CORCEPT THERAPEUTICS INC
Form 10-K
March 06, 2017

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, 2016

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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 or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer		Accelerated filer
Non-accelerated filer	(Do not check if a smaller reporting company)	Smaller reporting company

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 $427,665,971 as of June 30, 2016 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 28, 2017 there were 112,942,391 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 2016 Annual Meeting of Stockholders are incorporated by reference in Items 10, 11, 12, 13 and 14 of Part III.

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Form 10-K

For the year ended December 31, 2016

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 or elsewhere by management, the words "believe," "anticipate," "intend," "plan," "estimate," "expect," "may," "will," "should, "would," "could," "seek" and similar expressions a forward-looking statements. Such forward-looking statements are based on current expectations. The absence of these words does not mean that a statement is not forward-looking. Forward-looking statements made in this Form 10-K include, but are not limited to, statements about:

- our ability to manufacture, market and sell Korlym® (mifepristone) 300 mg Tablets;
- 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 in the United States;
- 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 compound in our families of selective cortisol modulators;
- our ability to manufacture, market, commercialize and achieve market acceptance for our future product candidates;
- uncertainties associated with obtaining and enforcing patents; and
- estimates regarding our capital requirements.

Forward-looking statements are not guarantees of future performance. They involve risks and uncertainties. Actual events or results may differ materially from those discussed in the forward-looking statements 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" section of this Form 10-K. Forward-looking statements reflect our view only as of the date of this report. Except as required by law, we undertake no obligation to update any forward-looking statement. You should carefully consider the other reports and documents that we file with the Securities and Exchange Commission (SEC).

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

ITEM 1. BUSINESS

Overview

We are a pharmaceutical company engaged in the discovery, development and commercialization of drugs that treat severe metabolic, oncologic and psychiatric disorders by modulating the effects of cortisol. Elevated levels and abnormal release patterns of cortisol are implicated in a broad range of human disorders. Since our inception in 1998, we have been developing mifepristone, a compound that modulates the effects of cortisol by acting as a competitive antagonist at the glucocorticoid receptor (GR). We have also discovered 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 and so do not cause effects associated with progesterone receptor affinity. Development of the lead compounds from these series is in progress.

In 2012, the United States Food and Drug Administration (FDA) approved Korlym® (mifepristone) 300 mg Tablets as a once-daily oral medication for the treatment of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery.

We are conducting two clinical trials of our proprietary selective cortisol modulator, CORT125134. One trial is investigating CORT125134 as a potential treatment for patients with Cushing syndrome. The second trial is investigating the combination of CORT125134 and nab-paclitaxel (Celgene Corporation's Abraxane®) to treat patients with solid-tumor cancers. These trials are enrolling patients.

We plan to begin clinical trials of two other selective cortisol modulators in 2017.

The Role of Cortisol in Disease

Cortisol is a steroid hormone that plays a significant role in the way the body reacts to stressful conditions. It influences metabolism and the immune system and contributes to emotional stability. It is essential for survival. Insufficient cortisol activity may lead to dehydration, hypotension, shock, fatigue, low resistance to infection, trauma, stress and hypoglycemia. Excessive cortisol activity 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 may reduce a patient's immune response to oncogenesis and shield certain cancer cells from the apoptotic effects of chemotherapy.

The challenge in regulating excessive levels of cortisol is that destroying the ability of the body to make cortisol can cause serious harm. An effective medication must modulate cortisol's effects without suppressing them below normal levels or disrupting the body's normal cortisol rhythm, in which cortisol levels rise at awakening and decrease during the day. The action of cortisol can effectively be modulated by the use of compounds that compete with cortisol as it attempts to bind to GR. Mifepristone, the active ingredient in Korlym, is a competitive GR antagonist, as are Corcept's 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 necessary, normal functions and rhythms. However, mifepristone also binds to the progesterone receptor and thereby terminates pregnancy and sometimes causes other side effects, including irregular vaginal bleeding. Our selective cortisol modulators block GR as potently as mifepristone does, but have no affinity for the progesterone receptor and so do not cause progesterone receptor-related side effects.

Cushing Syndrome

Background. Cushing syndrome is caused by prolonged exposure of the body's tissues to high levels of cortisol. It is relatively uncommon and most often affects adults aged 20 to 50. 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 an estimated total of 20,000 patients with Cushing syndrome in the United States.

Symptoms vary, but most people with Cushing syndrome have one or more of the following manifestations: 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 syndrome can affect every organ system in the body and can be lethal if not treated. The preferred treatment for Cushing syndrome patients 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 Syndrome. We have received Orphan Drug designation from the FDA for Korlym in the treatment of patients with endogenous Cushing syndrome. Drugs that receive Orphan Drug

designation receive seven years of marketing exclusivity for the approved indication, as well as tax credits for clinical trial costs, marketing application filing fee waivers and assistance from the FDA in the drug development process.

We first made Korlym available to patients on a commercial basis in April 2012. We sell Korlym using experienced sales representatives, who target U.S. endocrinologists who care for a large portion of the patients with Cushing syndrome. In addition, we have a field-based force of medical science liaisons. We also reach patients directly through web-based initiatives and interactions with patient groups. Because a large percentage of the people who suffer from Cushing syndrome remain undiagnosed or are inadequately treated, we have developed and continue to refine and expand programs to educate the medical community and patients about diagnosis of this syndrome and to increase awareness regarding the role of cortisol modulators to treat the disease.

We use a specialty pharmacy and a specialty distributor to distribute Korlym and provide logistical support. We have retained a vendor to help patients with the reimbursement process and to administer our financial assistance programs for uninsured or under-insured patients. We also donate money to independent charitable foundations. These organizations, along with our own programs, help us ensure that no Cushing syndrome patient is denied access to Korlym for financial reasons.

CORT125134 to Treat Patients with Cushing Syndrome. We are enrolling patients in a Phase 2 trial of our proprietary, selective cortisol modulator, CORT125134, to treat patients with Cushing syndrome. CORT125134 shares Korlym's affinity for GR. Data from the compound's Phase 1 trial showed that it potently modulates the effects of the steroid prednisone, a commonly-used GR agonist. Modulating the effect of prednisone is important because it is a strong surrogate for Korlym's modulation of cortisol – the essential quality of an effective treatment for patients with Cushing syndrome. Pharmacokinetic data indicate that CORT125134 is suitable for once-daily oral dosing. We expect to have data from this trial by the end of 2017.

FKBP5 Gene Expression. We are developing a CLIA-validated assay to measure expression of the gene FKBP5, which is stimulated by cortisol activity at GR. Our hypothesis is that FKBP5 expression increases in patients with Cushing syndrome and falls as their disease is treated. If our hypothesis is correct, our assay would allow physicians to measure the degree to which their patients suffer from excess cortisol activity – the cause of Cushing syndrome – which would help them more easily identify patients with the disease 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-tumor cancers to resist treatment. In some cancers, cortisol activity promotes tumor growth. Cortisol also stimulates genes that retard cellular apoptosis.

Our oncology development program also seeks to exploit a second mechanism. Cortisol suppresses the body's immune response. Suppression of the immune response is often beneficial, as it lessens the frequency of autoimmune diseases. However, activating, not suppressing, the body's immune system is beneficial in fighting certain cancers. Our hypothesis is that adding a cortisol modulator to a treatment regimen will help the patient's immune system combat the disease.

A range of tumor-types express GR and are potential targets for cortisol modulation therapy, among them triple-negative breast, ovarian, castration-resistant prostate, cervical and pancreatic cancer, as well as sarcoma and melanoma.

Korlym to Treat Patients with Solid-Tumor Cancers. In December 2016, we announced the results of our Phase 1/2 trial of Korlym in combination with eribulin (Eisai's Inc.'s drug, Halaven®) to treat patients with metastatic triple-negative breast cancer. 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 that the addition of Korlym to chemotherapy warrants further study, such as the double-blind, placebo-controlled, multicenter, University of Chicago-led trial described above that Celgene is funding.

