Company had sold 1,336,433 shares of its common stock through Maxim under the Equity Distribution Agreement for net proceeds of $905,000, including $33,000 of issuance costs. After the filing of this Annual Report on Form 10-K, the amount of additional securities that were eligible to be sold under the registration statement on Form S-3 would have been approximately $2.9 million. This agreement expired on January 16, 2018.

Armistice Private Placement

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 and4,179 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.

Term Loan

In August 2014, we received a $7.5 million secured term loan from a finance company. The loan was secured by a lien on all our assets, excluding intellectual property, which was subject to a negative pledge. The loan agreement contained certain additional nonfinancial covenants. In connection with the loan agreement, our cash and investment accounts were subject to account control agreements with the finance company that give the finance company the right to assume control of the accounts in the event of a loan default. Loan defaults were defined in the loan agreement and include, among others, the finance company's determination that there was a material adverse change in our operations, other than adverse results of clinical trials. Interest on the loan was at a rate of the greater of 7.95%, or 7.95% plus the prime rate as reported in The Wall Street Journal minus 3.25%. On August 1, 2017, we made the final payment of $494,231 under the loan, which included a termination fee of $187,500.

TRx Pharmaceuticals, LLC Acquisition

On November 17, 2017, Cerecor Inc. we and TRx Pharmaceuticals, LLC (TRx) entered into a purchase agreement in which we would acquire TRx, including subsidiary Zylera Pharmaceuticals, LLC and its franchise of commercial 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 $2.6 million.

Avadel Acquisition

On February 16, 2018, we entered into an Asset Purchase Agreement with Avadel US Holdings, Inc. ("Avadel"), 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. We made a nominal cash payment for the acquired assets, and assumed 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.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2017, 2016 and 2015:

	Year Ended December 31,		
	2017	2016	2015
	(in thousands)		
Net cash provided by (used in):			
Operating activities	$ 12,519	$ (14,573)	$ (10,163)
Investing activities	(18,912)	(35)	(20)
Financing activities	3,737	(1,426)	19,603
Net increase (decrease) in cash and cash equivalents	$ (2,656)	$ (16,034)	$ 9,420

Net cash used in operating activities

Net cash provided by operating activities was $12.5 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 used in operating activities was $14.6 million for the year ended December 31, 2016 and consisted primarily of a net loss of $16.5 million, offset by non-cash stock-based compensation expense of $1.7 million, non-cash interest expense of $162,000 and an increase in accounts payable of $332,000.

Net cash used in operating activities was $10.2 million for the year ended December 31, 2015 and consisted primarily of a net loss of $10.5 million, a non-cash $1.3 million gain on the change in fair value of the warrant liability, UPO liability and Investor Rights Obligation driven by the expiration of the Investor Rights Obligation during the year and a decrease in accounts payable of $269,000. These were offset by a $1.1 million increase in accrued expenses due to increased clinical trial activities and $528,000 of accrued severance expense due to the resignation of our former chief executive officer, non-cash stock compensation expense of $395,000 and non-cash interest expense of $294,000.

Net cash used in investing activities

Our 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 (used in) financing activities

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

Net cash used in financing activities was $1.4 million for the year ended December 31, 2016, which consisted of principal payments on our term loan of $3.3 million offset by net proceeds from the sale of common stock to Aspire Capital under the Purchase Agreement of $1.9 million.

Net cash provided by financing activities was $19.6 million for the year ended December 31, 2015 and consisted primarily of proceeds from our initial public offering including the over-allotment option, net of underwriting discounts, commissions and expenses of $23.7 million, offset by the payment of offering costs related to the initial public offering of $2.3 million and principal payments on our term loan of $1.8 million.

Operating and Capital Expenditure Requirements

Prior to the year ended December 31, 2017, the Company had incurred recurring operating losses since inception. For the year ended December 31, 2017, the Company generated net income of $11.9 million and positive cash flows from operations of $12.5 million. As a result of the Zylera and Avadel acquisitions, our commercial operations are expected to generate positive cash flows from sales of our marketed products.

Following the closing of our IPO in October 2015, we expect to continue to incur significant legal, accounting and other expenses that we were not previously required to incur as a private company. In addition, the Sarbanes-Oxley Act, as well as rules adopted by the Securities and Exchange Commission, or SEC, and the NASDAQ Stock Market, requires public companies to implement specified corporate governance practices that were previously inapplicable to us as a private company. We expect these rules and regulations will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We may also acquire or in-license new product candidates. Based on our plans, we expect that our existing cash and cash equivalents, plus anticipated revenue, should enable us to fund our operating expenses and capital expenditure requirements through 2019. However, we might require substantial additional financing to fund our operations and to continue to develop our product candidates.

We may have to seek funding for our operations from further offerings of equity or debt securities, non-dilutive financing arrangements such as federal grants, collaboration agreements or out-licensing arrangements, and to explore strategic alternatives such as an acquisition, merger, or business combination. Our future capital requirements will depend on many forward-looking factors, including:

- sales of our marketed products
- the progress of clinical trials for CERC-301 and any changes to our development plan with respect to CERC-301, if any;
- our plan and ability to enter into collaborative agreements for the development and commercialization of our product candidates;
- the scope, progress, results and costs of researching and developing our product candidates or any future product candidates, both in the United States and in territories outside the United States;
- the costs, timing and outcome of regulatory review of our product candidates or any future product candidates, both in the United States and in territories outside the United States;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution for any of our product candidates for which we receive marketing approval;
- the costs and timing of any product candidate acquisition or in-licensing opportunities;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel;
- the profits, if any, received from commercial sales of our product candidates for which we receive marketing approval; and
- the costs involved in preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending our intellectual property-related claims, both in the United States and in territories outside the United States

Please refer to the section entitled “Risk Factors” at Item 1A of this Annual Report on Form 10-K for additional risks associated with our substantial capital requirements.

Contractual Obligations and Commitments

The following is a summary of our long-term contractual cash obligations as of December 31, 2017 (in thousands):

Contractual Obligation(1)	Total	Less than one year	1 - 3 years	More than 3 years
Debt obligations (2)	$ —	$ —	$ —	$ —
Operating lease obligations (3)	159	159	—	—
Total contractual obligations	$ 159	$ 159	$ —	$ —

(1) This table does not include any contingent milestone or royalty payments that may become payable to third parties under license agreements because the timing and likelihood of such payments are not known.

(2) Amount represents principal and interest cash payments over the life of the debt obligations, including anticipated interest payments that are not recorded on our balance sheet.

(3) Operating lease obligations reflect our obligations pursuant to the terms of a lease agreement entered into on August 8, 2013 for our office space located in Baltimore, Maryland.

The following have been excluded from the above table due to their contingent nature as the amounts and timing of these payments cannot be reasonably predicted:

We have entered into agreements with contract research organizations, or CROs, and other external service providers for services, primarily in connection with the clinical trials and development of our product candidates. We were contractually obligated for up to approximately $1.9 million of future services under these agreements as of December 31, 2017. Our actual contractual obligations will vary depending upon several factors, including the progress and results of the underlying services.

We have entered into licensing arrangements with various partners where we could become obligated to make certain contingent payments. Payments under these agreements generally become due and payable only upon the achievement of certain developmental, regulatory, commercial and/or other milestones. In addition, we may be required to make s ales -based royalty payments under certain arrangements if certain products are approved for marketing. Due to the fact that it is uncertain if and when these milestones will be achieved, such contingencies have not been recorded in our Consolidated Balance Sheets. For additional information about potential payments pursuant to our license agreements, see Note 11 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K.

Uncertain Tax Positions: We are unable to predict the timing of tax settlements related to our obligations for uncertain tax positions as tax audits can involve complex issues and the resolution of those issues mays pan multiple years, particularly if subject to negotiation or litigation. The Company has no current, nor has it undergone any prior, tax audits by the IRS or other jurisdictions. Accordingly, we have not included obligations for uncertain tax positions in our table of contractual obligations (see Note 15 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K).

Also excluded from t he above table are potential payments related to our first Amended and Restated Exclusive related party Ulesfia Distribution Agreement, dated December 18, 2015, by and between Zylera and Lachlan Pharmaceutical. The agreement requires that Zylera make a royalty payment to Lachlan in the amount of 15% of net sales so long as net sales remain below $50 million annually. For annual net sales above $50 million, Zylera will owe Lachlan a royalty payment of 20% of net sales, and for annual net sales over $100 million, Zylera will owe Lachlan a royalty payment of 25% of net sales. Additionally, in the event Zylera's annual net sales of the product are less than $20 million, other than as a result of a "Market Change," Zylera shall pay Lachlan an amount sufficient to make total product payments equal to the amount that would have been paid if the net sales had been equal to $20 million. The practical effect of this provision is that there is a minimum annual royalty payment of $3,000,000. Zylera has asserted that a "Market Change" has occurred pursuant to the terms of this agreement and litigation is pending with respect to that assertion). There are also certain milestone payments which become payable upon the achievement of certain cumulative net sales milestones. Upon the achievement of cumulative net sales amounting to $90,000,000; $180,000,000; $270,000,000; and $400,000,000, Zylera will owe Lachlan payments of $3,000,000; $3,500,000; $4,000,000; and $5,000,000, respectively. Zylera is obligated to purchase a minimum of 20,000 units per year, or approximately $1,177,000 worth of product; however, the minimum purchase requirements are void upon the earliest of: (i) Lachlan's failure to fulfill Zylera's purchase orders for two consecutive quarters or any three quarters in a 12-month period; (ii) the first commercial sale of a generic version of the product, or (iii) termination

of the agreement. The purchase price for fully packaged product is the greater of a contractually agree upon price (subject to de minimis annual increases) or 20% of the prior year's net sales divided by the number of units sold in the prior year.

On December 10, 2016, Zylera informed Lachlan that a market change had occurred due to the introduction of Arbor Pharmaceutical's lice product, Sklice®. According to the terms of the distribution agreement if there is a market change, the minimum purchase obligation is void. On June 5, 2017, Lachlan and Zylera entered into joint legal representation along with other unrelated third parties in negotiation and arbitration of dispute with Summers Laboratory, Inc regarding the an ongoing arbitration proceeding with the ultimate recipient of the royalties over whether a Market Change has occurred. The Company has not made any payments to Lachlan in 2017 under the Lachlan Agreement (from the acquisition date through year-end).

Off-Balance Sheet Arrangements

We do 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, 2017, 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, 2017.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

We maintain a short-term investment portfolio consisting mainly of highly liquid short-term money market funds, which we consider to be cash equivalents. These investments earn interest at variable rates and, as a result, decreases in market interest rates would generally result in decreased interest income. We do not believe that a 10% increase or decrease in interest rates would have a material effect on the fair value of our investment portfolio due to the short-term nature of these instruments, and accordingly we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

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.

Notwithstanding the identified material weakness described below, management does not believe that these deficiencies had an adverse effect on the company's reported operating results or financial condition and management has determined that the financial statements and other information included in this report and other periodic filings present fairly in all material respects the company's financial condition, results of operations and cash flows at and for the periods presented in accordance with accounting principles generally accepted in the United States ("GAAP").

Our assessment of the effectiveness of our internal control over financial reporting as of December 31, 2017 did not include an assessment of the effectiveness of internal control over financial reporting of TRx Pharmaceuticals, which was acquired on November 17, 2017. The operating results of TRx are included in our consolidated financial statements from the period subsequent to the acquisition date and, excluding goodwill and intangible assets, include $3.5 million of assets as of December 31, 2017, and $2.2 million in net sales for the year then ended. We will include TRx in our 2018 annual assessment of internal control over financial reporting.

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 U.S. 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 U.S. 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, 2017, 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 the company had the following material weakness in its internal control over financial reporting.

Management determined that the company's internal controls were not adequately designed to prevent or timely detect unauthorized cash disbursements. Specifically, certain member's of the finance organization failed to exercise appropriate skepticism and oversight for disbursement of company-owned funds. Management has taken immediate action to begin remediating the material weakness. Management expects to complete the remediation during the first quarter of 2018.

Because of the material weakness, the company's Chief Executive Officer and Chief Financial Officer concluded that the company did not maintain effective internal control over financial reporting as of December 31, 2017. The material weakness did not result in a material misstatement of the company's consolidated financial statements.

Changes in Internal Control Over Financial Reporting

The Company has increased its cash disbursement controls to prevent and timely detect unauthorized cash disbursements beginning in the fourth quarter of 2017. The company believes these changes will improve its financial reporting with respect to our operations, which has materially affected, or is reasonably likely to materially affect, on 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 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, 2017 in connection with our 2018 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 and 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*. See the Exhibit Index and Exhibits filed as part of this report.

EXHIBIT INDEX

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, by and among Cerecor, Inc. and Janssen Pharmaceuticals (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).
3.1	Amended and Restated Certificate of Incorporation of Cerecor Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on October 20, 2015).
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).
3.2	Amended and Restated Bylaws of Cerecor Inc. (incorporated by reference to Exhibit 3.2 to Amendment No. 1 to the Current Report on Form 8-K filed on October 20, 2015).

