CORCEPT THERAPEUTICS INC
Form 10-K
February 26, 2019

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K
ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018
or
TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission File Number: 000-50679
CORCEPT THERAPEUTICS INCORPORATED
(Exact Name of Corporation as Specified in Its Charter)

Delaware	77-0487658
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

149 Commonwealth Drive
Menlo Park, CA 94025
(Address of principal executive offices) (zip code)
(650) 327-3270
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12 (b) of the Act:

Title of Each Class:	Name of Each Exchange on which Registered:
Common Stock, $0.001 par value	The Nasdaq Capital Market

Securities registered pursuant to Section 12 (g) of the Act:
None
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15 (d) of the Act. Yes No
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the Registrant's knowledge, in definitive proxy or information statements incorporated by reference to Part III of this Form 10-K or any amendment to this Form 10 K.
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 small reporting company)	Smaller reporting company
Emerging growth company		

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The aggregate market value of voting and non-voting common equity held by non-affiliates of the Registrant was $1,553,404,064 as of June 30, 2018 based upon the closing price on the Nasdaq Capital Market reported for such date. This calculation does not reflect a determination that certain persons are affiliates of the Registrant for any other purpose.

On February 20, 2019 there were 114,723,281 shares of common stock outstanding at a par value of $0.001 per share.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement for its 2019 Annual Meeting of Stockholders are incorporated by reference in Items 10, 11, 12, 13 and 14 of Part III.

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For the year ended December 31, 2018

PART I

This Annual Report on Form 10-K ("Form 10-K") contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended ("Exchange Act"), and Section 27A of the Securities Act of 1933, as amended ("Securities Act"). All statements contained in this Form 10-K, other than statements of historical fact, are forward-looking statements. When used in this report, the words "believe," "anticipate," "intend," "plan," "estimate," "expect," "may," "will," "should, "would," "could," "seek" and similar expressions are forward-looking statements based on management's current expectations. The absence of these words does not mean that a statement is not forward-looking. Forward-looking statements include, but are not limited to, statements about:

- our ability to manufacture, market and sell Korlym® (mifepristone) 300 mg Tablets ("Korlym");
- our estimates regarding enrollment in and the completion dates of our clinical trials and the anticipated results of these trials;
- the progress and timing of our research and development programs and the regulatory activities associated with them;
- our ability to realize the benefits of orphan drug designation for Korlym and the impact of possible future competition for Korlym or our product candidates;
- our estimates for future performance, including revenue and profits;
- the timing of the market introduction of future product candidates, including new uses for Korlym and any of our proprietary selective cortisol modulators;
- our ability to manufacture, market, commercialize and achieve market acceptance for our product candidates;
- uncertainties associated with obtaining and enforcing patents; and
- estimates regarding our capital requirements.

Forward-looking statements involve risks and uncertainties and are not guarantees of future performance. Actual events or results may differ materially for many reasons. For a more detailed discussion of the risks and uncertainties that may affect the accuracy of our forward-looking statements, see the "Risk Factors," "Overview" and "Liquidity and Capital Resources" sections of the "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this Form 10-K. You should also carefully consider the other reports and documents we file with the Securities and Exchange Commission ("SEC").

Forward-looking statements in this Form 10-K reflect our view only as of the date of this report. Except as required by law, we undertake no obligation to update forward-looking statements.

Unless stated otherwise, all references in this document to "we," "us," "our," "Corcept," the "Company," "our company" and similar words and phrases refer to Corcept Therapeutics Incorporated.

ITEM 1. BUSINESS

Overview

We are engaged in the discovery, development and commercialization of drugs that treat severe metabolic, oncologic and psychiatric disorders by modulating the effects of the hormone cortisol. Elevated levels and abnormal release patterns of cortisol are implicated in many diseases.

Our first approved product, Korlym, treats patients with Cushing's syndrome, a rare disease that is caused by excess cortisol activity. The active ingredient in Korlym is mifepristone, a compound that modulates cortisol activity by acting as a competitive antagonist at the glucocorticoid receptor ("GR"), one of the body's two cortisol receptors. We first made Korlym available to patients commercially in April 2012.

The United States Food and Drug Administration ("FDA") approved Korlym in February 2012 as a once-daily oral medication for the treatment of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery.

We have discovered and patented three structurally distinct series of proprietary, selective cortisol modulators, all of which share mifepristone's affinity for GR but, unlike mifepristone, do not bind to the progesterone receptor ("PR") and

therefore do not cause effects arising from antagonism of progesterone activity, such as termination of pregnancy, endometrial thickening and vaginal bleeding. We are conducting clinical trials of three of these compounds, including: (i) a Phase 3 trial of

relacorilant to treat patients with Cushing's syndrome; (ii) a Phase 2, controlled study of relacorilant combined with Celgene Corporation's drug Abraxane® (nab-paclitaxel) to treat patients with metastatic ovarian cancer; (iii) a Phase 1/2 trial of relacorilant plus Abraxane to treat patients with a variety of solid tumors; and (iv) a Phase 1/2 trial of CORT125281 combined with Pfizer Inc.'s androgen receptor antagonist Xtandi® (enzalutamide) to treat patients with castration-resistant prostate cancer ("CRPC"). We plan to open placebo-controlled, Phase 2 trials of CORT118335 as a potential treatment for two diseases - non-alcoholic steatohepatitis ("NASH") and antipsychotic-induced weight gain.

The Role of Cortisol in Disease

Cortisol is a steroid hormone that plays a significant role in the way the body reacts to stress. It is essential for survival. Cortisol influences metabolism and the immune system and contributes to emotional stability. Cortisol levels follow a diurnal rhythm that is essential to health, peaking upon awakening and decreasing during the day. Insufficient cortisol activity may lead to dehydration, hypotension, shock, fatigue and hypoglycemia. Excessive cortisol activity - known as hypercortisolism - may lead to a suppressed immune response, impaired glucose tolerance, diabetes, obesity, fatty liver disease, depressed mood, psychosis, wasting of the arms and legs, edema, fatigue, hypertension and other problems. Pre-clinical and clinical data suggest that cortisol reduces a patient's immune response to oncogenesis, shields certain cancer cells from the apoptotic effects of chemotherapy and facilitates the growth of others.

The challenge in treating a patient with hypercortisolism is modulating cortisol's effects without suppressing them below normal levels or disrupting cortisol's normal diurnal rhythm. Simply reducing or destroying the ability of the body to make cortisol can cause serious harm. Cortisol activity can be modulated effectively by a drug that competes with cortisol as it attempts to bind to GR. Mifepristone, the active ingredient in Korlym, is a competitive GR antagonist, as are our proprietary compounds.

Because mifepristone works by reducing the binding of excess cortisol to GR, it can modulate the effects of abnormal levels and release patterns of cortisol without compromising cortisol's healthy functions and rhythms. However, mifepristone also binds to PR, thereby terminating pregnancy and causing other adverse effects, including vaginal bleeding (a debilitating condition suffered by a significant portion of women who take Korlym). Our proprietary selective cortisol modulators bind to GR as potently as mifepristone does, but have no affinity for PR and so do not cause PR-related side effects.

Cushing's Syndrome

Background. Cushing's syndrome is the clinical manifestation of hypercortisolism. An estimated 10 to 15 of every one million people are newly diagnosed with this syndrome each year, resulting in approximately 3,000 new patients and about 20,000 patients with Cushing's syndrome in the United States, approximately half of whom are cured by surgery. It most often affects adults between the ages of 20 and 50.

Most people with Cushing's syndrome have one or more of the following symptoms: high blood sugar, diabetes, high blood pressure, upper body obesity, rounded face, increased fat around the neck, thinning arms and legs, severe fatigue and weak muscles. Irritability, anxiety, cognitive disturbances and depression are also common. Cushing's syndrome can affect every organ system in the body and can be lethal if not treated. The preferred treatment is surgery, which, if successful, can cure the disease. Depending on the type of tumor, surgery can result in a range of complications and has varying rates of success. In approximately half of the patients, surgery is not successful because the tumor cannot be located or removed completely.

Korlym to Treat Patients with Cushing's Syndrome. We sell Korlym exclusively in the United States, using experienced sales representatives targeting the endocrinologists and other physicians who care for patients with Cushing's syndrome. Because many people who suffer from Cushing's syndrome are undiagnosed or inadequately treated, we have developed and continue to refine and expand programs to educate physicians and patients about

diagnosis of this syndrome and the role cortisol modulators can play in treating the disease. In addition, we have a field-based force of medical science liaisons.

We use one specialty pharmacy and one specialty distributor to distribute Korlym and provide logistical support to physicians and patients. Our policy is that no patient with Cushing's syndrome will be denied access to Korlym for financial reasons. To help us achieve that goal, we fund our own patient support programs and donate money to independent charitable foundations that help patients cover the cost of all aspects of their Cushing's syndrome care, whether or not that care includes taking Korlym.

Relacorilant to Treat Patients with Cushing's Syndrome. We are advancing our proprietary, selective cortisol modulator, relacorilant, as a potential treatment for hypercortisolism. Patients in relacorilant's Phase 2 trial exhibited clinically

meaningful improvements in hyperglycemia and hypertension - two of Cushing syndrome's most common and pernicious symptoms. Relacorilant shares Korlym's affinity for GR, but unlike Korlym has no affinity for PR, and so does not cause the effects associated with PR affinity, including termination of pregnancy, endometrial thickening and vaginal bleeding. In addition, in its Phase 2 trial, relacorilant did not cause hypokalemia (low potassium levels), a potentially serious adverse event that is a leading cause of patients discontinuing treatment with Korlym. Forty-four percent of patients in Korlym's pivotal trial experienced hypokalemia.

We are currently conducting relacorilant's Phase 3 trial, in which we expect to enroll 130 patients at 60 sites in the United States and Europe. Each patient will receive relacorilant for 22 weeks, at which time any who have demonstrated pre-specified, clinically-meaningful improvements in hypertension or glucose metabolism will enter a twelve-week, double-blind, "randomized withdrawal" phase, in which half of the patients will continue to receive relacorilant and the rest will receive placebo. The rate and degree of relapse in patients receiving placebo will be measured against the rate and degree of relapse in those continuing to receive the medicine.

Relacorilant has been designated an orphan drug for the treatment of patients with Cushing's syndrome. See "Business - Orphan Drug Designation."

FKBP5 Gene Expression Assay. The tests available to physicians to diagnosis patients with hypercortisolism and optimize their treatment are imprecise and often fail to identify patients with less severe manifestations of the disease. We have developed an assay to measure expression of the gene FKBP5, which is stimulated by cortisol activity, and have completed analytical validation pursuant to the Clinical Laboratory Improvement Amendments ("CLIA"). Clinical data indicate that FKBP5 levels are high in patients suffering from hypercortisolism (i.e., excess cortisol activity), but subside when their hypercortisolism is successfully treated. We believe this assay will enable physicians to more easily identify new patients with hypercortisolism and better treat those already in their care.