Korlym to Treat Patients with Triple-Negative Breast Cancer and Castration-Resistant Prostate Cancer. Investigators at the University of Chicago have initiated a double-blind, placebo-controlled, multicenter Phase 2 study of Korlym in combination with Celgene's drug Abraxane to treat 64 patients with advanced, GR-positive triple-negative breast cancer. Celgene is funding the trial. We are providing Korlym. University of Chicago investigators are also leading a controlled, multicenter Phase 2 study of Korlym combined with the androgen deprivation agent enzalutamide (Astellas Pharma Inc.'s drug, Xtandi®) versus Xtandi monotherapy to treat 84 patients with metastatic, castration-resistant prostate cancer. The investigators' hypothesis is that adding cortisol modulation to androgen deprivation therapy will better suppress tumor growth. The Department of Defense and the Prostate Cancer Foundation are funding the trial. Astellas is providing Xtandi. We are providing Korlym.

We have exclusively licensed patents from the University of Chicago covering the use of cortisol modulators in combination with anti-cancer agents to treat triple-negative breast cancer and with androgen deprivation agents to treat castration-resistant prostate cancer.

CORT125134 to Treat Patients with Solid-Tumor Cancers. We are conducting a Phase 1/2 trial of Abraxane (nab-paclitaxel) in combination with CORT125134 to treat any solid-tumor cancer suitable for treatment with Abraxane. Once we identify a recommended dose of this combination, we will open 20-patient cohorts to test the combination's efficacy in one or more solid-tumor cancers. Our likely initial targets will be triple-negative breast cancer and ovarian cancer. Other possible indications include pancreatic cancer, cervical cancer and sarcoma. We may choose to open additional dose-finding cohorts to study CORT125134 in combination with different companion therapeutic agents, including immunotherapy, to treat other solid-tumor cancers.

Development of Our Other Selective Cortisol Modulators

CORT125134 is the lead compound in our portfolio of proprietary selective cortisol modulators, which consists of three structurally distinct series. All of these compounds, like Korlym, potently block GR but do not block the progesterone, estrogen or androgen receptors. In addition to our findings with CORT125134, several of our new compounds have demonstrated positive results in animal or in vitro models that test cortisol modulation. We are advancing the most promising of these compounds towards the clinic and expect to begin clinical trials of CORT118335 and CORT125281 in 2017. CORT118335 is a potential medication for fatty-liver disease, anti-psychotic-induced weight gain and other metabolic disorders. CORT125281 is a candidate for the treatment of castration-resistant prostate cancer (in combination with an androgen-deprivation agent such as Xtandi) and other indications.

The United States Patent & Trademark Office (USPTO) and the European Patent Office (EPO) have issued to us composition of matter patents related to our selective cortisol modulators. In addition, we own or have exclusively licensed patents for the use of all cortisol modulators (including Korlym) in a broad range of disorders. See "Business – Intellectual Property."

We intend to continue our discovery research program with the goal of identifying new selective cortisol modulators, to manufacture and conduct pre-clinical development of one or more of these compounds and to study the most promising of them in humans.

Studies by Independent Investigators

We have, for many years, sought to advance our understanding of cortisol modulation’s therapeutic potential by supporting the work of independent academic investigators. These researchers have studied the utility of our proprietary selective cortisol modulators in pre-clinical studies in a wide range of disorders, including post-traumatic

stress disorder, alcoholism, Alzheimer's disease, ALS, muscular dystrophy, Cushing syndrome, metabolic syndrome, fatty liver disease, ovarian cancer, castration-resistant prostate cancer and triple-negative breast cancer.

Clinical Trial Agreements

Some of our clinical trials are conducted through the use of clinical research organizations (CROs). Our Phase 2 trial of CORT125134 for the treatment of patients with Cushing syndrome is being conducted under an agreement with Chiltern International Limited (Chiltern). This agreement may be terminated by us upon 60-days written notice to Chiltern or sooner if the parties mutually agree.

Research and Development Spending

We incurred $23.8 million, $15.4 million and $18.4 million of research and development expenses in the years ended December 31, 2016, 2015 and 2014, which accounted for 33%, 29% 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. We have 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, pursuant to which we agree to purchase a minimum percentage of our mifepristone requirements. The initial term of the agreement is five years, with an automatic extension of one year, unless either party gives 12-months prior written termination notice. We have the right to terminate the agreement if PCAS is unable to manufacture mifepristone for nine consecutive months.

We have one tablet manufacturer for Korlym – Alcami Corporation (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. We have no minimum purchase obligations under this agreement.

Competition for Korlym

Korlym competes with established treatments, including surgery, radiation and other medications, 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 disease who are not candidates for pituitary surgery or for whom surgery did not work. (Cushing disease is a subset of Cushing syndrome that afflicts approximately 70 percent of patients with Cushing syndrome.)

Korlym may also experience competition from compounds under development for Cushing syndrome. For example, Strongbridge Biopharma plc has received Orphan Drug designation in the United States and the EU for the use of levoketoconazole, a chiral form of ketoconazole, to treat Cushing syndrome and has begun a Phase 3 clinical trial in Europe and the United States for this indication.

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, continuing technological innovations and licensing opportunities

to develop and maintain our competitive position.

Mifepristone. The composition of matter patent covering mifepristone has expired. The only other FDA-approved use of mifepristone is to terminate pregnancy. The FDA has imposed significant restrictions on the use of mifepristone to terminate pregnancy. To protect our market for Korlym we plan to rely on (1) the exclusive marketing rights conferred as a benefit of Orphan Drug designation in the United States, (2) the restrictions imposed by the FDA on the use of mifepristone to terminate pregnancy, (3) the different patient populations, administering physicians and treatment settings between the use of mifepristone to terminate pregnancy and to treat Cushing syndrome and (4) our method of use patents described below.

Oncology. We have an exclusive license agreement with the University of Chicago to patents covering the use of all cortisol modulators, including mifepristone, in the treatment of triple-negative breast cancer (in combination with anti-cancer agents) and castration-resistant prostate cancer (in combination with androgen deprivation agents). See "Business – License Agreements."

Other Method of Use Patents. We own issued U.S. patents for the use of cortisol modulators in the treatment of 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 also own a method of use patent for optimizing mifepristone levels in plasma serum in patients suffering from mental disorders, including the mental disorders seen in Cushing syndrome. The expiration dates of these patents and their foreign counterparts range from 2020 to 2034.

In addition, we have six U.S. method-of-use applications covering certain cortisol modulators, including the treatment of patients suffering from mental disorders by optimizing mifepristone absorption, and the treatment of patients suffering from muscular dystrophy and from ALS.

We estimate that the expiration dates of the patents that could issue from these applications and their foreign counterparts range from 2029 to 2036.

Composition of Matter Patents Covering Our Proprietary, Selective Cortisol Modulators. We have eight 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, with an additional U.S. application pending. The expiration dates of these patents and their foreign counterparts range from 2026 to 2033.

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 currently 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-party other than Stanford University and the University of Chicago.

License Agreements

We have exclusively licensed three issued U.S. patents from Stanford University for the use of cortisol modulators, including mifepristone, in the treatment of psychotic depression, cocaine-induced psychosis and early dementia, including early Alzheimer's disease. We are required to make milestone payments and pay royalties to Stanford University on sales of products commercialized under these patents. Milestone payments are creditable against future royalties. Our license will end upon expiration of the related patents in 2018 and 2019 or upon notification by us to

Stanford.

We have also exclusively licensed from the University of Chicago two issued U.S. patents for the use of cortisol modulators in the treatment of triple-negative breast cancer, and a second patent family consisting of an

issued U.S. patent and applications in Europe having claims directed to 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 related patents in 2031 and 2033 or upon notification by us to the University of Chicago.

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. Clinical trials are conducted with a small number of subjects to determine the early safety profile and pharmacokinetics of the product candidate in human volunteers, and to provide early information about drug effectiveness and/or activity.
- Phase 2. Clinical trials are conducted with groups of patients afflicted with the targeted disease to determine preliminary efficacy, optimal dosages and expanded evidence of safety.
- Phase 3. Large-scale, multi-center, trials are conducted with patients afflicted with a target disease to establish the overall risk/benefit ratio of the drug and to demonstrate with substantial evidence the efficacy and safety of the product.

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 the 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 studies 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") for approval to begin commercial sales. 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, request additional information or deny the application if it determines that the application does not meet the criteria for approval. 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, the subject drug becomes available for physicians to prescribe in the United States. The FDA may withdraw the product 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 and could result in the imposition of marketing restrictions through labeling changes or removal

of the product from the market. Product approvals may be withdrawn if problems with safety or efficacy occur. 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 these post-approval 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, such as suspension of manufacturing, or the seizure or recall of a product.