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).
4.9	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).
4.10	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).
4.11	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).
4.12	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).
4.13	Specimen Unit Certificate (incorporated by reference to Exhibit 4.13 to the Registration Statement on Form S-1 filed on October 13, 2015).
4.14	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).
4.15	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).
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 +	Cerecor Inc. 2011 Stock Incentive Plan, as amended, including forms of Incentive Stock Option Agreements and Nonqualified Stock Option Agreements thereunder (incorporated by reference to Exhibit 10.4 to the Registration Statement on Form S-1 filed on June 12, 2015).
10.5 +	Cerecor Inc. 2015 Omnibus Incentive Plan, including form of Nonqualified Stock Option Agreements thereunder (incorporated by reference to Exhibit 10.5 to the Registration Statement on Form S-1 filed on September 8, 2015).
10.6 +	Offer Letter Agreement by and between Cerecor Inc. and John Kaiser, dated as of September 12, 2012 (incorporated by reference to Exhibit 10.7 to the Registration Statement on Form S-1 filed on June 12, 2015).
10.7 +	Offer Letter Agreement by and between Cerecor Inc. and James Vornov, dated as of September 18, 2012 (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form S-1 filed on June 12, 2015).
10.8 +	Offer Letter Agreement by and between Cerecor Inc. and Ronald Marcus, dated as of May 5, 2015 (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form S-1 filed on June 12, 2015).
10.8.1+	Amendment to Offer Letter Agreement by and between Cerecor Inc. and Ronald Marcus, effective as of March 9, 2017.
10.9 +	Offer Letter Agreement by and between Cerecor Inc. and Uli Hacksell, dated as of May 20, 2015 (incorporated by reference to Exhibit 10.10 to the Registration Statement on Form S-1 filed on June 12, 2015).
10.10 +	Offer Letter Agreement by and between Cerecor Inc. and Mariam Morris, effective as of August 24, 2015 (incorporated by reference to Exhibit 10.11 to the Registration Statement on Form S-1 filed on September 8, 2015).
10.10.1+	Amendment to Offer Letter Agreement by and between Cerecor Inc. and Mariam Morris, effective as of March 9, 2017.
10.11 +	Employment Agreement by and between Cerecor Inc. and Uli Hacksell, effective January 1, 2016 (incorporated by reference to Exhibit 10.11 to the Annual Report on Form 10-K filed on March 23, 2016).
10.12 +	Separation Agreement by and between Cerecor Inc. and Blake Paterson, effective January 9, 2016 (incorporated by reference to Exhibit 10.12 to the Annual Report on Form 10-K filed on March 23, 2016).
10.13 +	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).
10.14	List of current directors with a Director Indemnification Agreement in the form provided as Exhibit 10.12 (incorporated by reference to Exhibit 10.13 to the Registration Statement on Form S-1 filed on September 8, 2015).

10.15	Lease Agreement by and between Cerecor Inc. and PDL Pratt Associates, LLC, dated as of August 8, 2013 (incorporated by reference to Exhibit 10.14 to the Registration Statement on Form S-1 filed on June 12, 2015).
10.16	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).
10.17	Non-Employee Director Compensation Plan (incorporated by reference to Exhibit 10.17 to the Annual Report on Form 10-K filed on March 23, 2016).
10.18 +	Cerecor Inc. 2016 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on May 20, 2016).
10.19 +	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).
10.20	Common Stock Purchase Agreement, dated as of September 8, 2016, by and between Aspire Capital Fund, LLC and Cerecor Inc. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on September 12, 2016).
10.21 #	Exclusive License Agreement, dated as of September 22, 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).
10.21.1	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).
10.22	Equity Distribution Agreement, dated as of January 27, 2017, by and between Cerecor Inc. and Maxim Group LLC (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on January 27, 2017).
10.23#	Securities Purchase Agreement, dated as of April 28, 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).
10.24	Registration Rights Agreement, dated as of April 28, 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).
10.25+	Employment Agreement by and between Cerecor Inc. and Robert C. Moscato, Jr., effective November 21, 2017.
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 Annual Report 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.

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: April 2, 2018

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)	April 2, 2018
/s/ Mariam E. Morris **Mariam E. Morris**	Chief Financial Officer (Principal Financial and Accounting Officer)	April 2, 2018
/s/ Uli Hacksell **Uli Hacksell**	Chairman of the Board	April 2, 2018
/s/ Isaac Blech **Isaac Blech**	Director	April 2, 2018
/s/ Phil Gutry **Phil Gutry**	Director	April 2, 2018
/s/ Magnus Persson **Magnus Persson**	Director	April 2, 2018
/s/ Steven J. Boyd **Steven J. Boyd**	Director	April 2, 2018
/s/ Robert C. Moscato **Robert C. Moscato**	Director	April 2, 2018
/s/ Randal Jones **Randal Jones**	Director	April 2, 2018

Item 16. 10K Summary

None.

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, 2017 and 2016, the related consolidated statements of operations, convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2017, 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, 2017 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, 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
April 2, 2018

CERECOR INC. and SUBSIDIARIES

Consolidated Balance Sheets

	December 31,	
	2017	**2016**
Assets		
Current assets:		
Cash and cash equivalents	$ 2,472,187	$ 5,127,958
Accounts receivable, net	3,252,212	132,472
Other receivables	427,241	—
Escrowed cash receivable	3,752,390	—
Inventory, net	382,153	—
Prepaid expenses and other current assets	703,225	391,253
Restricted cash—current portion	1,959	11,111
Total current assets	10,991,367	5,662,794
Property and equipment, net	44,612	43,243
Intangibles assets, net	17,664,480	—
Goodwill	14,292,282	—
Restricted cash, net of current portion	131,353	62,828
Total assets	$ 43,124,094	$ 5,768,865
Liabilities and stockholders' equity		
Current liabilities:		
Term debt, net of discount	$ —	$ 2,353,667
Accounts payable	1,298,980	1,010,209
Accrued expenses and other current liabilities	7,848,309	947,987
Income taxes payable	2,259,148	—
Total current liabilities	11,406,437	4,311,863
Contingent consideration	2,576,633	—
Deferred tax liability	7,144	—
License obligations	1,250,000	1,250,000
Long term liabilities - other	24,272	—
Total liabilities	15,264,486	5,561,863
Stockholders' equity:		
Preferred stock—$0.001 par value; 5,000,000 and zero shares authorized at December 31, 2017 and 2016, respectively; zero shares issued and outstanding at December 31, 2017 and 2016	—	—
Common stock—$0.001 par value; 200,000,000 shares authorized at December 31, 2017 and 2016; 31,266,989 and 9,434,141 shares issued and outstanding at December 31, 2017 and 2016, respectively	31,268	9,434
Additional paid-in capital	83,338,136	70,232,651
Contingently issuable shares	2,655,464	—
Accumulated deficit	(58,165,260)	(70,035,083)
Total stockholders' equity	27,859,608	207,002
Total liabilities and stockholders' equity	$ 43,124,094	$ 5,768,865

See accompanying notes to the consolidated financial statements.

CERECOR INC. and SUBSIDIARIES

Consolidated Statements of Operations

	Year Ended December 31,		
	2017	2016	2015
Revenues			
License and other revenue	$ 25,000,000	$ —	$ —
Product revenue, net	1,910,403	—	—
Sales force revenue	278,165	—	—
Grant revenue	624,569	1,152,987	—
Total revenues, net	27,813,137	1,152,987	—
Operating expenses:			
Cost of product sales	635,648	—	—
Research and development	4,372,578	10,149,879	6,587,183
General and administrative	7,941,584	7,083,155	4,422,764
Sales and marketing	973,345	—	—
Total operating expenses	13,923,155	17,233,034	11,009,947
Income (loss) from operations	13,889,982	(16,080,047)	(11,009,947)
Other income (expense):			
Change in fair value of warrant liability, unit purchase option liability and investor rights obligation	(29,624)	72,625	1,313,049
Interest expense, net	(24,016)	(464,181)	(793,205)
Total other (expense) income	(53,640)	(391,556)	519,844
Net income (loss) before taxes	13,836,342	(16,471,603)	(10,490,103)
Income tax expense	1,966,519	—	—
Net income (loss) after taxes	$ 11,869,823	$ (16,471,603)	$ (10,490,103)
Net income (loss)	$ 11,869,823	$ (16,471,603)	$ (10,490,103)
Net income (loss) attributable to common stockholders	$ 7,772,084	$ (16,471,603)	$ (10,490,103)
Net income (loss) per share of common stock, basic	$ 0.42	$ (1.87)	(4.71)
Net income (loss) per share of common stock, diluted	$ 0.42	$ (1.87)	(4.71)
Weighted-average shares of common stock outstanding, basic	18,410,005	8,830,396	2,226,023
Weighted-average shares of common stock outstanding, diluted	18,754,799	8,830,396	2,226,023

See accompanying notes to the consolidated financial statements.

CERECOR INC. and SUBSIDIARIES

Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

For the Period from January 1, 2015 to December 31, 2017

	Series A, A-1 and B convertible preferred stock		Stockholders' Equity (Deficit)					
			Common stock		Additional paid-in	Contingently issuable stock	Accumulated	Total stockholders' equity
	Shares	Amount	Shares	Amount	capital	Amount	deficit	(deficit)
Balance, January 1, 2015	99,139,637	$28,345,531	649,721	$ 650	$16,742,063	$ —	$(43,073,377)	$(26,330,664)
Issuance of securities in initial public offering, including over-allotment and underwriters' unit purchase option, net of offering costs and underwriting discounts, commissions and expenses	—	—	4,020,000	4,020	21,161,569	—	—	21,165,589
Issuance of common stock for conversion of preferred stock upon closing of initial public offering	(99,139,637)	(28,345,531)	3,980,422	3,980	28,340,177	—	—	28,344,157
Stock-based compensation	—	—	—	—	394,748	—	—	394,748
Net loss	—	—	—	—	—	—	(10,490,103)	(10,490,103)
Balance, December 31, 2015	—	$ —	8,650,143	$ 8,650	$66,638,557	—	$(53,563,480)	$ 13,083,727
Issuance of common stock from sale of shares under common stock purchase agreement, net of offering costs	—	—	763,998	764	1,899,223	—		1,899,987
Shares purchased through employee stock purchase plan	—	—	20,000	20	(20)	—	—	—
Stock-based compensation	—	—	—	—	1,694,891	—	—	1,694,891
Net loss	—	—	—	—	—	—	(16,471,603)	(16,471,603)
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	—	4	2,345,714	2,346	4,559,308	—	—	4,561,654
Conversion of Armistice Capital preferred to common stock	—	(4)	11,940,000	11,940	(11,936)	—	—	4
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
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

See accompanying notes to the consolidated financial statements.

CERECOR INC. and SUBSIDIARIES

Consolidated Statements of Cash Flows

	Year Ended December 31,		
	2017	2016	2015
Operating activities			
Net income (loss)	$ 11,869,823	$ (16,471,603)	$ (10,490,103)
Adjustments to reconcile net income (loss) provided by (used in) to net cash used in operating activities:			
Depreciation and amortization	425,476	26,856	23,508
Stock-based compensation expense	1,157,252	1,694,891	394,748
Deferred taxes	(832,629)	—	—
Amortization of inventory fair value adjustment associated with acquisition of TRx	137,900	—	—
Change in inventory reserve	178,346	—	—
Non-cash interest expense	20,364	162,270	293,748
Change in fair value of warrant liability, unit purchase option liability and investor rights obligation	29,624	(72,625)	(1,313,049)
Changes in assets and liabilities:			
Accounts receivable, net	(247,195)	(132,472)	—
Other receivables	(427,241)	—	—
Inventory, net	(202,622)	—	—
Prepaid expenses and other assets	(177,691)	22,047	(41,243)
Escrowed cash receivable	(3,752,390)	—	—
Restricted cash	(59,373)	(15,107)	116,666
Accounts payable	96,065	332,100	(268,709)
Income taxes payable	2,259,148	—	—
Accrued expenses and other liabilities	2,044,548	(119,495)	1,121,054
Net cash provided by (used in) operating activities	12,519,405	(14,573,138)	(10,163,380)
Investing activities			
Acquisition of business, net of cash acquired	(18,888,932)	—	—
Purchase of property and equipment	(23,325)	(34,883)	(19,984)
Net cash used in investing activities	(18,912,257)	(34,883)	(19,984)
Financing activities			
Proceeds from ESPP stock sales	46,861	—	—
Proceeds from Armistice Capital transaction	4,649,996	—	—
Proceeds from sale of shares under common stock purchase agreement	1,693,498	2,003,182	
Principal payments on term debt	(2,374,031)	(3,314,225)	(1,811,744)
Payment of fractional shares upon conversion of preferred stock to common stock	4	—	(1,373)
Proceeds from initial public offering, including over-allotment, net of underwriting discounts, commissions and expenses	—	—	23,685,270
Payment of offering costs	(279,247)	(114,945)	(2,269,171)
Net cash provided by (used in) financing activities	3,737,081	(1,425,988)	19,602,982
(Decrease) increase in cash and cash equivalents	(2,655,771)	(16,034,009)	9,419,618
Cash and cash equivalents at beginning of period	5,127,958	21,161,967	11,742,349
Cash and cash equivalents at end of period	$ 2,472,187	$ 5,127,958	$ 21,161,967
Supplemental disclosures of cash flow information			
Cash paid for interest	$ 72,526	$ 348,888	$ 568,299
Cash paid for taxes	$ 540,000	$ —	$ —
Supplemental disclosures of non-cash financing activities			
Issuance of common stock in TRx acquisition	$ 5,858,955	$ —	$ —
Contingently issuable shares in TRx acquisition	$ 2,655,464	$ —	$ —

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, 2017 and 2016

1. Business

We are a biopharmaceutical company with the near-term goal of becoming a self-sustained, integrated pharmaceutical company that is focused on pediatric healthcare. We have a diverse portfolio of products and product candidates in development with a focus on patients with rare neurological and psychiatric disorders. The Company's pipeline is led by CERC-301, which Cerecor currently intends to explore as a novel treatment for orphan neurological indications. The Company is also developing three preclinical stage compounds, CERC-611,CERC-406 and CERC-425.

We were incorporated in 2011 and commenced operations in the second quarter of 2011.In August 2017, we sold our 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 certain indemnification obligations to Janssen, as well as a potential future $20 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. On November 17, 2017, we acquired TRx Pharmaceuticals, LLC (“TRx”) and its wholly-owned subsidiaries (see Acquisition of TRx Pharmaceuticals for a description of the transaction).

On February 16, 2018, we purchased and acquired all rights to Avadel Pharmaceuticals PLC’s (“Advadel's)”) marketed pediatric products (the “Acquired Products”) for the assumption of certain of Avadel's financial obligations to Deerfield CSF, LLC, which includes a $15 million loan due in January 2021 and its related interest payments as well as a 15% annual royalty on net sales of the Acquired Products through February 2026.

