As filed with the Securities and Exchange Commission on November 14, 2017

Registration No. 333-208314

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Post-Effective Amendment
to
FORM S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

ACER THERAPEUTICS INC.

(Exact Name of Registrant as Specified in Its Charter)

Texas		**76-0333165**
(State or Other Jurisdiction of Incorporation or Organization)		(I.R.S. Employer Identification Number)

222 Third Street, Suite #2240
Cambridge, Massachusetts 02142
(844) 902-6100
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Chris Schelling
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Approximate date of commencement of proposed sale to the public: From time to time after this registration statement becomes effective, as determined by market conditions and other factors.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ☐

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. ☒

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ☐

If this form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	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 7(a)(2)(B) of the Securities Act. ☐

If applicable, place an X in the box to designate the appropriate rule provision relied upon in conducting this transaction:

Exchange Act Rule 13e-4(i) (Cross-Border Issuer Tender Offer) ☐

Exchange Act Rule 14d-1(d) (Cross-Border Third-Party Tender Offer) ☐

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell any of these securities until the registration statement filed with Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject To Completion, Dated November 14, 2017

PROSPECTUS

$100,000,000

ACER THERAPEUTICS INC.

Debt Securities, Common Stock,
Preferred Stock, Depositary Shares,
Warrants and Rights

We may, from time to time, offer and sell debt securities, preferred stock, either separately or represented by depositary shares, common stock, warrants or rights, either separately or together in any combination, in one or more offerings. The debt securities, preferred stock and warrants may be convertible into or exercisable or exchangeable for common or preferred stock or debt securities. The rights may be exercisable for common or preferred stock. The aggregate initial offering price of all securities sold under this prospectus will not exceed $100,000,000.

We will specify in an accompanying prospectus supplement more specific information about any such offering. This prospectus may not be used to sell any of these securities unless accompanied by the applicable prospectus supplement.

We may offer and sell the securities described in this prospectus and any prospectus supplement directly to investors or through underwriters, dealers or agents. We will set forth the names of any underwriters, dealers or agents and their compensation in the accompanying prospectus supplement.

Our common stock is listed on The NASDAQ Capital Market under the symbol “ACER.” On October 16, 2017, the last reported sale price of our common stock on The NASDAQ Capital Market was $19.35 per share. The aggregate market value of our outstanding common equity held by non-affiliates on October 16, 2017 was $46,322,604 based on 6,450,766 shares of common stock outstanding, of which 2,393,933 are held by non-affiliates, and a closing sale price on such date of $17.89. During the 12 calendar months prior to and including the date hereof, we have sold securities with aggregate market value of $490,098 pursuant to General Instruction I.B.6. of Form S-3.

Investing in our securities involves risks. See the section entitled “Risk Factors” in the accompanying prospectus supplement and in the documents we incorporate by reference in this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2017

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You should rely only on the information incorporated by reference or provided in this prospectus, any prospectus supplement and the registration statement. We have not authorized anyone else to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information in this prospectus and any prospectus supplement, or incorporated by reference, is accurate only as of the dates of those documents. Our business, financial condition, results of operations and prospects may have changed since those dates.

EXPLANATORY NOTE

On September 19, 2017, Acer Therapeutics Inc., formerly known as Opexa Therapeutics, Inc. (the "Registrant," "we," "us" or "our"), completed its business combination with what was then known as Acer Therapeutics Inc., or Private Acer, in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of June 30, 2017, or the Merger Agreement, by and among the Registrant, Opexa Merger Sub, Inc., a wholly owned subsidiary of the Registrant, or Merger Sub, and Private Acer, pursuant to which Merger Sub merged with and into Private Acer, with Private Acer surviving as a wholly owned subsidiary of the Registrant (the "Merger").

The Registrant is filing this Post-Effective Amendment on Form S-3 to the Registration Statement on Form S-3 (Registration No. 333-208314), originally declared effective March 25, 2016 (the "Registration Statement"), in order to (i) update the description of the Registrant's business, (ii) incorporate by reference Private Acer's audited consolidated financial statements as of December 31, 2016 and 2015, and for the years then ended included in the Registrant's prospectus filed on August 11, 2017 pursuant to Rule 424(b) under the Securities Act, relating to the registration statement on Form S-4, as amended, declared effective August 10, 2017 (File No. 333-219358), and (iii) update the Registrant's periodic reports listed under the heading "Where You Can Find More Information."

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, using a "shelf" registration, or continuous offering, process. Under this shelf registration process, we may, from time to time, offer and sell separately or together in any combination the securities described in this prospectus in one or more offerings up to a maximum aggregate offering price of $100,000,000.

We have previously sold 56,246 shares (pre-reverse split 582,462 shares) of our common stock for aggregate gross proceeds of $783,442 pursuant to a prospectus supplement dated March 25, 2016, as a supplement to the original prospectus dated March 25, 2016.

This prospectus provides you with a general description of the securities we may offer. Each time we sell securities, we will provide a prospectus supplement that will contain specific information about the terms of that offering and the offered securities. Any prospectus supplement may also add, update or change information contained in this prospectus. Any statement that we make in this prospectus will be modified or superseded by any inconsistent statement made by us in a prospectus supplement. The registration statement we filed with the SEC includes exhibits that provide more detail of the matters discussed in this prospectus. You should read this prospectus and the related exhibits filed with the SEC and any prospectus supplement, together with additional information described under the heading "Where You Can Find More Information," before making your investment decision.

Unless the context otherwise requires, references in this prospectus and the accompanying prospectus supplement to "Acer," the "Company," "we," "us" and "our" refer to Acer Therapeutics Inc.

"ACER THERAPEUTICS," "EDSIVO" and the Acer logo are trademarks of Acer Therapeutics Inc. This prospectus and the documents incorporated by reference into this prospectus may also contain trademarks and trade names that are the property of their respective owners. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply relationships with, or endorsements or sponsorship of us by, these other companies.

RISK FACTORS

Investing in our securities involves risk. The prospectus supplement relating to a particular offering will contain a discussion of risks applicable to an investment in the securities offered. Prior to making a decision about investing in our securities, you should carefully consider the specific factors discussed under the heading "Risk Factors" in the applicable prospectus supplement together with all of the other information contained in the prospectus supplement or appearing or incorporated by reference in this prospectus, including the risk factors incorporated by reference to our most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q or Current Reports on Form 8-K. The occurrence of any of these risks might cause you to lose all or part of your investment in the offered securities.

ACER THERAPEUTICS INC.

Overview

We are a pharmaceutical company focused on the acquisition, development and commercialization of therapies for patients with serious rare and ultra-rare diseases with critical unmet medical need. Our late-stage clinical pipeline includes two candidates for severe genetic disorders for which there are few or no FDA-approved treatments: EDSIVO™ (celiprolol) for vascular Ehlers-Danlos Syndrome, or vEDS, and ACER-001 (a fully taste-masked formulation of sodium phenylbutyrate) for urea cycle disorders, or UCD, and Maple Syrup Urine Disease, or MSUD. There are no FDA-approved drugs for vEDS and MSUD and limited options for UCD, which collectively impact more than 4,000 patients in the United States. Our products have clinical proof-of-concept and mechanistic differentiation, and we intend to seek approval for them in the United States by using the regulatory pathway established under section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FFDCA, that allows an applicant to rely for approval at least in part on third-party data, which is expected to expedite the preparation, submission, and approval of a marketing application.

Our Strategy

Our goal is to become a leading pharmaceutical company that acquires, develops and commercializes therapies for the treatment of rare diseases with significant unmet medical need. The key elements of our strategy include:

- focus on orphan and ultra-orphan opportunities with significant unmet need;
- accelerate development timelines and costs, while reducing risk;
- provide differentiated products that create value;
- protect our assets via intellectual property protections and regulatory and market exclusivities; and
- commercialize our products in geographies that make strategic sense.

We plan to continue evaluating external opportunities to acquire or license in order to enhance our pipeline and leverage our business development, clinical development, regulatory and commercial expertise. We believe our management team has the capability and experience to continue to execute this model.

Product Candidates

EDSIVO™

Background

Our most advanced product candidate is EDSIVO™ (celiprolol) for the treatment of vEDS. EDSIVO™ is a selective adrenergic modulator and a New Chemical Entity, or NCE, in the United States. Celiprolol is currently approved in the European Union for the treatment of hypertension and angina. Ehlers-Danlos syndrome, or EDS, is an inherited disorder caused by mutations in the genes responsible for the structure, production, or processing of collagen, an important component of the connective tissues in the human body, or proteins that interact with collagen. EDS is a spectrum disorder where patients present with various forms, the most serious of which is vEDS, also known as EDS type IV, which is generally caused by a mutation in the COL3A1 gene. vEDS causes abnormal fragility in blood vessels, which can give rise to aneurysms, abnormal connections between blood vessels known as arteriovenous fistulas, arterial dissections, and spontaneous vascular ruptures, all of which can be potentially life-threatening. Gastrointestinal and uterine fragility or rupture also commonly occur in vEDS patients. Spontaneous arterial rupture has a peak incidence in the third or fourth decade of life in vEDS patients, but may occur earlier and is the most common cause of sudden death in vEDS patients. The median survival age of vEDS patients in the United States is 51 years, with arterial rupture being the most common cause of sudden death.

Pregnancy-related complications also occur in women with vEDS and include arterial dissection or rupture, uterine rupture, hemorrhage, premature rupture of membranes, lacerations, and complications during and after surgery.

Diagnosis and Incidence

vEDS is diagnosed through clinical observation, which is usually confirmed by mutational analysis of the COL3A1 gene. In the absence of a family history of the disorder, however, most vEDS patients are not diagnosed until the occurrence of an arterial aneurysm or dissection, bowel perforation, or organ rupture. As a result, it has been difficult to precisely measure the incidence or prevalence of vEDS in any population. Studies estimate the prevalence of vEDS as ranging from approximately 1 in 90,000 to 1 in 250,000. In 2017, we commissioned a patient-finder study that identified 2,200 vEDS patients in the United States from an analysis of commercially available patient claims data. Based on that information, we estimate a prevalence of vEDS in the United States of approximately 1 in 140,000.

Current Treatment Options for vEDS

Currently, there are no approved pharmacologic therapies in the United States or the European Union for the treatment of vEDS. Medical intervention for vEDS focuses on surgery, symptomatic treatment, genetic counseling and prophylactic measures, such as avoiding intense physical activity, scuba diving and violent sports. Arterial, digestive or uterine complications in vEDS patients typically require immediate hospitalization, observation in an intensive care unit, and sometimes surgery. Pregnant women with vascular EDS are considered to be at risk and receive special care.

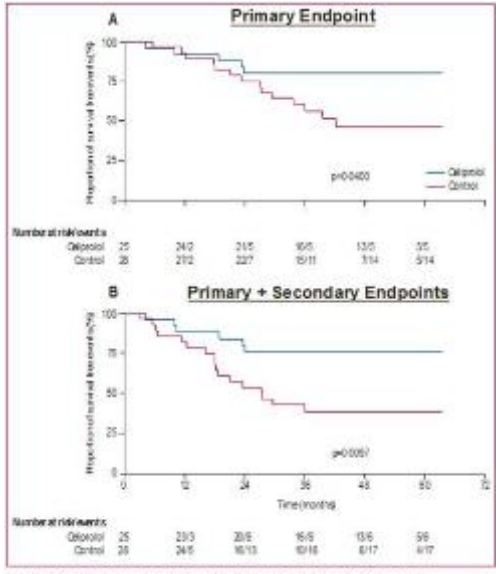
While vEDS patients are encouraged to take steps to minimize the chances of an arterial rupture or dissection, there are no pharmacologic options to reduce the likelihood of such an event, and accordingly all current treatments for vEDS focus on the repair of arterial ruptures or dissection. Therefore, patients must adopt a “watch and wait” approach following any confirmed diagnosis. Unfortunately, many of these arterial events have high mortality associated with them, and thus, a pharmacologic intervention that reduces the rate of events would be clinically meaningful.

EDSIVO™ for Treatment of vEDS

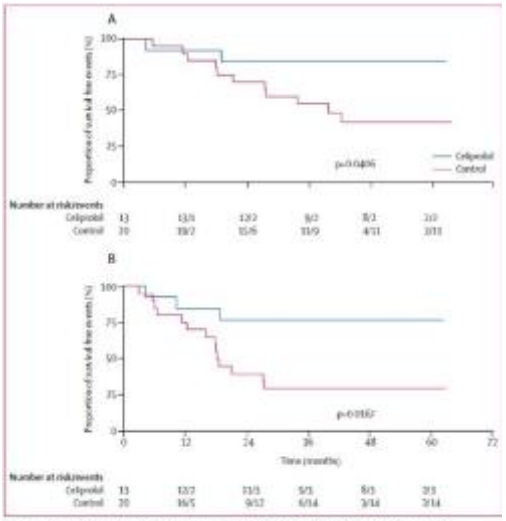
Rationale for EDSIVO™ Treatment in vEDS

In 2004, researchers at Assistance Publique—Hôpitaux de Paris, Hôpital Européen Georges Pompidou, or AP-HP, in Paris, France, observed that the innermost layers of the arterial walls of vEDS patients are abnormally thin, which can explain the risk of arterial dissection or rupture. This observation led to the proposal of celiprolol, a selective adrenergic modulator (or beta 1 antagonist, beta 2 agonist) approved in the European Union for the treatment of hypertension and angina, as a potential treatment for vEDS. The investigators aimed to assess the preventive effect of celiprolol for major cardiovascular events in patients with vEDS via a multicenter, prospective, randomized, open trial with blinded evaluation of clinical events designed trial, which is referred to herein as the Ong trial, and was published on October 30, 2010 in The Lancet.