The FDA imposes complex regulations on entities 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.

Orphan Drug Designation

We have received Orphan Drug designation for Korlym for the treatment of endogenous Cushing syndrome in the United States. Orphan designation qualifies the sponsor of the product for the tax credit and marketing incentives of the Orphan Drug Act, including seven years of exclusive marketing rights for the specific drug for the 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 does not prevent competitors from developing or marketing different drugs for an indication. It also does not convey an advantage in, or shorten the duration of, the review and approval process for a drug.

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 in foreign target markets 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.

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 $150,000 per year (or up to an aggregate of $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.

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 a core group of experienced pharmaceutical executives. We also enlist the expertise of associates and advisors with extensive pharmaceutical development experience.

As of December 31, 2016, we had 103 employees. Six of our employees have M.D.s. We consider our employee relations to be good. None of our employees are 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®, Korlym® and CORLUX®. Corluxin® is a registered trademark in the EU; the application for this trademark is pending in the United States. 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, financial statements and other matters. The reports, proxy statements and other information we file may be inspected and copied at prescribed rates at the SEC's Public Reference Room, 100 F Street, N.E., Washington, D.C. 20549, on official business days during the hours of 10:00 A.M. to 3:00 P.M (EST). You may obtain information on the operation of the SEC's Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site that contains reports, proxy statements and other information regarding issuers like us that file electronically with the SEC. The address of the SEC's Internet site is www.sec.gov. For more information about us, please visit our website at www.corcept.com. You may also obtain a free copy of our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports on the day the reports or amendments are filed with or furnished to the SEC by visiting our website at www.corcept.com. The information found on, or otherwise accessible through, our website, is not incorporated information, and does not form a part of, this Form 10-K.

ITEM 1A. RISK FACTORS

An investment in our common stock involves significant risks. You should carefully consider the risks described below and the other information in this Annual Report on Form 10-K, including our financial statements and related notes, before investing in our common stock. 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 decline and you could lose all or part of your investment. The risks and uncertainties described below are those that we currently believe may materially affect us; however, they may not be the only ones that we face. Additional risks and uncertainties of which we are unaware or currently deem immaterial may become important and may result in harm to our business.

Risks Related to the Commercialization of Korlym

We depend heavily on the success of Korlym®. If we are unable to increase revenue from the sale of Korlym to the levels investors expect, or experience significant delays in doing so, our stock price will likely decline.

We anticipate that for the foreseeable future our ability to generate meaningful revenue and fund our commercial operations and development programs will be solely dependent on the successful commercialization of Korlym. Many factors could hamper our efforts to commercialize Korlym, including:

- an inability to generate sufficient revenue due to low product usage or inadequate insurance coverage and reimbursement;
- competition from Novartis's Signifor and from other companies with greater financial and marketing resources than ours;
- an inability to manufacture Korlym or the active ingredient in Korlym in commercial quantities and at an acceptable cost;
- political concerns relating to other uses of mifepristone that could limit the market acceptance of Korlym;
- previously unknown, serious side effects that may be identified; and
- rapid technological change that makes Korlym obsolete.

Failure to meet investors' revenue expectations could cause our stock price to decline.

Physicians may accept Korlym slowly or may never accept it, which would adversely affect our financial results.

Physicians will prescribe Korlym only if they determine that it is preferable to other treatments, even if those products are not approved for Cushing syndrome. Because Cushing syndrome is rare, most physicians are inexperienced in the care of patients with the illness and it may be difficult to persuade them to prescribe Korlym, even with clinical trial results that show it is a compelling treatment.

Other factors that may affect the commercial success of Korlym include:

- the preference of some physicians for more familiar, long-standing off-label treatments for Cushing syndrome or for Novartis' drug, Signifor, for the treatment of Cushing disease;
- competition from alternative treatment methods, such as surgery and radiation therapy;
- the cost-effectiveness of Korlym and the availability of third-party insurance coverage and reimbursement;
- the product labeling required by the FDA for Korlym; and
- negative publicity concerning Korlym, RU-486, Mifeprex® or mifepristone.

The failure of Korlym to achieve commercial success would prevent us from generating sufficient revenue to fully fund our commercial and development activities.

The Orphan Drug designation for Korlym may not prevent competition from companies that develop other compounds for the treatment of Cushing syndrome. These companies may have significantly more resources than we do. Competition from them could limit our revenue from the commercialization of Korlym for the treatment of Cushing syndrome or other indications.

Although we have received Orphan Drug designation in the United States, we cannot be assured that we will realize the potential benefits of the designation. Even after an orphan drug is approved for its orphan indication, the FDA can subsequently approve a different drug for the same condition if it concludes that the later drug is safer, more effective or makes a major contribution to patient care. Upon expiration of the orphan drug exclusivity period, we may be subject to competition from manufacturers offering a generic form of Korlym at a lower price, in which case our business could be harmed.

In 2012 Novartis received approval in both the United States and the European Union (EU) to market its somatostatin analogue Signifor for adult patients with Cushing disease (a subset of Cushing syndrome that accounts for approximately 70 percent of all patients with Cushing syndrome) for whom pituitary surgery is not an option or has not been curative. In addition, Novartis has received Orphan Drug designation in the United States for the use of the experimental compound osilodrostat to treat Cushing disease and in the EU to treat Cushing syndrome. Novartis has begun a Phase 2 clinical trial in Japan investigating the use of this compound to treat Cushing syndrome due to causes other than Cushing disease and a Phase 3 clinical trial in the EU investigating its use to treat Cushing disease. Novartis has substantially more resources and experience than we do and may provide significant competition.

Laboratoire HRA Pharma (HRA) received Orphan Drug designation in the United States and the EU for the use of mifepristone to treat a subtype of Cushing syndrome. HRA began and terminated a Phase 2 clinical trial in Europe and the United States for this indication. Strongbridge Biopharma plc (Strongbridge) has received Orphan Drug designation in the United States and the EU for the use of levoketoconazole to treat Cushing syndrome. Strongbridge has begun a Phase 3 clinical trial in Europe and the United States for this indication. Exelgyn Laboratories, which operates as a subsidiary of Medi Challenge (Pty) Ltd., received Orphan Drug designation for mifepristone to treat Cushing syndrome in the EU, but has stated that it has not yet conducted any clinical trials.

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 whether insurance coverage and reimbursement is available. Government payors, including Medicare, Medicaid and the Veterans Administration, as well as commercial health maintenance organizations and other third-party payors, are increasingly attempting to contain healthcare costs by limiting reimbursement of new medicines. As a result, they may not cover or provide adequate payment for Korlym. Our dependence on the commercial success of Korlym makes us particularly susceptible to cost containment efforts. Unless government and other third-party payors continue to provide adequate and timely coverage and reimbursement, physicians may not prescribe it and patients may not purchase it. In addition, meaningful delays in coverage for individual patients may increase our costs and reduce our revenues.

In some foreign markets, pricing and profitability of prescription pharmaceuticals 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 reduce the cost of government insurance programs could significantly influence the purchase of health care services and products and may result in lower prices for Korlym or the exclusion from reimbursement programs.

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, particularly in light of the new presidential administration and U.S. Congress. In addition, Congress could consider subsequent legislation to replace repealed elements of the PPACA. On January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. At this time, the full effect that the PPACA, the Executive Order 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% per fiscal year, which went into effect on April 1, 2013 and will remain in effect through 2025 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law 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.

These new laws and the regulations and policies implementing them, as well as other healthcare reform measures that may be adopted in the future, may have a material adverse effect on our industry generally and on our ability to successfully develop and commercialize our products.

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 ethical and political debate in the United States and elsewhere. Public perception of mifepristone may limit our ability to engage alternative manufacturers and may limit the commercial acceptance of Korlym by patients and physicians. Even though we have taken measures to minimize the likelihood of the prescribing of Korlym to a pregnant woman, physicians may choose not to prescribe Korlym to a woman simply to avoid any risk of unintentionally terminating a pregnancy.

We have no manufacturing or pharmacy capabilities and currently depend on third-party vendors to manufacture Korlym and dispense it to patients. We also depend on other suppliers to manufacture the API and capsules for CORT125134 and the other selective cortisol modulators we are developing. If these third parties are unable or unwilling to continue to manufacture or dispense Korlym for us and we are unable to contract quickly with alternative sources, or if these third-parties fail to comply with FDA or other applicable regulations or otherwise fail to meet our requirements, our business will be harmed.