Liquidity

For the year ended December 31, 2017, the Company generated net income of $11.9 million and positive cash flows from operations of $12.5 million. Prior to the year ended December 31, 2017, the Company had incurred recurring operating losses since inception. As a result of the TRx and Avadel acquisitions, our commercial operations are expected to generate positive cash flows from product sales.

As of December 31, 2017, the Company had an accumulated deficit of $58.2 million and a balance of $2.5 million in cash and cash equivalents. The Company anticipates generating positive cash flows from our commercial operations to offset costs related to its preclinical programs, additional clinical development of its product candidates, business development and costs associated with its organizational infrastructure. We apply a disciplined decision making methodology as we evaluate the optimal allocation of our resources between investing in our current commercial product line, our development portfolio and acquisitions or in-licensing of new assets.The Company, however, may require additional financing to continue to execute its clinical development strategy. The Company plans to meet its capital requirements primarily through a combination of equity or debt financings, collaborations, or out-licensing arrangements, strategic alliances, federal and private grants, marketing, distribution or licensing arrangements and in the longer term, revenue from product sales to the extent its product candidates receive marketing approval and are commercialized.

The Company expects its cash on hand at December 31, 2017 and its cash flows from operations to fund future expenses through at least April 2, 2019.

2. Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity 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 (“FASB”).

Principles of Consolidation

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

Variable Interest Entities

The primary beneficiary of a variable interest entity (VIE) must consolidate the related assets and liabilities. Certain disclosures are required by sponsors, significant interest holders in VIE's and potential VIE's. The Company regularly assesses its relationships with contractual third party and other entities for potential VIE's. In making this assessment, the Company considers the potential that its contracts or other arrangements provide subordinated financial support, absorb losses or rights to residual returns of the entity and the ability to directly or indirectly make decisions about the entities' activities. Based on the Company's assessments performed, management concluded that there were no relationships that constitute a VIE for which the Company was determined to be the primary beneficiary at December 31, 2017. If the Company's management makes the determination that it is the primary beneficiary of a VIE, the Company will consolidate the statements of operations and financial condition of the VIE into its consolidated financial statements.

Fair Value Measurements

Fair value is a market-based measurement, not an entity-specific measurement. The objective of a fair value measurement is to estimate the price to sell an asset or transfer a liability in an orderly transaction between market participants at the measurement date under current market conditions. Such transactions to sell an asset or transfer a liability are assumed to occur in the principal market for that asset or liability, or in the absence of the principal market, the most advantageous market for the asset or liability.

Assets and liabilities subject to fair value measurement disclosures are required to be classified according to a three-level fair value hierarchy with respect to the inputs (or assumptions) used to determine fair value. The level in which an asset or liability is disclosed within the fair value hierarchy is based on the lowest level input that is significant to the related fair value measurement in its entirety. The guidance under the fair value measurement framework applies to other existing accounting guidance in the Financial Accounting Standards Board (FASB) codification that requires or permits fair value measurements. Refer to related disclosures in Note 5-Fair Value Measurements.

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, share-based compensation, fair value measurements (including those relating to contingent consideration), 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.

Net Income (Loss) per Share, Basic and Diluted

Earnings per share are computed using the two-class method. The two-class method of computing earnings per share is an earnings allocation formula that determines earnings per share for common stock and any participating securities according to dividends declared (whether paid or unpaid) and participation rights in undistributed earnings. Shares of the unexercised warrants issued in the Armistice Private Placement transaction are considered participating securities because these warrants contain a non-forfeitable right to dividends irrespective of whether the warrants are ultimately exercised. Under the two-class method, earnings per common share for the common 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 and participating warrants based on the weighted-average shares outstanding during the period.

Diluted net income (loss) 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 issued under the Company's Long-Term Incentive Plans 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) 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, net losses are not allocated to the participating securities.

Contingently issuable shares are included in the calculation of basic income (loss) per share as of the beginning of the period in which all the necessary conditions have been satisfied. Contingently issuable shares are included in diluted net income (loss) per share based on the number of shares, if any, that would be issuable under the terms of the arrangement if the end of the reporting period was the end of the contingency period, if the results are dilutive.

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 $25.0 million, of which $3.75 million was deposited into a twelve month escrow to secure certain indemnification obligations to Janssen Pharmaceuticals, Inc. The Company evaluates its escrowed cash receivable balance each reporting period and establishes a reserve for amounts deemed uncollectible. No reserve was recorded as of December 31, 2017.

Restricted Cash

The Company established the Employee Stock Purchase Plan in 2016. Eligible employees can purchase common stock through accumulated payroll deductions at such times as are established by the Plan administrator. At December 31, 2017, approximately $2,000 of deposits had been made by employees for potential future stock purchases.

In 2016 the Company entered into a bank services pledge agreement with Silicon Valley Bank. In exchange for receiving business credit card services from Silicon Valley Bank, the Company deposited $50,000 as collateral with Silicon Valley Bank. This amount will remain deposited with Silicon Valley Bank for the duration the business credit card services are used by the Company. In addition, the Company has deposited $13,000 with the landlord of the Company's office space as a security deposit. These deposits are recorded as restricted cash, net of current portion on the balance sheet at December 31, 2017 and 2016.

Accounts Receivable, net

Accounts receivable at December 31, 2017 are comprised of amounts due from customers in the ordinary course of business. Management considers all accounts receivable to be fully collectible at December 31, 2017, 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 which has a balance of $57,705 at December 31, 2017.

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 of finished goods acquired through the Purchase Agreement with TRx on November 17, 2017, and is 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.

Shipping, Handling, and Freight

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

Debt and Equity Issuance Costs

The Company may record debt and equity discounts in connection with raising funds through the issuance of convertible notes or equity instruments. These discounts may arise from (i) the receipt of proceeds less than the face value of the convertible notes or equity instruments, (ii) allocation of proceeds to beneficial conversion features and/or (iii) recording derivative liabilities related to embedded features. For debt instruments, these costs are amortized over the life of the debt to interest expense utilizing the effective interest method. For equity instruments, these costs are netted against the gross proceeds received from the issuance of the equity.

Property and Equipment

Property and equipment consists of computers, office equipment, and furniture 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. 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.

Goodwill

Goodwill relates to the amount that arose in connection with the acquisition of TRx. 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.

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 may not be recoverable. Impairment losses are measured and recognized to the extent the carrying value of such assets exceeds their fair value. The Company recorded no impairment losses during the year ended December 31, 2017.

Contingent Consideration

The Company’s TRx acquisition involves the potential for future payment of consideration that is contingent upon the achievement of operational and commercial milestones. The preliminary fair value of contingent consideration liabilities was determined at the acquisition date using unobservable level 3 inputs. These inputs include 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 current fair value with changes recorded in the consolidated statements of operations. Changes in any of the inputs may result in a significantly different fair value adjustment.

License and Other Revenue

The Company recognizes revenues from collaboration, license or other research or sale arrangements when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collectability is reasonably assured. Revenue from potential future milestones, if substantive, is recognized when the milestone is achieved and the payment is due and collectible. The sale of the CERC-501 license to Janssen Pharmaceuticals, Inc. in August 2017 was the sole source of license and other revenue.

Grant Revenue

The Company recognizes grant revenue when there is (i) reasonable assurance of compliance with the conditions of the grant and (ii) reasonable assurance that the grant will be received. In April 2016, the Company received a research and development grant from the National Institute on Drug Abuse ("NIDA") at the National Institutes of Health ("NIH") to provide additional resources for the period of May 2016 through April 2017 for the Company's now completed Phase 2 clinical trial for CERC-501, "*A Randomized, Double-Blind, Placebo-Controlled, Crossover Design Study of CERC-501 in a Human Laboratory Model of Smoking Behavior*." The amount of the NIDA award was $1.02 million. Additionally, in July 2016, the Company received a research and development grant from the National Institute on Alcohol Abuse and Alcoholism ("NIAAA") at the NIH to provide additional resources for the period of July 2016 through June 2017 to progress the development of CERC-501 for the treatment of alcohol use disorder. The amount of the NIAAA award was $1.0 million. The Company recognizes revenue under grants in earnings on a systemic basis in the period the related expenditures for which the grants are intended to compensate are incurred. As such, the Company recognized revenue in the amounts of $0.6 million for the year ended December 31, 2017 for the NIAAA award and $1.02 million and $132,000 for the year ended December 31, 2016 for the NIDA award and NIAAA award, respectively. As of December 31, 2016, the Company had received the full $1.02 million of the revenue earned under the NIDA award.

Product Revenues, net

Product sales revenue is recognized when title has transferred to the customer and the customer has assumed the risks and rewards of ownership, which is typically on delivery to the customer and collectability is reasonably assured. Revenue from sales transactions where the buyer has the right to return the product is recognized at the time of sale only if (i) the seller's price to the buyer is substantially fixed or determinable at the date of sale, (ii) the buyer has paid the seller, or the buyer is obligated to pay the seller and the obligation is not contingent on resale of the product, (iii) the buyer's obligation to the seller would not be changed in the event of theft or physical destruction or damage of the product, (iv) the buyer acquiring the product for resale has economic substance apart from that provided by the seller, (v) the seller does not have significant obligations for future performance to directly bring about resale of the product by the buyer, and (vi) the amount of future returns can be reasonably estimated.

Revenues from sales of products are recorded net of estimated allowances for returns, wholesaler fees, prompt payment discounts, customer coupon redemptions, government rebates, and rebates under managed care plans. Provisions for returns, specialty distributor fees, wholesaler fees, government rebates, and rebates under managed care plans are included within current liabilities in the consolidated balance sheet. Provisions for prompt payment discounts are generally shown as a reduction in 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.

Sales Force Revenue

Pursuant to a Marketing Agreement with Pharmaceutical Associates, Inc. *("PAI")*, the Company receives a monthly marketing fee to promote, market and sell certain products on behalf of PAI. The Company also receives a matching fee payment for each month of the term of the Marketing Agreement if certain provisions calculated in accordance with the terms and inputs set forth in the Marketing Agreement are met. Marketing fees and any matching payments are recognized as sale force revenue when all the performance obligations have been satisfied and earned.

The Company and PAI also share the net revenues from sales of certain products, after reimbursing certain expenditures, in a manner designed to achieve a 50/50 split of net revenues above a "break even" point, calculated in accordance with the terms and inputs set forth in the agreement. We recognize these revenue sharing payments as earned under the terms of the agreement when collectability is reasonably assured.

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; and (iv) the value of any write-offs of obsolete or damaged inventory that cannot be sold. The Company acquired the rights to sell certain of its commercial products through license and assignment agreements with the original developers or other parties with interests in these products. These agreements obligate the Company to make payments under varying payment structures based on its net revenue from related products.

Concentration with Customer

The Company sells its prescription pharmaceutical products 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 and research and development grants. In August 2017, the Company sold all of its licensing rights for a prior product candidate, CERC-501, to a third party.

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. At December 31, 2017, these top three customers represented, in the aggregate, approximately 42%, 26% and 21%, respectively, of the Company's consolidated accounts receivable balance.

The Company did not generate any product revenue for the year ended December 31, 2016.

Concentrations of Products and Sales

The Company's five prescription pharmaceutical product lines accounted for 100% of the Company's total product revenue, net for the year ended December 31, 2017.

The Company did not generate any product revenue for the year ended December 31, 2016.

Concentration with Vendor

The Company's top five vendors accounted for approximately 60% and 70% of the Company's accounts payable at December 31, 2017 and December 31, 2016, respectively.

Research and Development

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, which include direct and allocated expenses for rent, utilities and insurance; and costs associated with preclinical activities and regulatory operations.

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.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of professional fees, advertising and marketing cost and salaries, benefits and related costs for sales and sales support personnel, including stock-based compensation and travel expenses. Sales and marketing expense also includes amortization of marketing rights intangible assets acquired in the acquisition of TRx.

Comprehensive Loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss was equal to net loss for all periods presented.

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 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 net operating losses and research and development credit carryforwards, may be subject to an annual limitation under Sections 382 and 383 of the Internal Revenue Code (the "Code"). 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, 2017, the Company does not believe any material uncertain tax positions are present.

On December 22, 2017, President Trump signed into law the "Tax Cuts and Jobs Act," or TCJA, that significantly reforms the Internal Revenue Code of 1986, as amended. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest and net operating loss 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 the tax footnote below for further discussion related to the tax impact to the Company.

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 and non-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 on the board of directors, 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 options issued to non-employees, the Company initially measures the options at their grant date fair values and revalues as the underlying equity instruments vest and are recognized as expense over the earlier of the period ending with the performance commitment date or the date the services are completed in accordance with the provisions of ASC 718 and ASC 505-50, Equity-Based Payments to Non-Employees ("ASC 505-50").

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 may vary and may result in it reporting amounts that are too high or too low for any particular period. For the years ended December 31, 2017 and December 31, 2016, there were no material adjustments to the Company's prior period estimates of accrued expenses for clinical trials.

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 currently represented by the Company's management team which consists of our Chief Executive Officer, Chief Business Officer and Chief Financial Officer. The Company and the management team view the Company's operations and manage its business as one operating segment. All long-lived assets of the Company reside in the United States.

Recently Adopted Accounting Pronouncements

In October 2016, the FASB issued ASU No. 2016-17, *Consolidation (Topic 810): Interests Held through Related Parties That Are under Common Control*, which amends the consolidation guidance on how a reporting entity that is a single decision maker of a variable interest entity should treat indirect interest in the entity held through related parties that are under common control. This guidance is effective for annual periods beginning after December 15, 2016, including interim periods within those annual periods, with early adoption permitted. We adopted this standard in connection with our acquisition of TRx. The adoption of this standard did not have a material impact on our financial statements.

In March 2016, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2016-09, *Improvements to Employee Share-Based Payment Accounting*. The guidance is intended to simplify several areas of accounting for share-based compensation, classification on the statement of cash flows and forfeitures. The new standard was adopted by the Company effective January 1, 2017 and its adoption will have no impact on its financial position, results of operations or cash flows. Consistent with the update, the Company accounts for forfeitures as they occur as opposed to being estimated at the time of grant and revised. In connection with adoption, the Company has elected to account for forfeitures as they occur as opposed to being estimated at the time of grant and revised.