Fifty-three participants were enrolled in the Ong trial and randomized at eight centers in France and one center in Belgium. Patients were randomly assigned to a five-year intervention, receiving either celiprolol or no treatment. Patients assigned to the control group received the same attention as those assigned to the celiprolol group, but did not receive celiprolol or any beta blocker. Thirty-three of the 53 patients participating in the study had proven mutations in the COL3A1 gene. Of those patients with proven mutations, demographic and arterial characteristics did not differ from those of the study population as a whole. The duration of follow-up was five years or until the first qualifying cardiac or arterial event. The primary endpoint was a composite of cardiac or arterial events (rupture or dissection, fatal or not) during follow-up. Secondary endpoints were gastrointestinal or uterine rupture. The study was ended early after a consensus decision of the safety monitoring board, the methodologist of AP-HP, and the principal investigator because significant differences were recorded between the treatment group and the control group after 64 months. Mean duration of follow-up was 47 months prior to trial halt. As described in the tables below, in 5 of 25 patients on celiprolol a primary endpoint was recorded, compared with 14 of 28 patients in the control group. The hazard ratio, or HR, for event free survival was 0.36, (95% CI 0.15–0.88; p=0.040), meaning that with celiprolol the risk of having a cardiac or arterial event was reduced by 64% compared to control. Combined primary and secondary endpoints affected 6 patients on celiprolol and 17 patients in the control group, (HR 0.31; 95% CI 0.14–0.71; p=0.010):



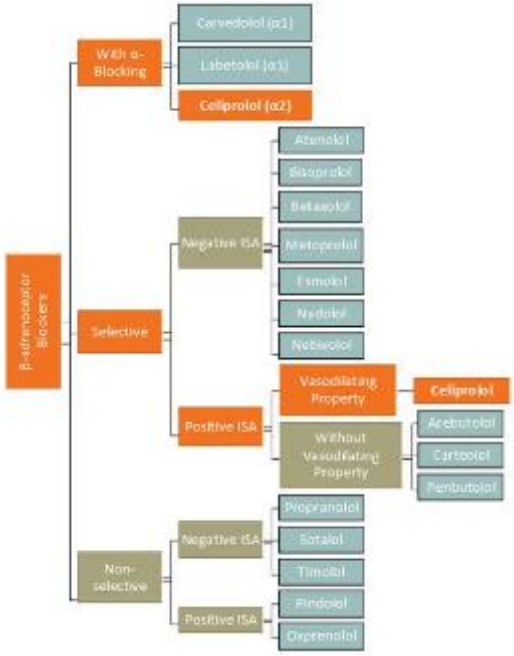
As described in the table below, in the 33 patients with COL3A1 mutations, the primary endpoint was noted in 2 of the 13 patients in the treatment group, compared with 11 of the 20 patients in the control group, (HR 0.24; 95% CI 0.08–0.71; p=0.041). Combined primary and secondary endpoints were recorded in 3 of 13 patients on celiprolol and 14 of the patients in the control group, (HR 0.25; 95% CI 0.10–0.64; p=0.017), correlating to a three times reduction in arterial events among treated patients compared to non-treated patients. The results in the trial did not vary significantly between those patients who had a confirmed mutation in the COL3A1 gene versus the overall 53-patient population:



AP-HP granted us an exclusive right to access and use the data generated by the Ong trial. We have conducted a retrospective, source verified analysis of that data, including the primary and secondary endpoints, which confirmed the published results of the Ong trial.

The precise mechanism of action of celiprolol in vEDS patients is not known. Celiprolol is a cardioselective beta1 antagonist, with beta2 agonist vasodilatory properties, meaning it demonstrates antihypertensive and antianginal activity; however, it lacks the typical side effects of beta1 antagonists, such as bronchoconstriction, depression of left ventricular function, and peripheral vasoconstriction, likely a result of its beta2 agonist activity. Accordingly, investigators initially surmised that celiprolol would reduce central blood pressure and thus mechanical load on collagen fibers within the arterial wall, thereby reducing the risk of arterial dissection and rupture. However, celiprolol did not decrease brachial blood pressure or heart rate. Moreover, systolic and pulse pressures substantially increased after treatment, which is consistent with findings of celiprolol treatment in normotensive individuals, or individuals with normal blood pressure. Celiprolol's lack of blood pressure lowering in normotensive people was explained by its beta2-adrenoceptor agonist properties. The impact of the beta1 antagonist and beta2 agonist properties of celiprolol are known to vary among individuals with high blood pressure and those with normal blood pressure. In individuals with high blood pressure, the beta1 antagonist properties predominate resulting in a reduction in blood pressure; however, in mildly hypertensive or healthy individuals, the beta2 agonist properties predominate, which does not induce a reduction in blood pressure. Most of the patients enrolled in the Ong trial had normal blood pressure at inclusion, and thus, the protective effect of celiprolol was found unlikely to be through blood pressure lowering. Researchers have hypothesized that another possible mechanism to explain the benefit patients experienced while treated with celiprolol in the Ong trial is the strong associations between beta-adrenergic receptors and transforming growth factor, or TGF, beta pathways. Chronic stimulation of beta2 receptors might enhance collagen synthesis through increased expression of TGF-beta. Thus, in response to celiprolol, an increase of collagen synthesis might have strengthened the arterial wall, thereby reducing its susceptibility to rupture.

We do not believe that there are any other drugs approved or in development in the United States or Europe that have a similar mechanism of action to celiprolol:



Registration Plan

Celiprolol has not been approved for any indication in the United States. Celiprolol has been approved for the treatment of hypertension in the European Union since 1984. An NDA for celiprolol for the treatment for hypertension was submitted by Aventis Pharms SA to the FDA in 1987, but was withdrawn prior to FDA review and ultimately not approved. We have obtained from Aventis Pharma SA the exclusive right to reference the celiprolol data included in the marketing authorization dossier filed with and approved by the U.K. Medicines and Healthcare Products Regulatory Agency, or MHRA. We have also licensed from AP-HP exclusive worldwide rights to the data from the Ong trial.

We intend to seek FDA approval for celiprolol for the treatment of vEDS by submitting an NDA under Section 505(b)(2) of the FFDCA, referred to as a 505(b)(2) NDA, where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use. FDA interprets this to mean that an applicant may rely for approval on data in published literature or on the FDA's finding of safety or effectiveness of a previously approved drug product owned by a third party. Use of third-party data would minimize the amount of original data we would be required to generate and shorten the time needed for preparation, submission, and review of the marketing applications.

In September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO™. At that meeting, the FDA agreed that additional clinical development is not needed and stated that we may submit a 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS. In addition, the FDA advised us that no significant additional work would be required for the chemistry, manufacturing and controls, nonclinical or pharmacology sections of the NDA. The FDA also indicated to us at that time that it expected that the 505(b)(2) NDA for EDSIVO™ would qualify for priority review, which provides an expedited six-month review cycle, instead of the traditional 10-month cycle, for a drug that treats a serious condition and demonstrates the potential to be a significant improvement in safety or effectiveness of the treatment, prevention, or diagnosis of the condition. The FDA determines whether an application will receive priority review at the time the application is submitted. We expect to submit to the FDA the 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS in the first half of 2018.

ACER-001

Background

Our product candidate ACER-001 is a fully-taste masked formulation of sodium phenylbutyrate, or NaPB, designed to treat Urea Cycle Disorders, or UCD, and Maple Syrup Urine Disease, or MSUD. NaPB is currently approved in the United States and the European Union to treat patients with UCD.

Urea Cycle Disorders (UCD)

Background

The urea cycle is a series of biochemical reactions that occurs in the liver, which converts toxic ammonia produced by the breakdown of protein and other nitrogen-containing molecules in the human body into urea for excretion. UCD are a group of disorders caused by genetic mutations that result in a deficiency in one of the six enzymes that catalyze the urea cycle, which can lead to an excess accumulation of ammonia in the blood stream, a condition known as hyperammonemia. Acute hyperammonemia can cause lethargy, somnolence, coma, and multi-organ failure, while chronic hyperammonemia can lead to headaches, confusion, lethargy, self-chosen vegetarian diet, failure to thrive, behavioral changes, and learning and cognitive deficits. Common symptoms of both acute and chronic hyperammonemia also include seizures and psychiatric symptoms.

Diagnosis and Incidence

The diagnosis of UCD is based on clinical observations, confirmed by biochemical and molecular genetic testing. A plasma ammonia concentration of 150 lmol/L or higher associated with a normal anion gap and a normal plasma glucose concentration is an indication for the presence of UCD. Plasma quantitative amino acid analysis and measurement of urinary orotic acid can distinguish between the various types of UCD. A definitive diagnosis of UCD depends on either molecular genetic testing or measurement of enzyme activity. Molecular genetic testing is possible for all urea cycle defects. Studies suggest that the incidence of UCD in the United States ranges between 1 in 35,000 live births to 1 in 8,200 live births.

Current Treatment Options for UCD

The current treatment of UCD consists of dietary management to limit ammonia production in conjunction with medications that provide alternative pathways for the removal of ammonia from the bloodstream. Dietary protein must be carefully monitored and some restriction is necessary; too much dietary protein causes excessive ammonia production. However, if protein intake is too restrictive or insufficient calories are provided, the body will break down lean muscle mass to obtain the amino acids or energy it requires, which can also lead to excessive ammonia in the blood stream. Dietary management may also include supplementation with special amino acid formulas developed specifically for UCD, which can be prescribed to provide approximately 50% of the daily dietary protein allowance. Some patients may also require individual branched chain amino acid supplementation.

Medications for UCD primarily comprise nitrogen scavenger drugs, which are substances that provide alternative excretion pathways for nitrogen by bypassing the urea cycle. The use of these alternative pathways for nitrogen removal is important for the management of acute episodes of hyperammonemia and are also included as part of a long-term treatment regime for UCD patients. Current nitrogen scavenger treatments for UCD are based on sodium benzoate or phenylbutyrate, which conjugate with glycine and glutamine, respectively, allowing for urinary excretion of nitrogen as hippurate and phenylacetylglutamine, respectively.

According to a 2016 study by Shchelochkov et al., published in Molecular Genetics and Metabolism Reports, while nitrogen scavenging medications are effective in helping to manage UCD, non-compliance with treatment is common. Reasons given for non-compliance include the unpleasant taste associated with medications, the frequency with which medication must be taken and the high cost of the medication.

Phenylbutyrate is available as both NaPB, which is marketed as Buphenyl®, and glycerol phenylbutyrate, which is marketed as Ravicti®. While a study provided by Horizon Therapeutics, Inc. in the Ravicti package insert involving 46 adults with UCD demonstrated that Buphenyl and Ravicti were similarly effective in controlling the blood level of ammonia over a 24-hour period, many patients who take their medicine orally prefer Ravicti, as it is significantly more palatable than Buphenyl. However, the cost of Ravicti – approaching $600,000 to $800,000 per patient per year – is prohibitive.

ACER-001 for Treatment of UCD

Rationale for ACER-001 Treatment in UCD

ACER-001 is a proprietary, immediate release, taste-masked suspension formulation of NaPB. Buphenyl, a non-taste masked formulation of NaPB, has been approved by the FDA for UCD with demonstrated efficacy and safety in UCD patients of all ages. We believe that if it is approved, ACER-001's taste-masked properties will make it a compelling alternative to existing phenylbutyrate-based treatments, as the unpleasant taste associated with NaPB is cited as a major impediment to patient compliance with those treatments.

Registration Plan

We intend to initially seek FDA approval to market ACER-001 in the United States using a 505(b)(2) NDA through which we may reference data from an application previously approved by the FDA. We also intend to seek approval in the European Union and potentially other territories outside the United States, after the 505(b)(2) NDA for treatment of UCD is filed. Because the FDA has approved an NDA for NaPB, which is referred to as the reference listed drug, or RLD, we intend to rely on the RLD's pre-clinical and clinical safety data, while supplementing the data with a bridging study that demonstrates bioequivalence of ACER-001 to NaPB.

We plan to undertake a clinical study designed to evaluate the bioequivalence of ACER-001 and NaPB in healthy adult male and female subjects in fed and fasted states. Under the protocol, subjects will be randomized to one of four sequences, which will determine study treatment. There will be a minimum 12-hour washout period between the treatment periods for each sequence.

The safety of ACER-001 will also be evaluated in this study, which we plan to initiate in the first half of 2018.