PCAS, a third-party manufacturer, supplies all of the API in Korlym. Alcami, another third-party manufacturer, produces all of our Korlym tablets. Dohmen Life Science Services, a specialty pharmacy, dispenses Korlym. We have entered into agreements with these vendors that automatically renew. We rely on other third-parties to manufacture the API and capsules of the selective cortisol modulators that we are developing, including CORT125134. If any of these vendors is unable or unwilling to meet our future requirements, we may not be able to manufacture our product in a timely manner. Our current arrangements with these manufacturers are terminable by them, subject to notice provisions.

Our specialty pharmacy is subject to regulation by the FDA and other governmental authorities. We do not control the pharmacy's processes or operations and cannot assure that they will meet all regulatory requirements. In the event it fails to do so, we may be required to identify an alternative pharmacy, which we may not be able to do in a timely manner, which would harm our business.

The facilities used by our vendors to manufacture our product and product candidates must be approved by the FDA. We do not control the manufacturing processes of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements known as current good manufacturing practices (cGMPs). If our contract manufacturers cannot successfully 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 manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our products or if it withdraws any such approval, we may need to find alternative manufacturing facilities, which would significantly hamper our ability to develop, obtain regulatory approval for or market our products. In addition, sanctions could be imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could harm our business. If our suppliers fail to manufacture Korlym or our product candidates on a timely basis in the quantities that we require, or fail to maintain manufacturing capabilities that meet FDA standards, we may exhaust our Korlym inventory and not be able to generate revenue, or our clinical development programs may be delayed.

If we or others identify previously unknown, serious side effects of Korlym, we may be required to perform lengthy clinical trials, change the labeling of Korlym or withdraw it from the market.

The FDA's approval of Korlym requires us to study drug utilization to better characterize the reporting rates of adverse events associated with the long-term use of Korlym. If we or others identify previously unknown, serious side effects of Korlym:

- regulatory authorities may withdraw their approvals;
- we may be required to conduct clinical trials, make changes in labeling, implement changes to or obtain re-approvals of our manufacturing facilities;
- we may experience a significant drop in the sales of Korlym;
- our reputation in the marketplace may suffer; and
- we may become the target of lawsuits, including class action lawsuits.

Any of these events could harm or prevent sales of Korlym or could increase our marketing costs.

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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. A product liability claim may damage our reputation by raising questions about Korlym or any of our product candidates' safety and could limit our ability to sell a product by preventing or interfering with product commercialization. In some cases, less common adverse effects of a pharmaceutical product are not known until long after the FDA approves the product for marketing. The active ingredient in Korlym is used to terminate pregnancy. Therefore, clinicians using the medicine in our clinical trials and physicians prescribing the medicine to women with childbearing potential must take strict precautions to ensure that the medicine is not administered to pregnant women. The 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 prevent or inhibit the commercialization of Korlym or our product candidates, or result in meaningful underinsured or uninsured liability. Defending a lawsuit could be costly and significantly divert management's attention from conducting our business. If we were sued successfully, our liability could exceed our assets.

We are subject to ongoing and continued regulatory review. If we are unable to maintain regulatory approval of Korlym for the treatment of patients with Cushing 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 will be harmed.

The FDA's approval of Korlym was subject to limitations on the indicated uses for which the product may be marketed and requirements for post-marketing information reporting. If we violate any of the FDA's restrictions or other marketing requirements, the FDA could withdraw its approval.

We are subject to ongoing obligations and continued regulatory review by the FDA and other regulatory authorities in the United States and other countries 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 and other post-marketing information and reports, annual updates on manufacturing activities and continued compliance with cGMPs, and current good clinical practices (cGCPs), for any clinical trials that we conduct post-approval. cGMPs and cGCPs are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities through periodic inspections of manufacturing sites, trial sponsors, clinical investigators and clinical sites. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with FDA regulations and other applicable foreign and U.S. regulatory requirements may result in, among other things, untitled letters, warning letters, 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 supplements to approved NDAs, and suspension or revocation of product approvals.

The FDA's policies may change and additional governmental regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. Indeed, we cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump 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, 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. For example, on January 23, 2017, President Trump ordered a hiring freeze for all

executive departments and agencies, including the FDA, which prohibits the FDA from filling employee vacancies or creating new positions. Under the terms of the order, the freeze will remain in effect until implementation of a plan to be recommended by the Director for the Office of Management and Budget, or OMB, in

consultation with the Director of the Office of Personnel Management, to reduce the size of the federal workforce through attrition. An under-staffed FDA could result in delays in FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all.

Moreover, on January 30, 2017, President Trump issued an Executive Order directing all executive agencies, including the FDA, that, for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. Similarly, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may place at risk the FDA marketing approval for Korlym and any other marketing approval that we may obtain, which would adversely affect our business, prospects and ability to sustain profitability.

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 of health care products. Although physicians are permitted, based on their medical judgment, to prescribe drugs for indications other than those approved by the FDA, manufacturers are prohibited from promoting their products for such "off-label" uses. In the United States, we market Korlym for treatment of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery and provide promotional materials and training programs to physicians regarding the use of Korlym for this indication. Although we believe our marketing materials and training programs for physicians 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 request that we modify our training or promotional materials or other activities or subject us to regulatory enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal or state enforcement authorities might take action 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 later determined that we are not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our position and have to divert significant management resources from other matters.

In addition, there are health care fraud and abuse regulations and enforcement by both the federal government and the states in which we conduct our business. Laws that may affect our ability to operate include:

- 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;
- 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 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; 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 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 fully 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 such laws, 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 under one or more of such laws. We are also exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, distributors, and CROs may engage in fraudulent or other illegal activity. While we have policies and procedures in place prohibiting such activity, it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from governmental health care programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

A break-down or breach of our information technology systems 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 third-party vendors, including our intellectual property and confidential information relating to our business and our employees. Despite the implementation of security measures, our internal computer systems and those of our vendors are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, unauthorized access to electronic and other confidential information, and other security breaches or accidents could cause interruptions in our operations, and could result in a material disruption of our clinical and commercialization activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that a disruption or security breach resulted in the theft or loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our product research, development and commercialization efforts could be delayed or otherwise harmed.

The occurrence of a catastrophic disaster or other similar events could cause damage to 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 disasters or other similarly disruptive events, including earthquake, fire, flood, power loss and communications failures. For example, our headquarters are located in the San Francisco Bay Area, which is earthquake-prone, and our specialty pharmacy and warehouses are located in areas that are subject to severe weather conditions. In addition, political considerations relating to mifepristone may put us and our manufacturers at increased risk for terrorist attacks, protests or other disruptive events. If any disaster or other similar event were to occur, we may not be able to operate our business and our manufacturers may not be able to produce Korlym or our product candidates. Our insurance may not be adequate to cover, and our insurance policies may exclude coverage for, our losses resulting from disasters or other business interruptions.

Risks Related to the Development of our Product Candidates

Clinical drug development is lengthy and expensive and has an uncertain outcome. Results of earlier studies and trials may not be predictive of future trial results.

Clinical development is a long, expensive and uncertain process, and data obtained from clinical trials and supportive studies 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 eventually obtained in later clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed

through preclinical studies and initial clinical trials. A number of companies have suffered significant setbacks in advanced clinical trials due to the lack of efficacy or adverse safety profile of their medication candidate, despite promising results in earlier trials. Clinical trials may not demonstrate sufficient safety and efficacy to obtain regulatory approval.

Our ongoing clinical trials are too small to support 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 that are beyond our control, including:

- delays obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with Clinical Research Organizations ("CROs") and clinical trial sites;
- obtaining institutional review board (IRB) approval at each site;
- slower than anticipated patient enrollment;
- lack of funding;
- negative or inconclusive results;
- patient noncompliance with the protocol;
- adverse medical events or side effects among patients during the clinical trials;
- negative or problematic FDA or other regulatory authority inspections of our clinical operations or manufacturing operations; and
- real or perceived lack of effectiveness or safety.

We could encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the clinical trial sites where such trials are being conducted, the data safety monitoring board for such trial, or the FDA or other regulatory authorities. Such authorities may suspend or terminate a trial for many reasons, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations, or lack of adequate funding to continue the clinical trial.