In July 2015, the FASB issued ASU No. 2015-11, "*Simplifying the Measurement of Inventory*" (ASU 2015-11). ASU 2015-11 states that an entity should measure inventory at the lower of cost or net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. For public entities, ASU 2015-11is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. We adopted this standard in connection with our acquisition of TRx. The adoption of this standard did not have a material impact on our consolidated financial statements and accompanying notes.

In November 2015, the FASB issued ASU 2015-17, *Income Taxes: Balance Sheet Classification of Deferred Taxes*. This ASU simplifies the presentation of deferred income taxes and requires that deferred tax liabilities and assets be classified as noncurrent amounts in the consolidated balance sheets. Such amounts were previously required to be classified as current and noncurrent assets and liabilities. The Company adopted ASU 2015-17 effective January 1, 2017. The adoption of this standard did not have a material impact on our consolidated financial statements and accompanying notes.

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09*, Revenue from Contracts with Customers* (Topic 606). Topic 606 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. Additional disclosures are required regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In addition, ASU 2014-09 defines a five-step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP. Under the new guidance, there are specific criteria to determine if a performance obligation should be recognized over time or at a point in time.

In August 2015, the FASB issued ASU No. 2015-04, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date.* The amendment in this ASU defers the effective date of ASU No. 2014-09 for all entities for one year. Public business entities should apply the guidance in ASU 2014-09 to annual reporting periods beginning December 15, 2017, including interim reporting periods within that reporting period. Earlier application is permitted only as of annual reporting periods beginning after December 31, 2016, including interim reporting periods within that reporting period.

In March 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-08, *Revenue from Contracts with Customers*. The update addresses the implementation guidance on principal versus agent considerations in ASU 2014-09. The ASU clarifies how an entity should identify the unit of accounting (i.e. the specified good or service) for the principal versus agent evaluation and how it should apply the control principle to certain types of arrangements.

Subsequently, the FASB has issued the following updates related to ASU 2014-09 and ASU No. 2016-08: ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing* (“ASU 2016-10”); ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients* (“ASU 2016-12”); ASU No. 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers* (“ASU 2016-20”); and, ASU 2017-05-*Other Income-Gains and Losses from the Derecognition of Nonfinancial Assets (Subtopic 610-20): Clarifying the Scope of Asset Derecognition Guidance and Accounting for Partial Sales of Nonfinancial Assets* (“ASU 2017-05). The Company must adopt ASU 2016-10, ASU 2016-12, ASU 2016-20 and ASU 2017-05 with ASU 2014-09 (collectively, the “new revenue standards”) effective January 1, 2018 (the “effective date”) using either a “full retrospective” approach for all periods presented in the period of adoption or a “modified retrospective” approach. On January 1, 2018, the Company adopted the new revenue standards for all contracts not completed as of the adoption date using the modified retrospective method.

The Company has completed an analysis of its existing contracts with customers and assessed the differences in accounting for such contracts under the new revenue standards compared with current revenue accounting standards. The Company has identified and implemented appropriate changes to its business policies, processes, and controls to support the adoption, recognition and disclosures under the new revenue standards. Based on the Company’s review of current customer contracts, the Company does not expect the implementation of the new revue standards to have a material quantitative impact on its consolidated financial statements as the timing of revenue recognition for product sales is not expected to significantly change. In addition, the Company does not expect a material cumulative effect adjustment to Retained earnings upon adoption of the new revenue standards on January 1, 2018.

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 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 annual reporting periods beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. The Company is currently evaluating the potential impact of the adoption of this standard on its 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. Early adoption is permitted. The Company expects to adopt this standard on January 1, 2018 and does not expect its adoption will have a significant impact on the Company’s financial statements.

In November 2016, the FASB issued ASU 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. Early application is permitted. The Company expects to adopt this standard on January 1, 2018 and does not expect its adoption will have a significant impact on the Company’s financial statements.

In October 2016, the FASB issued ASU 2016-16, “ *Income Taxes (Topic 740), Intra-Entity Transfers of Assets Other Than Inventory*,” 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 Company does not expect the adoption of ASU 2016-16 to have a significant impact on the Company’s financial statements.

In January 2017, the FASB issued ASU No. 2017-04 (ASU 2017-04) “ *Intangibles-Goodwill and Other (Topic 350)*: *Simplifying the Test for Goodwill Impairment*.” 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. Additionally, the amount of goodwill allocated to each reporting unit with a zero or negative carrying amount of net assets should be disclosed. ASU 2017-04 is effective for annual or interim goodwill impairment tests performed in fiscal years beginning after December 15, 2019; early adoption is permitted. The Company is currently evaluating the potential impact of the adoption of this standard on its financial statements.

In January 2017, the FASB issued ASU 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 expects to adopt this standard on January 1, 2018 and does not expect its adoption will have a significant impact on the Company's financial statements.

In May 2017, the FASB issued ASU 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 share-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 Company expects to adopt this standard on January 1, 2018 and does not expect its adoption will have a significant impact on the Company's financial statements.

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

The following table sets forth the computation of basic and diluted net loss per share of common stock for the years ended December 31, 2017, 2016 and 2015 which includes both classes of participating securities:

	Year ended December 31,		
Net income (loss) per share, basic and diluted calculation:	**2017**	**2016**	**2015**
Basic income (loss) per share			
Net income (loss)	$ 11,869,823	$ (16,471,603)	$ (10,490,103)
Undistributable earnings (loss) allocable to common shares	$ 7,772,084	$ (16,471,603)	$ (10,490,103)
Undistributable earnings (loss) allocable to participating warrants	$ 4,097,739	$ —	$ —
Weighted average shares, basic			
Common stock	18,410,005	8,830,396	2,226,023
Participating warrants	9,706,458	—	—
	28,116,463	8,830,396	2,226,023
Basic income (loss) per share:			
Common stock	$ 0.42	$ (1.87)	$ (4.71)
Participating warrants	$ 0.42	$ —	$ —
Diluted income (loss) per share:			
Net income (loss) attributable to common shares	$ 7,772,084	$ (16,471,603)	$ (10,490,103)
Net income (loss) reallocated	49,642	—	—
Undistributed earnings (loss) allocable to common shares	$ 7,821,726	$ (16,471,603)	$ (10,490,103)
Weighted average number of shares attributable to common shareholders - basic	18,410,005	8,830,396	2,226,023
Effect of dilutive securities:			
Stock options	61,510	—	—
Contingently issuable shares	283,284	—	—
Potentially dilutive shares	344,794	—	—
Weighted average number of shares - diluted	18,754,799	8,830,396	2,226,023
Diluted income (loss) per share	$ 0.42	$ (1.87)	$ (4.71)

The following outstanding securities at December, 31, 2017, 2016 and 2015 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive:

	December 31,		
	2017	**2016**	**2015**
Stock options	2,812,006	1,849,359	959,188
Non-participating warrants on common stock	4,661,145	7,400,934	7,400,934
Underwriters' unit purchase option	40,000	40,000	40,000

4. Acquisition

On November 17, 2017, Cerecor Inc. (the “Company”) entered into, and consummated the transactions contemplated by, an Equity Interest Purchase Agreement (the “Purchase Agreement”) by and among the Company, TRx Pharmaceuticals, LLC, a North Carolina limited liability company (“TRx”), Fremantle Corporation and LRS International LLC, the selling members of TRx (collectively, the “Sellers”) which agreement provided for the purchase of all of the equity and ownership interests of TRx by the Company. The consideration for the 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 and certain Contingent Payments, if any become payable. Upon closing, the Company issued 5,184,920 shares of our common stock. Pursuant to the Purchase Agreement, the issuance of the remaining 2,349,968 shares as a part of the Equity Consideration is subject to stockholder approval and entirely contingent upon gaining such stockholder approval. These shares have been recorded within stockholder's equity on the consolidating balance sheet date. As a result of the TRx acquisition, the Company recorded goodwill of $14.3 million, of which $9.2 million was deducible for income taxes.

The acquisition-date fair value of the consideration transferred is as follows:

	At November 17, 2017
Cash	$ 18,900,000
Common stock (including contingently issuable shares)	8,514,419
Contingent payments	2,576,633
Total consideration transferred	$ 29,991,052

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 leveraging TRx's R&D, intellectual property, and processes.

The following table summarizes the preliminary fair values of the assets acquired and liabilities assumed at the date of acquisition:

	At November 17, 2017
Fair value of assets acquired:	
Current assets:	
Cash and cash equivalents	$ 11,068
Accounts receivable, net	2,872,545
Inventory	495,777
Prepaid expenses and other current assets	134,281
Identifiable intangible assets	
Acquired product marketing rights - Metafolin	10,465,000
PAI sales and marketing agreement	2,334,000
Acquired product marketing rights - Millipred	4,714,000
Acquired product marketing rights - Ulesfia	555,000
Total assets acquired	21,581,671
Fair value of liabilities assumed:	
Accounts payable	192,706
Accrued expenses and other current liabilities	4,850,422
Deferred tax liability	839,773
Total liabilities assumed	5,882,901
Total identifiable net assets	15,698,770
Fair value of consideration transferred	29,991,052
Goodwill	$ 14,292,282

Based on valuation estimates utilizing the income approach, a step-up in the value of inventory of $0.2 million was recorded in the opening balance sheet, of which approximately $138,000 was charged to cost of goods sold during the post-acquisition period, November 18, 2017 through December 31, 2017.

The purchase price allocation has been prepared on a preliminary basis and is subject to change as additional information becomes available concerning the fair value and tax basis of the assets acquired and liabilities assumed. Any adjustments to the purchase price allocation will be made as soon as practicable but no later than one year from the November 17, 2017 acquisition date.

The intangible assets acquired included a sales and marketing agreement with an estimated useful life of two years; and the product marketing rights to Metafolin, Millipred, and Ulesfia, which are estimated to have useful lives of fifteen, four, and three years, respectively. The fair values of intangible assets, including product marketing rights, 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 preliminary fair value of intangible assets includes the following:

	At November 17, 2017
Acquired product marketing rights - Metafolin	$ 10,465,000
PAI Sales & Marketing Agreement	2,334,000
Acquired product marketing rights - Millipred	4,714,000
Acquired product marketing rights - Ulesfia	555,000
Fair value of identified intangible assets	**$ 18,068,000**

Pro Forma Impact of Business Combinations

The following supplemental unaudited pro forma information presents Cerecor's financial results as if the acquisition of TRx had occurred on January 1, 2016:

	Years Ended December 31,	
	2017	2016
Total revenues, net	$ 43,602,212	$ 19,586,923
Net income	$ 14,564,584	$ (19,499,137)

5. Fair Value Measurements

ASC 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.

At December 31, 2017 and 2016, the Company's financial instruments included cash and cash equivalents, restricted cash, accounts payable, accrued expenses and other current liabilities, long term debt, the term loan warrant liability and the underwriters' unit purchase option liability. The carrying amounts reported in the accompanying consolidated financial statements for cash and cash equivalents, restricted cash, accounts payable, and 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 debt of $2.4 million as of December 31, 2016 was based on current interest rates for similar types of borrowings and is in Level 2 of the fair value hierarchy.

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, 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

	December 31, 2016 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*	$ 4,758,539	$ —	$ —
Liabilities			
Warrant liability	$ —	$ —	$ 5,501
Unit purchase option liability	$ —	$ —	$ 51

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

Level 3 Valuation

The Company's TRx acquisition (see Note 4) involves the potential for future payment of consideration that is contingent upon the achievement of operational and commercial milestones. The fair value of contingent consideration is determined using unobservable inputs. These inputs include 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 current fair value with changes recorded in the Company's consolidated statements of operations. Changes in any of the inputs may result in a significantly different fair value adjustment.

The warrant liability (which relates to warrants to purchase shares of common stock) is marked-to-market each reporting period with the change in fair value recorded to other income (expense) 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, 2017, include (i) volatility of 55%, (ii) risk free interest rate of 1.96%, (iii) strike price ($8.40), (iv) fair value of common stock ($3.20), and (v) expected life of 2.8 years.

The underwriters' unit purchase option (the "UPO") was issued to the underwriters of the Company's initial public offering ("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 (see Note 9 for additional information on the UPO). 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 (expense) 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 within a Monte Carlo simulation model framework. The significant assumptions used in preparing the simulation model for valuing the UPO as of December 31, 2017, include (i) volatility range of 40% to 50%, (ii) risk free interest rate range of 1.28% to 2.17%, (iii) unit strike price ($7.48), (iv) underwriters' Class A warrant strike price ($5.23), (v) underwriters' Class B warrant strike price ($4.49), (vi) fair value of underlying equity ($3.20), and (vii) optimal exercise point of immediately prior to the expiration of the underwriters' Class B warrants, which occurred on April 20, 2017.

The investor rights obligation expired in October 2015 upon the closing of the Company's IPO. While outstanding, the investor rights obligation was remeasured at each reporting period and changes in fair value were recorded as a component of other income (expense) in the Company's statements of operations. The fair value of the investor rights obligation was determined using a valuation model, which considered the probability of achieving certain milestones, the entity's cost of capital, the estimated period the rights were to be outstanding, consideration received for the instrument with the rights, the number of shares to be issued to satisfy the rights, the price of such shares and any changes in the fair value of the underlying instrument.

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 investor rights obligation for the years ended December 31, 2017 and 2016:

	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

	Warrant liability	Unit purchase option liability	Investor rights obligation	Total
Balance at December 31, 2015	$ 27,606	$ 50,571	$ —	$ 78,177
Change in fair value	(22,105)	(50,520)	—	(72,625)
Balance at December 31, 2016	$ 5,501	$ 51	$ —	$ 5,552

No other changes in valuation techniques or inputs occurred during the years ended December 31, 2017 and 2016. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the years ended December 31, 2017 and 2016. There was no change in the fair value of contingent consideration between date of the TRx acquisition and December 31, 2017.