Maple Syrup Urine Disease (MSUD)

Background

Maple syrup urine disease, or MSUD, is a rare inherited disorder caused by defects in the mitochondrial branched-chain ketoacid dehydrogenase complex, which results in elevated blood levels of the branched-chain amino acids, or BCAA, leucine, valine, and isoleucine, as well as the associated branded-chain ketoacids, or BCKA, in a patient's blood. Left untreated, this can result in neurological damage, mental disability, coma or death. There are currently no approved pharmacologic therapies in the United States or the European Union for MSUD. Treatment of MSUD consists primarily of a severely restricted diet to limit the intake of BCAA, with aggressive medical interventions when blood-levels of BCAA or BCKA become elevated. The most severe presentation of MSUD, known as "classic" MSUD, accounts for 80% of cases and can result in neonatal onset with encephalopathy and coma. Although metabolic management of the disease is possible via a highly restrictive diet, the outcome is unpredictable and a significant portion of affected individuals are mentally impaired or experience neurological complications.

Studies indicate that MSUD affects an estimated 1 in 185,000 infants worldwide. The disorder occurs more frequently in the Old Order Mennonite population, with an estimated incidence of about 1 in 380 newborns, and the Ashkenazi Jewish population, with an estimated incidence of 1 in 26,000. Approximately 3,000 patients suffer from MSUD worldwide, of whom approximately 800 are located in the United States.

ACER-001 for Treatment of MSUD

Rationale for ACER-001 Treatment in MSUD

Therapy with NaPB in UCD patients has been associated with a selective reduction in BCAA despite adequate dietary protein intake.

Based on this clinical observation, investigators at Baylor College of Medicine, or BCM, explored the potential of NaPB treatment to lower BCAA and their corresponding BCKA in patients with MSUD. The investigators found that BCAA and BCKA were both significantly reduced following NaPB therapy in control subjects and in patients with MSUD, although there was no simple correlation between the patients' levels of residual enzymatic activity with the response of plasma BCAA and their BCKA to NaPB. NaPB demonstrated a statistically significant reduction of leucine in all three healthy subjects and in three out of the five MSUD patients who participated in the trial. The reduction in leucine, the most toxic of the BCAAs, in the three responsive MSUD patients ranged between 28-34%, which is considered by clinicians to be a meaningful response.

Registration Plan

We intend to seek FDA approval to market ACER-001 for the treatment of MSUD in the United States by submitting a 505(b)(2) NDA through which we may be able to rely on the preclinical and clinical safety data from the RLD's NDA while supplementing the data with additional pharmokinetic, pharmodynamic, efficacy and safety data specifically in the MSUD population. We also intend to seek approval in the European Union and other territories outside the United States, including the EU, after the supplemental NDA for treatment of MSUD is filed.

ACER-001 Clinical Development in MSUD Patients

Subject to our ability to generate sufficient capital resources, we intend to support a 505(b)(2) NDA for ACER-001 for the treatment of MSUD by submitting an Investigational New Drug Application, or IND, in 2018 that will include protocols for the following four clinical trials:

Study One

This multicenter, open-label, uncontrolled clinical trial will enroll approximately 60 subjects with MSUD ages 8 to 48 years, who have baseline blood leucine levels >150 µmol/L, while achieving steady-state leucine intake via a restricted diet. All subjects will receive ACER-001 for 7 days. Response will be defined as a greater than or equal to 30% decrease in blood leucine from baseline. We anticipate that at day seven, 40 subjects will be identified as responders.

Study Two

This multicenter, double-blind, placebo-controlled study will enroll approximately 40 subjects with MSUD who responded to sodium phenylbutyrate in Study 1. After a washout period from Study 1, subjects will be randomized equally to either ACER-001 or placebo for 4 weeks. Efficacy will be assessed by the mean change in blood leucine level from baseline to week four in the ACER-001-treated group as compared to the mean change in the placebo group.

Study Three

This multicenter, open-label, uncontrolled clinical trial will enroll approximately 20 subjects with MSUD who did not respond to sodium phenylbutyrate in Study 1. After a washout period from Study 1, subjects will undergo six weeks of forced dose-titration with three different doses of ACER-001. Treatments will consist of three consecutive two-week courses of ACER-001 at increasing doses above the top dose studied in Study 1. Blood leucine levels will be monitored after two weeks of treatment at each dose level.

Study Four

This multicenter, open-label, extension study will enroll up to 60 subjects who respond to ACER-001 treatment in Study 1 and complete Study 2, and any subjects from Study 3 who are identified as responders following dose titration. Blood leucine levels will be monitored every four weeks, and additional safety information will be collected.

Commercialization Strategy

Assuming the FDA approves EDSIVO™ and ACER-001, we expect that the majority of vEDS, UCD and MSUD patients will be treated at tertiary care centers, and therefore can be addressed with a targeted sales force. vEDS patients will primarily be treated by vascular medicine or cardiology specialists, while the UCD and MSUD patients will primarily be managed by metabolic geneticists and dietitians. We intend to build our own commercial infrastructure in the United States to target these centers, and will evaluate whether to commercialize in other geographies ourselves or with an experienced partner.

Competition

The pharmaceutical industry is highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Given the significant unmet medical need for novel therapies to treat vEDS, UCD, and MSUD, many companies, public and private universities and research organizations are actively engaged in the discovery, research and development of product candidates to treat these conditions. As a result, there are and will likely continue to be extensive resources invested in the discovery and development of new products to treat these unmet medical needs. We anticipate facing intense and increasing competition as new products enter the market and advanced technologies become available.

We are not aware of any other companies that are pursuing a treatment for vEDS, although we are aware of a study that is currently enrolling vEDS patients at AP-HP that includes adding irbesartan, an angiotensin II receptor blocker, with celiprolol, to provide supplemental vascular protection and thus reduce recurrence of arterial events in vEDS patients. Our potential competitors and the related stage of development for their product candidates in our other target indications include the following:

- UCD: Horizon Pharma plc / SOBI, Inc. (Marketed); Promethera Biosciences S.A./N.V. (Phase 2); Aeglea BioTherapeutics Inc. (Phase 1/2); Dimension Therapeutics Inc. (Phase 1/2); PhaseRx, Inc. (Phase 1); Synlogic, Inc. (preclinical)
- MSUD: Synlogic, Inc. (preclinical)

Many of our competitors, either alone or with strategic partners, have or will have substantially greater financial, technical and human resources than us. Accordingly, our competitors may be more successful than us in developing or marketing products and technologies that are more effective, safer or less costly. Additionally, our competitors may obtain regulatory approval for their products more rapidly and may achieve more widespread market acceptance. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical study sites and patient registration for clinical studies and acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

There are other non-pharmaceutical therapeutic approaches that are used or may be used for our targeted indications. For example, liver transplantation may be used in some cases to treat UCD or MSUD in pediatric patients who have developed acute liver failure.

We believe that the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety and tolerability profile, convenience in dosing, product labeling, price, and the availability of reimbursement.

Licenses and Royalties

Baylor College of Medicine License

In April 2014, we obtained exclusive rights to patents and certain other intellectual property relating to ACER- 001 and preclinical and clinical data, through an exclusive license agreement with BCM. Under the terms of the agreement, as amended, we have worldwide exclusive rights to develop, manufacture, use, sell and import products incorporating the licensed intellectual property. The license agreement requires us to make upfront and annual payments to BCM, reimburse certain of BCM's legal costs, make payments upon achievement of defined milestones, and pay royalties on net sales of any developed product over the royalty term.

Aventis Pharma SA

In June 2016, we entered into an agreement with Aventis Pharma SA granting us the exclusive access and exclusive right to use the data included in the marketing authorization application dossier filed with and approved by the MHRA in 1986 for the treatment of mild to moderate hypertension pursuant to the UK regulatory approval procedure, for the sole purpose of allowing us to further develop, manufacture, register and commercialize celiprolol in the U.S. and Brazil for the treatment of EDS, Marfan syndrome and Loeys-Dietz syndrome. We have paid in full for the exclusive access and right to use the data.

Assistance Publique – Hôpitaux de Paris (AP-HP)

In August 2016, we entered into an agreement with the AP-HP granting us the exclusive worldwide rights to access and use data from the Ong trial. We intend to use this pivotal clinical data to support an NDA filing for EDSIVO™ for the treatment of vEDS. The agreement requires us to make certain upfront payments to AP-HP, reimburse certain of AP-HP's costs, make payments upon achievement of defined milestones and pay royalties on net sales of celiprolol over the royalty term.

Manufacturing

We contract with third parties for the manufacture, testing and storage of our product candidates and intend to continue to do so in the future. We do not own and have no plans to build our own manufacturing capabilities for clinical or commercial supply. Because we rely on contract manufacturers, we have hired consultants with extensive technical, manufacturing, analytical, regulatory and quality assurance and control experience to oversee contract manufacturing and testing activities, and to compile manufacturing and quality information for our regulatory submissions.

Intellectual Property

EDSIVO™

We intend to protect our commercial rights to EDSIVO™ in the U.S. via multiple pathways. We believe that we will be eligible for NCE Exclusivity for EDSIVO™, which provides upon approval of a drug five years of marketing exclusivity during which time the FDA will not approve another drug with the same active ingredient, regardless of the indication for use, in the United States. In January 2015, the FDA granted EDSIVO™ Orphan Drug Designation, which provides upon the approval of a drug intended to treat a rare condition seven years of marketing exclusivity during which time the FDA will not approve the same drug for the same indication, unless it demonstrates clinical superiority. Orphan Drug Exclusivity does not prevent the FDA from approving the same drug for a different indication, or a different drug for the same indication. NCE Exclusivity and Orphan Drug Exclusivity run concurrently. Furthermore, EDSIVO™ may qualify for an additional six months of Pediatric Exclusivity in the United States, which requires the submission of one or more studies that meet requirements to be specified by the FDA in a Written Request for pediatric studies. Pediatric Exclusivity can be obtained either before or after NDA approval. Pediatric Exclusivity is attached to the end of an existing exclusivity and runs consecutively. We may also consider making modifications to the formulation to obtain additional intellectual property. While unapproved drugs may be imported into the United States under specified circumstances, such as for use in clinical studies under a valid and effective IND or for further manufacture into an IND drug or an approved drug, we intend to aggressively assert our rights, via regulatory and legal

means, to limit the importation of non-FDA approved versions of celiprolol. We intend to provide a robust patient assistance program, or PAP, to offset costs associated with a high priced therapeutic to minimize the incentive for vEDS patients in the United States to seek to obtain celiprolol elsewhere.

ACER-001

We obtained exclusive rights to certain patents and other intellectual property from BCM for the use of NaPB for the treatment of inborn errors of BCAA metabolism, including MSUD.

The licensed patent covers methods and compositions for treating humans (and animals) with various formulations and prodrugs of NaPB for inborn errors of BCAA metabolism, including MSUD, and does not expire until 2030. We made filings in the geographic regions that represent the largest incidence and prevalence of MSUD: United States, selected countries in Europe (including Turkey) and Brazil. BCM has been issued one patent in each of the United States and the European Union with respect to ACER-001, each of which was exclusively licensed to us pursuant to our agreement with BCM.

We filed a formulation patent application with respect to ACER-001 in January 2016 and plan to seek further patent protection in major markets, including the United States and the European Union.

We also expect to benefit from potential commercial exclusivity afforded to the first drug approved after obtaining Orphan Drug Designation for the treatment of MSUD. Orphan Drug Exclusivity provides upon the approval of a drug intended to treat a rare condition seven years of marketing exclusivity during which time the FDA will not approve the same drug for the same indication, unless it demonstrates clinical superiority, in the United States and ten years in the European Union post approval. Orphan Drug Exclusivity does not prevent the FDA from approving the same drug for a different indication, or a different drug for the same indication. NCE Exclusivity and Orphan Drug Exclusivity run concurrently. We were granted Orphan Drug Designation for ACER-001 for the treatment of MSUD by the FDA in August 2014.

Furthermore, we may qualify to receive an additional six months of Pediatric Exclusivity in the United States, which runs consecutively to an existing exclusivity, and an additional two years in the European Union.

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 use of unapproved drugs, pre-clinical and clinical studies, development, testing, quality control, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, import, and export of pharmaceutical products such as those we are developing. The process for obtaining approvals or authorizations to market a drug product in the United States and in foreign countries and jurisdictions, along with pre- and post-approval compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources. Our product candidates must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of approval requirements within the European Union are addressed uniformly, while country-specific requirements must also be met.

U.S. Drug Approval Process

In the United States, the FDA regulates drugs under the FFDCA and the FDA's implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining marketing approvals and pre- and post-approval compliance with applicable federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time before or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve a pending NDA, withdrawal of an approval, imposition of a clinical hold on a clinical study or studies, issuance of a warning letter or untitled letter, product recall, product seizure, total or partial suspension of production or distribution, injunction, fines, refusals or cancellation of government contracts, restitution, disgorgement, or civil or criminal penalties.

The process required by the FDA before a 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 current good laboratory practice, or cGLP, regulations;
- submission to the FDA of an IND to which the FDA has no objections and which must become effective before clinical trials in the United States may begin;
- approval by an institutional review board, or IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug candidate for each proposed indication in accordance with the FDA's current Good Clinical Practice, or cGCP, regulations, IND regulations, and human subject protection regulations;
- submission to the FDA of an NDA;
- satisfactory review by an FDA advisory committee, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with the FDA's current Good Manufacturing Practice, cGMP, regulation and to assure that the methods used in, and the facilities and controls used for, manufacture, processing, and packing are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA.