Oncology

There is substantial in vitro, in vivo and clinical evidence that cortisol's activity allows certain solid tumors to resist treatment. In some cancers, cortisol activity promotes tumor growth. In other cancers, cortisol stimulates genes that retard cellular apoptosis. Cortisol also suppresses the body's immune response, which is often useful, as it lessens the frequency of autoimmune diseases. However, activating, not suppressing, the immune system is beneficial in fighting certain cancers. Adding a cortisol modulator to a treatment regimen may help the patient's immune system combat the disease. Many types of solid tumors express GR and are potential targets for cortisol modulation therapy, among them pancreatic, ovarian, castration-resistant prostate, triple-negative breast, cervical and vulvar cancers, as well as sarcoma and melanoma. We own, or have exclusively licensed, several patents covering the use of cortisol modulators to treat pancreatic, cervical, breast, and prostate cancers.

Relacorilant to Treat Patients with Metastatic Ovarian Cancer. We are conducting a Phase 2, controlled trial of relacorilant in combination with Abraxane to treat patients with metastatic ovarian cancer. The trial is expected to enroll 180 patients at sites in the United States and Europe. Patients will be randomly assigned to receive either 100 mg of relacorilant plus 80 ng/m2 of Abraxane or 80 ng/m2 of Abraxane alone.

We initiated our Phase 2 trial in metastatic ovarian cancer because of promising early data generated by our Phase 1/2 open label study of relacorilant plus Abraxane to treat a wide variety of solid tumors. That trial continues to enroll patients. As we identify indications of clinical activity in particular tumor types, we will further test the combination's efficacy and safety in expansion cohorts of approximately 20 patients or in separate, larger clinical trials. We have opened an expansion cohort in patients with pancreatic cancer and continue to explore opening cohorts in patients with other solid tumors, including triple-negative breast cancer and may initiate trials evaluating relacorilant with other cancer therapies, including immunotherapy.

Korlym to Treat Patients with Triple-Negative Breast Cancer ("TNBC"). In December 2016, we announced the results of our Phase 1/2 trial of Korlym in combination with eribulin (Eisai Inc.'s drug, Halaven®) to treat patients with

metastatic TNBC. The trial studied 21 patients with GR-positive tumors, one with GR-negative tumors and one with tumors whose GR status was not known. As determined using the Response Evaluation Criteria in Solid Tumors ("RECIST"), efficacy results were as follows: four patients exhibited a partial response, defined as a 30 percent or greater reduction in tumor size; eight had stable disease; and 11 had progressive disease. Six patients achieved progression-free survival ("PFS") longer than the upper bound of the 95% confidence interval for PFS (15 weeks) in patients receiving Halaven® monotherapy in a comparable population (Aogi et al., Annals of Oncology 23: 1441-1448, 2012). Median PFS in the trial was 11.1 weeks - compared to 7.2 weeks in the Halaven monotherapy study reported by Aogi.

We believe the addition of Korlym to chemotherapy warrants further study. University of Chicago investigators are leading a 64-patient double-blind, placebo-controlled, multi-center, Phase 2 trial of Korlym combined with Abraxane to treat patients with TNBC. Celgene is funding the trial. University of Chicago investigators are also conducting a 74-patient, open label trial of Korlym combined with Merck's drug Keytruda® (pembrolizumab) in patients with advanced HER2-negative and triple-negative breast cancer. Merck is funding the trial. We are providing Korlym to both trials.

Cortisol Modulators to Treat Patients with Castration-Resistant Prostate Cancer ("CRPC"). Because androgens stimulate prostate tumor growth, androgen deprivation is a common treatment for metastatic prostate cancer. Tumors eventually escape androgen deprivation therapy through the proliferation of cells for which cortisol's stimulation of GR and cortisol's stimulation of mutated androgen receptors are primary growth factors. Combining a cortisol modulator with an androgen modulator such as Xtandi may block this escape route.

We have begun dosing patients at sites in the United States and Europe in an open label, Phase 1/2 trial of our proprietary, selective cortisol modulator CORT125281 combined with Xtandi in patients with metastatic CRPC. University of Chicago investigators are leading an 84-patient, controlled, multicenter Phase 2 trial of Korlym combined with Xtandi to treat patients with metastatic CRPC. The Department of Defense and the Prostate Cancer Foundation are funding the trial. Pfizer is providing Xtandi. We are providing Korlym. These investigators are also conducting a dose-finding trial of relacorilant combined with Xtandi in patients with metastatic CRPC. We are providing relacorilant.

We have exclusively licensed patents from the University of Chicago covering the use of cortisol modulators combined with anticancer agents to treat TNBC and with androgen deprivation agents to treat CRPC. We also own two U.S. patents and two allowed patent applications covering the use of relacorilant and CORT125281 to treat pancreatic cancer.

Antipsychotic-Induced Weight Gain and NASH

In animal models, our proprietary selective cortisol modulator CORT118335 potently prevents and reverses the weight gain caused by Eli Lilly and Company's antipsychotic medication Zyprexa® (olanzapine). These findings replicate data from placebo-controlled clinical trials we conducted in which mifepristone significantly reduced the weight gain and adverse metabolic effects experienced by healthy subjects administered Zyprexa or Johnson & Johnson's antipsychotic medication Risperdal® (risperidone). We published the results of these trials in the journals Advances in Therapy, Gross et al (2009) and Obesity, Gross et al (2010).

We plan to conduct three placebo-controlled trials of CORT118335 as a potential treatment for antipsychotic-induced weight gain. The first trial will study whether CORT118335 prevents weight gain in healthy volunteers administered a two-week course of antipsychotic medication. The second two trials will be in patients taking antipsychotic medications - one to study the reversal of recently-established weight gain and the other to study the reversal of long-standing weight gain.

CORT118335 also prevents and reverses non-alcoholic fatty liver disease and liver fibrosis in animal models. We conducted these pre-clinical studies in response to data suggesting that cortisol modulation with Korlym played a role in reversing fatty liver disease in patients with hypercortisolism. Fatty liver disease is a precursor to NASH. We plan to conduct a placebo-controlled Phase 2 trial of CORT118335 as a possible treatment for NASH.

Development of our Other Selective Cortisol Modulators

Our portfolio of proprietary selective cortisol modulators, which includes relacorilant, CORT125281 and CORT118335, consists of more than 500 compounds in three structurally distinct series, all covered by our ten issued U.S. composition of matter patents. All of these compounds potently bind to GR but not the progesterone, estrogen or androgen receptors. Many of these compounds have demonstrated positive results in animal or in vitro models of cortisol modulation. We plan to continue identifying new compounds and advancing the most promising of them towards the clinic. We hold United States and foreign patents covering these compounds and their methods of use in a

wide range of range of indications. We have applied, and will continue to apply, for U.S. and foreign patents covering the composition and method of use of our products and product candidates. See “Business – Intellectual Property.”

Studies by Independent Investigators

For many years we have advanced our understanding of cortisol modulation by supporting the work of independent academic investigators. These researchers have studied the utility of mifepristone or our proprietary selective cortisol modulators in a wide range of disorders, including central serous retinopathy, post-traumatic stress disorder, anxiety, alcoholism, cocaine addiction, Alzheimer’s disease, ALS, muscular dystrophy, Cushing’s syndrome, metabolic syndrome, atherosclerosis, fatty liver

disease, and solid tumors, including triple-negative breast, prostate, ovarian and non-small cell lung cancers, as well as sarcoma and melanoma.

Clinical Trial Agreements

Some of our clinical trials are conducted through the use of clinical research organizations ("CROs"). Our Phase 3 trial of relacorilant for the treatment of patients with Cushing's syndrome is being conducted under an agreement with ICON plc ("ICON"). Novella Clinical LLC ("Novella") is helping us conduct our Phase 2 trial of relacorilant to treat patients with metastatic ovarian cancer and our Phase 1/2 trial of CORT125281 to treat patients with CRPC. Our agreements with ICON and Novella may be terminated by us on 60 days' written notice or sooner if the parties mutually agree.

Research and Development Spending

We incurred $75.2 million, $40.4 million and $23.8 million of research and development expenses in the years ended December 31, 2018, 2017 and 2016, respectively, which accounted for 47%, 38% and 34%, respectively, of our total operating expenses in those years.

Manufacturing Korlym

We do not have manufacturing capabilities and intend to continue to rely on experienced contract manufacturers to produce Korlym and our product candidates. In March 2014, we entered into a long-term agreement with one contract manufacturer - Produits Chimiques Auxiliaires et de Synthese SA ("PCAS") - to produce mifepristone, the active pharmaceutical ingredient ("API") for Korlym. On July 25, 2018, we amended this agreement to add a second manufacturing site and extend its term to December 31, 2021, with two one-year automatic renewals, unless either party provides 12 months advance written notice of its intent not to renew. The amendment provides exclusivity between PCAS and Corcept. If PCAS is unable to meet our requirements, we may purchase mifepristone from another supplier.

We have one tablet manufacturer for Korlym – Alcami Corporation ("Alcami," formerly known as AAI Pharma Services Corp., or AAI). In April 2014, we entered into an agreement with Alcami for the manufacture and packaging of Korlym tablets. The initial term of this agreement is three years, with consecutive automatic extensions of two years, unless either party gives written termination notice (in the case of Alcami, 18 months prior to the end of the applicable term; in our case, 12 months prior to the end of the applicable term). We have the right to terminate the agreement if (i) Alcami is unable to manufacture our product for four consecutive months or (ii) our product is withdrawn from the market.

Orphan Drug Designation

Prior to its approval, the FDA designated Korlym an orphan drug for the treatment of endogenous Cushing's syndrome. Orphan designation qualifies the sponsor of a drug candidate for tax credit and marketing incentives under the Orphan Drug Act, including seven years of exclusive marketing rights in the United States for drug in the specified orphan indication, if it receives the first regulatory approval for that indication, with limited exceptions. A marketing application for a prescription drug product that has been designated as a drug for a rare disease or condition is not subject to a prescription drug user fee unless the application includes an indication for other than a rare disease or condition. Orphan Drug designation for one medication does not prevent competitors from developing or marketing different drugs for the same Orphan indication. It also does not convey an advantage in, or shorten the duration of, the review and approval process for a drug. The FDA has designated relacorilant an orphan drug for the treatment of patients with endogenous Cushing's syndrome and pancreatic cancer.

Our orphan drug marketing exclusivity period for Korlym to treat patients with Cushing's syndrome ended on February 17, 2019, which means a competitor who receives FDA approval for a generic equivalent of Korlym may market its drug to patients with Cushing's syndrome, provided doing so would not infringe any of our patents. We have eight patents listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, that we believe would be infringed by a generic competitor for Korlym. These patents

have terms ranging from 2028 to 2037. Additional applications for patents we believe would qualify for the Orange Book are under examination by the USPTO.

Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act ("FDCA")

The FDCA establishes an approval process for generic versions of approved drugs ("Innovator Drugs") through the submission of an Abbreviated New Drug Application, or ANDA. An ANDA provides for marketing of a generic drug with the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use,

among other things, to the Innovator Drug. ANDAs are termed “abbreviated” because they are generally not required to include preclinical and clinical data establishing safety and efficacy. Instead, generic applicants must demonstrate that their product is bioequivalent to, or performs in the same manner as, the Innovator Drug.

In seeking approval, ANDA applicants must certify to the FDA that any Orange Book patents relating to the Innovator Drug are invalid or will not be infringed by the manufacture, use or sale of the generic product. This is known as a “Paragraph IV certification.” If the owner of the Innovator Drug responds to receipt of a paragraph IV certification by suing the ANDA applicant for patent infringement, the FDA may not approve the ANDA application until the earlier of 30 months or when the infringement case concerning each such patent is favorably decided in the ANDA applicant's favor or settled, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the “30-month stay.” Owners of Innovator Drugs regularly challenge paragraph IV certifications and trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve.

On February 5, 2018, we received notice that Teva Pharmaceuticals USA, Inc. (“Teva”) had submitted an ANDA seeking FDA approval to market a generic form of Korlym. Teva’s Paragraph IV certification stated that our listed Orange Book patents listed at that time, U.S. Patent No. 8,921,348 (the “’348 patent”) and U.S. Patent No. 9,829,495 (the “’495 patent”), will not be infringed by Teva’s proposed product, are invalid and/or are unenforceable. In March 2018, we sued Teva, alleging infringement of our the ‘348 and ‘495 patents. The FDA has tentatively approved Teva’s ANDA. However, in accordance with the Hatch-Waxman Act, as a result of Corcept’s lawsuit against Teva, the FDA cannot grant Teva’s ANDA final approval, until the earlier of 30 months following the initiation of our lawsuit or a District Court decision finding that the ‘348 and ‘495 patents are invalid, unenforceable or not infringed.

On July 6, 2018, we amended our original complaint against Teva and on February 8, 2019 we filed a second lawsuit against Teva, each time alleging the infringement of additional patents. These actions by us will not result in additional 30-month stays. On February 21, 2019 the District Court consolidated the two lawsuits. Although we will vigorously enforce our intellectual property rights relating to Korlym, we cannot predict the outcome of this lawsuit. See "Part I, Item 3, Legal Proceedings."

Inter Partes Review at the U.S. Patent Trial and Appeal Board

In August 2018, Neptune Generics, LLC submitted a petition for Inter Partes Review (“IPR”) at the U.S. Patent Trial and Appeal Board (“PTAB”) of U.S. Patent No. 8,921,348 (‘348) which is related to Korlym. Neptune Generics, LLC does not have regulatory approval to sell any drug in the United States. It is backed by the litigation finance firm, Burford Capital Ltd., a U.K.-based company. On February 15, 2019, the PTAB granted institution to the IPR, and an oral argument hearing date has been set for November 14, 2019. We plan to vigorously defend the validity of the ‘348 patent.

Competition for Korlym

Korlym competes with established treatments, including surgery, radiation and other medications, and including “off-label” uses of drugs such as ketoconazole, an anti-fungal medication. Korlym also competes with Novartis’ drug, Signifor® (pasireotide) Injection, which the FDA approved in December 2012 for the treatment of adult patients with Cushing’s disease who are not candidates for pituitary surgery or for whom surgery did not work. Cushing’s disease is a subset of Cushing’s syndrome.

In the future, Korlym may experience competition from generic versions and from new compounds. For example, Strongbridge Biopharma plc is developing levoketoconazole, a chiral form of ketoconazole. Novartis is developing osilodrostat, a cortisol synthesis inhibitor. Both compounds are in Phase 3 testing in the United States and European Union.

Intellectual Property

Patents and other proprietary rights are important to our business. It is our policy to seek patent protection for our inventions and to rely upon trade secrets, know-how, technological innovation and intellectual property licensing

opportunities to develop and maintain our competitive position. We own ten composition of matter patents covering our selective cortisol modulators and 33 patents covering the use of cortisol modulators to treat a wide range of serious disorders, including Cushing's syndrome. We have exclusively licensed five method of use patents from the University of Chicago. We also own an extensive portfolio of patents in countries around the world. We have applied, and will continue to apply, for U.S. and foreign patents covering the composition and method of use of our products and product candidates.

Korlym. The composition of matter patent covering Korlym's active ingredient, mifepristone, has expired. The only other FDA-approved use of mifepristone is to terminate pregnancy. We hold eight method of use patents listed in the FDA Orange Book covering various uses of Korlym in the treatment of patients with Cushing's syndrome, with additional patent applications that may be suitable for listing in the Orange Book standing allowed or currently under examination at the USPTO. Our current Orange Book patents have expiration dates ranging from 2028 to 2037.

To protect our market for Korlym we rely on (1) our method of use patents, (2) the significant restrictions imposed by the FDA on the use of mifepristone to terminate pregnancy and (3) the different patient populations, administering physicians and treatment settings between the use of mifepristone to terminate pregnancy and to treat Cushing's syndrome.

Oncology. We have exclusively licensed patents from the University of Chicago covering the use of glucocorticoid receptor antagonists, including mifepristone, in the treatment of castration-resistant prostate cancer in combination with androgen deprivation agents and triple-negative breast cancer in combination with anti-cancer agents. See "Business - License Agreements."

Other Method of Use Patents. In addition to our patents relating to Cushing's syndrome, we own U.S. patents for the use of cortisol modulators in the treatment of pancreatic cancer, mild cognitive impairment, the prevention and treatment of stress disorders, improving the therapeutic response to electroconvulsive therapy, the treatment of delirium, the treatment of catatonia, the treatment of psychosis with Interferon-Alpha therapy, inhibiting cognitive deterioration in adults with Down's Syndrome, the treatment of weight gain following treatment with antipsychotic medication, the treatment of gastroesophageal reflux disease, the treatment of migraine headaches, the treatment of neurological damage in premature infants and the treatment of diseases using combination steroid and GR antagonist therapy. We own a method of use patent for optimizing mifepristone levels in plasma serum in patients suffering from any disorder, including Cushing's syndrome, amenable to treatment with mifepristone. The expiration dates of these patents and their foreign counterparts range from 2020 to 2037.

Composition of Matter Patents Covering Our Proprietary, Selective Cortisol Modulators. We have ten U.S. composition of matter patents containing claims relating to three structurally distinct series of next-generation cortisol modulators. Four of these patents have issued in Europe. The expiration dates of these patents and their foreign counterparts range from 2026 to 2034.

We have also filed, where we deemed appropriate, foreign patent applications corresponding to our U.S. patents and applications. We cannot assure you that any of our patent applications will result in the issuance of patents, that any issued patent will include claims of the breadth sought in these applications, or that competitors or other third-parties will not successfully challenge or circumvent our patents if they are issued.

We believe that our patents are valid and that we do not infringe any third-party's patents or other proprietary rights, and we are not obligated to pay royalties relating to the use of intellectual property to any third-parties other than the University of Chicago.

License Agreements

We have exclusively licensed from the University of Chicago five issued U.S. patents for (a) the use of cortisol modulators in the treatment of triple-negative breast cancer, and (b) the use of cortisol modulators to treat castration-resistant prostate cancer. We are required to pay the University of Chicago customary milestone fees and royalties on revenue from products commercialized under the issued patents or patents that may issue pursuant to the pending applications. Our license will end upon expiration of the licensed patents in 2031 and 2033 or upon notification by us to the University of Chicago. Three patents licensed from Stanford University expired in October 2018. See "Business – Intellectual Property."

Government Regulation

Prescription pharmaceutical products are subject to extensive pre- and post-approval regulation, including regulations that govern the testing, manufacturing, safety, efficacy, labeling, storage, record keeping, advertising, and promotion of the products under the Federal Food, Drug and Cosmetic Act. All of our product candidates require regulatory approval by government agencies prior to commercialization. The process required by the FDA before a new drug may be marketed in the United States generally involves the following: completion of preclinical laboratory and

animal testing; submission of an Investigational New Drug ("IND"), which must become effective before clinical trials may begin; performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug's intended use; and approval by the FDA. The process of complying with these and other federal and state statutes and regulations involves significant time and expense.

Preclinical studies are generally conducted in laboratory animals to evaluate the potential safety and the efficacy of a product. Drug developers submit the results of preclinical studies to the FDA as a part of an IND, which must be approved before

beginning clinical trials in humans. If it is anticipated that the clinical trial will be conducted in Europe, a Clinical Trial Authorization (CTA) must be submitted and approved by the appropriate European regulatory agency prior to the commencement of the study. Typically, human clinical trials are conducted in three sequential phases that may overlap.

- Phase 1. The product candidate is administered to a small number of healthy subjects to provide preliminary information as to its safety, tolerability and pharmacokinetics and sometimes to provide preliminary information as to its activity and/or efficacy.
- Phase 2. The product candidate is administered to patients afflicted with the target disease to determine its preliminary efficacy, optimal dosages and to provide more evidence of safety.
- Phase 3. The product candidate is administered to a larger group of patients afflicted with the target disease to establish its risk/benefit ratio and to demonstrate with substantial evidence its efficacy and safety.

The FDA and the institutional review boards associated with clinical trial sites closely monitor the progress of clinical trials conducted in the United States and may reevaluate, alter, suspend or terminate a trial at any time for various reasons, including a belief that the subjects are being exposed to unacceptable risks. The FDA may also require that additional trials be conducted.

After Phase 3 trials are completed, drug developers submit the results of preclinical studies, clinical trials, formulation studies and data supporting manufacturing to the FDA in the form of a New Drug Applications ("NDA"). The FDA reviews an NDA upon submission and may request additional information rather than accept an NDA for filing. If the FDA accepts an NDA for filing, it may grant marketing approval (i.e., permit commercial sales), request additional information or deny the application. Once an NDA has been accepted for filing, by law the FDA has 180 days to examine the application and respond to the applicant. However, the review process is often significantly extended by FDA requests for additional information or clarification. Under the Prescription Drug User Fee Act, the FDA has a goal of responding to NDAs within ten months of the filing date for standard review, and six months for priority review if a sponsor shows that its drug candidate provides a significant benefit compared to marketed drugs. FDA approvals may not be granted on a timely basis or at all.

If the FDA approves an NDA, physicians may prescribe the subject drug to patients in the United States. The FDA may withdraw a product's marketing approval if compliance with regulatory standards is not maintained. The drug developer must submit periodic reports to the FDA. Adverse patient experiences with the product must be reported to the FDA, which could result in the imposition of marketing restrictions through labeling changes or removal of the product from the market. In addition, the FDA may require post-marketing studies, referred to as Phase 4 studies, to monitor the effect of approved products, and may limit further marketing of the product based on the results of such studies.