At December 31, 2017, the fair value of the contingent consideration is unchanged as there were no significant changes in the assumptions from the period between November 17, 2017 and December 31, 2017.

6. Inventory

Inventory consists of finished goods acquired through the Purchase Agreement with TRx on November 17, 2017, and is stated at the lower of cost or net realizable value with cost determined on a first-in, first-out basis. As of December 31, 2017 the Company's finished goods inventory totaled $382,153 which is net of reserves for excess and obsolete inventory totaling $178,346. During the year ended December 31, 2017, the Company recorded a related charge to cost of goods sold for obsolete inventory of $178,346. The Company did not record any reserves for excess and obsolete inventory during the year ended December 31, 2016.

7. Property and Equipment

Property and equipment as of December 31, 2017 and 2016 consisted of the following:

	December 31,	
	2017	2016
Furniture and equipment	$ 58,126	$ 58,126
Computers and software	96,133	72,808
Total property and equipment	154,259	130,934
Less accumulated depreciation	(109,647)	(87,691)
Property and equipment, net	$ 44,612	$ 43,243

Depreciation expense was $21,956 and $26,856 for the years ended December 31, 2017 and December 31, 2016, respectively.

8. Goodwill

The below table reflects Goodwill acquired through the Purchase Agreement with TRx on November 17, 2017. Changes in the carrying amount of goodwill for the year ended December 31, 2017 was as follows:

Goodwill balance at December 31, 2016	$ —
Goodwill from acquisition of TRx Pharmaceuticals	14,292,282
Goodwill balance at December 31, 2017	$ 14,292,282

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

9. Intangible Assets

The below table reflects intangible assets acquired through the Purchase Agreement with TRx on November 17, 2017. For the year ended December 31, 2017, changes in the gross carrying amount of intangible assets consisted of the following:

Intangible assets at December 31, 2016	$ 0
Intangible assets from acquisition of TRx Pharmaceuticals	18,068,000
Intangible assets at December 31, 2017	$ 18,068,000

The following is a summary intangible assets held by the Company at:

	December 31, 2017			
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Weighted-Avg.Remaining Life
				(in years)
Acquired product marketing rights	$ 15,734,000	$ 257,645	$ 15,476,355	11.2
Sales and marketing agreement	2,334,000	145,875	2,188,125	1.9
Total Intangible Assets	$ 18,068,000	$ 403,520	$ 17,664,480	

Amortization expense was $403,520 for the year ended December 31, 2017. There was no amortization expense for the year ended December 31, 2016

The estimated aggregate amortization of intangible assets based on the preliminary values assigned as of December 31, 2017, for each of the five succeeding years and thereafter is as follows:

For the Years Ending December 31,	Estimated Amortization Expense
2018	$ 3,228,167
2019	3,082,292
2020	2,038,030
2021	1,728,867
2022	697,667
Thereafter	6,889,457
Total amortization expense	$ 17,664,480

10. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities as of December 31, 2017 and 2016 consisted of the following:

	December 31,	
	2017	2016
Sales returns and allowances	$ 4,146,217	$ —
Compensation and benefits	1,401,514	272,601
General and administrative	1,001,454	160,116
Royalties payable	743,010	—
Research and development expenses	299,480	315,937
Other	256,634	—
Accrued interest	—	193,781
Total accrued expenses and other current liabilities	$ 7,848,309	$ 942,435

11. License 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, 2017. 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 & Cie ("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-ViFlor" trademarks and agreed not to oppose TRx's seeking the marks Poly-Vi-Flor and Tri-ViFlor in the United States and in any other countries where Mead Johnson does not have an active rregistration 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 PolyVi-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 and Veripred Related Contracts

Marketing Agreement between Pharmaceutical Associates, Inc. ("PAI"), and TRx and TRx Corp., effective April 1, 2017

TRx entered into a Marketing Agreement with PAI, effective April 1, 2017. Under the agreement, TRx will promote, market and sell PSP 10 and PSP 20 on behalf of PAI. TRx agrees to maintain the size of its current sales force, 16 salespersons, to perform the services under the agreement. Assuming a sales force of 16 salespeople, PAI will pay a monthly fee and a matching fee of $62,500 each to TRx. PAI and TRx also agree to share the net revenues from sales of the products, after reimbursing certain expenditures, in a manner designed to achieve a 50/50 split of net revenues above the "break even" point, calculated in accordance with the terms and inputs set forth in the agreement. The revenue sharing continues for a period of six months after termination of the agreement, unless the agreement is terminated due to a breach. The agreement has an initial six-month term, which automatically renews for additional six-month terms, unless terminated. Either party may terminate at any time with 90 days' written notice. Amounts received under this agreement are

included as Sales force revenue in the Company's Consolidated Statements of Operations. The Company recorded revenues from revenue sharing payments of approximately $90,000 for the year-ended December 31, 2017 which are included in sales force revenue on the statement of operations.

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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")

Zylera entered into the First Amended and Restated Distribution Agreement with Lachlan, effective December 18, 2015. The agreement amends, restates and supersedes all previous agreements between the parties with respect to the Ulesfia (benzyl alcohol) lotion 5%. Pursuant to the agreement, Lachlan named Zylera as its exclusive distributor of Ulesfia in the U.S. and agreed to supply Ulesfia to Zylera exclusively for marketing and sale in the U.S. The agreement provides that all trademark rights used in connection with Ulesfia will remain the intellectual property of Lachlan, and all goodwill associated with the use of the trademarks for the marketing and sale of Ulesfia in the territory will inure to the sole benefit of Lachlan. The agreement also requires that Zylera make a royalty payment to Lachlan in the amount of 15% of net sales so long as net sales remain below $50 million annually. For annual net sales above $50 million, Zylera will owe Lachlan a royalty payment of 20% of net sales, and for annual net sales over $100 million, Zylera will owe Lachlan a royalty payment of 25% of net sales. Additionally, in the event Zylera's annual net sales of the product are less than $20 million, other than as a result of a "Market Change," Zylera shall pay Lachlan an amount sufficient to make total product payments equal to the amount that would have been paid if the net sales had been equal to $20 million. The practical effect of this provision is that there is a minimum annual royalty payment of $3,000,000. Zylera has asserted that a "Market Change" has occurred pursuant to the terms of this agreement and litigation is pending with respect to that assertion. There are also certain milestone payments which become payable upon the achievement of certain cumulative net sales milestones. Upon the achievement of cumulative net sales amounting to $90,000,000; $180,000,000; $270,000,000; and $400,000,000, Zylera will owe Lachlan payments of $3,000,000; $3,500,000; $4,000,000; and $5,000,000, respectively. Zylera is obligated to purchase a minimum of 20,000 units per year, or approximately $1,117,700 worth of product; however, the minimum purchase requirements are void upon the earliest of: (i) Lachlan's failure to fulfill Zylera's purchase orders for two consecutive quarters or any three quarters in a 12-month period; (ii) the first commercial sale of a generic version of the product, or (iii) termination of the agreement. Lachlan entered into a First Amended and Restated Exclusive Distribution Agreement with Concordia on January 1, 2014, and the agreement is substantively similar to the First Amended and Restated Exclusive Distribution Agreement between Lachlan and Zylera discussed above (with the exception of the parties thereto, the agreements are substantially identical.

On December 10, 2016, Zylera informed Lachlan that a market change had occurred due to the introduction of Arbor Pharmaceutical's lice product, Sklice®. According to the terms of the distribution agreement if there is a market change, the minimum purchase obligation is void. On June 5, 2017, Lachlan and Zylera entered into joint legal representation along with other unrelated third parties in negotiation and arbitration of dispute with Summers Laboratory, Inc regarding the an ongoing arbitration proceeding with the ultimate recipient of the royalties over whether a Market Change has occurred. The Company has not made any payments to Lachlan in 2017 under the Lachlan Agreement (from the acquisition date through year-end).

12. Term Loan

In August 2014, the Company received a $7.5 million secured term loan from a finance company. The loan was secured by a lien on the Company's assets, excluding intellectual property, which is subject to a negative pledge. The loan contained certain additional nonfinancial covenants. In connection with the loan agreement, the Company's cash and investment accounts were subject to account control agreements with the finance company that give the finance company the right to assume control of the accounts in the event of a loan default. Loan defaults are defined in the loan agreement and include, among others, the finance company's determination that there

is a material adverse change in the Company's operations, notwithstanding adverse results of clinical trials. Interest on the loan was at a rate of the greater of 7.95%, or 7.95% plus the prime rate as reported in The Wall Street Journal minus 3.25%. On August 1, 2017, the term loan matured and the Company made a final payment of $494,231 which included a termination fee of $187,500.

Debt consisted of the following as of December 31, 2017 and 2016:

	December 31, 2017	December 31, 2016
Term loan	$ —	$ 2,374,031
Less: debt discount	—	(20,364)
Term Loan, net of debt discount	—	2,353,667
Less: current portion, net of debt discount	—	(2,353,667)
Long term debt, net of current portion and debt discount	$ —	$ —

Interest expense, which includes amortization of a discount and the accrual of a termination fee, was approximately $95,000 and $489,000 for the years ended December 31, 2017 and 2016, respectively, and is included in interest income (expense), net on the accompanying statements of operations.

Upon issuance of the term loan, the Company paid lender fees of $110,000 and was required to pay a one-time fee at maturity of $187,500. The lender fees were recorded as a discount to the carrying amounts of the current and long term portions of the term loan. Amortization of the debt discount was $23,000 and $106,000 during the years ended December 31, 2017 and 2016, respectively. Accretion of the one-time fee was $12,000 and $56,000 during the years ended December 31, 2017 and 2016, respectively. The amortization of the debt discount and the accretion of the one-time fee are reflected as a components of interest expense within the accompanying statements of operations.

13. Capital Structure

On October 20, 2015, the Company filed an amended and restated certificate of incorporation in connection with the closing of its IPO. The amended and restated certificate of incorporation authorizes the Company to issue two classes of stock, common stock and preferred stock, and eliminates all references to the previously existing series of preferred stock. At December 31, 2017, 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 amended and restated certificate of incorporation in connection with the closing of the Armistice Private Placement 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"). The Certificate of Designation 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. On July 6, 2017, Armistice converted all of its outstanding shares of Series A Preferred Stock into common stock. Subsequent to the conversion of Armistice's Series A Preferred Stock into common stock, Armistice has a majority voting control over the Company.

Common Stock

IPO

On October 20, 2015, the Company closed its IPO of its units. Each unit consisted of one share of common stock, one Class A warrant to purchase one share of common stock at an exercise price of $4.55 per share and one Class B warrant to purchase one-half share of common stock at an exercise price of $3.90 per full share (the "units"). The Class A warrants expire on October 20, 2018 and the Class B warrants expired on April 20, 2017 (the "Class B Expiration Date."). The closing of the IPO resulted in the sale of 4,000,000 units at an initial public offering price of $6.50 per unit for gross proceeds of $26.0 million. The net proceeds of the IPO, after underwriting discounts, commissions and expenses, and before offering expenses, to the Company were approximately $23.6 million. On November 13, 2015, the units separated into common stock, Class A warrants and Class B warrants and began trading separately on the NASDAQ Capital Market. On the Class B Expiration Date, the Class B warrants ceased trading on the NASDAQ Capital Market. No Class B warrants were exercised prior to the Class B Expiration Date.

On November 23, 2015, the underwriter of the IPO exercised its over-allotment option for 20,000 shares of common stock, 551,900 Class A warrants to purchase one share of common stock and 551,900 Class B warrants to purchase one-half share of common stock for additional gross proceeds of $135,319.

The common stock and accompanying Class A warrants and Class B warrants have been classified to stockholders' equity (deficit) in the Company's balance sheet.

Underwriter's Unit Purchase Option

The underwriter of the IPO received, for $100 in the aggregate, the right to purchase up to a total of $40,000 units (or 1.0% of the units sold in the IPO) exercisable at $7.48 per unit (or 115% of the public offering price per unit in the IPO). The units underlying the UPO will be, immediately upon exercise, separated into shares of common stock and the Underwriters' Warrants such that, upon exercise, the holder of a UPO will not receive actual units but will instead receive the shares of common stock and Underwriters' Warrants, to the extent that any portion of the Underwriters' Warrants underlying such units have not otherwise expired. The exercise prices of the underwriters' Class A warrants and underwriter's Class B warrants underlying the UPO are $5.23 and $4.49, respectively. The UPO may be exercised for cash or on a cashless basis, at the holder's option, and expires on October 14, 2020; however, following the expiration of underwriters' Class B warrants on April 20, 2017, the UPO is exercisable only for shares of common stock and underwriters' Class A warrants at an exercise price of $7.475 per unit; provided further, that, following the expiration of underwriters' Class A warrants on October 20, 2018, the UPO will be exercisable only for shares of common stock at an exercise price of $7.47. The Company classified 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 fair value of the UPO is re-measured each reporting period and the change in fair value is recognized in the statement of operations (see Note 5).

The Aspire Capital Transaction

On September 8, 2016, the Company entered into a common stock purchase agreement (the "Purchase Agreement") with Aspire Capital Fund, LLC ("Aspire Capital"), pursuant to which Aspire Capital committed to purchase up to an aggregate of $15.0 million of shares of the Company's common stock over the 30-month term of the Purchase Agreement. Under the Purchase Agreement, on any trading day selected by the Company on which the closing price of the Company's common stock exceeds $0.50, the Company may, in its sole discretion, present a purchase notice directing Aspire Capital to purchase up to 50,000 shares of common stock per day, up to $15.0 million of the Company's common stock in the aggregate at a per share price calculated by references to the prevailing market price of the Company's common stock. Upon execution of the Purchase Agreement, the Company issued and sold to Aspire Capital 250,000 shares of common stock at a price per share of $4.00, for gross proceeds of $1.0 million, and concurrently entered into a registration rights agreement with Aspire Capital registering the shares of the Company's common stock that have been and may be issued to Aspire Capital under the Purchase Agreement. Additionally, as consideration for Aspire Capital entering into the Purchase Agreement, the Company issued 175,000 shares of common stock as a commitment fee. The net proceeds of the Aspire Capital transaction, after offering expenses, to the Company were approximately $1.9 million for the year ended December 31, 2016. During the twelve months ended December 31, 2017, the Company sold an additional 965,165 shares of common stock to Aspire Capital under the terms of the Purchase Agreement for gross proceeds of approximately $789,000. As of the date of this Annual Report on Form 10-K, the Company does not have any remaining shares available to issue under the purchase agreement. The Company may not issue any additional shares of common stock to Aspire Capital under the Purchase Agreement unless shareholder approval is obtained. The Board of Directors approved a board resolution to terminate this agreement on January 20, 2018.