Preclinical Studies

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical trial protocol, among other things, to the FDA as part of an IND. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises questions or concerns, including concerns that human research subjects will be exposed to unreasonable health risks, related to one or more proposed clinical trials and places the 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 patients under the supervision of qualified investigators in accordance with IND regulations and human subject protection regulations as well as cGCP standards, which include the requirement that all research patients provide their informed consent for their participation in any clinical trial and that an IRB approve each study before it begins. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical trial must review and approve each protocol and protocol amendment for any clinical trial before it commences at that institution. Information about certain clinical trials 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 or four sequential phases, which may overlap or be combined:

Phase 1: The drug is initially introduced into a small number of healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution, and excretion or, on occasion, in patients with severe problems or life-threatening disease to gain an early indication of its effectiveness.

Phase 2: The drug is administered to a limited patient population to preliminarily evaluate the efficacy of the product for a specific targeted disease, gather additional safety information and to determine dosage tolerance, optimal dosage and method of delivery.

Phase 3: The drug is administered to a larger patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product to determine effectiveness, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product and ultimately to support approval.

Phase 4: In some cases, the FDA may condition approval of an NDA for a product candidate on the sponsor's agreement to conduct additional clinical trials after NDA approval. In other cases, a sponsor may voluntarily conduct additional clinical trials post approval to gain more information about the drug. Such post approval trials are typically referred to as Phase 4 clinical trials.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious and unexpected adverse reactions occur. Trial sponsors must monitor other information including published as well as unpublished scientific papers, reports from foreign regulatory authorities and reports of foreign commercial marketing experience for the investigational drug and notify the FDA and clinical trial investigators of certain information. Phase 1, Phase 2 and Phase 3 clinical trials may fail to be completed successfully within a specified period, or at all. Furthermore, the FDA may impose a clinical hold on one or more or all of the clinical studies or the sponsor may suspend or terminate a clinical trial or development of an investigational product at any time for a variety of reasons, including a finding that the research patients are being exposed to an unacceptable health risk. Development, or the aspects of development, that are affected by the clinical hold may not continue unless and until the sponsor addresses all of the FDA's concerns and has been notified that the hold is removed. Similarly, an IRB can suspend or terminate its approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the protocol or the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Nearly all Phase 3 trials and some other trials are overseen by a Data and Safety Monitoring Board, or DSMB, which is composed of doctors, statisticians, and others who are independent of the clinical trial sponsor. Similar to IRBs, the DSMBs review the progress of a clinical trial and participant safety, but they also review data on the effectiveness of the drug being studied. DSMB members can stop a trial early if safety concerns arise or if they determine that the trial should be stopped due to "futility" meaning that the trial will not be able to answer the question or questions it set out to explore.

Concurrent with clinical trials, companies may need to complete additional animal trials and must develop information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the drug in commercial quantities in accordance with Current Good Manufacturing Practice, or cGMP,requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested and stability studies must be completed to establish an expiration date and demonstrate that the drug candidate does not undergo unacceptable deterioration prior to the expiration date.

The NDA Approval Process

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, 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 to support 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.

The FDA is required to conduct a preliminary review of an NDA within the first 60 days after submission, before accepting it for filing, to determine whether it is sufficiently complete to permit substantive review. The FDA may accept the NDA for filing, potentially refuse to file the NDA due to deficiencies but work with the applicant to rectify the deficiencies (in which case the NDA is filed upon resolution of the deficiencies) or refuse to file the NDA. The FDA must notify the applicant of a refusal to file decision within 60 days after the original receipt date of the application. If the FDA refuses to file the NDA the applicant may resubmit the NDA with the deficiencies addressed. The resubmitted NDA is considered a new application subject to a new ten-month review goal, as described below. If the NDA is resubmitted for the same product (by the same person) a new application fee will not be required. The resubmitted application is also subject to review before the FDA accepts it for filing. Once an NDA is accepted for filing, the FDA begins an in-depth substantive review. Under the Prescription Drug User Fee Act, or PDUFA, and the FDA's commitments under the current PDUFA Reauthorization Act, the FDA has a goal of reviewing and acting on 90% of standard non-priority NDA applications within ten months from the filing date of the NDA.

The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective for its intended use 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. The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation in response to specific questions raised by the FDA, which may include 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 inspects 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 cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect and audit data at one or more clinical sites to evaluate the integrity of the data and confirm compliance with cGCP.

After the FDA evaluates the NDA and conducts its inspections, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug subject to specific prescribing information for specific indications and, if applicable, specific post-approval requirements. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. After receiving a Complete Response Letter, the applicant must decide within twelve months (subject to extension), if it wants to resubmit the NDA addressing the deficiencies identified by the FDA in the Complete Response Letter, withdraw the NDA, or request an opportunity for a hearing to challenge the FDA's determination. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret data.

The FDA also may require implementation of a Risk Evaluation and Mitigation Strategy, or REMS, to mitigate any identified or suspected serious 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 drug testing and approval process requires substantial time, effort and financial resources, and may take several years to complete. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent marketing approval. The FDA may not grant marketing approval on a timely basis, or at all.

Even if the FDA approves a product, it may limit the approved indications for use for the product. The FDA requires that the approved product labeling include information regarding contraindications, warnings or precautions. It may also, require that post-approval studies, including Phase 4 clinical trials, including a long-term registry, 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, 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, some types of changes to the approved product, such as adding new indications or labeling claims or manufacturing changes may be subject to further testing requirements and FDA review and approval. Also after approval, the FDA may require labeling changes as new information becomes known, particularly if new risks are identified, such as unexpected adverse events. The FDA has the authority to prevent or limit further marketing of a drug based on the results of these post-marketing studies and programs or other information that may become known after approval.

Hatch-Waxman Amendments and Exclusivity

The Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, amended the FFDCA and established abbreviated pathways to market, as well as incentives for the development of new drug products. The Hatch-Waxman Amendments established section 505(b)(2) of the FFDCA that provides an alternative pathway for submission of an NDA, referred to as the 505(b)(2) application, when some or all of the safety and efficacy investigations relied on for approval were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Amendments also established the abbreviated new drug application, or ANDA, approval pathway, which provides an expedient route for generic drugs that have the same active ingredient as a previously approved drug. At the same time, to incentivize continued pharmaceutical innovation, the Hatch-Waxman Amendments authorized periods of market exclusivity to protect certain approved new drugs from competition for five or three year periods.

Under the Hatch-Waxman Amendments, a new drug containing an active ingredient that had never before been approved in any other NDA, ANDA, or 505(b)(2) NDA is provided five years of market exclusivity upon approval. The FDA refers to this exclusivity as NCE Exclusivity. During the NCE Exclusivity period, the FDA cannot approve an ANDA or a 505(b)(2) application for a drug containing the same active ingredient. For NCE Exclusivity, the FDA regulations interpret "active ingredient" to mean "active moiety," which is defined as "the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt . . . , or other noncovalent derivative . . . of the molecule, responsible for the physiological or pharmacological action of the drug substance." Although the FDA may not approve an ANDA or 505(b)(2) NDA with the same active ingredient during the five-year NCE Exclusivity period, an ANDA or 505(b)(2) NDA may be submitted to the FDA after four years if it contains a certification of patent invalidity or non- infringement.

The Hatch-Waxman Amendments also provide three years of market exclusivity for an NDA, a 505(b)(2) NDA, or a supplement to either of these applications for a drug product containing an active moiety that has been previously approved, 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. During this three-year exclusivity period, the FDA will not make effective the approval of any ANDA or 505(b)(2) NDA for the same active moiety for the same conditions of use. Five-year and three-year exclusivity will not delay the submission or approval of a new drug containing the same active moiety if it is the subject of a full NDA for which the applicant conducted, sponsored, or obtained a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Other Regulatory Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, annual establishment registration and product listing and associated user fees, compliance with the cGMP, recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion, and adverse drug experience monitoring and reporting with the product. After approval, most changes to the approved product labeling, such as adding new indications are subject to prior FDA review and approval. Also, any post-approval changes in the drug substance, drug product, production process, quality controls, equipment, or facilities that have a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product is subject to FDA review and approval. Any such changes that have a moderate potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product must be submitted to the FDA for review 30 days prior to implementation. All manufacturing facilities as well as records required to be maintained under FDA regulations are subject to inspection or audit by the FDA. In addition, manufacturers are required to pay annual user fees for establishment registration and user fees for the submission of each new or 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-approval testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. The Food and Drug Administration Amendments Act of 2007 gave the FDA the authority to require a REMS from drug manufacturers to manage a known or potential serious risk associated with the drug and to ensure that the benefits of a drug outweigh its risks. Examples of a REMS include, but are not limited to, a Medication Guide, a patient package insert to help mitigate a serious risk of the drug, and a communication plan to health care providers to support implementation of an element of the REMS.

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 register or obtain permits or licenses in states where they do business, and are subject to periodic unannounced inspections by the FDA and state regulatory authorities with jurisdiction over their activities to determine compliance with regulatory requirements. A drug manufacturer is responsible for ensuring that its third party contractors operate in compliance with applicable laws and regulations including the cGMP regulation. The failure of a drug manufacturer or any of its third party contractors to comply with federal or state laws or regulations may subject the drug manufacturer to possible legal or regulatory action, such as an untitled letter, warning letter, recall, suspension of manufacturing or distribution or both, suspension of state permit or license, seizure of product, import detention, injunctive action, civil and criminal penalties.

Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require a drug manufacturer to conduct investigations and implement appropriate corrective actions to address any deviations from cGMP requirements, and impose reporting and documentation requirements upon the manufacturer and any third-party contractors (including contract manufacturers and laboratories) involved in the manufacture of a drug product. Accordingly, manufacturers must continue to expend significant time, money and effort to maintain and ensure ongoing cGMP compliance and to confirm and ensure ongoing cGMP compliance of their third party contractors.

Once an approval is granted, the FDA may withdraw the approval if there is new information or evidence that the drug is unsafe or not shown to be safe for use under the conditions of its approval, or that new information shows there is a lack of substantial evidence of effectiveness, or that the approved application contained an untrue statement of material fact, or that the required patent information was not submitted within 30 days after receiving notice from the FDA of the failure to submit such information. 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 revisions to the approved labeling to add new safety and risk information; imposition of a post-market study requirement to assess new safety risks; or implementation of a REMS that may include distribution or other restrictions.

The FDA closely regulates drug advertising and promotional activities, including promotion of an unapproved drug, direct-to-consumer advertising, dissemination of scientific information about a drug not on the approved labeling, off-label promotion, communications with payors and formulary committees, industry-sponsored scientific and educational activities, and promotional activities involving the internet and social media. A company's product claims must be true and not misleading, provide fair balance, provide adequate risk information, and be consistent with the product label approved by the FDA. Failure to comply with these requirements can lead to regulatory actions including, among other things, warning letters, corrective advertising, injunction, violation and related penalties under the False Claims Act, and result in reputational and economic harm.

Physicians may prescribe FDA-approved drugs for uses that are not described in the product's labeling and that differ from those uses tested by the manufacturer. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments for their individual patients. The FDA does, however, regulate manufacturers' communications about their drug products and interprets the FFDCA to prohibit pharmaceutical companies from promoting their FDA-approved drug products for uses that are not specified in the FDA-approved labeling. Companies that market drugs for off-label uses have been subject to warning letters, related costly litigation, criminal prosecution, and civil liability under the FFDCA and the False Claims Act.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drug and drug samples at the federal level, and sets minimum standards for the registration and regulation of wholesale drug distributors by the states.

Orphan Designation

The Orphan Drug Act of 1983 provides incentives, including marketing exclusivity, user fee waivers and tax benefits, to companies that undertake development and marketing of products to treat rare diseases, which are defined as diseases for which there is a patient population of fewer than 200,000 persons in the United States or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. A drug that receives orphan drug designation may receive up to seven years of exclusive marketing in the United States for that indication, 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 or where the manufacturer is unable to assure sufficient product quantity. A drug may be entitled to an additional six months of exclusive marketing if it satisfies the requirements for pediatric exclusivity.

The European Medicines Agency (EMA) Committee for Orphan Medicinal Products, or COMP, grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the European Union Community and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the medicinal product. In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following medicinal product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

New Legislation and Regulations

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the testing, approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations and policies are often revised or interpreted by the agency in ways that may significantly affect our business and products. It is impossible to predict whether further legislative changes will be enacted or FDA regulations, guidance, policies or interpretations will be changed, or what the impact of such changes, if any, may be.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we may obtain marketing approval. Sales of any of our product candidates, if approved, will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a third-party payor will provide coverage for a drug product typically is separate from the process for establishing the reimbursement rate that a payor will pay for the drug product once coverage is approved. Some third-party payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the approved drugs for a particular indication.

In order to obtain coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Whether or not we conduct such studies, our product candidates may not be considered medically necessary or cost-effective. A third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Third-party reimbursement may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost-effectiveness of drug products and medical services and questioning safety and efficacy. Emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on drug pricing. If third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover the products for which we receive FDA approval or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit.