Facilities involved in the manufacture of drugs are subject to periodic inspection by the FDA and other authorities where applicable and must comply with FDA-mandated current Good Manufacturing Practices regulations ("cGMP"). Failure to comply with statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, including suspension of manufacturing or a product recall.

The FDA imposes complex regulations on entities, such as Corcept, that advertise and promote pharmaceuticals. These include standards and regulations for direct-to-consumer advertising, off-label promotion, and industry-sponsored scientific and educational activities. The FDA has broad enforcement authority under the Federal Food, Drug and Cosmetic Act. Failure to abide by its regulations can result in penalties including the issuance of a warning letter directing a company to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and state and federal civil and criminal penalties.

In addition to studies requested by the FDA after approval, a drug developer may conduct other preclinical and clinical trials investigating use of the approved compound to treat additional indications. Data supporting the use of a drug for new indications must be approved by the FDA before the drug can be marketed for these indications.

Marketing Approvals Outside the United States

We are not seeking regulatory approval to market Korlym outside the United States. If we do so, we (or our potential future partners) will have to complete an approval process similar to the U.S. approval process before we can

distribute our product candidates in those countries. The approval procedure and the time required for approval vary from country to country and can involve additional preclinical and clinical trials. Foreign approvals may not be granted on a timely basis, or at all. Regulatory approval of pricing is required in most countries other than the United States. The prices approved may be too low to generate an acceptable return.

Coverage and Reimbursement

Sales of our products will depend, in part, on the extent to which they will be covered by government health care programs and commercial insurance and managed healthcare organizations. Although this trend has not had a material impact on the amount or timing of our revenues, these third-party payors are increasingly limiting coverage and reducing reimbursements for medical products and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could limit our net revenue and results. Decreases in third-party reimbursement for our products or a decision by a third-party payor to not cover our products could reduce physician utilization of our products and have a material adverse effect on our sales, results of operations and financial condition.

Other Healthcare Laws

We are subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we conduct our business. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and physicians' sunshine laws and regulations. The federal Anti-Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. The Anti-Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the Anti-Kickback Statute to reach large settlements with healthcare companies based on sham consulting and other financial arrangements with physicians. Further, the recently enacted Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the PPACA, among other things, amends the intent requirement of the federal Anti-Kickback Statute and the criminal statute governing healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them. In addition, the PPACA provides 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 federal False Claims Act or federal civil money penalties statute. The majority of states also have anti-kickback laws which establish similar prohibitions and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers. Additionally, the civil False Claims Act prohibits knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-billion dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. We expect that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program. In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, imposes certain requirements relating to the privacy, security and transmission of protected health information on HIPAA covered entities, which include certain healthcare providers, health plans and healthcare clearinghouses, and their business associates who conduct certain activities for or on their behalf involving protected health information on their behalf.

In addition, there has been increased federal and state regulation of payments made to physicians and other healthcare providers. The PPACA, among other things, imposes new reporting requirements on drug manufacturers for payments

made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $166,000 per year (or up to an aggregate of $1.1 million per year for “knowing failures”), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Drug manufacturers must report such payments to the government by the 90th day of each calendar year. Certain states also mandate implementation of commercial compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians.

State and foreign laws and regulations restrict business practices in the pharmaceutical industry and complicate our compliance efforts. For example, some states require companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the federal government's compliance guidance or otherwise restrict payments to healthcare providers and other potential referral sources. Some states require manufacturers to file reports relating to pricing and marketing information. Some state and local governments require the public registration of pharmaceutical sales representatives. Some state and foreign laws govern the privacy and security of health information in ways that differ significantly from one another and are not preempted by HIPAA.

The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may violate one or more of the requirements. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Employees

We are managed by experienced pharmaceutical executives. We also enlist the expertise of associates and advisors with extensive pharmaceutical development experience. As of December 31, 2018, we had 166 employees, five of whom have MDs. We consider our employee relations to be good. Our employees are not covered by a collective bargaining agreement.

About Corcept

We were incorporated in the State of Delaware on May 13, 1998. Our registered trademarks include Corcept® and Korlym®. Other service marks, trademarks and trade names referred to in this document are the property of their respective owners.

Available Information

We are subject to the information requirements of the Securities Exchange Act of 1934, as amended, and we therefore file periodic reports, proxy statements and other information with the SEC relating to our business, consolidated financial statements and other matters. The SEC maintains an Internet site, www.sec.gov, that contains reports, proxy statements and other information regarding issuers such as Corcept.

For more information about Corcept, including free access to our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports, visit our website, www.corcept.com. The information found on or accessible through our website is not incorporated into, and does not form a part of, this Form 10-K.

ITEM 1A. RISK FACTORS

An investment in our common stock involves significant risks. Carefully consider the risks described below and the other information in this Annual Report on Form 10-K, including our consolidated financial statements and related notes, before investing. If any of the following risks or uncertainties actually occurs, our business, results of operations or financial condition could be materially harmed, the price of our common stock could fall and you could lose part or all of your investment. The risks and uncertainties described below are those that we currently believe may materially affect us; however, there may be others of which we are unaware. Moreover, new risks and uncertainties may arise and harm our business.

Risks Related to the Commercial Sale of Korlym®

Failure to generate sufficient revenue from the sale of Korlym would harm our financial results and would likely cause our stock price to decline.

Our ability to generate revenue and fund our commercial operations and development programs is entirely dependent on the sale of Korlym to treat patients with Cushing's syndrome. Physicians will prescribe Korlym only if they determine that it is preferable to other treatments, even if those treatments are not approved for Cushing's

syndrome. Because Cushing's syndrome is rare, most physicians are inexperienced diagnosing or caring for patients with the illness and it may be difficult to persuade them to identify appropriate patients and prescribe Korlym.

Many factors could limit our Korlym revenue, including:

- the preference of some physicians for long-standing off-label treatments for Cushing's syndrome, such as ketoconazole;
- competition from non-medical treatments, such as surgery and radiation;
- the potential introduction of a competitor for Korlym, including a generic version of Korlym;
- negative publicity and political concerns about Korlym, RU-486, Mifeprex® or mifepristone;
- the lack of availability of adequate private and government insurance coverage; and
- rapid technological change that makes Korlym obsolete.

Failure to generate sufficient Korlym revenue may prevent us from fully funding our planned commercial and clinical activities and would likely cause our stock price to decline.

If generic products that compete with Korlym or any future Corcept product are approved and launched, our business, financial position or results of operations would be adversely affected.

Although Korlym is protected by patents covering its method of use, including its use to treat patients with Cushing's syndrome, we cannot assure you that third parties will not attempt to invalidate or design around the patents or assert that they are invalid or otherwise unenforceable and introduce generic equivalents of Korlym or any future products. In February 2018, we received notice that Teva had filed an ANDA requesting approval to market a generic form of Korlym. Teva's Paragraph IV Notice Letter asserted that our patents listed in the Orange Book for Korlym at the time Teva filed its ANDA are invalid, unenforceable or will not be infringed by Teva's proposed generic product. We have filed suit against Teva in Federal District Court defending our patents, triggering the statutory automatic 30-month stay of FDA approval, beginning as of the date we received the Notice Letter. Litigation to enforce or defend intellectual property rights is complex, costly and involves significant commitments of management time. If our Orange Book patents are successfully challenged by Teva or any other party and a generic version of Korlym is approved, the sale of Korlym tablets and their price could decline significantly.

The period of marketing exclusivity provided by Korlym's orphan drug designation expired on February 17, 2019, which means that other companies may seek to introduce generic equivalents of Korlym, provided they receive FDA approval and can show that their products do not infringe our patents or that our patents are invalid or unenforceable. After the introduction of a generic competitor, a significant percentage of the prescriptions written for a product may be filled with the generic version, resulting in a loss in sales of the branded product and reducing its price. Generic competition for Korlym could have a material adverse effect on our sales, results of operations and financial condition.

Other companies are attempting to develop different medications to treat patients with Cushing's syndrome. The availability of competing treatments could limit our revenue from the sale of Korlym.

In 2012, Novartis received approval in both the United States and the European Union ("EU") to market its somatostatin analogue Signifor® (pasireotide) Injection for adult patients with Cushing's disease (a subset of Cushing's syndrome) for whom pituitary surgery is not an option or has not been curative. Novartis is also conducting Phase 3 trials of the experimental cortisol synthesis inhibitor osilodrostat to treat patients with Cushing's syndrome. It has received orphan drug designation for osilodrostat in the United States and the EU for that use. Novartis has substantially more resources and experience than we do and may provide significant competition.

Strongbridge Biopharma plc ("Strongbridge") has received orphan drug designation in the United States and the EU for the use of the cortisol synthesis inhibitor levoketoconazole to treat patients with Cushing's syndrome. Levoketoconazole is an enantiomer of the generic anti-fungal medication, ketoconazole, that is sometimes prescribed off-label to treat patients with Cushing's syndrome. Strongbridge has completed one Phase 3 trial, which met its primary endpoint of reducing cortisol synthesis and is conducting a second Phase 3 trial.

If we cannot continue to obtain acceptable prices or adequate insurance coverage and reimbursement for Korlym, we will be unable to generate significant revenues.

The commercial success of Korlym depends on the availability of insurance coverage and reimbursement. Government payors, including Medicare, Medicaid and the Veterans Administration, as well as private insurers and health maintenance organizations, are increasingly attempting to contain healthcare costs by limiting reimbursement

for medicines. If government or private payors cease to provide adequate and timely coverage and reimbursement for Korlym, physicians may not prescribe the medication and patients may not purchase it, even if it is prescribed. In addition, delays in coverage for individual patients may reduce our revenues.

In some foreign markets, drug prices and the profitability of prescription medications are subject to government control. In the United States, we expect that there will continue to be federal and state proposals for similar controls. Also, the trends toward managed health care in the United States and recent laws and legislation intended to increase the public visibility of drug prices and reduce the cost of government and private insurance programs could significantly influence the purchase of health care services and products and may result in lower prices for Korlym. In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. The Patient Protection and Affordable Care Act ("PPACA"), which was passed in 2010, substantially changed the way health care is financed by both governmental and private insurers and significantly impacts the U.S. pharmaceutical industry. The PPACA, among other things, expanded Medicaid program eligibility and access to commercial health insurance coverage, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and promoted a new Medicare Part D coverage gap discount program. The PPACA also appropriated additional funding to comparative clinical effectiveness research, although it remains unclear how the research will impact current Medicare coverage and reimbursement or how new information will influence other third-party payor policies.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the PPACA, and we expect there will be additional challenges and amendments to the PPACA in the future. For example, the Tax Cuts and Jobs Acts (the "Tax Act") was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the PPACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the PPACA are invalid as well. While the Trump Administration and the Centers for Medicare & Medicaid Services have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, and other efforts to repeal and replace the PPACA will impact the law. At this time, the full effect that the PPACA and any subsequent legislation would have on our business remains unclear. Any new limitations on, changes to, or uncertainty with respect to the ability of individuals to enroll in governmental reimbursement programs or other third-party payor insurance plans could impact demand for Korlym, which in turn could affect our ability to successfully develop and commercialize our products.