The Maxim Group Equity Distribution Agreement

On January 27, 2017, the Company entered into an Equity Distribution Agreement with Maxim Group LLC ("Maxim"), as sales agent, pursuant to which the Company may offer and sell, from time to time, through Maxim, up to $12,075,338 in shares of its common stock. The Company has no obligation to sell any of the Shares, and may at any time suspend offers under the Equity Distribution Agreement.

As of December 31, 2017, the Company had sold 1,336,433 shares of its common stock through Maxim under the Equity Distribution Agreement for total gross proceeds of $905,000, including $33,000 of issuance costs. After the filing of this Annual Report, the amount of additional securities that were eligible to be sold under the registration statement on Form S-3 would have been approximately $2.9 million. This agreement expired on January 16, 2018.

Armistice Private Placement

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.

Contingently Issuable Shares

Under the terms of TRx acquisition noted above in Note 4, the Company is required to issues common stock having an aggregate value as calculated in the Purchase Agreement on the Closing Date of $8.1 million (the "Equity Consideration"). Upon closing, the Company issued 5,184,920 shares of our common stock. Pursuant to the Purchase Agreement, the issuance of the remaining 2,349,968 shares as a part of the Equity Consideration is subject to stockholder approval and entirely contingent upon gaining such stockholder approval.

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, 2017, the following common stock warrants were outstanding:

Number of shares underlying warrants		Exercise price per share	Expiration date
80,966	$	28.00	August 2018
4,551,900	$	4.55	October 2018
40,000*	$	5.23	October 2018
3,571	$	28.00	December 2018
22,328*	$	8.40	October 2020
2,380*	$	8.68	May 2022
14,285,714	$	0.40	June 2022
18,986,859			

*Accounted for as a liability instrument (see Note 5)

Warrants Issued to Term Loan Lender

In August 2014, warrants to purchase 625,208 shares of Series B convertible preferred stock, at an exercise price equal to $0.2999 per share, were issued to the term loan lender in conjunction with the loan of $7.5 million (see Note 12). Upon the closing of the Company's IPO, these warrants to purchase 625,208 shares of Series B convertible preferred stock became warrants to purchase 22,328 shares of common stock at an exercise price of $8.40 per share, in accordance with their terms. These warrants represent a freestanding financing instrument indexed to an obligation of the Company and as such is accounted for as a liability in accordance with ASC 480. The Company adjusts the carrying value of the liability, which appears as "warrant liability" on the accompanying balance sheets, to its estimated fair value at each reporting date (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. During the term of the 2016 Plan, the share reserve will automatically increase on the first trading day in January of each calendar year, beginning in 2017, 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, 2017, there were 41,448 shares available for future issuance under the 2016 Plan. On January 1, 2018, an additional 1,250,679 shares were made 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. For stock options issued to non-employees, the Company measures the options at their fair value on the date at which the related service is complete. Expense is recognized over the period during which services are rendered by such non-employees until completed. At the end of each financial reporting period prior to the completion of the service, the fair value of the awards is remeasured using the then current fair market value of the Company's common stock and updated assumptions in the Black-Scholes option pricing model. Stock-based compensation expense includes stock options and ESPPP shares. The amount of stock based compensation expense recognized for the years ending December 31, 2017, 2016 and 2015 was as follows:

	Year Ended December 31,		
	2017	2016	2015
Research and development	$ 156,047	$ 141,247	$ 67,021
General and administrative	1,001,205	1,553,644	327,727
Total stock-based compensation	$ 1,157,252	$ 1,694,891	$ 394,748

During the first quarter of 2016, the Company modified stock options of its former chief executive officer by extending the life of the awards, which were set to expire in March 2016, to coincide with their original life. This modification resulted in the recording of approximately $781,000 of compensation expense, which is included in general and administrative expenses for the year ended December 31, 2016 in the accompanying statement of operations. During the fourth quarter of 2017 two members of the Company's board of directors resigned. The Company modified the stock options of the directors by extending the life of the awards, which were set to expire in January, 2017, to August 15, 2018. Also, during the fourth quarter of 2017, the Company modified stock options of a former executive officer by extending the life of the awards, which were set to expire in February 2018, to May 2019. These modifications resulted in recording approximately $67,000 of compensation expense.

A summary of option activity for the years ended December 31, 2017 and 2016 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, January 1, 2016	959,188	$ 7.68		7.51
Granted	915,242	$ 3.35	$ 2,155,234	
Forfeited	(25,071)	$ 5.04		
Balance, December 31, 2016	1,849,359	$ 5.57		8.44
Granted	1,020,377	$ 0.94	$ 669,816	
Forfeited	(46,247)	$ 3.57		
Balance, December 31, 2017	2,823,489	$ 3.93		7.29
Vested and expected to vest at December 31, 2017	2,823,489	$ 3.93		7.29
Exercisable at December 31, 2017	1,762,908	$ 5.02		6.16

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, 2017, the aggregate intrinsic value of options outstanding, vested and expected to vest was $2.4 million. The total grant date fair value of shares which vested during the years ended December 31, 2017, 2016 and 2015 was $2.9 million, $0.4 million and $0.7 million, respectively. The per-share weighted-average grant date fair value of the options granted during 2017, 2016 and 2015 was estimated at $0.66, $2.35 and $2.80, respectively. There were 997,902 options that vested during the year ended December 31, 2017 with a weighted average grant date fair value of $2.98. There were no options exercised during the years ended December 31, 2017, 2016 and 2015.

The assumptions used to determine the grant date fair value of stock options granted to employees and non-employee directors are as follows:

	Year Ended December 31,		
	2017	2016	2015
Risk-free interest rate	1.85% — 2.38%	1.01% — 1.93%	1.64% — 1.97%
Expected term of options (in years)	5.0 — 6.25	5.0 — 6.25	5.00 — 6.25
Expected stock price volatility	55% — 100.0%	80.00% — 100.0%	70.0%
Expected annual dividend yield	—% — —%	—% — —%	—% — —%

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 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. The Company estimates the expected life of its stock options granted to consultants and nonemployees to be the contractual term of the options.
- 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%.

The Company considered numerous objective and subjective factors in the assessment of fair value of its common stock for grants made prior to the date the Company's common stock began trading separately on the NASDAQ Capital Market, which was November 13, 2015, and includes all grants made to date. The factors considered include the price for the Company's convertible preferred stock that was sold to investors and the rights, preferences and privileges of the convertible preferred stock and common stock, the trading price of the Company's units between the IPO date and November 13, 2015, the Company's financial condition and results of operations during the relevant periods, including the status of the development of the Company's product candidates, and the status of strategic initiatives. These estimates involve a significant level of judgment.

As of December 31, 2017, there was approximately $1,342,072 of total unrecognized compensation expense related to unvested options granted under the Plan to be recognized as follows:

Year ending December 31,	
2018	$ 732,441
2019	352,657
2020	188,351
2021	68,623
	$ 1,342,072

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, 2016, 480,000 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 $76,305 for the year ended December 31, 2017, which is 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 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 the financial statements for the calendar year 2017. Tax years beginning in 2014 are generally subject to examination by taxing authorities, although net operating losses from all years are subject to examinations and adjustments for at least three years following the year in which the attributes are used.

ASC Topic 740 provides guidance on the recognition of interest and penalties related to income taxes. There were no interest or penalties related to income taxes that have been accrued or recognized as of and for calendar year 2017. 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, 2017, 2016 and 2015:

	2017	2016	2015
Current:			
Federal	$ 2,309,285	$ —	$ —
State	489,863	—	—
	2,799,148	—	—
Deferred:			
Federal	(789,274)	—	—
State	(43,355)	—	—
	(832,629)	—	—
Net Income Tax Expense	$ 1,966,519	$ —	$ —

The net deferred tax liabilities consisted of the following for the years ending December 31, 2017 and 2016:

	December 31,	
	2017	2016
Deferred tax assets:		
Net operating losses	$ 716,819	$ 20,587,955
Research and development credits	—	1,840,505
Deferred rent	4,051	11,902
Accrued compensation	271,437	90,936
Stock-based compensation	1,291,230	2,169,070
Other reserves	72,881	—
Basis difference in tangible and intangible assets	2,554,924	6,174,163
Total deferred tax assets	4,911,342	30,874,531
Deferred tax liabilities:		
Basis difference in intangible assets	(535,652)	—
Installment sale	(358,844)	—
Total deferred tax liabilities	(894,496)	—
Deferred tax asset, net	4,016,846	30,874,531
Less valuation allowance	(4,023,990)	(30,874,531)
Net deferred taxes	$ (7,144)	$ —

As of December 31, 2017, the Company has approximately $3,012,000 of gross net operating losses for Federal and State purposes that will begin to expire in 2031.

The income tax expense for the years ended December 31, 2017 and 2016 differed from the amounts computed by applying the U.S. federal income tax rate of 34% as follows:

	December 31,		
	2017	2016	2015
Federal statutory rate	34.00 %	34.00 %	34.00 %
Permanent differences	0.02 %	(0.02)%	(0.02)%
Warrants	0.07 %	0.15 %	4.26 %
Acquisition costs	0.08 %	— %	— %
Built in loss	1.52 %	— %	— %
State taxes	27.91 %	3.44 %	5.12 %
Research and development credit	(1.04)%	2.18 %	2.69 %
Change in statutory rate due to Tax Cuts and Job Act	15.82 %	— %	— %
NOL adjustment per § 382	126.82 %	— %	— %
Other	0.04 %	— %	0.03 %
Change in valuation allowance	(191.03)%	(39.75)%	(46.08)%
Effective income tax rate	14.21 %	— %	— %

The valuation allowance recorded by the Company as of December 31, 2017 and 2016 resulted from the uncertainties of the future utilization of deferred tax assets relating from net operating loss carry forwards for federal and state income tax purposes. Realization of the NOL carry forwards is contingent on future taxable earnings. The net 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 full valuation allowance continues to be recorded against the Company's net deferred tax asset as of December 31, 2017 and 2016, as it was determined based upon past and projected future losses that it was "more likely than not" that the Company's net deferred tax assets would not be realized. In future years, if the net 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, 2017 and 2016 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.

Sections 382 and 383 of the Internal Revenue Code of 1986 subject the future utilization of net operating losses and certain other tax attributes, such as research and experimental tax credits, to an annual limitation in the event of certain ownership changes, as defined. The Company has undergone an ownership change study and has determined that a "change in ownership" as defined by IRC Section 382 of the Internal Revenue Code of 1986, as amended, and the rules and regulations promulgated thereunder, did occur in February 2012, July 2014, and April 2017. Accordingly, about $52,170,000 of the Company's NOL carryforwards are limited. Based on the Company having undergone multiple ownership changes throughout their history these NOLs are subject to limitation at varying rates each year. Approximately, $2,800,000 of these NOLs can be utilized before the 2017 ownership change and $46,000,000 of NOLs and R&D Credits are expected to expire unused. The deferred tax assets associated with the attributes that will expire without utilization have been written-off. There are $107,702 of NOLs available for use after the April 2017 change in 2017. In subsequent years, the NOLs available from the April 2017 change under section 382 are $158,513, annually.

On December 22, 2017, H.R. 1 (also, known as the Tax Cuts and Jobs Act (the “Act”)) was signed into law. Among its numerous changes to the Internal Revenue Code, the Act reduces U.S. federal corporate tax rate from 35% to 21%. As a result, the Company believes that the most significant impact on its consolidated financial statements is the reduction of approximately $2,200,000 in deferred tax assets and liabilities related to net operating losses and other assets. Such reduction is largely offset by changes to the Company’s valuation allowance. The Company is reporting the impacts of the Act provisionally based upon reasonable estimates.

In addition, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Act ("SAB 118") which allows 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 are expected over the next year, and significant data and analysis is required to finalize amounts recorded pursuant to the Tax Act, the Company considers the accounting for the deferred tax re-measurements and other items to be incomplete due to the forthcoming guidance and its ongoing analysis of final year-end data and tax positions. The Company expects to complete its analysis within the measurement period in accordance with SAB 118.

16. Commitments and Contingencies

Office Lease

In 2013, the Company entered into a lease for new corporate office space location in Baltimore, Maryland. The lease provides for three months of rent abatement and includes escalating rent payments. Rent expense is recognized on a straight-line basis over the term of the lease. Rent expense under the lease amounted to approximately $142,000 for the years ended December 31, 2017 and 2016. Pursuant to the terms of such lease, the Company’s future lease obligation is as follows:

Year ending December 31,		
2018	$	158,716
2019		—
	$	158,716

Obligations to Contract Research Organizations and External Service Providers

The Company has entered into agreements with contract research organizations and other external service providers for services, primarily in connection with the clinical trials and development of the Company’s product candidates. The Company was contractually obligated for up to approximately $1.9 million of future services under these agreements as of December 31, 2017, for which amounts have not been accrued as services have not been performed. The Company’s actual contractual obligations will vary depending upon several factors, including the progress and results of the underlying services.

17. Selected Quarterly Financial Data (Unaudited)

The following table sets forth certain unaudited quarterly financial data for 2017 and 2016. This unaudited information has been prepared on the same basis as the audited information included elsewhere in this Annual Report on Form 10-K and includes all adjustments necessary to present fairly the information set forth therein.