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs and drug prices in general, including for therapies for rare diseases. These measures include price controls, transparency requirements triggered by the introduction of new high-cost drugs into the market, drug re-importation, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. Some laws and regulations have already been enacted in these areas, and additional measures have been introduced or are under consideration at both the federal and state levels. Additionally, at the request of U.S. Senators, the Government Accountability Office is currently investigating abuses of the Orphan Drug Act, which could potentially lead to legislation that affects reimbursement for drugs with small patient populations. Adoption of such controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals such as our drug product candidates and could adversely affect our net revenue and results.

In addition, in the United States, the Patient Protection and Affordable Care Act, or the Affordable Care Act, contains provisions that have the potential to substantially change healthcare delivery and financing, including impacting the profitability of drugs. For example, the Affordable Care Act revised the methodology by which rebates owed by manufacturers for covered outpatient drugs are calculated under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of covered drugs dispensed to individuals enrolled in Medicaid managed care organizations and subjected manufacturers to new annual fees for certain branded prescription drugs. On May 4, 2017, the House of Representatives passed the American Health Care Act, or AHCA, which contains provisions that would change the level of federal funding of state Medicaid programs and affect funding for long term care recipients, including the elderly and disabled. The Senate then moved to craft its own "repeal and replace" legislation known as the Better Care Reconciliation Act, or BCRA, with more onerous funding changes affecting the elderly and disabled. The BCRA and two other amendments failed in the Senate and it is unclear if the Senate will debate potential amendments further. However, even if a different bill or amendment passed in the Senate, reconciliation with the House's AHCA bill would be required. Under any new legislation, we expect additional rules, regulations and interpretations to be issued that may materially affect our financial condition and operations. Even if the Affordable Care Act is not amended or repealed, the new administration could propose changes impacting implementation of the Affordable Care Act. The ultimate composition and timing of any legislation enacted under the new administration that would impact the current implementation of the Affordable Care Act remains uncertain. Given the complexity of the Affordable Care Act and the substantial requirements for regulation thereunder, the impact of the Affordable Care Act on our financial conditions and operations cannot be predicted, whether in its current form or as amended or repealed.

Pricing and reimbursement methodologies vary widely from country to country. Some countries require that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or they may instead adopt a system of direct or indirect controls on our profitability in placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements for any of our products.

Coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time, and there is the potential for significant movement in these areas in the foreseeable future. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Law and Regulation

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescribing of any product candidates for which we may obtain marketing approval. Our business operations and arrangements with investigators, healthcare professionals, consultants, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws. These laws may constrain the business or financial arrangements and relationships through which we research, manufacture, market, promote, sell and distribute our products that obtain marketing approval. Restrictions under applicable federal and state healthcare laws, include, but are not limited to, the following:

- the federal healthcare Anti-Kickback Statute prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act and civil monetary penalties law impose penalties and provide for civil whistleblower or qui tam actions against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent or making a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the civil monetary penalties statute, which 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 Health Insurance Portability and Accountability Act of 1996, or HIPAA, among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without proper written authorization;
- the federal transparency requirements under the Affordable Care Act requires manufacturers of drugs, devices, biologicals and medical supplies to annually report to the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS, information related to payments and other transfers of value provided to physicians and teaching hospitals and certain ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws, 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 relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state 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; and state and foreign laws governing the privacy and security of health 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.

Further, the Affordable Care Act, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal statutes governing healthcare fraud. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to it, we may be subject to significant administrative, civil, and/or criminal penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to administrative, civil, and/or criminal sanctions, including exclusions from government funded healthcare programs.

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 and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. The cost of establishing a regulatory compliance system for numerous varying jurisdictions can be very significant. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

The U.S. Foreign Corrupt Practices Act and Other Anti-Corruption Laws

We may be subject to a variety of domestic and foreign anti-corruption laws with respect to our regulatory compliance efforts and operations. The U.S. Foreign Corrupt Practices Act, commonly known as the FCPA, is a criminal statute that prohibits an individual or business from paying, offering, promising or authorizing the provision of money (such as a bribe or kickback) or anything else of value (such as an improper gift, hospitality, or favor), directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision in order to assist the individual or business in obtaining, retaining, or directing business or other advantages (such as favorable regulatory rulings). The FCPA also obligates companies with securities listed in the United States to comply with certain accounting provisions. Those provisions require a company such as ours to (i) maintain books and records that accurately and fairly reflect all transactions, expenses, and asset dispositions, and (ii) devise and maintain an adequate system of internal accounting controls sufficient to provide reasonable assurances that transactions are properly authorized, executed and recorded. The FCPA is subject to broad interpretation by the U.S. government. The past decade has seen a significant increase in enforcement activity. In addition to the FCPA, there are a number of other federal and state anti-corruption laws to which we may be subject, including, the U.S. domestic bribery statute contained in 18 USC § 201 (which prohibits bribing U.S. government officials) and the U.S. Travel Act (which in some instances addresses private-sector or commercial bribery both within and outside the United States). Also, a number of the countries in which we may conduct activities have their own domestic and international anti-corruption laws, such as the UK Bribery Act 2010. There have been cases where companies have faced multi-jurisdictional liability under the FCPA and the anti-corruption laws of other countries for the same illegal act.

We can be held liable under the FCPA and other anti-corruption laws for the illegal activities of our employees, representatives, contractors, collaborators, agents, subsidiaries, or affiliates, even if it did not explicitly authorize such activity. Although we will seek to comply with anti-corruption laws, there can be no assurance that all of our employees, representatives, contractors, collaborators, agents, subsidiaries or affiliates will comply with these laws at all times. Noncompliance with these laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain governments or other persons, the loss of export privileges, reputational harm, adverse media coverage, and other collateral consequences. In addition, our directors, officers, employees, and other representatives who engage in violations of the FCPA and certain other anti-corruption statutes may face imprisonment, fines, and penalties. If any subpoenas or investigations are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of our management's attention and resources and significant defense costs and other professional fees. Enforcement actions and sanctions could further harm our business, results of operations, and financial condition.

Employees

As of November 14, 2017, we had a total of five full-time employees, no part-time employees, and three consultants or independent contractors working for us. None of our employees are represented by a labor union or subject to a collective bargaining agreement. We have not experienced a work stoppage and consider our relations with our employees to be good.

Our Background and Other Information

We were originally incorporated in Texas in March 1991 as Opexa Therapeutics, Inc. In September 2017, we merged with Acer Therapeutics Inc. and changed our name to Acer Therapeutics Inc. Our principal executive offices are located at 222 Third Street, Suite #2240, Cambridge, Massachusetts 02142, and our telephone number is (844) 902-6100. Our website address is www.acertx.com. We do not incorporate the information on, or accessible through, our website into this prospectus, and you should not consider any information on, or accessible through, our website as part of this prospectus.

FORWARD-LOOKING STATEMENTS

When used in this prospectus, the words "expects," "believes," "anticipates," "estimates," "may," "could," "intends," and similar expressions are intended to identify forward-looking statements. These statements are subject to known and unknown risks and uncertainties that could cause actual results to differ materially from those projected or otherwise implied by the forward-looking statements. These forward-looking statements speak only as of the date of this prospectus. Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements. We will discuss many of these risks and uncertainties in greater detail in any prospectus supplement under the heading "Risk Factors." Additional cautionary statements or discussions of risks and uncertainties that could affect our results or the achievement of the expectations described in forward-looking statements may also be contained in the documents we incorporate by reference into this prospectus.

These forward-looking statements speak only as of the date of this prospectus. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based. You should, however, review additional disclosures we make in our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K filed with the SEC.

USE OF PROCEEDS

Unless we state otherwise in the applicable prospectus supplement, we intend to use the net proceeds from the sale of the securities offered by this prospectus for general corporate purposes. General corporate purposes may include additions to working capital, financing of capital expenditures, repayment or redemption of existing indebtedness, and future acquisitions and strategic investment opportunities. Unless we state otherwise in the applicable prospectus supplement, pending the application of net proceeds, we expect to invest the net proceeds in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

DESCRIPTION OF DEBT SECURITIES

The following is a summary of the general terms of the debt securities. We will file a prospectus supplement that may contain additional terms when we issue debt securities. The terms presented here, together with the terms in a related prospectus supplement, together with any pricing supplement or term sheet, will be a description of the material terms of the debt securities.

We may issue, from time to time, debt securities, in one or more series. These debt securities that we may issue include senior debt securities, senior subordinated debt securities, subordinated debt securities, convertible debt securities and exchangeable debt securities. The debt securities we offer will be issued under an indenture between us and the trustee named in the indenture. The following is a summary of the material provisions of the form of indenture filed as an exhibit to the registration statement of which this prospectus is a part. For each series of debt securities, the applicable prospectus supplement for the series may change and supplement the summary below.

General Terms of the Indenture

The indenture does not limit the amount of debt securities that we may issue. It provides that we may issue debt securities for any series of debt securities up to the principal amount that we may authorize. Except for the limitations on consolidation, merger and sale of all or substantially all of our assets contained in the indenture, the terms of the indenture do not contain any covenants or other provisions designed to give holders of any debt securities protection against changes in our operations, financial condition or transactions involving us. For each series of debt securities, any restrictive covenants for those debt securities will be described in the applicable prospectus supplement for those debt securities.

We may issue the debt securities issued under the indenture as “discount securities,” which means they may be sold at a discount below their stated principal amount. These debt securities, as well as other debt securities that are not issued at a discount, may, for United States federal income tax purposes, be treated as if they were issued with “original issue discount,” or OID, because of interest payment and other characteristics. Special United States federal income tax considerations applicable to debt securities issued with original issue discount will be described in more detail in any applicable prospectus supplement.

You should refer to the prospectus supplement relating to a particular series of debt securities for a description of the following terms of the debt securities offered by that prospectus supplement and by this prospectus:

- the title and authorized denominations of those debt securities;
- any limit on the aggregate principal amount of that series of debt securities;
- the date or dates on which principal and premium, if any, of the debt securities of that series is payable;
- interest rates, and the dates from which interest, if any, on the debt securities of that series will accrue, and the dates when interest is payable and the maturity;

- the right, if any, to extend the interest payment periods and the duration of the extensions;
- if the amount of payments of principal or interest is to be determined by reference to an index or formula, or based on a coin or currency other than that in which the debt securities are stated to be payable, the manner in which these amounts are determined and the calculation agent, if any, with respect thereto;
- the place or places where and the manner in which principal of, premium, if any, and interest, if any, on the debt securities of that series will be payable and the place or places where those debt securities may be presented for transfer and, if applicable, conversion or exchange;
- the period or periods within which, the price or prices at which, and other terms and conditions upon which those debt securities may be redeemed, in whole or in part, at our option or the option of a holder of those securities, if we or a holder is to have that option;
- our obligation or right, if any, to redeem, repay or purchase those debt securities pursuant to any sinking fund or analogous provision or at the option of a holder of those securities, and the terms and conditions upon which the debt securities will be redeemed, repaid or purchased, in whole or in part, pursuant to that obligation;
- the terms, if any, on which the debt securities of that series will be subordinate in right and priority of payment to our other debt;
- the denominations in which those debt securities will be issuable;
- if other than the entire principal amount of the debt securities when issued, the portion of the principal amount payable upon acceleration of maturity as a result of a default on our obligations;
- whether any securities of that series are to be issued in whole or in part in the form of one or more global securities and the depositary for those global securities;
- if the principal of or any premium or interest on the debt securities of that series is to be payable, or is to be payable at our election or the election of a holder of those securities, in securities or other property, the type and amount of those securities or other property, or the manner of determining that amount, and the period or periods within which, and the terms and conditions upon which, any such election may be made;
- the events of default and covenants relating to the debt securities that are in addition to, modify or delete those described in this prospectus;
- conversion or exchange provisions, if any, including conversion or exchange prices or rates and adjustments thereto;
- whether and upon what terms the debt securities may be defeased, if different from the provisions set forth in the indenture;
- the nature and terms of any security for any secured debt securities;
- the terms applicable to any debt securities issued at a discount from their stated principal amount; and
- any other specific terms of any debt securities.

The applicable prospectus supplement will present material United States federal income tax considerations for holders of any debt securities and the securities exchange or quotation system on which any debt securities are to be listed or quoted.

Conversion or Exchange Rights

Debt securities may be convertible into or exchangeable for shares of our equity securities or other securities. The terms and conditions of conversion or exchange will be stated in the applicable prospectus supplement. The terms will include, among others, the following:

- the conversion or exchange price;
- the conversion or exchange period;
- provisions regarding our ability or the ability of any holder to convert or exchange the debt securities;
- events requiring adjustment to the conversion or exchange price; and
- provisions affecting conversion or exchange in the event of our redemption of the debt securities.

Consolidation, Merger or Sale

The indenture provides that we cannot consolidate with or merge with or into, or transfer or lease all or substantially all of our assets to, any person, unless we are the surviving corporation or the successor person is a corporation organized under the laws of the United States, any state of the United States or the District of Columbia and expressly assumes our obligations under the debt securities and the indenture. In addition, we cannot complete such a transaction unless immediately after completing the transaction, no event of default under the indenture, and no event that, after notice or lapse of time or both, would become an event of default under the indenture, has occurred and is continuing. When the successor person has assumed our obligations under the debt securities and the indenture, we will be discharged from all our obligations under the debt securities and the indenture except in limited circumstances.