Other legislative and regulatory changes have been proposed and adopted in the United States since the PPACA was enacted. These changes included an aggregate reduction in Medicare payments to providers of up to 2 percent per fiscal year, which went into effect on April 1, 2013 and will remain in effect through 2027 unless additional Congressional action is taken, and the American Taxpayer Relief Act of 2012, which further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. On February 1, 2016, the Centers for Medicare & Medicaid Services, or CMS, published a final rule that revised certain requirements involved in our calculation of prices we report in connection with our participation in government reimbursement programs so that Korlym will be eligible for purchase by, or qualify for partial or full reimbursement from, Medicaid and other government programs. The extent to which this rule may alter our reported prices and estimated rebates and chargebacks under government programs remains unclear. Moreover, the federal government and the individual states in the United States have become increasingly active in developing proposals, passing legislation and implementing regulations designed to control drug product pricing, including price or patient reimbursement constraints, discounts, formulary flexibility, marketing cost disclosure and transparency measures. These new laws and the regulations and policies implementing them, as well as other healthcare reform measures that may be adopted in the future, could materially reduce our ability to successfully develop and commercialize Korlym and our product candidates.

The unfavorable public perception of mifepristone may limit our ability to sell Korlym.

The active ingredient in Korlym, mifepristone, is approved by the FDA in another drug for the termination of early pregnancy. As a result, mifepristone has been and continues to be the subject of considerable debate in the United

States and elsewhere. Public perception of mifepristone may limit the acceptance of Korlym by patients and physicians. Even though we have taken measures to minimize the chance that Korlym will be accidentally be prescribed to a pregnant woman, physicians may choose not to prescribe Korlym to a woman simply to avoid the risk of unintentionally terminating a pregnancy.

We have no manufacturing or pharmacy capabilities and depend on third parties to manufacture Korlym's active ingredient, form it into tablets, package it and dispense it to patients. We also depend on third parties to manufacture the API and capsules or tablets for relacorilant, CORT118335, CORT125281 and our other product candidates. If these suppliers become unable or unwilling to perform these functions and we cannot transfer our business to qualified replacement vendors in a timely manner, our business will be harmed.

A single third-party manufacturer, PCAS, supplies the API in Korlym. Another third-party manufacturer, Alcami, produces and bottles our Korlym tablets. Our agreement with Alcami automatically renews and can be terminated by either party, subject to notice provisions. Our agreement with PCAS automatically renews for two one-year terms, unless either party provides 12 months advance written notice of its intent not to renew. A single specialty pharmacy, Optime Care, Inc. ("Optime"), dispenses the Korlym we sell directly to patients and collects payments from insurers and other payers representing approximately 99 percent of our revenue. If Optime does not adhere to its agreements with payers, it may not be able to collect some or all of the payments due to us. Our agreement with Optime has a five-year term and renews upon the written consent of both parties subject to the ability of either party to terminate upon material breach by either party or bankruptcy or insolvency. In addition, we may terminate the agreement for convenience.

If any of these vendors is unable or unwilling to meet our requirements, we may not be able to manufacture or dispense Korlym or our product candidates in a timely manner, which may prevent us from generating revenue or advancing our clinical development programs. Identifying replacement vendors and transitioning our business to them would be time-consuming, complex and expensive. Failure to do so efficiently and in a timely manner would harm our business.

The facilities used by our vendors to manufacture and package Korlym and our product candidates must be approved by the FDA and, in some cases, the European Medicines Agency ("EMA"). We do not control the manufacturing activities of these vendors and are dependent on them for compliance with the regulatory requirements known as current good manufacturing practices ("cGMPs"). If our vendors cannot manufacture material that conforms to our specifications and the strict requirements of the FDA or others, they will not be able to maintain regulatory approval for their facilities, which could prohibit us from using materials they have provided to us. We have no control over whether our vendors maintain adequate quality control and hire qualified personnel. If the FDA, EMA or other regulatory authority does not approve the facilities used to manufacture our products or if a necessary approval is withdrawn, we may need to find alternative facilities, which would be expensive and could significantly hamper our ability to develop, obtain regulatory approval for and market our products. In addition, sanctions could be imposed on us, including fines, injunctions, civil penalties, failure of regulators to approve our product candidates, delays, suspensions or withdrawals of approvals, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could harm our business.

We may not have adequate insurance to cover our exposure to product liability claims.

We may be subject to product liability or other claims based on allegations that Korlym or one of our product candidates has caused adverse effects. Such a claim may damage our reputation by raising questions about Korlym or our product candidates' safety and could prevent or interfere with product commercialization. Less common adverse effects of a pharmaceutical product are sometimes not known until long after the product is approved for marketing. Because the active ingredient in Korlym is used to terminate pregnancy, clinicians using the medicine in our clinical trials and physicians prescribing the medicine to women must take strict precautions to ensure that the medicine is not administered to pregnant women. Failure to observe these precautions could result in significant product liability claims.

We have product liability insurance with coverage limits we believe to be appropriate for a company marketing a single pharmaceutical product and developing others. However, this insurance may become prohibitively expensive or may not fully cover our potential liabilities. Our inability to obtain adequate insurance coverage at an acceptable cost could inhibit the commercialization of Korlym or our product candidates or could result in significant underinsured or uninsured liability. Defending a lawsuit could be costly and divert management's productive activities.

We are subject to ongoing regulatory review. If we are unable to maintain regulatory approval of Korlym for the treatment of patients with Cushing's syndrome or if we fail to comply with regulatory requirements, we will be unable

to generate revenue or may be subject to penalties and our business would be harmed.

We are subject to ongoing obligations and continued regulatory review by the FDA and other regulatory authorities in the United States and elsewhere with respect to the research, testing, manufacturing, labeling, distribution, adverse event reporting, storage, selling, advertising, promotion, recordkeeping and marketing of products. These requirements include submissions of safety information, annual updates on manufacturing activities and continued compliance with FDA regulations known as “cGMPs,” current good laboratory practices (“cGLPs”) for the nonclinical studies we conduct and current good clinical practices (“cGCPs”) for our clinical studies. The FDA enforces these regulations through periodic inspections of us and the laboratories, manufacturers and clinical sites we use. Foreign regulatory authorities have comparable requirements and enforcement

mechanisms. Discovery of previously unknown problems with a product or product candidate, including adverse events of unanticipated severity or frequency or with our manufacturers or their manufacturing processes, or failure to comply with FDA and applicable foreign and U.S. regulatory requirements, may subject us to substantial civil and criminal penalties, injunctions, holds on clinical trials, product seizure or detention, refusal to permit the import or export of products, restrictions on product marketing, withdrawal of the product from the market, voluntary or mandatory product recalls, total or partial suspension of production, refusal to approve pending NDAs or supplemental NDAs, and suspension or revocation of product approvals.

In addition, we must comply with requirements concerning the advertising and promotion for our products. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use. If we market our products outside of their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the FDA's restrictions relating to the promotion of prescription products may also lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws. The FDA's policies may change or new regulations may be enacted that prevent, limit or delay regulatory approval of our product candidates. We cannot predict the nature or scope of future government regulations. For example, the administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these Executive Orders will be implemented, if at all, and the extent to which they will affect the FDA's ability to exercise its authority. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities or if we are slow or unable to adapt to sudden changes in existing requirements or the adoption of new requirements or policies, we may not be able to maintain regulatory compliance, and we may lose marketing approval or face other enforcement action.

We may be subject to civil or criminal penalties if we market Korlym in a manner that violates FDA regulations or health care fraud and abuse laws.

In the United States, we are subject to FDA regulations governing the promotion and sale of medications. Although physicians are permitted to prescribe drugs for indications other than those approved by the FDA, manufacturers are prohibited from promoting products for such "off-label" uses. In the United States, we market Korlym to treat hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. We provide promotional materials and training programs to physicians covering the use of Korlym for this indication. Although we believe our marketing materials and training programs do not constitute "off-label" promotion of Korlym, the FDA may disagree. If the FDA determines that our promotional materials, training or other activities by our employees or agents constitute "off-label" promotion of Korlym, it could ask us to change our training or promotional materials or other activities. The FDA could also subject us to regulatory enforcement actions, including issuance of a public "warning letter," injunction, seizure, civil fine or criminal penalties. Other federal or state enforcement authorities might act if they believe that the alleged improper promotion led to the submission and payment of claims for an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. Even if it is determined that we are not in violation of these laws, we may be faced with negative publicity, incur significant expenses and be forced to devote management time to defending our position.

We are subject to federal and state healthcare fraud and abuse regulations, including:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal health care programs such as the Medicare and Medicaid programs; A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

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federal false claims laws, including, without limitation, the False Claims Act, which prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as allegedly providing free product to or entering into "sham" consulting arrangements with customers to induce such customers to purchase, order or recommend the company's products in violation of the Anti-Kickback Statute and federal false claims laws and regulations; reporting to pricing services inflated average wholesale prices that were then used by certain governmental programs to set reimbursement rates; engaging in the promotion of "off-label" uses that caused customers to submit claims to and obtain reimbursement from governmental payors for non-covered "off-label" uses; and submitting inflated best price information to the Medicaid Drug Rebate Program; the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the federal Civil Monetary Penalties law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created federal criminal laws that prohibit executing a scheme to defraud any health care benefit program or making false statements relating to health care matters;
- federal "sunshine" laws, including the federal Physician Payment Sunshine Act, that require transparency regarding financial arrangements with health care providers, such as the reporting and disclosure requirements imposed by the PPACA on drug manufacturers regarding any "transfer of value" made or distributed to prescribers and other health care providers, and ownership or investment interests held by physicians and their immediate family members. Manufacturers are required to submit reports detailing these financial arrangements by the 90th day of each calendar year;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state 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 pricing information; and state 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.

The risk of our being found in violation of these laws and regulations is increased by the fact that many of them have not been definitively interpreted by the regulatory authorities or the courts and their provisions are open to a variety of interpretations. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under them, it is possible that some of our business activities, including our relationships with physicians and other healthcare providers (some of whom recommend, purchase and/or prescribe our products) and the manner in which we promote our products, could be subject to challenge. We are also exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, distributors, and contract research organizations ("CROs") may engage in fraudulent or other illegal activity. Although we have policies and procedures prohibiting such activity, it is not always possible to identify and deter misconduct and the precautions we take may not be effective in

controlling unknown risks or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with applicable laws and regulations.