	Three Months Ended			
	March 31, 2017	June 30, 2017	September 30, 2017	December 31, 2017
	(in thousands, except per share data)			
License and other revenue	$ —	$ —	$ 25,000	$ —
Product revenue, net	—	—	—	1,911
Sales force revenue	—	—	—	278
Grant revenue	384	158	38	45
Operating expenses:				
Cost of product sales	—	—	—	636
Research and development	953	494	965	1,961
General and administrative	1,330	1,439	2,152	3,021
Sales and marketing	—	—	—	973
Change in fair value of warrant liability and unit purchase option liability	(4)	2	—	(28)
Interest (expense) income, net	(58)	(26)	29	31
Net (loss) income after taxes	$ (1,961)	$ (1,799)	$ 18,721	$ (3,091)
Net (loss) income per share of common stock, basic	$ (0.19)	$ (0.14)	$ 0.52	$ (0.11)
Net (loss) income per share of common stock, diluted	$ (0.19)	$ (0.14)	$ 0.52 —	$ (0.11)

	Three Months Ended			
	March 31, 2016	June 30, 2016	September 30, 2016	December 31, 2016
	(in thousands, except per share data)			
Operating expenses:				
Research and development	$ 2,293	$ 2,502	$ 4,582	$ 773
General and administrative	2,649	1,636	1,703	1,095
Change in fair value of warrant liability, unit purchase option liability and investor rights obligation	(47)	91	(101)	130
Interest income (expense), net	(151)	(127)	(104)	(83)
Net loss	$ (5,140)	$ (3,524)	$ (6,169)	$ (1,639)
Net loss per share of common stock, basic and diluted	$ (0.59)	$ (0.41)	$ (0.70)	$ (0.18)

18. Related Party Transactions

In November 2017, the Company acquired Zylera Pharmaceuticals, LLC. Each of Zylera's previous owners beneficially own more than 5% of the outstanding common stock of the Company. In addition both individuals serve on the Company's Board of Directors and one of the individuals served through March 27, 2018 as the Company's President and COO.

Zylera, entered into the First Amended and Restated Distribution Agreement (the "Lachlan Agreement") with Lachlan Pharmaceuticals, an Irish company controlled by Zylera's previous owners ("Lachlan"), effective December 18, 2015. Pursuant to the Lachlan Agreement, Lachlan named Zylera as its exclusive distributor of Ulesfia in the U.S. and agreed to supply Ulesfia to Zylera exclusively for marketing and sale in the U.S. The Lachlan Agreement provides that all trademark rights used in connection with Ulesfia will remain the intellectual property of Lachlan, and all goodwill associated with the use of the trademarks for the marketing and sale of Ulesfia in the territory will inure to the sole benefit of Lachlan. The Lachlan Agreement term continues as long as (i) there exists an issued and unexpired patent right for the product in the United States, or (ii) no generic version of the product is being sold in the United States. The Lachlan Agreement can be terminated by Zylera upon the introduction of a generic product in the territory or upon the expiration or invalidity of all patent rights for the product in the territory.

Zylera is obligated to purchase a minimum of 20,000 units per year, or approximately $1,177,000 of product, from Lachlan, subject to certain termination rights. The Lachlan Agreement also requires that Zylera make certain cumulative net sales milestone

payments and royalty payments to Lachlan with a $3,000,000 annual minimum payment unless and until there has been a "Market Change" involving a new successful competitive product. Zylera has asserted that a "Market Change" has occurred pursuant to the terms of this agreement and litigation is pending with respect to that assertion). Lachlan is obligated to pay identical amounts to an unrelated third party from which it obtained rights to Ulesfia, and there is an ongoing arbitration proceeding with the ultimate recipient of the royalties over whether a Market Change has occurred. Additionally, Zylera must pay Lachlan management and handling fees that were 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 aggregate gross amount the Company paid to Lachlan in 2017 under the Lachlan Agreement (from the acquisition date through year-end) was $0.

TRx entered into a Master Quality Agreement with Concordia and Lachlan Pharma Holdings, Ltd., effective January 1, 2014 (the date the First Amended and Restated Exclusive Distribution Agreement between Concordia and Lachlan was effective). The purpose of the agreement is to specify the regulatory, quality, and current good manufacturing practices responsibilities of the respective parties in relation to the maintenance of NDA 22-129 for the supply and marketing of Ulesfia® (benzyl alcohol) 5% lotion pursuant to the First Amended and Restated Exclusive Distribution Agreement between Concordia and Lachlan (the "EDA"). The agreement continues in effect for the term of the EDA, but Concordia or Lachlan may terminate the agreement upon thirty days written notice to the other party, following early termination or expiration of the EDA.

On December 10, 2016, Zylera informed Lachlan that a market change had occurred due to the introduction of Arbor Pharmaceutical's lice product, Sklice®. According to the terms of the distribution agreement if there is a market change, the minimum purchase obligation is void. On June 5, 2017, Lachlan and Zylera entered into joint legal representation along with other unrelated third parties in negotiation and arbitration of dispute with Summers Laboratory, Inc regarding the an ongoing arbitration proceeding with the ultimate recipient of the royalties over whether a Market Change has occurred. The Company has not made any payments to Lachlan in 2017 under the Lachlan Agreement (from the acquisition date through year-end).

19. Subsequent Events

On February 12, 2018, the Company closed an acquisition with Avadel U.S. Holdings, Inc., and certain of its subsidiaries ("Avadel"), to purchase and acquire all rights to Avadel's marketed pediatric products. The acquired products consist of Karbinal™ ER, AcipHex® Sprinkle™, Cefaclor for Oral Suspension, and Flexichamber™. Additionally, Avadel Ireland will develop and provide the Company with four stable product formulations of the Company's choosing utilizing its proprietary LiquiTime™ and Micropump® technology. Under the terms of the asset purchase agreement, the Company purchased Avadel's interest in the Avadel pediatric assets for nominal cash payment and assumed 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. Trailing twelve-month net sales for the acquired products were approximately $8 million.

Management is in the process of verifying data related to the Avadel transaction including the valuation and recording of identifiable assets, intangible assets, liabilities assumed and the resulting effects on the value of goodwill, if any.

400 East Pratt Street
Suite 606
Baltimore, MD 21202

November 20, 2017

Robert Moscato
9116 Winged Thistle Ct
Raleigh, NC 27617

Dear Rob:

On behalf of Cerecor Inc., a Delaware corporation (the "Company"), we are pleased to offer you a position with the Company under the terms set forth in this letter agreement (the "Agreement").

1. **In General**. The Company agrees to employ you commencing as of **November 20, 2017** (the "Effective Date").

2. **Position and Duties**. During the term of your employment with the Company (the "Employment Term"), you shall serve as the P**resident and Chief Operating Officer** of the Company, reporting to Cerecor's Board of Directors. You will be based in North Carolina**.** It is possible that this reporting relationship will change as the Company hires additional senior management personnel. In your capacity as VP you shall have duties, authorities and responsibilities commensurate with your position, and such other duties, authorities and responsibilities as your supervisor shall designate from time to time. During the Employment Term, you shall devote all of your business time, energy and skill and your best efforts to the performance of your duties with the Company; provided, that (i) you may be a passive investor in other entities and (ii) you may engage in civic and not-for-profit activities so long as such activities do not interfere with the performance of your duties hereunder.

3. **Base Salary**. Beginning on the Effective Date, the Company agrees to pay you a base salary at an annual rate of not less than **US $300,000,** payable in accordance with the regular payroll practices of the Company. The base salary as increased from time to time shall constitute "Base Salary for purposes of this Agreement.

4. **Bonus Compensation.** During the Employment Term, you shall be eligible to receive a discretionary annual bonus as determined by the Board or the Compensation Committee of the Board, in its sole discretion, provided you are employed on the date such annual bonus is paid. Such bonus may consist of cash and/or grants of additional equity awards in the Company, and is intended to be substantially consistent with cash bonuses and equity award bonuses paid to executives of similar grade in similarly situated companies in the biotechnology industry, subject to the results of operations and financial condition of the Company and your

level of individual performance. **Your cash bonus target for 2018 will be 50% of your base salary, prorated for time in grade.**

5. **Employee Benefits**. You shall be entitled to participate in any employee benefit plans that the Company has adopted or may adopt, maintain or contribute to for the benefit of its employees generally, subject to satisfying the applicable eligibility requirements. Notwithstanding the foregoing, the Company may modify or terminate any employee benefit plan at any time. In addition, you shall be entitled to paid vacation in accordance with the Company's vacation policy in effect from time to time. Upon presentation of appropriate documentation, you shall be reimbursed in accordance with the Company's expense reimbursement policy, for all reasonable business expenses incurred in connection with the performance of your duties hereunder. You will are also eligible to participate in the Stock Option Plan.

6. **Termination of Employment**.

a. Death or Disability. Your employment shall immediately terminate on the date of your death or upon ten (10) days' prior written notice by the Company for Disability (as defined in the Company's long term disability plan as in effect from time to time or, if no such plan is in effect, as defined under Code Section 409A (as defined in Section 19 below)). Upon your termination due to death or Disability, you (or your estate or legal representative, if applicable) shall be entitled to the following payments and benefits: (i) any unpaid Base Salary through the date of termination, reimbursement for any unreimbursed business expenses under the Company's expense reimbursement policy incurred through the date of termination and any accrued but unused vacation time in accordance with Company policy, payable within thirty (30) days following such termination of employment and (ii) all other vested payments, benefits or fringe benefits to which you shall be entitled under the terms of any applicable compensation arrangement or benefit, equity or fringe benefit plan or program or grant (collectively, Sections 6(a)(i) and 6(a)(ii) hereof shall be hereafter referred to as the "Accrued Benefits").

b. For Cause. Your employment with the Company shall terminate immediately upon written notice by the Company for Cause. "Cause" shall mean: (i) your willful misconduct or gross negligence in the performance of your duties to the Company that, if capable of cure, is not cured within thirty (30) days of your receipt of written notice from the Company; (ii) your failure to perform your duties to the Company or to follow the lawful directives of the Board (other than as a result of death or a physical or mental incapacity) that, if capable of cure, is not cured within thirty (30) days of your receipt of written notice from the Company; (iii) your commission of, indictment for, conviction of, or pleading of guilty or nolo contendere to, a felony or any crime involving moral turpitude; (iv) any act of theft, fraud, malfeasance or dishonesty in connection with the performance of your duties to the Company; or; (v) a material breach of this Agreement or any other agreement with the Company, or a material violation of the Company's code of conduct or other written policy that, if capable of cure, is not cured within thirty (30) days of your receipt of written notice from the Company. Upon a termination for Cause, the Company shall pay to you the Accrued Benefits.

c. Without Cause. Your employment may be terminated by the Company without Cause (other than for death or Disability) immediately upon written notice by the Company. If you timely elect, you may remain eligible for continued health insurance coverage under federal COBRA law or, if applicable, state insurance laws, provided you continue to pay the respective premiums.

d. For Good Reason. Your employment shall terminate upon your written notice to the Company of a termination for Good Reason. "Good Reason" shall mean, without your written consent, (i) a material diminution in your duties, authorities or responsibilities (other than temporarily while physically or mentally incapacitated), or (ii) a material breach of this Agreement, including, without limitation, a diminution of your Base Salary hereunder. You shall provide the Company with a written notice detailing the specific circumstances alleged to constitute Good Reason within thirty (30) days after the first occurrence of such circumstances, and the Company shall have thirty (30) days following

the receipt of such notice to cure such alleged "Good Reason" event. If the Company does not cure such event within the cure period, you must terminate your employment within ten (10) days following the end of such cure period, or any claim of such circumstances as "Good Reason" shall be deemed irrevocably waived by you.

7. **Release**. Any payments and benefits provided under this Agreement, including the restricted Stock Award, beyond the Accrued Benefits shall only be payable if you execute and deliver to the Company and do not revoke a general release of claims in favor of the Company in a form reasonably satisfactory to the Company. Such release shall be executed and delivered (and no longer subject to revocation, if applicable) within sixty (60) days following termination. The Company shall deliver to you such release within seven (7) days after termination.

8. **Restrictive Covenants**.

a. Confidentiality. You agree that you shall not, directly or indirectly, use, make available, sell, disclose or otherwise communicate to any person, either during your employment or at any time thereafter, any business and technical information or trade secrets, nonpublic, proprietary or confidential information, knowledge or data relating to the Company, any of its subsidiaries, affiliated companies or businesses, which shall have been obtained by you during your employment by the Company (or any predecessor). This restriction shall not apply to disclosures made during the routine course of business in fulfillment of your duties during the Employment Term, as described in Section 2. The foregoing shall not apply to information that (A) was known to the public prior to its disclosure to you or (B) you are required to disclose by applicable law, regulation or legal process (provided that you provide the Company with prior notice of the contemplated disclosure and cooperate with the Company at its expense in seeking a protective order or other appropriate protection of such information). The terms and conditions of this Agreement shall remain strictly confidential, and you hereby agree not to disclose the terms and conditions hereof to any person or entity, other than immediate family members, legal visors or personal tax or financial advisors, or prospective future employers solely for the purpose of disclosing the limitations on your conduct imposed by the provisions of this Section 8.

b. Non-Competition. You acknowledge that you perform services of a unique nature for the Company that are irreplaceable, and that your performance of such services to a competing business will result in irreparable harm to the Company. Accordingly, during your employment hereunder and for a period of one (1) year thereafter, you agree that you will not, directly or indirectly, own, manage, operate, control, be employed by (whether as an employee, consultant, independent contractor or otherwise, and whether or not for compensation) or render services to any person, firm, corporation or other entity, in whatever form, engaged in competition with the Company or any of its subsidiaries or affiliates or in any other material business in which the Company or any of its subsidiaries or affiliates is engaged on the date of termination or in which they have planned, on or prior to such date, to be engaged in on or after such date, in any locale of any country in which the Company conducts business. Notwithstanding the foregoing, nothing herein shall prohibit you from being a passive owner of not more than two percent (2%) of the equity securities of a publicly traded corporation engaged in a business that is in competition with the Company or any of its subsidiaries or affiliates.

c. Non-Solicitation; Non-Interference - During your employment with the Company and for a period of one (1) year thereafter, you agree that you shall not, directly or indirectly, individually or on behalf of any other person, firm, corporation or other entity, solicit, aid or induce any customer of the Company or any of its subsidiaries or affiliates to purchase goods or services then sold by the Company or any of its subsidiaries or affiliates from another person, firm, corporation or other entity or assist or aid any other persons or entity in identifying or soliciting any such customer.