This covenant would not apply to any recapitalization transaction, a change of control affecting us or a highly leveraged transaction, unless the transaction or change of control were structured to include a merger or consolidation or transfer or lease of all or substantially all of our assets.

Events of Default

The indenture provides that the following will be “events of default” with respect to any series of debt securities:

- failure to pay interest for 30 days after the date payment is due and payable;
- failure to pay principal or premium, if any, on any debt security when due, either at maturity, upon any redemption, by declaration or otherwise and, in the case of technical or administrative difficulties, only if such default persists for a period of more than three business days;
- failure to make sinking fund payments when due and continuance of such default for a period of 30 days;
- failure to perform other covenants for 60 days after notice that performance was required;

- events in bankruptcy, insolvency or reorganization relating to us; or
- any other event of default provided in the applicable officer's certificate, resolution of our board of directors or the supplemental indenture under which we issue a series of debt securities.

An event of default for a particular series of debt securities does not necessarily constitute an event of default for any other series of debt securities issued under the indenture. For each series of debt securities, any modifications to the above events of default will be described in the applicable prospectus supplement for those debt securities.

The indenture provides that if an event of default specified in the first, second, third, fourth or sixth bullets above occurs and is continuing, either the trustee or the holders of at least 25% in aggregate principal amount of the outstanding debt securities of that series may declare the principal amount of all those debt securities (or, in the case of discount securities or indexed securities, that portion of the principal amount as may be specified in the terms of that series) to be due and payable immediately. If an event of default specified in the fifth bullet above occurs and is continuing, then the principal amount of all those debt securities (or, in the case of discount securities or indexed securities, that portion of the principal amount as may be specified in the terms of that series) will be due and payable immediately, without any declaration or other act on the part of the trustee or any holder. In certain cases, holders of a majority in principal amount of the outstanding debt securities of any series may, on behalf of holders of all those debt securities, rescind and annul a declaration of acceleration.

The indenture imposes limitations on suits brought by holders of debt securities against us. Except for actions for payment of overdue principal or interest, no holder of debt securities of any series may institute any action against us under the indenture unless:

- the holder has previously given to the trustee written notice of default and continuance of such default;
- the holders of at least 25% in principal amount of the outstanding debt securities of the affected series have requested that the trustee institute the action;
- the requesting holders have offered the trustee indemnity for the reasonable expenses and liabilities that may be incurred by bringing the action;
- the trustee has not instituted the action within 60 days of the request and offer of indemnity; and
- the trustee has not received inconsistent direction by the holders of a majority in principal amount of the outstanding debt securities of the affected series.

We will be required to file annually with the trustee a certificate, signed by one of our officers, stating whether or not the officer knows of any default by us in the performance, observance or fulfillment of any condition or covenant of the indenture.

Discharge, Defeasance and Covenant Defeasance

We can discharge or decrease our obligations under the indenture as stated below.

We may discharge obligations to holders of any series of debt securities that have not already been delivered to the trustee for cancellation and that have either become due and payable or are by their terms to become due and payable, or are scheduled for redemption, within one year. We may effect a discharge by irrevocably depositing with the trustee cash or government obligations, as trust funds, in an amount certified to be enough to pay when due, whether at maturity, upon redemption or otherwise, the principal of, and any premium and interest on, the debt securities and any mandatory sinking fund payments.

Unless otherwise provided in the applicable prospectus supplement, we may also discharge any and all of our obligations to holders of any series of debt securities at any time, which we refer to as defeasance. We may also be released from the obligations imposed by any covenants of any outstanding series of debt securities and provisions of the indenture, and we may omit to comply with those covenants without creating an event of default under the trust declaration, which we refer to as covenant defeasance. We may effect defeasance and covenant defeasance only if, among other things:

- we irrevocably deposit with the trustee cash or government obligations denominated in the currency of the debt securities, as trust funds, in an amount certified to be enough to pay at maturity, or upon redemption, the principal (including any mandatory sinking fund payments) of, and any premium and interest on, all outstanding debt securities of the series; and
- we deliver to the trustee an opinion of counsel from a nationally recognized law firm to the effect that the holders of the series of debt securities will not recognize income, gain or loss for U.S. federal income tax purposes as a result of the defeasance or covenant defeasance and that defeasance or covenant defeasance will not otherwise alter the holders' U.S. federal income tax treatment of principal, and any premium and interest payments on, the series of debt securities.

In the case of a defeasance by us, the opinion we deliver must be based on a ruling of the Internal Revenue Service issued, or a change in U.S. federal income tax law occurring, after the date of the indenture, since such a result would not occur under the U.S. federal income tax laws in effect on that date.

Although we may discharge or decrease our obligations under the indenture as described in the two preceding paragraphs, we may not avoid, among other things, our duty to register the transfer or exchange of any series of debt securities, to replace any temporary, mutilated, destroyed, lost or stolen series of debt securities or to maintain an office or agency in respect of any series of debt securities.

Modification of the Indenture

The indenture provides that we and the trustee may enter into supplemental indentures without the consent of the holders of debt securities to, among other things:

- evidence the assumption by a successor entity of our obligations;
- add to our covenants for the benefit of the holders of debt securities, or to surrender any rights or power conferred upon us;
- add any additional events of default;
- add to, change or eliminate any of the provisions of the indenture in a manner that will become effective only when there is no outstanding debt security which is entitled to the benefit of the provision as to which the modification would apply;
- add guarantees with respect to or secure any debt securities;
- establish the forms or terms of debt securities of any series;
- evidence and provide for the acceptance of appointment by a successor trustee and add to or change any of the provisions of the indenture as is necessary for the administration of the trusts by more than one trustee;
- cure any ambiguity or correct any inconsistency or defect in the indenture;

- modify, eliminate or add to the provisions of the indenture as shall be necessary to effect the qualification of the indenture under the Trust Indenture Act of 1939 or under any similar federal statute later enacted, and to add to the indenture such other provisions as may be expressly required by the Trust Indenture Act; and
- make any other provisions with respect to matters or questions arising under the indenture that will not be inconsistent with any provision of the indenture as long as the new provisions do not adversely affect the interests of the holders of any outstanding debt securities of any series created prior to the modification.

The indenture also provides that we and the trustee may, with the consent of the holders of not less than a majority in aggregate principal amount of debt securities of each series of debt securities affected by such supplemental indenture then outstanding, add any provisions to, or change in any manner, eliminate or modify in any way the provisions of, the indenture or any supplemental indenture or modify in any manner the rights of the holders of the debt securities. We and the trustee may not, however, without the consent of the holder of each outstanding debt security affected thereby:

- extend the final maturity of any debt security;
- reduce the principal amount or premium, if any;
- reduce the rate or extend the time of payment of interest;
- reduce the amount of the principal of any debt security issued with an original issue discount that is payable upon acceleration;
- change the currency in which the principal, and any premium or interest, is payable;
- impair the right to institute suit for the enforcement of any payment on any debt security when due;
- if applicable, adversely affect the right of a holder to convert or exchange a debt security; or
- reduce the percentage of holders of debt securities of any series whose consent is required for any modification of the indenture or for waivers of compliance with or defaults under the indenture with respect to debt securities of that series.

The indenture provides that the holders of not less than a majority in aggregate principal amount of the then outstanding debt securities of any series, by notice to the relevant trustee, may on behalf of the holders of the debt securities of that series waive any default and its consequences under the indenture except:

- a default in the payment of, any premium and any interest on, or principal of, any such debt security held by a nonconsenting holder; or
- a default in respect of a covenant or provision of the indenture that cannot be modified or amended without the consent of the holder of each outstanding debt security of each series affected.

Registered Global Securities and Book Entry System

The debt securities of a series may be issued in whole or in part in book-entry form and will be represented by one or more fully registered global securities. We will deposit any registered global securities with a depositary or with a nominee for a depositary identified in the applicable prospectus supplement and registered in the name of such depositary or nominee. In such case, we will issue one or more registered global securities denominated in an amount equal to the aggregate principal amount of all of the debt securities of the series to be issued and represented by such registered global security or securities. This means that we will not issue certificates to each holder.

Unless and until it is exchanged in whole or in part for debt securities in definitive registered form, a registered global security may not be transferred except as a whole:

- by the depositary for the registered global security to its nominee;
- by a nominee of the depositary to the depositary or another nominee of the depositary; or
- by the depositary or its nominee to a successor of the depositary or a nominee of the successor.

The prospectus supplement relating to a series of debt securities will describe the specific terms of the depositary arrangement involving any portion of the series represented by a registered global security. We anticipate that the following provisions will apply to all depositary arrangements for debt securities:

- ownership of beneficial interests in a registered global security will be limited to persons that have accounts with the depositary for such registered global security, these persons being referred to as "participants," or persons that may hold interests through participants;
- upon the issuance of a registered global security, the depositary for the registered global security will credit, on its book-entry registration and transfer system, the participants' accounts with the respective principal amounts of the debt securities represented by the registered global security beneficially owned by the participants;
- any dealers, underwriters, or agents participating in the distribution of the debt securities will designate the accounts to be credited; and
- ownership of beneficial interest in the registered global security will be shown on, and the transfer of the ownership interest will be effected only through, records maintained by the depositary for the registered global security for interests of participants, and on the records of participants for interests of persons holding through participants.

The laws of some states may require that specified purchasers of securities take physical delivery of the securities in definitive form. These laws may limit the ability of those persons to own, transfer or pledge beneficial interests in registered global securities.

So long as the depositary for a registered global security, or its nominee, is the registered owner of the registered global security, the depositary or such nominee, as the case may be, will be considered the sole owner or holder of the debt securities represented by the registered global security for all purposes under the indenture. Except as stated below, owners of beneficial interests in a registered global security:

- will not be entitled to have the debt securities represented by a registered global security registered in their names;
- will not receive or be entitled to receive physical delivery of the debt securities in the definitive form; and
- will not be considered the owners or holders of the debt securities under the relevant indenture.

Accordingly, each person owning a beneficial interest in a registered global security must rely on the procedures of the depositary for the registered global security and, if the person is not a participant, on the procedures of a participant through which the person owns its interest, to exercise any rights of a holder under the indenture.

We understand that under existing industry practices, if we request any action of holders or if an owner of a beneficial interest in a registered global security desires to give or take any action that a holder is entitled to give or take under the indenture, the depositary for the registered global security would authorize the participants holding the relevant beneficial interests to give or take the action, and the participants would authorize beneficial owners owning through the participants to give or take the action or would otherwise act upon the instructions of beneficial owners holding through them.

We will make payments of principal and premium, if any, and interest, if any, on debt securities represented by a registered global security registered in the name of a depositary or its nominee to the depositary or its nominee, as the case may be, as the registered owners of the registered global security. Neither we nor the trustee, or any other agent of ours or the trustee will be responsible or liable for any aspect of the records relating to, or payments made on account of, beneficial ownership interests in the registered global security or for maintaining, supervising or reviewing any records relating to the beneficial ownership interests.

We expect that the depositary for any debt securities represented by a registered global security, upon receipt of any payments of principal and premium, if any, and interest, if any, in respect of the registered global security, will immediately credit participants' accounts with payments in amounts proportionate to their respective beneficial interests in the registered global security as shown on the records of the depositary. We also expect that standing customer instructions and customary practices will govern payments by participants to owners of beneficial interests in the registered global security held through the participants, as is now the case with the securities held for the accounts of customers in bearer form or registered in "street name." We also expect that any of these payments will be the responsibility of the participants.

If the depositary for any debt securities represented by a registered global security is at any time unwilling or unable to continue as depositary or stops being a clearing agency registered under the Exchange Act, we will appoint an eligible successor depositary. If we fail to appoint an eligible successor depositary within 90 days, we will issue the debt securities in definitive form in exchange for the registered global security. In addition, we may at any time and in our sole discretion decide not to have any of the debt securities of a series represented by one or more registered global securities. In that event, we will issue debt securities of the series in a definitive form in exchange for all of the registered global securities representing the debt securities. The trustee will register any debt securities issued in definitive form in exchange for a registered global security in the name or names as the depositary, based upon instructions from its participants, shall instruct the trustee.

Concerning the Trustee

The indenture provides that there may be more than one trustee under the indenture, each for one or more series of debt securities. If there are different trustees for different series of debt securities, each trustee will be a trustee of a trust under the indenture separate and apart from the trust administered by any other trustee under that indenture. Except as otherwise indicated in this prospectus or any prospectus supplement, any action permitted to be taken by a trustee may be taken by such trustee only on the one or more series of debt securities for which it is the trustee under the indenture. Any trustee under the indenture may resign or be removed from one or more series of debt securities. All payments of principal of, and any premium and interest on, and all registration, transfer, exchange, authentication and delivery of, the debt securities of a series will be effected by the trustee for that series at an office designated by the trustee in New York, New York.

The indenture provides that, except during the continuance of an event of default, the trustee will perform only such duties as are specifically set forth in the indenture. During the existence of an event of default, the trustee will exercise those rights and powers vested in it under the indenture and use the same degree of care and skill in its exercise as a prudent person would exercise under the circumstances in the conduct of such person's own affairs.