Over the course of clinical development of any product candidate, we may decide, or the FDA or other regulatory authorities may require us, to pursue clinical or preclinical studies in addition to those we had initially planned. These may require additional funding, the availability of which is not assured. Also, additional trials or studies that we decide are necessary or desirable may delay or prevent the completion of our development programs or increase their cost. Even if we are able to conduct all of the clinical trials and supportive studies that we consider appropriate, we may never receive regulatory approval to market our product candidates.

We depend on third-parties to conduct and manage many of our clinical trials and to perform related data collection and analysis. Failure of these third-parties to successfully carry out their contractual duties or meet expected timelines may prevent or delay regulatory approval for the commercialization of our product candidates, which could substantially harm our business.

We rely on clinical investigators and clinical sites to enroll patients and other third-parties such as CROs to manage many of our trials and to perform related data collection and analysis. We control only certain aspects of these third-parties' activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the prescribed protocol and the applicable legal, regulatory and scientific standards. Our reliance on third-parties does not relieve us of our regulatory responsibilities. We and these third-parties are required to comply with cGCPs. If we or any of the third-parties working on or conducting our trials fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approval of our marketing applications. We cannot assure you that upon inspection by a regulatory authority, such regulatory authority will determine that any of our clinical trials complies with cGCP requirements. In addition, our clinical trials must be conducted with drug product produced under cGMP regulations. Our failure to comply with these regulations may

require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, we may not be able to control the timing of identification and selection of appropriate sites for our planned trials and the effectiveness of those sites. If our clinical investigators and clinical sites fail to enroll a sufficient number of patients or fail to enroll them on schedule, we may be unable to complete our trials as planned, which could delay or prevent us from completing the clinical development of our product candidates.

We have agreements with the CROs and consultants helping to conduct our clinical trials and to perform investigator supervision, data collection and analysis for these trials. We may not be able to maintain relationships with these or other CROs and consultants, or with the clinical investigators and clinical sites conducting our trials. If any of our agreements with these third-parties terminate, we may not be able to enter into alternative arrangements on commercially reasonable terms, or at all. If the third-parties on which we rely do not carry out their contractual duties or fail to meet expected deadlines, or if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised, our clinical trials may be extended, delayed or terminated and we may be unable to obtain regulatory approval for, or successfully commercialize, any of our product candidates.

We may be unable to obtain and maintain regulatory approvals for our product candidates.

We are not permitted to market or promote any products before we receive regulatory approval from the FDA or comparable foreign regulatory authorities. Although we have received FDA approval to market Korlym, we may be unable to maintain such approval. We may not receive regulatory approval for any of our product candidates. Obtaining regulatory approval of a new drug is an uncertain, lengthy and expensive process. Success is never guaranteed. Failure can occur at any stage. In order to receive approval from the FDA for a product candidate, we must demonstrate that the new drug product is safe and effective for its intended use and that our manufacturing processes for the product candidate comply with FDA regulations known as “cGMPs.” cGMPs include requirements related to production processes, quality control and assurance, and recordkeeping. Our inability or the inability of our suppliers to comply with applicable FDA and other regulatory requirements can result in, among other things, 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 in the United States. As of January 23, 2017, FDA is prohibited from filling employee vacancies or creating new positions pursuant to an Executive Order issued by President Trump. Under the terms of the order, the freeze will remain in effect until implementation of a plan to be recommended by the Director for the OMB, in consultation with the Director of the Office of Personnel Management, to reduce the size of the federal workforce through attrition. An under-staffed FDA could result in delays in FDA’s responsiveness or in its ability to review submissions or applications, including NDAs, and may also hinder FDA’s ability to issue and implement regulations or guidance in a timely fashion or at all. In addition, because the only other currently FDA-approved use of mifepristone is the termination of pregnancy, we expect that the label for mifepristone for any indication will include, as Korlym’s does, some limitations, 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 market our product candidates and/or may be subject to product recalls or seizures. Any regulatory approvals that we receive for our future product candidates may also be subject to limitations on the indicated uses for which the medicine may be marketed or contain requirements for potentially costly post-marketing follow-up studies.

Failure to obtain regulatory approval in foreign jurisdictions would prevent us from commercializing our product candidates abroad.

We may seek to commercialize our products and product candidates in international markets with the help of one or more partners or on our own. Outside the United States, we may commercialize a product only if we 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 approval process, and, in some cases, additional risks. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. 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 regulatory authorities in other foreign countries or by the FDA, but a 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. Although we have received Orphan Drug designation in the EU of Korlym to treat patients with Cushing syndrome, we are not currently seeking to obtain any foreign approvals.

We face competition from companies with substantial financial, technical and marketing resources.

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, as well as specialized pharmaceutical firms, universities and public and private research institutions. Moreover, we expect competition to intensify as technical advances are made. These competitors, may develop and commercialize medications that are superior to and more cost-effective than ours.

Many of our competitors and related private and public research and academic institutions have greater experience, more financial and marketing resources and larger research and development staffs than we do. In addition, many of these competitors, 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 succeed in developing medicinal products that are superior to our product candidates, which could render our product candidates obsolete or non-competitive.

Our efforts to discover, develop and commercialize product candidates beyond Korlym for the treatment of patients with Cushing syndrome are at an early stage and we may fail to successfully commercialize any of them.

To develop additional sources of revenue, we must identify and develop new product candidates or new therapeutic uses for Korlym. Cortisol modulators may not be effective to treat any additional indications. Moreover, we could discover that the use of cortisol modulators has unacceptable side effects or is 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 entering multiple compounds into development, which will increase our rate of spending with no assurance that we will be successful in developing drugs that are safe and effective.

We may elect to enter into collaboration arrangements with respect to one or more of our product candidates. If we do enter into such an arrangement, we would be dependent on a collaborative partner for the success of the product candidates developed under the arrangement. Any future collaborative partner may fail to successfully develop or commercialize a product candidate under a collaborative arrangement.

We only have significant clinical experience with mifepristone, the active ingredient in Korlym, and we may determine that mifepristone is not desirable for uses other than for the treatment of patients with Cushing syndrome. We may pursue other cortisol modulators for this use. The compounds developed pursuant to our early discovery, preclinical and clinical research programs may fail to become viable product candidates regardless of the resources we dedicate to their development. Even if product candidates are identified, we may abandon further development efforts after expending significant expense and time due to financial constraints, concerns over safety or efficacy, marketing considerations, manufacturing difficulties or other reasons. Moreover, governmental authorities may enact new legislation or regulations that could limit or restrict our development efforts. If we are unable to successfully discover and commercialize new uses for cortisol modulators, we may be unable to generate sufficient revenue to support our operations.

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

We expect that the further development of our research and development efforts will be constrained by our existing administrative, operational and management resources. Growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. To date, we have relied on a small management team. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to manage growth effectively.

To that end, we must be able to:

- 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.

We may not be able to accomplish these tasks, and our failure to accomplish any of them 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 our potential future growth depends significantly upon retaining key managerial, scientific, sales, marketing, and financial personnel, and attracting and retaining additional highly qualified personnel in these areas. 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 these key individuals could result in competitive harm because we could experience delays in our product research, development and commercialization efforts without their expertise.

We face intense competition for qualified personnel from numerous companies, as well as universities and nonprofit research organizations in the highly competitive San Francisco Bay Area. Although we believe that we have been successful in attracting and retaining qualified personnel to date, we may not be able to attract and retain sufficient qualified personnel in the future. The inability to attract and retain these personnel could harm our commercial business or delay the discovery, development and commercialization of our product candidates.

Rapid technological change could make our product and product candidates obsolete.

Pharmaceutical technologies undergo rapid and significant change. Our future will depend in large part on our ability to maintain a competitive position with respect to these technologies. Korlym and any products and processes that we develop may become obsolete or uneconomical before we recover any of the cost of their development. Rapid technological change could make Korlym and our product candidates obsolete or uneconomical, which could materially adversely affect our business, financial condition and results of operations.

Risks Related to Our Capital Needs and Financial Results

We may need additional capital in order to complete the development of Korlym for additional indications or for the development and commercialization of our proprietary, selective cortisol modulators. Additional capital may not be available to us at all or on favorable terms, which could adversely affect our business.