If our operations are found to be in violation of any of the laws described above or any other government regulations, we may be subject to civil and criminal penalties, damages, fines, exclusion from governmental health care programs, a corporate integrity agreement or other agreement to resolve allegations of non-compliance, individual imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our financial results and ability to operate.

A breakdown or breach of our information technology systems or our failure to protect confidential information concerning patients or others could subject us to liability or interrupt the operation of our business.

We store sensitive data on our computer networks and on the networks of our vendors, including intellectual property and confidential information relating to our business, patients and employees. Despite the implementation of security measures, our internal computer systems and those of our vendors are subject to the risk of cyberattacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. They may also be manipulated by criminals seeking to commit fraud or theft. In addition, system failures could cause the loss or theft of valuable clinical trial data or otherwise disrupt our clinical and commercial activities and be expensive and time-consuming to remedy. If a disruption or security breach resulted in the disclosure of confidential or proprietary information, we could incur liability and our research, development and commercialization efforts could be delayed or otherwise harmed.

We are subject to government regulation and other legal obligations relating to privacy and data protection. Compliance with these requirements could result in additional costs and liabilities and inhibit our ability to collect and process data. The failure to comply with such requirements could have a material adverse effect on our business.

As we receive, collect, process, use and store personal and confidential data, we are subject to subject to diverse laws and regulations relating to data privacy and security, including, in the United States, HIPAA, and, in the EU and shortly in the European Economic Area (EEA), Regulation 2016/679, known as the General Data Protection Regulation ("GDPR"). Compliance with these privacy and data security requirements is rigorous and may increase our cost of doing business. Despite our best efforts, we may be subject to fines and penalties, litigation and reputational harm, which could materially and adversely affect our business, financial condition and results of operations.

Regulations governing the receipt, collection, processing, use, safeguarding, sharing and transfer of personal and confidential data is evolving rapidly and is likely to remain uncertain for the foreseeable future as new global privacy rules are enacted and existing ones updated and made more stringent. The GDPR took effect in Europe on May 25, 2018. It establishes new requirements for the use and safeguarding of personal data in the EU and applies to companies established in the EU as well as companies that collect and use personal data to offer goods or services to, or monitor the behavior of, individuals in the EU (including in clinical trials). Penalties for failure to comply with GDPR include fines of up to €20 million or four percent of worldwide annual revenue, whichever is greater. Data protection authorities in some of the EU member states have not completed their interpretative guidance and implementing laws and regulations regarding GDPR, which makes compliance difficult. In addition, the data protection authorities of the different EU countries may interpret the regulation differently. Once promulgated, national and EU guidance are likely to be updated from time to time, which will add complexity and cost to our collection and handling of data.

If we or our vendors fail to comply with the GDPR or other applicable data privacy laws, or if the data protection measures and disclosures we or our vendors undertake are not considered adequate, we could be subject to government enforcement actions and substantial penalties and fines, which could harm our business.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impair the ability of the FDA to review

and process our regulatory submissions, which could have a material adverse effect on our business.

Many of our patients pay for Korlym with insurance or other support provided by payers who are funded in whole or in part by the U.S. federal government, such as Medicare, Medicaid, Tricare and the Veterans Administration. If a partial or total shutdown of the federal government prevents these payers from fully-funding their obligations, our revenues will fall and our business will be harmed. In addition, we are dependent on the continued functioning of the SEC, FDA and other federal instrumentalities that regulate us and our industry. The partial or complete closure of these entities, or their inability to hire and

retain talented professionals due to uncertainties about their ability to reliably pay their employees, could materially harm our business.

Recent U.S. tax legislation may materially adversely affect our results of operations, financial condition and cash flows.

Recently enacted U.S. tax legislation has significantly changed the U.S. federal income taxation of U.S. corporations, including reducing the U.S. corporate income tax rate, limiting interest deductions, permitting immediate expensing of certain capital expenditures, adopting elements of a territorial tax system, revising the rules governing net operating losses and foreign tax credits, and introducing new anti-base erosion provisions. Many of these changes became effective immediately, without transition periods or grandfathering for existing transactions. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and Internal Revenue Service, which could increase certain adverse impacts of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often use federal taxable income as a starting point for computing state and local tax liabilities.

A catastrophic disaster could damage our own or our manufacturers' facilities and equipment, which could require us to cease or curtail operations.

Our business is vulnerable to damage from various types of natural disasters or other disruptive events, including earthquakes, fires, floods, power losses and communications failures. Our headquarters are located in the San Francisco Bay Area, which is earthquake-prone. Our specialty pharmacy and our tablet manufacturer are located in areas that are subject to severe weather conditions. Political considerations relating to mifepristone put us and our manufacturers at increased risk for terrorist attacks, protests or other disruptive events. If a disaster or similar event were to occur, we might not be able to operate our business or our manufacturers might not be able to produce or dispense Korlym or our product candidates. Our insurance may not cover or be adequate to cover losses resulting from disasters or other business interruptions.

Risks Related to the Development of our Product Candidates

Clinical drug development is lengthy, expensive and often unsuccessful. Results of early studies and trials may not be predictive of later trial results.

Clinical development is expensive and takes a long time. Data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The results from early clinical trials may not be predictive of results in later clinical trials. Product candidates may ultimately fail to show the desired safety and efficacy traits despite having produced positive results in preclinical studies and initial clinical trials. Many companies have suffered significant setbacks in advanced clinical trials due to lack of efficacy or the adverse safety profile of a product candidate.

Except for our Phase 3 trial evaluating relacorilant to treat patients with Cushing's syndrome, our current clinical trials are too small to support regulatory submissions seeking marketing approvals for the compounds being studied. Even if these trials generate positive results, those results would have to be confirmed in one or more substantially larger, more expensive and lengthier trials before we could seek regulatory approvals.

The commencement and completion of clinical trials may be delayed by many factors, including:

- delays obtaining regulatory permission to start a trial or changes to the size or design or regulatory requirements with respect to a trial already underway;
- inability to secure acceptable terms with vendors and clinical trial sites;
- delays or inability to obtain institutional review board ("IRB") approval at prospective trial sites;
- slow patient enrollment;
- failure of patients or investigators to comply with the clinical trial protocol;
- negative or inconclusive trial results; and
- negative findings of inspections of clinical sites or manufacturing operations by us, the FDA or other authorities.

We may not be able to select and qualify appropriate sites for our trials. If our clinical sites fail to enroll a sufficient number of patients in a timely way, we may be unable to complete our trials as planned, which could delay or prevent the approval of our product candidates. We could also encounter delays if a clinical trial is suspended or terminated by

us, the trial's data safety monitoring board or the IRBs governing the sites where the trial is being conducted. The FDA or other regulatory authorities may suspend or terminate a trial for many reasons, including failure to conduct the trial in accordance with regulatory requirements or our clinical protocols, negative findings in an inspection by the FDA or other authorities of our clinical trial operations or clinical trial sites, unforeseen safety issues, failure to demonstrate a benefit from using a product candidate or changes in government regulations.

During the clinical development of a product candidate, we may decide, or the FDA or other regulatory authorities may require us, to conduct more pre-clinical or clinical studies than we had planned or to change the size or design of a trial already underway, which could delay or prevent the completion of our development program and increase its cost. Even if we conduct all of the clinical trials and supportive studies that we consider appropriate and we consider the results of those trials and studies to be positive, we may not receive regulatory approval of a product candidate.
We depend on vendors to conduct and manage some of our clinical trials and to perform data collection and analysis. Failure of these vendors to perform their contractual duties or meet expected timelines may prevent or delay approval of our product candidates, which could harm our business.

We rely on third-party clinical investigators and clinical sites to enroll patients and CROs to manage many of our trials and to perform data collection and analysis. Although we control only certain aspects of these third-parties' activities, we are still responsible for ensuring that every study adheres to its protocol and meets all applicable regulatory and scientific standards. If any of them does not perform its contractual duties or meet expected deadlines or fails to adhere to applicable cGCPs, or if the quality or accuracy of the data it produces is otherwise compromised, the affected clinical trial or trials may be extended, delayed or terminated and we may be unable to obtain approval for our product candidates. Similarly, failure of our manufacturers to perform their contractual duties or comply with cGMP may require us to repeat clinical trials, which would delay regulatory approval.
If our agreements with any of these third parties terminate, we may not be able to enter into alternative arrangements in a timely manner or on reasonable terms.
We may be unable to obtain and maintain regulatory approvals for our product candidates. Failure can occur at any stage of drug development.

We cannot promote any product before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, which we may not receive. Obtaining regulatory approval of a drug is uncertain, lengthy and expensive. Failure can occur at any stage. In order to receive approval from the FDA, we must demonstrate that the new drug is safe and effective for its intended use and that our manufacturing processes comply with cGMPs, which govern production processes, quality control and recordkeeping. Our inability or the inability of our suppliers to comply with applicable FDA and other regulatory requirements can result in delays in or denials of new product approvals, warning letters, fines, consent decrees restricting or suspending manufacturing operations, injunctions, civil penalties, recall or seizure of products, total or partial suspension of product sales and criminal prosecution. Any of these or other regulatory actions could materially harm our business and our financial condition.
Future governmental action or changes in FDA policy or personnel may also result in delays or rejection of an NDA or supplemental NDA. We expect that the label for mifepristone for any indication will include, as Korlym's does, some limitations on its use, including a so-called "black-box" warning that it should not be used by pregnant women or women seeking to become pregnant.

If we receive regulatory approval for our future product candidates, we will be subject to ongoing FDA obligations and continued regulatory oversight and review, such as continued safety reporting requirements; and we may also be subject to additional FDA post-marketing restrictions and obligations. If we are not able to maintain regulatory compliance, we may not be permitted to develop our product candidates or market our products and may be subject to product recalls or seizures. Any regulatory approvals that we may receive for our product candidates may limit the indicated uses for which the medicine may be marketed or require costly post-marketing studies.
Obtaining regulatory approval of our product candidates in foreign jurisdictions would be costly and difficult. Failure to obtain such approvals would prevent us from commercializing our product candidates outside the United States.
We may seek to commercialize our products in international markets, which would require us to receive a marketing authorization and, in many cases, pricing approval, from the appropriate regulatory authorities, whose approval processes include all of the risks associated with the FDA's approval process and, in some cases, additional risks. The approval procedure varies between countries and can involve conducting additional pre-clinical or clinical studies. The time required to obtain approval may differ from that required to obtain FDA approval. Although approval by the

FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by others, failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our product candidates in any foreign market.

We face competition from companies with financial, technical and marketing resources substantially greater than our own.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our present and potential competitors include major pharmaceutical companies, specialized pharmaceutical firms, universities and public and private research institutions. These competitors may develop and commercialize medications that are superior to and less expensive than ours. We expect competition to intensify as technical advances are made.

Many of our competitors and potential competitors have greater experience, more financial and marketing resources and larger research and development staffs than we do. In addition, many of them, either alone or together with their collaborative partners, have significantly greater experience than we do in drug development, obtaining regulatory approvals, manufacturing and commercializing products. They may develop drugs that are superior to our product candidates, which could render our product candidates obsolete or uncompetitive.