If the trustee becomes a creditor of ours, the indenture places limitations on the right of the trustee to obtain payment of claims or to realize on property received in respect of any such claim as security or otherwise. The trustee may engage in other transactions. If it acquires any conflicting interest relating to any duties concerning the debt securities, however, it must eliminate the conflict or resign as trustee.

No Individual Liability of Incorporators, Shareholders, Officers or Directors

The indenture provides that no past, present or future director, officer, shareholder or employee of ours, any of our affiliates, or any successor corporation, in their capacity as such, shall have any individual liability for any of our obligations, covenants or agreements under the debt securities or the indenture.

Governing Law

The indenture and the debt securities will be governed by, and construed in accordance with, the laws of the State of New York.

DESCRIPTION OF PREFERRED STOCK

As of November 14, 2017, our authorized preferred stock, no par value, was 10,000,000 shares, none of which were issued and outstanding. We may issue preferred stock, in series, with such designations, powers, preferences and other rights and qualifications, limitations or restrictions as our board of directors may authorize, without further action by our shareholders, including:

- the distinctive designation of each series and the number of shares that will constitute the series;
- the voting rights, if any, of shares of the series and the terms and conditions of the voting rights;
- the dividend rate on the shares of the series, the dates on which dividends are payable, any restriction, limitation or condition upon the payment of dividends, whether dividends will be cumulative, and the dates from and after which dividends shall accumulate;
- the prices at which, and the terms and conditions on which, the shares of the series may be redeemed, if the shares are redeemable;
- the terms and conditions of a sinking or purchase fund for the purchase or redemption of shares of the series, if such a fund is provided;
- any preferential amount payable upon shares of the series in the event of the liquidation, dissolution or winding up of, or upon the distribution of any of our assets; and
- the prices or rates of conversion or exchange at which, and the terms and conditions on which, the shares of the series may be converted or exchanged into other securities, if the shares are convertible or exchangeable.

The particular terms of any series of preferred stock, and the transfer agent and registrar for that series, will be described in a prospectus supplement. Any material United States federal income tax consequences and other special considerations with respect to any preferred stock offered under this prospectus will also be described in the applicable prospectus supplement.

DESCRIPTION OF DEPOSITARY SHARES

The following description of the depositary shares does not purport to be complete and is subject to and qualified in its entirety by the relevant deposit agreement and the depositary receipts with respect to the depositary shares relating to any particular series of preferred stock. You should read these documents as they, and not this description, will define your rights as a holder of depositary shares. Forms of these documents will be filed with the SEC in connection with the offering of depositary shares.

General

If we elect to offer fractional interests in shares of preferred stock, we will provide for the issuance by a depositary to the public of receipts for depositary shares. Each depositary share will represent fractional interests of preferred stock. We will deposit the shares of preferred stock underlying the depositary shares under a deposit agreement between us and a bank or trust company selected by us. The bank or trust company must have its principal office in the United States and a combined capital and surplus of at least $50 million. The depositary receipts will evidence the depositary shares issued under the deposit agreement.

The deposit agreement will contain terms applicable to the holders of depositary shares in addition to the terms stated in the depositary receipts. Each owner of depositary shares will be entitled to all the rights and preferences of the preferred stock underlying the depositary shares in proportion to the applicable fractional interest in the underlying shares of preferred stock. The depositary will issue the depositary receipts to individuals purchasing the fractional interests in shares of the related preferred stock according to the terms of the offering described in a prospectus supplement.

Dividends and Other Distributions

The depositary will distribute all cash dividends or other cash distributions received for the preferred stock to the entitled record holders of depositary shares in proportion to the number of depositary shares that the holder owns on the relevant record date. The depositary will distribute only an amount that can be distributed without attributing to any holder of depositary shares a fraction of one cent. The depositary will add the undistributed balance to and treat it as part of the next sum received by the depositary for distribution to holders of depositary shares.

If there is a non-cash distribution, the depositary will distribute property received by it to the entitled record holders of depositary shares, in proportion, insofar as possible, to the number of depositary shares owned by the holders, unless the depositary determines, after consultation with us, that it is not feasible to make such distribution. If this occurs, the depositary may, with our approval, sell such property and distribute the net proceeds from the sale to the holders. The deposit agreement also will contain provisions relating to how any subscription or similar rights that we may offer to holders of the preferred stock will be available to the holders of the depositary shares.

Conversion, Exchange, Redemption and Liquidation

If any series of preferred stock underlying the depositary shares may be converted or exchanged, each record holder of depositary receipts will have the right or obligation to convert or exchange the depositary shares represented by the depositary receipts.

The terms on which the depositary shares relating to the preferred stock of any series may be redeemed, and any amounts distributable upon our liquidation, dissolution or winding up, will be described in the relevant prospectus supplement.

Voting

When the depositary receives notice of a meeting at which the holders of the preferred stock are entitled to vote, the depositary will mail the particulars of the meeting to the record holders of the depositary shares. Each record holder of depositary shares on the record date may instruct the depositary on how to vote the shares of preferred stock underlying the holder's depositary shares. The depositary will try, if practical, to vote the number of shares of preferred stock underlying the depositary shares according to the instructions. We will agree to take all reasonable action requested by the depositary to enable it to vote as instructed.

Amendments

We and the depositary may agree to amend the deposit agreement and the depositary receipt evidencing the depositary shares. Any amendment that (a) imposes or increases certain fees, taxes or other charges payable by the holders of the depositary shares as described in the deposit agreement or that (b) otherwise prejudices any substantial existing right of holders of depositary shares, will not take effect until 30 days after the depositary has mailed notice of the amendment to the record holders of depositary shares. Any holder of depositary shares that continues to hold its shares at the end of the 30-day period will be deemed to have agreed to the amendment.

Termination

We may direct the depositary to terminate the deposit agreement by mailing a notice of termination to holders of depositary shares at least 30 days prior to termination. In addition, a deposit agreement will automatically terminate if the depositary has redeemed all related outstanding depositary shares, or we have liquidated, terminated or wound up our business and the depositary has distributed the preferred stock of the relevant series to the holders of the related depositary shares.

Payment of Fees and Expenses

We will pay all fees, charges and expenses of the depositary, including the initial deposit of the preferred stock and any redemption of the preferred stock. Holders of depositary shares will pay transfer and other taxes and governmental charges and any other charges as are stated in the deposit agreement for their accounts.

Resignation and Removal of Depositary

At any time, the depositary may resign by delivering notice to us, and we may remove the depositary. Resignations or removals will take effect upon the appointment of a successor depositary and its acceptance of the appointment. The successor depositary must be appointed within 60 days after delivery of the notice of resignation or removal and must be a bank or trust company having its principal office in the United States and having a combined capital and surplus of at least $50 million.

Reports

The depositary will forward to the holders of depositary shares all reports and communications from us that are delivered to the depositary and that we are required by law, the rules of an applicable securities exchange or our restated certificate of formation, as amended, to furnish to the holders of the preferred stock. Neither we nor the depositary will be liable if the depositary is prevented or delayed by law or any circumstances beyond its control in performing its obligations under the deposit agreement. The deposit agreement limits our obligations and the depositary's obligations to performance in good faith of the duties stated in the deposit agreement. Neither we nor the depositary will be obligated to prosecute or defend any legal proceeding connected with any depositary shares or preferred stock unless the holders of depositary shares requesting us to do so furnish us with satisfactory indemnity. In performing our obligations, we and the depositary may rely upon the written advice of our counsel or accountants, on any information that competent people provide to us and on documents that we believe are genuine.

DESCRIPTION OF COMMON STOCK

This section describes the general terms and provisions of the shares of our common stock, $0.01 par value. This description is only a summary and is qualified in its entirety by reference to the description of our common stock incorporated by reference in this prospectus. Our restated certificate of formation, as amended, and our amended and restated bylaws, as amended, have been filed as exhibits to our periodic reports filed with the SEC, which are incorporated by reference in this prospectus. You should read our restated certificate of formation, as amended, and our amended and restated bylaws, as amended, for additional information before you buy any of our common stock or other securities. See "Where You Can Find More Information."

We have 150,000,000 shares of authorized common stock. As of November 14, 2017, there were 6,450,766 shares of common stock issued and outstanding. Each holder of common stock is entitled to one vote for each share of common stock held on all matters submitted to a vote of shareholders. We have not provided for cumulative voting for the election of directors in our restated certificate of formation, as amended. This means that the holders of a majority of the shares voted can elect all of the directors then standing for election. Subject to preferences that may apply to shares of preferred stock outstanding at the time, the holders of outstanding shares of our common stock are entitled to receive dividends out of assets legally available at the times and in the amounts that our board of directors may determine from time to time. Upon our liquidation, dissolution or winding-up, the holders of common stock are entitled to share ratably in all assets remaining after payment of all liabilities and the liquidation preferences of any outstanding preferred stock. Holders of common stock have no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are fully paid and nonassessable.

Anti-Takeover Effects of Our Restated Certificate of Formation and Bylaws

Certain provisions of our restated certificate of formation, as amended, and our amended and restated bylaws, as amended, could have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions, which are summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids. These provisions are also designed, in part, to encourage persons seeking to acquire control of us to first negotiate with our board of directors. Our restated certificate of formation, as amended, and our amended and restated bylaws, as amended, include provisions that:

- authorize our board of directors to issue, without further action by the shareholders, up to 10,000,000 shares of undesignated preferred stock; and
- authorize us to indemnify officers and directors against losses that they may incur in investigations and legal proceedings resulting from their services to us, which may include services in connection with takeover defense measures.

Transfer Agent

The transfer agent and registrar for our common stock is Continental Stock Transfer and Trust Company.

DESCRIPTION OF WARRANTS

We may issue warrants for the purchase of debt securities, preferred stock, common stock, depositary shares, or any combination thereof. We may issue warrants independently or together with any other securities offered by any prospectus supplement and may be attached to or separate from the other offered securities. Each series of warrants may be issued under a separate warrant agreement to be entered into by us with a warrant agent. The applicable warrant agent will act solely as our agent in connection with the warrants and will not assume any obligation or relationship of agency or trust for or with any holders or beneficial owners of warrants. Further terms of the warrants and the applicable warrant agreements will be set forth in the applicable prospectus supplement.

The applicable prospectus supplement relating to any particular issue of warrants will describe the terms of the warrants, including, as applicable, the following:

- the title of the warrants;
- the aggregate number of the warrants;
- the price or prices at which the warrants will be issued;
- the designation, terms and number of shares of debt securities, preferred stock or common stock purchasable upon exercise of the warrants;

- the designation and terms of the offered securities, if any, with which the warrants are issued and the number of the warrants issued with each offered security;
- the date, if any, on and after which the warrants and the related debt securities, preferred stock or common stock will be separately transferable;
- the price at which each share of debt securities, preferred stock or common stock purchasable upon exercise of the warrants may be purchased;
- the date on which the right to exercise the warrants shall commence and the date on which that right shall expire;
- the minimum or maximum amount of the warrants which may be exercised at any one time;
- information with respect to book-entry procedures, if any;
- a discussion of certain federal income tax considerations; and
- any other terms of the warrants, including terms, procedures and limitations relating to the exchange and exercise of the warrants.

We and the applicable warrant agent may amend or supplement the warrant agreement for a series of warrants without the consent of the holders of the warrants issued thereunder to effect changes that are not inconsistent with the provisions of the warrants and that do not materially and adversely affect the interests of the holders of the warrants.

DESCRIPTION OF RIGHTS

We may issue rights to purchase common stock or preferred stock. This prospectus and any accompanying prospectus supplement will contain the material terms and conditions for each right. The accompanying prospectus supplement may add, update or change the terms and conditions of the rights as described in this prospectus.

We will describe in the applicable prospectus supplement the terms and conditions of the issue of rights being offered, the rights agreement relating to the rights and the rights certificates representing the rights, including, as applicable:

- the title of the rights;
- the date of determining the shareholders entitled to the rights distribution;
- the title, aggregate number of shares of common stock or preferred stock purchasable upon exercise of the rights;
- the exercise price;
- the aggregate number of rights issued;
- the date, if any, on and after which the rights will be separately transferable;
- the date on which the right to exercise the rights will commence and the date on which the right will expire; and
- any other terms of the rights, including terms, procedures and limitations relating to the distribution, exchange and exercise of the rights.

Each right will entitle the holder of rights to purchase for cash the principal amount of shares of common stock or preferred stock at the exercise price provided in the applicable prospectus supplement. Rights may be exercised at any time up to the close of business on the expiration date for the rights provided in the applicable prospectus supplement. After the close of business on the expiration date, all unexercised rights will be void.

Holders may exercise rights as described in the applicable prospectus supplement. Upon receipt of payment and the rights certificate properly completed and duly executed at the corporate trust office of the rights agent or any other office indicated in the prospectus supplement, we will, as soon as practicable, forward the shares of common stock or preferred stock purchasable upon exercise of the rights. If less than all of the rights issued in any rights offering are exercised, we may offer any unsubscribed securities directly to persons other than shareholders, to or through agents, underwriters or dealers or through a combination of such methods, including pursuant to standby underwriting arrangements, as described in the applicable prospectus supplement.