We may need to raise funds to continue the development of our proprietary selective cortisol modulators for any indication or for additional indications for Korlym. We may also raise funds for other research and development

activities, including clinical trials, for working capital or for other general corporate purposes, or to acquire or invest in businesses, products and technologies that are complementary to our own.

Factors affecting our liquidity include the following:

- the pace at which physicians adopt Korlym as a treatment;
- the willingness of insurance companies and the government payors to provide coverage for Korlym;
- the outcome of clinical trials of Korlym and our other product candidates and the further clinical development of those compounds;
- changes in our research and development plans for Korlym and our other product candidates; and
- disputes concerning patents or proprietary rights, including announcements of claims of infringement, interference or litigation against us or our licensors.

We may also choose to raise additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current and future operating plans.

We cannot be certain that additional funding will be available on acceptable terms or at all. Our sales of common stock and warrants and the exercises of warrants have been dilutive to stockholders and any additional equity financing could cause further dilution. Debt financing, if available, may involve restrictive covenants. If we obtain funds through collaborations with others, these 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.

We have incurred substantial losses and we may incur losses in the future.

We have financed our operations and internal growth in recent years primarily through revenue from the sale of Korlym, the sale of our common stock and our financing agreement with Biopharma. Prior to that we relied on the public sale of common stock and private placements of preferred and common stock. We may incur additional losses as we continue our discovery and clinical development programs, apply for regulatory approvals, acquire and/or develop treatments in other therapeutic areas, and expand our sales and marketing capabilities.

We may not be able to pursue all of our product research and development opportunities if we are unable to generate sufficient revenue or secure adequate funding for these programs.

The costs required to start or continue many of the programs that our intellectual property allows us to consider for further development are collectively greater than the funds currently available to us. For example, we have successfully discovered three series of compounds that are selective cortisol modulators but do not appear to block the progesterone receptor. Further development of these proprietary compounds or any further development stemming from our method of use patents may be delayed or cancelled if we determine that our expected revenue will be insufficient to support such programs and we are unable to obtain funding from other sources.

Global economic conditions could adversely affect our liquidity and financial condition.

Renewed or increased turbulence in the global markets and economies may cause lenders and institutional investors to reduce, or cease, to provide credit to businesses such as ours, which could adversely affect our liquidity and financial condition.

If we do not have sufficient cash flow to continue operating our business and are unable to borrow funds or raise equity or debt capital, we may need to find alternative ways to increase our liquidity. Such alternatives may include, without limitation, curtailing clinical or drug development activity or limiting our commercial efforts, which would have an adverse effect on our business, results of operations, cash flows and financial condition.

If we acquire other selective cortisol modulators or other technologies or 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 are complementary to our operating plan. We currently have no commitments, agreements or plans for any acquisitions. Acquiring rights to another potential product or technology may result in unforeseen difficulties and expenditures and may absorb significant management attention that would otherwise be available for ongoing development of our business. In addition, we may fail to realize the anticipated benefits of any acquired potential product or technology. Future acquisitions could dilute our stockholders' ownership interest in us and could cause us to incur debt, expose us to future liabilities and result in amortization or other expenses related to goodwill and other intangible assets.

Failure to meet our obligations under our Financing Agreement with Biopharma could adversely affect our financial results and liquidity.

Pursuant to our Financing Agreement with Biopharma entered into in August 2012, we are obligated to make payments to Biopharma equal to 20 percent of our net product sales of Korlym, any future mifepristone-based products and our next-generation selective cortisol modulators, subject to certain quarterly caps, as well as an un-capped 20 percent of any upfront, milestone or other contingent payments we receive with respect to Covered Products, until such payments to Biopharma total $45.0 million, at which point the obligation will be extinguished.

Pursuant to this agreement, we may not: (i) incur indebtedness greater than the sum of earnings before interest, taxes, depreciation and amortization, including such items as non-cash stock-based compensation, for the four calendar quarters preceding such incurrence, which we refer to as the Indebtedness Covenant; (ii) pay a dividend or other cash distribution, unless we have cash and cash equivalents in excess of $50.0 million after such payment; (iii) amend or restate our certificate of incorporation or bylaws unless such amendments or restatements do not affect Biopharma's interests under the transaction; and (iv) encumber any of the collateral securing our performance under the agreement.

The percentage used to calculate our payments to Biopharma would increase to 50 percent and any applicable payment caps would lapse if we (i) fail to provide Biopharma with certain information regarding our promotion and sales of Covered Products, (ii) do not devote a commercially reasonable amount of resources to the promotion and marketing of the Covered Products or (iii) violate the Indebtedness Covenant and, in each case, fail to cure within the applicable cure period.

Upon a Corcept change of control transaction, as defined in the agreement, Biopharma will be automatically entitled to receive any amounts not previously paid, up to our maximum repayment obligation of $45.0 million. As defined in the agreement, "Change of Control" includes, among other things, (i) a greater than 50 percent change in the ownership of Corcept, (ii) certain changes in Board composition of Corcept and (iii) the licensing of Korlym to a third-party for sale in the United States.

To secure our obligations under the agreement, we granted Biopharma a security interest in our rights in patents, trademarks, trade names, domain names, copyrights, know-how and regulatory approvals related to the Covered Products, all books and records relating to the foregoing and all proceeds of the foregoing, which we refer to as the Collateral. If we (i) fail to deliver a royalty payment when due and do not remedy that failure within 30 days, (ii) fail to maintain a first-priority perfected security interest in the Collateral in the United States and do not remedy that failure within five business days of receiving notice of such failure or (iii) become subject to an event of bankruptcy, then Biopharma may attempt to recover up to $45.0 million (after deducting any payments we have already made).

We cannot assure that we will not breach the covenants or other terms of, or that an event of default will not occur under this agreement and, if a breach or event of default occurs, we cannot assure that we will be able to cure the event within the time permitted. Any failure to pay our obligations when due, any breach or default of our covenants or other obligations, or any other event that causes an acceleration of payment at a time when we do not have

sufficient resources to meet these obligations, could have a material adverse effect on our business, results of operations, financial condition and future viability.

The acceleration of the payment obligation in the event of a change of control transaction may make us less attractive to potential acquirers, and the payment of such funds out of our available cash or acquisition proceeds would reduce acquisition proceeds for our stockholders.

Risks Relating to Our Intellectual Property

If Korlym or future product candidates conflict with the patents of others or if we become involved in other intellectual property disputes, we may have to engage in costly litigation or obtain a license and we may be unable to commercialize our product candidates.

The patent positions of companies in the pharmaceutical industry are highly uncertain, involve complex legal and factual questions and have been and continue to be the subject of much litigation. Our product candidates may give rise to claims that our patents are invalid or that we infringe on the products or proprietary rights of others. If it is determined that our product candidates infringe on others' patent rights, we may be required to obtain licenses to those rights. If we fail to obtain licenses when necessary, we may experience delays in commercializing our product candidates while attempting to design around other patents, or determine that we are unable to commercialize our product candidates at all. If we do become involved in intellectual property litigation, we are likely to incur considerable costs in defending or prosecuting the litigation. We believe that we do not currently 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 except to Stanford University and the University of Chicago.

Our success depends in part on our ability to obtain and maintain adequate patent protection for the use of Korlym for the treatment of triple-negative breast cancer, castration-resistant prostate cancer and other potential uses of cortisol modulators. If we do not adequately protect our intellectual property, competitors may be able to use our intellectual property and erode our competitive advantage.

We own 20 issued U.S. method of use patents and have exclusively licensed six issued U.S. method of use patents. We have six U.S. method of use patent applications pending for our next-generation selective cortisol modulators. We also own eight U.S. composition of matter patents, with one additional U.S. application pending. In addition, we have been issued foreign method of use patents and composition of matter patents around the world. We have applied, and will continue to apply, for patents covering our product candidates as we deem appropriate. We have filed, and will continue to file, where we deem appropriate, foreign patent applications corresponding to our U.S. patents and applications.

We have exclusively licensed three issued U.S. patents from Stanford University for the use of cortisol modulators, including mifepristone, in the treatment of psychotic depression, cocaine-induced psychosis and early dementia, including early Alzheimer's disease. We have also exclusively licensed from the University of Chicago two issued U.S. patents for the use of cortisol modulators in the treatment of triple-negative breast cancer and a third issued U.S. patent covering the use of cortisol modulators to treat castration-resistant prostate cancer.