Our efforts to discover, develop and commercialize product candidates beyond Korlym for the treatment of patients with Cushing's syndrome may not succeed.

To develop additional sources of revenue, we must develop new product candidates or new therapeutic uses for Korlym. Our selective cortisol modulators, including relacorilant, may not be effective to treat any disorder. We could discover that cortisol modulators have unacceptable side effects or are otherwise not safe. Due to the potential for lack of efficacy and side effects inherent in novel compounds and in new uses for existing medications, we are developing multiple compounds, which will increase our spending, with no assurance of developing drugs that are safe, effective or commercially viable.

We will need to increase the size of our organization and we may experience difficulties in managing growth.

Our commercial and research and development efforts are constrained by our limited administrative, operational and management resources. To date, we have relied on a small management team. Growth will impose significant added responsibilities on members of management, including the need to recruit and retain additional employees. Our future financial performance and our ability to compete effectively will depend on our ability to manage growth effectively. To that end, we must:

- manage our sales and marketing efforts, clinical trials, research and development activities and supply chain effectively;
- hire additional management, clinical development, administrative and sales and marketing personnel; and
- develop our administrative, accounting and management information systems and controls.

Our failure to accomplish any of these tasks could harm our business.

If we lose our key personnel or are unable to attract and retain additional skilled personnel, we may be unable to pursue our product development and commercialization efforts.

Our ability to operate successfully and manage growth depends significantly upon retaining key managerial, scientific, sales, marketing, and financial personnel. We face intense competition for qualified personnel. We depend substantially on the principal members of our management and scientific staff. We do not have agreements with any of our executive officers that provide for their continued employment with us or employment insurance covering any of our key personnel. Any officer or employee can terminate his or her relationship with us at any time and work for one of our competitors. The loss of key individuals could delay our research, development and commercialization efforts.

Risks Related to Our Capital Needs and Financial Results

We may need additional capital to fund our operating plans, including our clinical development programs, or for strategic reasons. Such capital may not be available on acceptable terms or at all.

We are dependent on revenue from the sale of Korlym to fund our development programs. If our Korlym revenues decline, we may need to raise funds to support our operating plans, including our research and development activities. We may choose to raise funds for strategic reasons. We cannot be certain that additional funding will be available on acceptable terms or at all. Equity financing would cause dilution. Debt financing, if available, may involve restrictive covenants. If we obtain funds through collaborations with other companies, those arrangements may be on

unfavorable terms or may require us to relinquish certain rights to Korlym or our product candidates. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or we may be required to discontinue operations.

If we acquire other potential products, we will incur a variety of costs and may never realize the anticipated benefits of the acquisition.

If appropriate opportunities arise, we may attempt to acquire products or product candidates that complement our operating plan. Acquiring rights to another potential product or technology may result in unforeseen difficulties and expenditures and may absorb significant management attention that would be spent developing our existing business. We may fail to realize the anticipated benefits of any acquisition, which could dilute our stockholders' ownership interest or cause us to incur debt, expose us to future liabilities and result in amortization or other expenses related to goodwill and other intangible assets.

Risks Relating to Our Intellectual Property

To succeed, we must secure and maintain adequate patent protection for the composition and methods of use of our proprietary, selective cortisol modulators and for the use of Korlym to treat Cushing's syndrome and other disorders. Patents in the pharmaceutical industry are highly uncertain, involve complex legal and factual questions and are the subject of very costly litigation. If we do not adequately protect our intellectual property, competitors may erode our competitive advantage. Our patent applications and patents licensed or issued to us may be challenged by third parties in court and in administrative proceedings. Responding to such challenges is costly, time-consuming and the outcomes are uncertain.

We are currently defending patents covering the use of Korlym in two separate proceedings. In March 2018, in response to the Teva ANDA submission, we filed suit in the U.S. District Court for the District of New Jersey against Teva for infringement of patents covering the use of Korlym. Prosecuting this lawsuit is costly and requires a great deal of management's time. Its outcome is uncertain. Please see "Part I, Item 3, Legal Proceedings." In August 2018, Neptune Generics, LLC ("Neptune") submitted a petition for IPR before the PTAB of U.S. Patent No. 8,921,348 (the "348 patent"). On February 15, 2019, the PTAB granted institution to the IPR, and an oral argument hearing date has been set for November 14, 2019. If we do not prevail in the IPR trial proceedings, the PTAB could invalidate the '348 patent or one or more of its claims. PTAB final judgments are appealable to the Court of Appeals of the Federal Circuit for review. The outcome of such an appeal would be uncertain.

Our patent applications may not result in issued patents. Any patent issued to us may be challenged, invalidated, held unenforceable or circumvented. Our patent claims may not prevent third parties from producing competing products. The foreign countries in which we may someday operate may not protect our intellectual property to the extent of the laws of the United States. If we fail to obtain adequate patent protection in other countries, our competitors may produce competing products in those countries based on our technology.

Third parties may allege that our patents infringe their rights. Defending against such allegations may result in costly litigation and may require us to obtain a license or bar us from commercializing our product candidates or Korlym for a new indication.

Our commercialization of Korlym and the development and potential commercialization of our selective cortisol modulators may give rise to claims that our patents or the patents we have licensed infringe the rights of others, which may require us to engage in costly, time-consuming and possibly unsuccessful litigation. If it is determined that Korlym or one or more of our product candidates infringe others' patent rights, we may be required to obtain licenses to those rights. If we fail to obtain such licenses, we may have to delay or suspend commercial activity while we attempt to design around the infringed patent. If our efforts fail, we may be unable to commercialize the infringing product or product candidate. We do not have liability insurance for patent infringement.

We do not believe that we infringe any patents or other proprietary rights. We are not obligated to pay royalties relating to the use of intellectual property except to the University of Chicago. To maintain our licenses, we must make milestone and royalty payments. If we do not comply with our payment and other obligations, we may lose the right to commercialize cortisol modulators, including mifepristone, for the treatment of TNBC and CRPC.

Our ability to compete could be diminished if we are unable to protect our trade secrets and proprietary information. In addition to patents, we rely on a combination of confidentiality, nondisclosure and other contractual provisions, laws protecting trade secrets and security measures to protect our proprietary information. These measures may not provide adequate protection, in which case competitors could exploit our proprietary information to our disadvantage. If employees, consultants or anyone else breaches their agreements with us regarding our proprietary information, we may not have adequate remedies for the breach.

The mifepristone patents we own or license cover the use of mifepristone, not its composition, which may make it harder to prevent patent infringement.

We own or have exclusively licensed issued U.S. patents covering the use of cortisol modulators to treat a variety of disorders. A method of use patent covers only a particular use of a compound, not its composition. Because our patents do not cover the composition of mifepristone, we cannot prevent others from commercializing mifepristone to treat disorders not covered by our method of use patents. The availability of mifepristone for these disorders may enable patients to obtain mifepristone from other companies for indications covered by our patents. Although such "off-label" use would violate our patents, effectively monitoring compliance and enforcing our rights may be difficult and costly. Mifepristone is sold in the United States by Danco Laboratories for the termination of pregnancy. Although distribution is limited to a single dose provided in the physician's office and covered by other restrictions, we cannot be certain that patients with Cushing's syndrome will not be able to obtain mifepristone from this or other sources, should another company receive approval to market mifepristone for another indication.

Risks Related to Our Stock

The price of our common stock fluctuates widely and is likely to continue to do so. Opportunities for the sale of shares at any particular time may be limited.

We cannot assure you that an active trading market for our common stock will exist at any particular time. As a result, holders of our common stock may not be able to sell shares quickly or at the current market price. During the 52-week period ended February 20, 2019, our average daily trading volume was approximately 1,441,412 shares and the intra-day sales prices per share of our common stock on The Nasdaq Capital Market ranged from $9.14 to $20.00. As of February 20, 2019, our officers, directors and principal stockholders beneficially owned approximately 16 percent of our common stock.

Our stock price, like the stock price of many biotechnology companies, sometimes experiences extreme price and volume fluctuations that are unrelated or disproportionate to our operating performance or prospects. Securities class action lawsuits are often instituted against companies following periods of stock market volatility. Such litigation is costly and diverts management's attention from productive efforts.

The price of our common stock can fluctuate rapidly and widely in response to a variety of factors, including:

- actual or anticipated variations in our operating results or changes to any public guidance we have provided;
- actual or anticipated timing and results of our clinical trials;
- changes in the expected or actual timing of our competitors' potential development programs, including the announcement of ANDA filings seeking approval to market generic versions of Korlym and developments in ANDA litigation;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- changes in estimates or recommendations by securities analysts or the failure of our performance to meet the published expectations of those analysts or any public guidance we have provided;
- actual or anticipated regulatory approvals of our product candidates or of competing products;
- purchases or sales of our common stock by our officers, directors or stockholders;
- purchases of our common stock pursuant to our Stock Repurchase Program or changes to that program;
- changes in laws or regulations applicable to our product candidates or our competitors' products;

- announcements of technological innovations by us, our collaborators or our competitors;
- trading volume of our common stock;
- conditions or trends in the biotechnology and pharmaceutical industries, including the market valuations of companies similar to Corcept;
- general market and economic conditions;
- additions or departures of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments; and
- our cash and short-term investment position;
- additional financing activities.

Our stock price may decline if our financial performance does not meet the guidance that we provided to the public, estimates published by research analysts or other investor expectations.

The guidance we provide as to our expected 2019 revenue is only an estimate of what we believe is realizable at the time we give such guidance. Our actual results may vary materially. It is difficult to predict the amount of Korlym that we will sell. For example, the rate of physician adoption of Korlym and the actions of government and private payors is uncertain. We may not meet our financial guidance or other investor expectations for other reasons, including those arising from the risks and uncertainties described in this report and in our other public filings and public statements. Research analysts have published revenue estimates based on their own analyses. The guidance we provide may be one factor they consider when determining their estimates.

Our acquisition of Corcept shares through our Stock Repurchase Program will reduce our cash reserves and could fail to improve our business and results of operations.

In August 2018, our Board of Directors authorized the repurchase of up to $100 million of our common stock pursuant to the Stock Repurchase Program. Unless it is terminated or suspended prior to its expiration, the Stock Repurchase Program will remain in effect until June 30, 2019. The Stock Repurchase Program does not require us to acquire any specific number of shares and it may be modified, suspended or discontinued at any time without notice. Any change to the Stock Repurchase Program could cause our stock price to decline. If we repurchase shares of our common stock, it is because we believe our shares are trading at an attractive price relative to other uses of our capital. It is possible, however, that other uses of our capital would have been more advantageous or that our future capital requirements increase unexpectedly. Our repurchases of common stock could fail to improve our results of operations or hamper our ability to execute our plans, meet financial obligations, access financing or raise additional capital, which could harm our business and results of operations.