PLAN OF DISTRIBUTION

We may sell the securities offered by this prospectus to one or more underwriters or dealers for public offering and sale by them or to investors directly or through agents. The accompanying prospectus supplement will set forth the terms of the offering and the method of distribution and will identify any firms acting as underwriters, dealers or agents in connection with the offering, including:

- the name or names of any underwriters, dealers or agents;
- the purchase price of the securities and the proceeds to us from the sale;
- any underwriting discounts and other items constituting compensation to underwriters, dealers or agents;
- any public offering price;
- any discounts or concessions allowed or reallowed or paid to dealers; and
- any securities exchange or market on which the securities offered in the prospectus supplement may be listed.

Only those underwriters identified in such prospectus supplement are deemed to be underwriters in connection with the securities offered in the prospectus supplement.

The distribution of the securities may be effected from time to time in one or more transactions at a fixed price or prices, which may be changed, or at prices determined as the applicable prospectus supplement specifies. The securities may be sold through an at-the-market offering, a rights offering, forward contracts or similar arrangements. In addition, we may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement so indicates, in connection with those derivatives, the third parties may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use securities pledged by us or borrowed from us or others to settle those sales or to close out any related open borrowings of stock, and may use securities received from us in settlement of those derivatives to close out any related open borrowings of stock. The third party in such sale transactions will be an underwriter and, if not identified in this prospectus, will be named in the applicable prospectus supplement (or a post-effective amendment). In addition, we may otherwise loan or pledge securities to a financial institution or other third party that in turn may sell the securities short using this prospectus and an applicable prospectus supplement. Such financial institution or other third party may transfer its economic short position to investors in our securities or in connection with a concurrent offering of other securities.

In connection with the sale of the securities, underwriters, dealers or agents may be deemed to have received compensation from us in the form of underwriting discounts or commissions and also may receive commissions from securities purchasers for whom they may act as agent. Underwriters may sell the securities to or through dealers, and the dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters or commissions from the purchasers for whom they may act as agent.

We will provide in the applicable prospectus supplement information regarding any underwriting discounts or other compensation that we pay to underwriters or agents in connection with the securities offering, and any discounts, concessions or commissions that underwriters allow to dealers. Underwriters, dealers and agents participating in the securities distribution may be deemed to be underwriters, and any discounts, commissions or concessions they receive and any profit they realize on the resale of the securities may be deemed to be underwriting discounts and commissions under the Securities Act of 1933. Underwriters and their controlling persons, dealers and agents may be entitled, under agreements entered into with us, to indemnification against and contribution toward specific civil liabilities, including liabilities under the Securities Act. Some of the underwriters, dealers or agents who participate in the securities distribution may engage in other transactions with, and perform other services for, us or our subsidiaries in the ordinary course of business.

Our common stock is currently listed on The NASDAQ Capital Market, but any other securities may or may not be listed on a national securities exchange. To facilitate the offering of securities, certain persons participating in the offering may engage in transactions that stabilize, maintain or otherwise affect the price of the securities. This may include over-allotments or short sales of the securities, which involve the sale by persons participating in the offering of more securities than were sold to them. In these circumstances, these persons would cover such over-allotments or short positions by making purchases in the open market or by exercising their over-allotment option, if any. In addition, these persons may stabilize or maintain the price of the securities by bidding for or purchasing securities in the open market or by imposing penalty bids, whereby selling concessions allowed to dealers participating in the offering may be reclaimed if securities sold by them are repurchased in connection with stabilization transactions. The effect of these transactions may be to stabilize or maintain the market price of the securities at a level above that which might otherwise prevail in the open market. These transactions may be discontinued at any time.

LEGAL MATTERS

The validity of any securities offered by this prospectus will be passed upon for us by Pillsbury Winthrop Shaw Pittman LLP, San Diego, California.

EXPERTS

The consolidated financial statements incorporated in this prospectus by reference from our Annual Report on Form 10-K for the year ended December 31, 2016 have been audited by MaloneBailey, LLP, an independent registered public accounting firm, as stated in their report, which is incorporated by reference and has been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

The consolidated financial statements of Private Acer as of December 31, 2016 and 2015, and for the years then ended, have been incorporated in this prospectus by reference to our prospectus filed on August 11, 2017 pursuant to Rule 424(b) under the Securities Act, relating to the registration statement on Form S-4, as amended, declared effective August 10, 2017 (File No. 333-219358), in reliance upon the report of Wolf & Company, P.C., an independent registered public accounting firm, and upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-3 with the SEC under the Securities Act of 1933. This prospectus is part of the registration statement but the registration statement includes and incorporates by reference additional information and exhibits. We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy the registration statement and any other document we file with the SEC at the public reference room maintained by the SEC at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the public reference room by calling the SEC at 1-800-SEC-0330. The SEC also maintains a web site that contains reports, proxy and information statements and other information regarding companies, such as ours, that file documents electronically with the SEC. The address of that site on the world wide web is http://www.sec.gov. The information on the SEC's web site is not part of this prospectus, and any references to this web site or any other web site are inactive textual references only.

The SEC permits us to "incorporate by reference" the information contained in documents we file with the SEC, which means that we can disclose important information to you by referring you to those documents rather than by including them in this prospectus. Information that is incorporated by reference is considered to be part of this prospectus and you should read it with the same care that you read this prospectus. Later information that we file with the SEC will automatically update and supersede the information that is either contained, or incorporated by reference, in this prospectus, and will be considered to be a part of this prospectus from the date those documents are filed. We have filed with the SEC, and incorporate by reference in this prospectus:

- our Annual Report on Form 10-K for the year ended December 31, 2016;
- our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2017, June 30, 2017 and September 30, 2017;
- our Current Reports on Form 8-K filed with the SEC on February 1, 2017, April 14, 2017, May 22, 2017, July 3, 2017, July 19, 2017, August 9, 2017, September 11, 2017, September 20, 2017, October 5, 2017 (except Item 7.01) and November 14, 2017;
- Private Acer's audited consolidated financial statements as of December 31, 2016 and 2015, and for the years then ended included in our Prospectus filed on August 11, 2017 pursuant to Rule 424(b) under the Securities Act, relating to the Registration Statement on Form S-4, as amended, declared effective August 10, 2017 (File No. 333-219358); and
- the description of our common stock contained in our Registration Statement on Form 8-A filed on August 30, 2006, as amended by our Form 8-12B/A filed on August 31, 2006.

We are not, however, incorporating any documents or information that we are deemed to furnish and not file in accordance with SEC rules (including with respect to the above-listed periodic reports). We also incorporate by reference all additional documents that we file with the SEC under the terms of Section 13(a), 13(c), 14 or 15(d) of the Exchange Act that are made after the initial filing date of the registration statement of which this prospectus is a part and the effectiveness of the registration statement, as well as between the date of this prospectus and the termination of any offering of securities offered by this prospectus.

You may request a copy of any or all of the documents incorporated by reference but not delivered with this prospectus, at no cost, by writing or telephoning us at the following address and number: Acer Investor Relations: 222 Third Street, Suite #2240, Cambridge, Massachusetts 02142, telephone (844) 902-6100. We will not, however, send exhibits to those documents, unless the exhibits are specifically incorporated by reference in those documents.

Up to $100,000,000 Shares of

Common Stock

PROSPECTUS

, 2017

PART II

Information Not Required In Prospectus

Item 14. Other Expenses of Issuance and Distribution.

The following is a statement of estimated expenses in connection with the issuance and distribution of the securities being registered, other than underwriting discounts and commissions.

SEC Registration Fee	$	10,070
The NASDAQ Stock Market Listing Fees		(1)
Transfer Agent and Registrar, Trustee and Depositary Fees		(1)
Printing Expenses		(1)
Legal Fees and Expenses		(1)
Accounting Fees and Expenses		(1)
Miscellaneous		(1)
	$	(1)

(1) These fees are calculated based on the securities offered and the number of issuances and, accordingly, cannot be estimated at this time.

Item 15. Indemnification of Directors and Officers.

Section 8.101 of the Texas Business Organizations Code, or the TBOC, authorizes the Registrant to indemnify certain persons, including any person who was, is or is threatened to be made a named defendant or respondent in a threatened, pending or completed action or other proceeding, because the person is or was a director or officer, against judgments and reasonable expenses actually incurred by the person in connection with the threatened, pending or completed action or other proceeding. The Registrant is required by Section 8.051 of the TBOC to indemnify a director or officer against reasonable expenses actually incurred by him or her in connection with a threatened, pending, or completed action or other proceeding in which he or she is a named defendant or respondent because he or she is or was a director or officer if he or she has been wholly successful, on the merits or otherwise, in the defense of the action or proceeding.

The Registrant's restated certificate of formation, as amended, provides that none of its directors shall be personally liable to the Registrant or its shareholders for monetary damages for an act or omission in such director's capacity as a director; provided, however, that the liability of such director is not limited to the extent that such director is found liable for (i) a breach of the director's duty of loyalty to the Registrant or its shareholders, (ii) an act or omission not in good faith that constitutes a breach of duty of the director to the Registrant or an act or omission that involves intentional misconduct or a knowing violation of the law, (iii) a transaction from which the director received an improper benefit, whether or not the benefit resulted from an action taken within the scope of the director's office, or (iv) an act or omission for which the liability of the director is expressly provided by an applicable statute.

The Registrant's restated certificate of formation, as amended, and amended and restated bylaws, as amended, provide that the Registrant shall indemnify its officers, directors, agents and any other persons to the fullest extent permitted by applicable law. The Registrant's directors and officers are covered by insurance indemnifying them against certain liabilities which might be incurred by them in their capacities as such.

At the present time, there is no pending litigation or proceeding involving a director, officer, employee or other agent of the Registrant in which indemnification would be required or permitted. The Registrant is not aware of any threatened litigation or proceeding which may result in a claim for such indemnification.

Item 16. Exhibits.

Exhibit No.	Description
1.1*	Form of Underwriting Agreement.
4.1†^	Form of Indenture relating to debt securities.
4.2*	Form of supplemental indenture or other instrument establishing the issuance of one or more series of debt securities (including the form of such debt security).
4.3*	Form of Warrant Agreement and Warrant Certificate.
4.4*	Form of Deposit Agreement.
4.5*	Form of Depositary Receipt (included in Exhibit 4.4).
4.6*	Form of Specimen Preferred Stock Certificate.
4.7*	Form of Rights Agreement and Rights Certificate.
4.8	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to Acer's Quarterly Report on Form 10-Q filed on November 13, 2017).
5.1†	Opinion of Pillsbury Winthrop Shaw Pittman LLP.
23.1†	Consent of Pillsbury Winthrop Shaw Pittman LLP (included in Exhibit 5.1).
23.2	Consent of Wolf & Company, P.C., independent registered public accounting firm.
23.3	Consent of MaloneBailey, LLP, Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included on the signature page hereof).
25.1+	Form T-1 Statement of Eligibility of the trustee for the debt securities.

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† Previously filed.

^ Note that references to "Opexa Therapeutics, Inc." in this document are hereby amended to read "Acer Therapeutics Inc."

* To be filed by amendment or pursuant to a report to be filed pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, if applicable, and incorporated herein by reference.

+ To be filed by amendment or pursuant to Trust Indenture Act Section 305(b)(2), if applicable.

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (i), (ii) and (iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Securities and Exchange Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(6) That, for the purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(7) To file an application for the purpose of determining the eligibility of the trustee to act under subsection (a) of Section 310 of the Trust Indenture Act (the "Act") in accordance with the rules and regulations prescribed by the Commission under Section 305(b)(2) of the Act.

The undersigned registrant hereby undertakes to supplement the prospectus, after the expiration of the subscription period (if any), to set forth the results of the subscription offer, the transactions by the underwriters during the subscription period, the amount of unsubscribed securities to be purchased by the underwriters, and the terms of any subsequent reoffering thereof. If any public offering by the underwriters is to be made on terms differing from those set forth on the cover page of the prospectus, a post-effective amendment will be filed to set forth the terms of such offering.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to any charter provision, by law or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Cambridge, State of Massachusetts, on this 14th day of November, 2017.

ACER THERAPEUTICS INC.

By: /s/ Chris Schelling
Chris Schelling
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Chris Schelling and Harry Palmin, and each of them, his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments, including post-effective amendments, to this Registration Statement, and any registration statement relating to the offering covered by this Registration Statement and filed pursuant to Rule 462(b) under the Securities Act of 1933, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that each of said attorneys in fact and agents or their substitute or substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Name	Title	Date
/s/ Chris Schelling Chris Schelling	President, Chief Executive Officer and Director *(Principal Executive Officer)*	November 14, 2017
/s/ Harry Palmin Harry Palmin	Chief Financial Officer *(Principal Financial and Accounting Officer)*	November 14, 2017
/s/ Steve Aselage Steve Aselage	Director	November 14, 2017
/s/ Jason Amello Jason Amello	Director	November 14, 2017

/s/ Hubert Birner Hubert Birner, Ph.D.	Director	November 14, 2017
/s/ John Dunn John Dunn	Director	November 14, 2017
/s/ Michelle Griffin Michelle Griffin	Director	November 14, 2017
/s/ Luc Marengere Luc Marengere, Ph.D.	Director	November 14, 2017