We bear the costs of prosecuting, protecting and defending these patents. In order to maintain the exclusive license to these patents until their expiration, we are obligated to make milestone and royalty payments to both universities. If we do not comply with our obligations under our agreement with Stanford, we may lose the right to commercialize mifepristone for the treatment of psychotic depression, cocaine-induced psychosis and early dementia. If the University of Chicago were to terminate our licenses, we may not be able to commercialize any cortisol modulators, including mifepristone, for the treatment of triple-negative breast cancer or castration-resistant prostate cancer.

Our patent applications and patents licensed or issued to us may be challenged by third-parties and our patent applications may not result in issued patents. Our presently pending and future patent applications may not issue as patents, and any patent issued to us may be challenged, invalidated, held unenforceable or circumvented. Our patent claims may not be sufficiently broad to prevent third-parties from producing competing products. The laws of foreign

countries in which we may someday compete may not protect our intellectual property to the same extent as do the laws of the United States. If we fail to obtain adequate patent protection for our proprietary technology, our competitors may produce competing products based on our technology in these countries, which would impair our ability to succeed.

If a third-party successfully asserted an infringement claim against us, we could be forced to pay damages and be prevented from developing, manufacturing or marketing our potential products. We do not have liability insurance for patent infringement. A third-party could require us to obtain a license to use their intellectual property, which we may not be able to do on commercially acceptable terms, or at all. If we become involved in litigation, it could consume a substantial portion of our resources and of management's time. Regardless of the merit of any particular claim, defending a lawsuit is expensive and diverts management's attention from productive business.

Our ability to compete in the market 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 trade secrets and proprietary information. Nevertheless, these measures may not provide adequate protection, in which case third-parties could use our proprietary information to diminish our ability to compete in the market. In addition, employees, consultants and others who participate in the development of our product candidates may breach their agreements with us regarding our trade secrets and other proprietary information and we may not have adequate remedies for the breach. We also realize that our trade secrets may become known despite our best efforts.

The mifepristone patents that we own cover the use of mifepristone, not its composition, which may make it more difficult for us to prove patent infringement if physicians prescribe another manufacturer's mifepristone or if patients acquire mifepristone from other sources, such as the internet or underground market.

We own or have exclusively licensed issued U.S. patents covering the methods of using cortisol modulators to treat a variety of disorders, including triple-negative breast cancer and castration-resistant prostate cancer. A method of use patent covers only a specified use of a particular 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 for indications covered by our patents. Although any such "off-label" use would violate our patents, effectively monitoring compliance and enforcing our rights may be difficult and costly. In addition, we cannot be assured that patients will not obtain mifepristone from other sources. As with other pharmaceutical products, patients may be able to purchase mifepristone through the internet or underground market. Mifepristone is also sold in the United States by Danco Laboratories for the termination of early pregnancy. While distribution is limited to a single dose provided in the physician's office and covered by other restrictions, we cannot be certain that Cushing syndrome patients will not be able to obtain mifepristone from this source or others, should another company receive approval to market mifepristone for another indication.

Risks Related to Our Stock

The market price of our common stock has been and is likely to continue to be highly volatile due to the limited number of shares of our common stock held by non-affiliates or factors influencing the stock market and opportunities for sale at any given time may be limited.

We cannot assure that an active trading market for our common stock will exist at any time. Holders of our common stock may not be able to sell shares quickly or at the market price if trading in our common stock is not active. During the 52-week period ended February 28, 2017, our average daily trading volume was approximately 453,215 shares and the intra-day sales prices per share of our common stock on The NASDAQ Capital Market ranged from $3.80 to $10.00. As of February 28, 2017, our officers, directors and principal stockholders controlled 22 percent of our common stock. The trading price of our common stock has been and is likely to continue to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

- actual or anticipated variations in quarterly operating results;
- changes in financial estimates or recommendations by securities analysts or failure of our financial performance to meet the guidance we have provided to the public;

- actual or anticipated timing and results of our clinical trials;
- distributions in-kind of our common stock by our venture capital or private equity stockholders, which will increase the supply of our common stock and could decrease its price;
- purchases or sales of our common stock by us, our officers, directors or our stockholders;
- trading volume of our common stock;
- actual or anticipated regulatory approvals of our product candidates or of competing products;
- new products or services introduced or announced by us or our competitors;
- our cash and short-term investment position;
- changes in laws or regulations applicable to our product candidates or our competitors' products;
- changes in the expected or actual timing of our development programs or our competitors' potential development programs;
- announcements of technological innovations by us, our collaborators or our competitors;
- general market and economic conditions;
- conditions or trends in the biotechnology and pharmaceutical industries;
- changes in the market valuations of similar companies;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- additions or departures of key personnel;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- limited number of shares of our common stock held by our non-affiliates;
- developments concerning collaborations;
- maintaining compliance with the listing requirements of the stock exchange on which we are listed; and
- additional financing activities.

All stock markets, including the NASDAQ Capital Market on which our stock is listed, and the market for biotechnology and life sciences companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. This volatility may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources.

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.

We have provided guidance as to our expected 2017 revenue. Our guidance is only an estimate of what management believes is realizable as of the date of the release of such guidance. Our actual results may vary materially from our guidance.

Reasons why we might fail to meet our financial guidance or other investor expectations include, without limitation, the risks and uncertainties described in this report and in our other public filings and public statements. There are inherent difficulties in predicting the amount of Korlym that will be sold. For example, the rate of physician adoption of Korlym is uncertain. Research analysts have published a range of revenue estimates, based on their own analyses. We believe research analysts will consider the guidance we have provided as one factor in determining their own estimates. Readers of this annual report should rely on our guidance and the estimates of research analysts at their own discretion.

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

The trading market for our common stock may be affected in part by the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts who elects to cover us downgrades our stock, our stock price could decline rapidly and significantly. Securities analysts currently covering our common stock may discontinue research coverage. Additional securities analysts may elect not to provide research coverage of our common stock. A lack of research coverage may adversely affect our common stock's market 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 common stock in the public market could harm the market price of our common stock. As additional shares of our common stock become available for resale in the public market, whether as a result of distributions in-kind of our common stock by our venture capital or private equity stockholders, the exercise of stock options by employees, or equity financing by us, the supply of our common stock will increase, which could decrease the share price. Substantially all of the shares of our common stock are eligible for sale, subject to applicable volume and other resale restrictions.

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

As of February 28, 2017, our officers and directors control 22 percent of our common stock. As a result, these stockholders, acting together, will be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders 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 investors often 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, affecting our company, 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 result in increased costs to us as we respond to their requirements. We are investing resources to comply with evolving laws and regulations, and this investment may result in increased selling, general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. At present, we cannot predict or estimate the amount of the additional costs related to new rules and regulations or the timing of such costs.

In addition, new rules and regulations could make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur higher costs to obtain the same or similar coverage. The impact of these events could also make it more

difficult for us to attract and retain qualified persons to serve on our Board of Directors, or our board committees, or as executive officers.

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

We are a small company with limited resources. 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. These requirements have increased and will continue to increase our legal compliance costs.

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 financial statements must attest to and report on the effectiveness of our internal controls over financial reporting. If we are unable to complete management's required assessment and report as to the adequacy of our internal control over financial reporting in or if our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal control over financial reporting, investors could lose confidence in the reliability of our financial reporting.

Changes in or interpretations of accounting rules and regulations could result in unfavorable accounting charges or require us to change our accounting policies or operating practices.

Accounting methods and policies for business and marketing practices of pharmaceutical companies are subject to continual review, interpretation and guidance from relevant accounting authorities, including the SEC. Although we believe that our accounting practices are consistent with current accounting pronouncements, changes to or interpretations of accounting methods or policies in the future may require us to reclassify, restate or otherwise change or revise our financial statements. Any such changes could result in corresponding changes to the amounts of assets, liabilities, revenues, expenses and income, which could have a material adverse effect on our business, financial position and results of operations and could cause the price of our common stock to decline.

Anti-takeover provisions in our charter and bylaws and under Delaware law and payment acceleration provisions under the Biopharma Financing Agreement 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. In addition, our payment obligations to Biopharma accelerate in the event of a change of control transaction. See "Risk Factors – Failure to meet our obligations under our Financing Agreement with Biopharma could adversely affect our financial results and liquidity." These provisions in our charter and bylaws and under Delaware law and the Financing Agreement could reduce the price that investors would be willing to pay for shares of our common stock and result in the market price being lower than it would be without these provisions.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

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ITEM 2. PROPERTIES

We lease 20,831 square feet of office space in Menlo Park, California for our corporate facilities. Our current lease extended our occupancy through March 2019.