Research analysts may not continue to provide or initiate coverage of our common stock or may issue negative reports.

The market for our common stock may be affected by the reports financial analysts publish about us. If one of the analysts covering us downgrades or discontinues coverage of our stock, its price could decline rapidly and significantly. Paucity of research coverage may adversely affect our stock price.

Sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

Sales of a substantial number of shares of our stock in the public market could reduce its price. As additional shares of our stock become available for resale in the public market, whether by the exercise of stock options by employees or directors or because of an equity financing by us, the supply of our stock will increase, which could cause its price to fall. Substantially all of the shares of our stock are eligible for sale, subject to applicable volume and other resale restrictions under securities law.

Our officers, directors and principal stockholders, acting as a group, could significantly influence corporate actions.

As of February 21, 2019, our officers and directors beneficially owned approximately 16 percent of our common stock. Acting together, these stockholders could significantly influence any matter requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combinations. The interests of this group may not always coincide with our interests or the interests of other stockholders and may

prevent or delay a change in control. This significant concentration of share ownership may adversely affect the trading price of our common stock because many investors perceive disadvantages to owning stock in companies with controlling stockholders.

Changes in laws and regulations may significantly increase our costs, which could harm our financial results.

New laws and regulations, as well as changes to existing laws and regulations, including statutes and regulations concerning the development, approval, and marketing of medications, the provisions of the PPACA requiring the reporting of aggregate spending related to health care professionals, the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted by the SEC and

by The Nasdaq Capital Market have and will likely continue to increase our cost of doing business. Complying with these regulations may increase our expenses and divert management's time and attention from revenue-generating activities.

We may fail to comply with our public company obligations, including securities laws and regulations. Such compliance is costly and requires significant management attention.

The federal securities laws and regulations, including the corporate governance and other requirements of the Sarbanes-Oxley Act of 2002, impose complex and continually changing regulatory requirements on our operations and reporting. Section 404 of the Sarbanes-Oxley Act of 2002 requires that we evaluate the effectiveness of, and provide a management report with respect to, our internal controls over financial reporting. It also requires that the independent registered public accounting firm auditing our consolidated financial statements must attest to and report on the effectiveness of our internal controls over financial reporting. These requirements have increased and will continue to increase our compliance costs. Furthermore, if we are unable to complete the required assessment and report as to the adequacy of our internal control over financial reporting or if our independent registered public accounting firm is unable to issue an unqualified opinion as to the effectiveness of our internal control over financial reporting, investors could lose confidence in our financial reporting.

Anti-takeover provisions in our charter and bylaws and under Delaware law may make an acquisition of us or a change in our management more expensive or difficult, even if an acquisition or a management change would be beneficial to our stockholders.

Provisions in our charter and bylaws may delay or prevent an acquisition of us or a change in our management. Some of these provisions allow us to issue preferred stock without any vote or further action by the stockholders, require advance notification of stockholder proposals and nominations of candidates for election as directors and prohibit stockholders from acting by written consent. In addition, a supermajority vote of stockholders is required to amend our bylaws. Our bylaws provide that special meetings of the stockholders may be called only by our Chairman, President or the Board of Directors and that the authorized number of directors may be changed only by resolution of the Board of Directors. These provisions may prevent or delay a change in our Board of Directors or our management, which our Board of Directors appoints. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law. Section 203 may prohibit large stockholders, in particular those owning 15 percent or more of our outstanding voting stock, from merging or combining with us. These provisions in our charter and bylaws and under Delaware law could reduce the price that investors would be willing to pay for shares of our common stock and result in our stock price being lower than it would otherwise be.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We lease 28,309 square feet of office space in Menlo Park, California for our corporate facilities. Our current lease expires in March 2020.

ITEM 3. LEGAL PROCEEDINGS

We are involved from time to time in various legal proceedings arising in the ordinary course of business. Although the outcome of any pending matters, and the amount, if any, of our ultimate liability and any other forms of remedies with respect to these matters, cannot be determined or predicted with certainty, we do not believe that the ultimate outcome of these matters will have a material adverse effect on our business, financial position or results of operations.

Teva ANDA Litigation.

On February 5, 2018, we received a Paragraph IV Notice Letter advising that Teva Pharmaceuticals USA, Inc. ("Teva") submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking authorization to manufacture, use or sell a generic version of Korlym in the United States prior to the expiration of certain of our patents related to Korlym, U.S. Patent No. 8,921,348 (the "'348 patent") and U.S. Patent No. 9,829,495 (the "'495 patent"), which are listed in the

FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (referred to as the “Orange Book”). Teva’s February 5, 2018 Notice Letter alleges that the ’348 patent, with an expiration date in August 2028, and the ’495 patent with an expiration date in August 2036, will not be infringed by Teva’s proposed product, are invalid and/or are unenforceable. On March 15, 2018, we filed a lawsuit in the U.S. District Court for the District of New Jersey against Teva for infringement of these patents. On October 12, 2018, Teva received tentative approval from the FDA for its ANDA. In accordance with the Hatch-Waxman Act, however, as a result of having filed

a timely lawsuit against Teva, FDA final approval of Teva's ANDA will be stayed until the earlier of (i) 30 months from our February 5, 2018 receipt of Teva's Paragraph IV Notice Letter or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed.

On July 6, 2018, we filed an Amended Complaint against Teva, asserting infringement of U.S. Patent No. 9,943,526 (the "'526 patent"). On February 8, 2019, we filed a second lawsuit against Teva, asserting infringement of U.S. Patent Nos. 10,166,242 ("the 242 patent"), 10,166,243 ("the 243 patent"), and 10,195,214 ("the 214 patent"). No new 30-month stay results from the filing of the Amended Complaint or new lawsuit. On February 21, 2019 the District Court consolidated the two lawsuits.

We will vigorously enforce our intellectual property rights relating to Korlym, but we cannot predict the outcome of this matter.

Inter Partes Review at the U.S. Patent Trial and Appeal Board

In August 2018, Neptune Generics, LLC submitted a petition for Inter Partes Review ("IPR") at the U.S. Patent Trial and Appeal Board ("PTAB") of U.S. Patent No. 8,921,348 ('348) which is related to Korlym. Neptune Generics, LLC does not have regulatory approval to sell any drug in the United States. It is backed by the litigation finance firm, Burford Capital Ltd., a U.K.-based company. On February 15, 2019, the PTAB granted institution to the IPR, and an oral argument hearing date has been set for November 14, 2019. We plan to vigorously defend the validity of the '348 patent.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is traded on The Nasdaq Capital Market under the symbol "CORT."

Stockholders of Record and Dividends

As of February 20, 2019, we had 114,723,281 shares of common stock outstanding held by 29 stockholders of record. Because almost all of our common stock is held by brokers, nominees and other institutions on behalf of stockholders, we are unable to estimate the actual number of our stockholders. We have never declared or paid cash dividends. We do not anticipate paying cash dividends in the foreseeable future.

Sale of Unregistered Securities

None.

Repurchases of Securities

The following table contains information relating to the repurchases of our common stock made by us in the year ended December 31, 2018 (in thousands, except per share data):

Fiscal Period	Total Number of Shares Purchased As Part of a Publicly Announced Program[1]	Average Price Paid Per Share	Approximate Dollar Amount of Shares That May Yet be Purchased Under the Program[2]
July 1, 2018 to July 31, 2018	—	$ —	$ —
August 1, 2018 to August 31, 2018	441	12.67	94,420
September 1, 2018 to September 30, 2018	233	14.25	91,096
October 1, 2018 to October 31, 2018	—	—	—
November 1, 2018 to November 30, 2018	522	12.94	84,337
December 1, 2018 to December 31, 2018	611	13.08	76,343
Total	1,807	$ 13.09	$ 76,343

[1] No shares were purchased except as part of our publicly announced program.

[2] On August 9, 2018, our board of directors authorized the repurchase of up to $100 million of our common stock pursuant to our Stock Repurchase Program. Unless terminated or suspended prior, the Stock Repurchase Program will remain in effect until June 30, 2019.

Market Performance Graph

The graph and the accompanying text below is not "soliciting material," is not deemed filed with the SEC and is not to be incorporated by reference in any filings by us under the Securities Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in such filing.

We have elected to use the Nasdaq Biotechnology Index (consisting of a group of 120 companies in the biotechnology sector, including us) for purposes of the performance comparison that appears below, which shows the cumulative stockholder return assuming the investment of $100 and the reinvestment of any dividends and is based on the returns of the component companies weighted according to their market capitalizations.

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The graph shows the cumulative total stockholder return assuming the investment of $100 and the reinvestment of any dividends and is based on the returns of the component companies weighted according to their market capitalizations as of the end of the period for which returns are indicated. We have never paid dividends on our common stock.

The return shown in the graph below for our common stock is not necessarily indicative of future performance. We do not make or endorse any predictions as to future stockholder returns.

Five-Year Cumulative Total Returns of our Common Stock (CORT),
the Nasdaq US Benchmark TR Index (NBI) and
the Nasdaq Biotechnology Index (NQUSBT)

ITEM 6. SELECTED FINANCIAL DATA

SELECTED FINANCIAL DATA
(in thousands, except per share data)

The selected financial data set forth below are derived from our audited consolidated financial statements. The statement of operations data for the years ended December 31, 2018, 2017 and 2016 and the balance sheet data as of December 31, 2018 and 2017 are derived from our audited consolidated financial statements included in this Annual Report. The statement of operations data for the years ended December 31, 2015 and 2014 and the balance sheet data as of December 31, 2016, 2015 and 2014 have been derived from our audited financial statements, which are not included in this Annual Report. Our historical results are not necessarily indicative of our results for any future period. The selected financial data set forth below should be read in conjunction with our financial statements, the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Annual Report.

	Year Ended December 31,				
	2018	2017	2016	2015	2014
	(In thousands, except per share data)				
Statement of Operations Data:					
Product revenue, net	$251,247	$159,201	$81,321	$50,286	$26,551
Operating expenses:					
Cost of sales*	5,215	3,554	2,058	1,361	882
Research and development*	75,247	40,376	23,844	15,419	18,372
Selling, general and administrative*	81,289	62,416	45,240	36,949	34,916
Total operating expenses	161,751	106,346	71,142	53,729	54,170
Income (loss) from operations	89,496	52,855	10,179	(3,443)	(27,619)
Non-operating income (expense), net*	2,657	(49)	(2,039)	(2,965)	(3,764)
Income (loss) before income taxes	92,153	52,806	8,140	(6,408)	(31,383)
Income tax expense (benefit)	16,743	(76,316)	—	—	—
Net income (loss)	$75,410	$129,122	$8,140	$(6,408)	$(31,383)
Net income (loss) per share:					
Basic	$0.65	$1.14	$0.07	$(0.06)	$(0.31)
Diluted	$0.60				