During your employment with the Company and for a period of one (1) year thereafter, you agree that you shall not, directly or indirectly, individually or on behalf of any other person, firm, corporation or other entity, (A) solicit, aid or induce any employee, representative or agent of the Company or any of its subsidiaries or affiliates to leave such employment or retention or to accept employment with or render services to or with any other person, firm, corporation or other entity unaffiliated with the Company or directly hire or retain any such employee, representative or agent, or take any action to materially assist or aid any other person, firm, corporation or other entity in identifying, hiring or soliciting any such employee, representative or agent, or (B) Interfere, or aid or induce any other person or entity in interfering, with the relationship between the Company or any of its subsidiaries or affiliates and any of their respective vendors, Joint ventures or licensors. An employee, representative or agent shall be deemed covered by this Section 8(c) if such person was employed or retained during anytime within six (6) months prior to, or after, your termination of employment.

d. Non-Disparagement. You agree not to make negative comments or otherwise disparage the Company or its officers, directors, employees, shareholders, agents or products, in any manner likely to be harmful to them or their business, business reputation or personal reputation. The foregoing shall not be violated by truthful statements in response to legal process, required governmental testimony or filings, or administrative or arbitral proceedings (including, without limitation, depositions in connection with such proceedings).

e. Inventions.

You acknowledge and agree that all ideas, methods, inventions, discoveries, improvements, work products or developments ("Inventions"), whether patentable or unpatentable, (A) that relate to your work with the Company, made or conceived by you, solely or jointly with others, during the Employment Term, or (B) suggested by any work that you perform in connection with the Company, either while performing your duties with the Company or on your own time, but only insofar as the Inventions are related to your work as an employee or other service provider to the Company, shall belong exclusively to the Company (or its designee), whether or not patent applications are filed thereon. You will keep full and complete written records (the "Records"), in the manner prescribed by the Company, of all Inventions, and will promptly disclose all Inventions completely and in writing to the Company. The Records shall be the sole and exclusive property of the Company, and you will surrender them upon the termination of the Employment Term, or upon the Company's request. You will assign to the Company the Inventions and all patents that may issue thereon in any and all countries, whether during or subsequent to the Employment Term, together with the fight to file, in your name or in the name of the Company (or its designee), applications for patents and equivalent rights (the "Applications"). You will, at any time during and subsequent to the Employment Term, make such applications, sign such papers, take all rightful oaths, and perform all acts as may be requested from time to time by the Company with respect to the Inventions. You will also execute assignments to the Company (or its designee) of the Applications, and give the Company and its attorneys all reasonable assistance (including the giving of testimony) to obtain the Inventions for its benefit, all without additional compensation to you from the Company, but entirely at the Company's expense.

In addition, the Inventions will be deemed Work for Hire, as such term is defined under the copyright laws of the United States, on behalf of the Company and you agree that the Company will be the sole owner of the Inventions, and all underlying rights therein, in all media now known or hereinafter devised, throughout the universe and in perpetuity without any further obligations to you. If the Inventions, or any portion thereof, are deemed not to be Work for Hire, you hereby irrevocably convey, transfer and assign to the Company, all rights, in all media now known or hereinafter devised, throughout the universe and in perpetuity, in and to the Inventions, including, without limitation, all of your right, title and interest in the copyrights (and all renewals, revivals and extensions thereof) to the Inventions, including, without limitation, all rights of any kind or any nature now or hereafter recognized, including without limitation, the unrestricted right to make modifications, adaptations and revisions to the Inventions, to exploit and allow others to exploit the Inventions and all rights to sue at law or in equity for any infringement, or other unauthorized use or conduct in

derogation of the Inventions, known or unknown, prior to the date hereof, including, without limitation, the right to receive all proceeds and damages therefrom. In addition, you hereby waive any so-called "moral rights" with respect to the Inventions. You hereby waive any and all currently existing and future monetary rights in and to the Inventions and all patents that may Issue thereon, including, without limitation, any rights that would otherwise accrue to your benefit by virtue of you being an employee of or other service provider to the Company.

Return of Company Property. On the date of your termination of employment with the Company for any reason (or at any time prior thereto at the Company's request), you shall return all property belonging to the Company or its affiliates (including, but not limited to, any Company-provided laptops, computers, cell phones, wireless electronic mail devices or other equipment, or documents and property belonging to the Company).

Reformation. If it is determined by a court of competent jurisdiction in any state that any restriction in this Section 8 is excessive in duration or scope or is unreasonable or unenforceable under the laws of that state, it is the intention of the parties that such restriction may be modified or amended by the court to render it enforceable to the maximum extent permitted by the laws of that state.

Survival of Provisions. The obligations contained in Sections 8 and 9 hereof shall survive the termination or expiration of the Employment Term and your employment with the Company and shall be fully enforceable thereafter.

9. **Cooperation.** Upon the receipt of reasonable notice from the Company (including outside counsel), you agree that while employed by the Company and thereafter, you will respond and provide information with regard to matters in which you have knowledge as a result of your employment with the Company, and will provide reasonable assistance to the Company, its affiliates and their respective representatives in defense of any claims that may be made against the Company or its affiliates, and will assist the Company and its affiliates in the prosecution of any claims that may be made by the Company or its affiliates, to the extent that such claims may relate to the period of your employment with the Company. You agree to promptly inform the Company if you become aware of any lawsuits involving such claims that may be filed or threatened against the Company or its affiliates. You also agree to promptly inform the Company (to the extent that you are legally permitted to do so) if you are asked to assist in any investigation of the Company or its affiliates (or their actions), regardless of whether a lawsuit or other proceeding has then been filed against the Company or its affiliates with respect to such investigation, and shall not do so unless legally required. Upon presentation of appropriate documentation, the Company shall pay or reimburse you for all reasonable out-of-pocket travel, duplicating or telephonic expenses incurred by you in complying with this Section 9.

10. **Equitable Relief and Other Remedies.** You acknowledge and agree that the Company's remedies at law for a breach or threatened breach of any of the provisions of Section 8,or 9 hereof would be inadequate and, in recognition of this fact, you agree that, in the event of such a breach or threatened breach, in addition to any remedies at law, the Company, without posting any bond, shall be entitled to equitable relief in the form of specific performance, a temporary restraining order, a temporary or permanent injunction or any other equitable remedy which may then be available. In the event of a violation by you of Section 8, or 9 hereof, any severance being paid to you pursuant to this Agreement or otherwise shall immediately cease, and any severance previously paid to you (other than $1,000) shall be immediately repaid to the Company.

11. **No Assignments**. This Agreement is personal to each of the parties hereto. Except as provided in this Section 11 no party may assign or delegate any rights or obligations hereunder without first obtaining the written consent of the other party hereto. The Company may assign this Agreement to any successor to all or substantially all of the business and/or assets of the Company.

12. **Notice**. For purposes of this Agreement, notices and all other communications provided for in this Agreement shall be in writing and shall be deemed to have been duly given (a) on the date of delivery, if delivered by hand, (b) on the date of transmission, if delivered by confirmed facsimile or electronic mail, (c) on

the first business day following the date of deposit, if delivered by guaranteed overnight delivery service, or (d) on the fourth business day following the date delivered or mailed by United States registered or certified mail, return receipt requested, postage prepaid, addressed as follows:

If to you:

At the address (or to the facsimile number) shown on the records to the Company

If to the Company:

400 East Pratt Street
Suite 606
Baltimore, MD 21202
Attention: Mariam Morris
Email mmorris@cerecor.com

or to such other address as either party may have furnished to the other in writing in accordance herewith, except that notices of change of address shall be effective only upon receipt.

13. **Severability**. The provisions of this Agreement shall be deemed severable and the invalidity or unenforceability of any provision shall not affect the validity or enforceability of the other provisions hereof

14. **Counterparts**. This Agreement may be executed in several counterparts, each of which shall be deemed to be an original but all of which together will constitute one and the same instrument.

15. **Governing Law; Disputes**. The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the State of Delaware without regard to the choice of law principles thereof that would result in the application of the laws of any other jurisdiction. You and the Company agree that any action or proceeding to enforce or arising out of this Agreement may be commenced in the state appellate courts of New Castle County, Wilmington, Delaware or the United States District Court for the District of Delaware in Wilmington, Delaware. You and the Company consent to such jurisdiction, agree that venue will be proper in such courts and waive any objections upon "forum non conveniens."

16. **Miscellaneous.** No provision of this Agreement may be modified, waived or discharged unless such waiver, modification or discharge is agreed to in writing and signed by you and such officer or director as may be designated by the Board. No waiver by either party hereto at any time of any breach by the other party hereto of, or compliance with, any condition or provision of this Agreement to be performed by such other party shall be deemed a waiver of similar or dissimilar provisions or conditions at the same or at any prior or subsequent time. This Agreement together with all exhibits hereto sets forth the entire agreement of the parties hereto in respect of the subject matter contained herein and supersedes any and all prior agreements or understandings between you and the Company with respect to the subject matter hereof. No agreements or representations, oral or otherwise, express or implied, with respect to the subject matter hereof have been made by either party which are not expressly set forth in this Agreement.

17. **Representations.** You represent and warrant to the Company that (a) you have the legal right to enter into this Agreement and to perform all of the obligations on your part to be performed hereunder in accordance with its terms, and (b) you are not a party to any agreement or understanding, written or oral, and is not subject to any restriction, which, in either case, could prevent you from entering into this Agreement or performing all of your duties and obligations hereunder.

18. **Tax Withholding**. The Company may withhold from any and all amounts payable under this Agreement such federal, state and local taxes as may be required to be withheld pursuant to any applicable law or regulation.

19. **Code Section 409A**.

The intent of the parties is that payments and benefits under this Agreement comply with, or be exempt from, Internal Revenue Code Section 409A and the regulations and guidance promulgated thereunder (collectively "Code Section 409A") and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith. In no event whatsoever shall the Company be liable for any additional tax, interest or penalty that may be imposed on you by Code Section 409A or any damages for failing to comply with Code Section 409A.

A termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits upon or following a termination of employment that are considered *'non-qualified deferred compensation" under Code Section 409A unless such termination is also a "separation from service" within the meaning of Code Section 409A and, for purposes of any such provision of this Agreement, references to a "termination," "termination of employment" or like terms shall mean "separation from service." If you are deemed on the date of termination to be a "specified employee" within the meaning of that term under Code Section 409A(a)(2)(B), then with regard to any payment that is considered non-qualified deferred compensation under Code Section 409A payable on account of a "separation from service," such payment or benefit shall be made or provided at the date which is the earlier of (A) the expiration of the six (6)-month period measured from the date of your "separation from service", and (B) the date of your death (the "Delay Period"). Upon the expiration of the Delay Period, all payments and benefits delayed pursuant to this Section 19 (whether they would have otherwise been payable in a single sum or in installments in the absence of such delay) shall be paid or reimbursed to you in a lump sum and any remaining payments and benefits due under this Agreement shall be paid or provided in accordance with the normal payment dates specified for them herein.

With regard to any provision herein that provides for reimbursement of costs and expenses or in-kind benefits, except as permitted by Code Section 409A, (i) the right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for another benefit, (ii) the amount of expenses eligible for reimbursement, or in-kind benefits, provided during any taxable year shall not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year, provided that the foregoing clause (ii) shall not be violated with regard to expenses reimbursed under any arrangement covered by Internal Revenue Code Section 95(b) solely because such expenses are subject to a limit related to the period the arrangement is in effect and (iii) such payments shall be made on or before the last day of your taxable year following the taxable year in which the expense occurred.

For purposes of Code Section 409A, your right to receive any installment payments pursuant to this Agreement shall be treated as a right to receive a series of separate and distinct payments. In no event may you, directly or indirectly, designate the calendar year of any payment to be made under this Agreement that is considered non-qualified deferred compensation.

[END OF TEXT. SIGNATURE PAGE FOLLOWS.]

To indicate your acceptance of the Company's offer, please sign and date this letter in the space provided below and return it to **Mariam E. Morris via email to mmorris@cerecor.com**.

Sincerely,

Mariam E. Morris
Chief Financial Officer

ACCEPTED AND AGREED:

Robert C. Moscato, Jr.

Date: 11-28-17

Exhibit 21.1

List of Subsidiaries of Cerecor Inc.

Entity Name	**Jurisdiction**
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 Form (Form S-8 No. 333-207949) pertaining to the 2015 Omnibus Incentive Compensation Plan,

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

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

(4) Registration Statement on (Form S-1 No. 333-211491) as filed on September 16, 2016, and

(5) Registration Statement on (Form S-3 No. 333-214507) as filed on November 8, 2016;

of our report dated April 2, 2018, with respect to the consolidated financial statements of Cerecor Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2017.

/s/ Ernst & Young LLP
Baltimore, Maryland
April 2, 2018

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
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: April 2, 2018

/s/ Peter Greenleaf

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

Exhibit 31.2

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

I, Mariam E. Morris, 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: April 2, 2018

/s/ Mariam E. Morris
Mariam E. Morris
Chief Financial Officer
(Registrant's Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Annual Report of Cerecor Inc. (the "Registrant") on Form 10-K for the year ended December 31, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Uli Hacksell, Chief Executive Officer of the Registrant, and I, Mariam E. Morris, Chief Financial Officer of the Registrant, each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: April 2, 2018	By:	/s/ Peter Greenleaf
	Name:	**Peter Greenleaf**
	Title:	**Chief Executive Officer** **(Registrant's Principal Executive Officer)**
Date: April 2, 2018	By:	/s/ Mariam E. Morris
	Name:	**Mariam E. Morris**
	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.