ITEM 3. LEGAL PROCEEDINGS

We are not currently involved in any material legal proceedings.

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." The following table sets forth the high and low intra-day sale prices per share of our common stock on The NASDAQ Capital Market for the periods indicated. These prices represent quotations among dealers without adjustments for retail mark-ups, markdowns or commissions and may not represent prices of actual transactions.

2016	High	Low
First Quarter	$4.92	$3.22
Second Quarter	$6.33	$4.55
Third Quarter	$6.72	$5.24
Fourth Quarter	$10.00	$6.11

2015	High	Low
First Quarter	$6.34	$2.69
Second Quarter	$7.67	$5.40
Third Quarter	$6.15	$3.36
Fourth Quarter	$5.71	$3.45

Stockholders of Record and Dividends

As of February 28, 2017, we had 112,942,391 shares of common stock outstanding held by 41 stockholders of record. We have never declared or paid cash dividends. We currently intend to retain any future earnings to finance the growth and development of our business and therefore do not anticipate paying any cash dividends in the foreseeable future. In addition, the Biopharma Financing Agreement prohibits payment of dividends unless we have cash and cash equivalents in excess of $50 million after making such a payment.

Sale of Unregistered Securities

None.

Repurchases of Securities

None.

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.

The rules of the SEC require that we include a graph comparing cumulative stockholder returns on our common stock with the NASDAQ US Benchmark Total Return Index and either a published industry or line-of-business standard

index or an index of peer companies selected by us. 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.

The graph shows the cumulative total stockholder return assuming the investment of $100.00 and the reinvestment of 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. No dividends have been declared on our common stock.

The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN* AMONG

CORCEPT THERAPEUTICS,

THE NASDAQ US BENCHMARK TOTAL RETURN (TR) INDEX

AND THE NASDAQ BIOTECHNOLOGY INDEX

* $100 invested on December 31, 2011 including reinvestment of dividends. Fiscal year ended December 31.

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 financial statements. The statement of operations data for the years ended December 31, 2016, 2015, and 2014 and the balance sheet data as of December 31, 2016 and 2015 are derived from our audited financial statements included in this Annual Report. The statements of operations data for the years ended December 31, 2013 and 2012, and the balance sheet data as of December 31, 2014, 2013 and 2012 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 expected for 2017 or for any other 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,				
	2016	2015	2014	2013	2012
	(In thousands, except per share data)				
Statement of Operations Data:					
Product sales, net	$81,321	$50,286	$26,551	$10,357	$3,307
Operating expenses:					
Cost of sales	2,058	1,361	882	143	91
Research and development*	23,844	15,419	18,372	20,470	14,074
Selling, general and administrative*	45,240	36,949	34,916	31,240	25,414
Total operating expenses	71,142	53,729	54,170	51,853	39,579
Income (loss) from operations	10,179	(3,443)	(27,619)	(41,496)	(36,272)
Non-operating income (expense), net*	(2,039)	(2,965)	(3,764)	(4,515)	(1,776)
Net income (loss)	$8,140	$(6,408)	$(31,383)	$(46,011)	$(38,048)
Net income (loss) per share:					
Basic and diluted	$0.07	$(0.06)	$(0.31)	$(0.46)	$(0.41)
Weighted average shares – basic	110,566	106,883	100,978	99,819	93,015
Weighted average shares – diluted	116,139	106,883	100,978	99,819	93,015
* Includes certain non-cash expenses, of the following:					
Stock-based compensation					
Research and development	$1,312	$839	$723	$618	$546
Selling, general and administrative	5,746	5,174	4,478	4,578	4,764
Total stock-based compensation	7,058	6,013	5,201	5,196	5,310
Non-operating expense related to accretion of interest on long-term obligation	1,929	2,848	3,678	4,410	1,680
Total non-cash expenses	$8,987	$8,861	$8,879	$9,606	$6,990

	As of December 31,				
	2016	2015	2014	2013	2012
	(In thousands)				
Balance Sheet Data:					
Cash, cash equivalents and investments	$51,536	$40,435	$24,248	$54,877	$93,032
Working capital	38,315	28,104	16,675	45,573	86,703
Total assets	68,753	51,937	34,630	63,077	99,166
Long-term obligation - current portion	14,664	14,965	9,424	5,743	2,650
Long-term obligation, net of current portion	—	12,528	24,405	29,234	28,907
Total stockholders' equity (deficit)	41,379	18,498	(3,388)	21,017	61,777

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A) is intended to help the reader understand our results of operations and financial condition. MD&A is provided as a supplement to, and should be read in conjunction with, our audited Financial Statements and the accompanying Notes to Financial Statements and other disclosures included in this Annual Report on Form 10-K (including the disclosures under Item 1A, Risk Factors). Our Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles and are presented in U.S. dollars.

We make statements in this section that are forward-looking statements within the meaning of the federal securities laws. For a complete discussion of such forward-looking statements and the potential risks and uncertainties that may impact upon their accuracy, see "Forward-Looking Statements" included in "Risk Factors" in Part I, Item 1A of this Form 10-K and the "Overview" and "Liquidity and Capital Resources" sections of this Management's Discussion and Analysis of Financial Condition and Results of Operations.

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 a broad range of human disorders. Since our inception in 1998, we have been developing mifepristone, a compound that modulates the effects of cortisol by acting as a competitive antagonist at the glucocorticoid receptor (GR). We have also discovered 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 and so do not cause effects associated with progesterone receptor antagonism. Both pre-clinical and clinical development of the lead compounds from these series are in progress.

In 2012, the United States Food and Drug Administration (FDA) approved Korlym® (mifepristone) 300 mg tablets as a once-daily oral medication for the treatment of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery.

We are conducting two clinical trials of our proprietary selective cortisol modulator, CORT125134. One trial is investigating CORT125134 as a potential treatment for patients with Cushing syndrome. The second trial is investigating the combination of CORT125134 and Abraxane as a treatment for patients with a variety of solid-tumor cancers. Both trials are currently enrolling patients.

We are advancing other compounds from our portfolio of selective cortisol modulators towards the clinic and expect to begin clinical trials of two of them in 2017.

Cushing Syndrome

Background. Cushing syndrome is caused by prolonged exposure of the body's tissues to high levels of the stress hormone cortisol. It is relatively uncommon and most often affects adults aged 20 to 50. 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 an estimated prevalence of 20,000 patients with Cushing syndrome in the United States, approximately half of whom are cured by surgery.

Korlym to Treat Patients with Cushing Syndrome. We have received Orphan Drug designation from the FDA for Korlym for the treatment of patients with endogenous Cushing syndrome. Drugs that receive Orphan Drug designation receive seven years of marketing exclusivity for the approved indication from the date of drug approval,

as well as tax credits for clinical trial costs, marketing application filing fee waivers and assistance from the FDA in the drug development process.

We first made Korlym available to patients on a commercial basis in April 2012. We sell Korlym using experienced sales representatives, who target U.S. endocrinologists who care for a large portion of the patients with Cushing syndrome. We also reach patients directly through web-based initiatives and interactions with patient groups. Because a large percentage of the people who suffer from Cushing syndrome remain undiagnosed or are inadequately treated, we have developed and continue to refine and expand programs to educate the medical community and patients about diagnosis of this syndrome and to increase awareness regarding the role of cortisol modulators to treat the disease. In addition, we have a field-based force of medical science liaisons.

We use a specialty pharmacy and a specialty distributor to distribute Korlym and provide logistical support. We have retained a vendor to help patients with the reimbursement process and to administer our financial assistance programs for uninsured or under-insured patients. We donate money to independent charitable foundations. These organizations, along with our own programs, help us ensure that no Cushing syndrome patient is denied access to Korlym for financial reasons.

CORT125134 to Treat Patients with Cushing Syndrome. In the second quarter of 2016, we began a Phase 2 trial of our proprietary, selective cortisol modulator, CORT125134, to treat patients with Cushing syndrome. CORT125134 shares Korlym's affinity for GR. Data from the compound's Phase 1 trial showed that it can potently modulate the effects of the steroid prednisone, a commonly-used GR agonist, on serum osteocalcin, white blood cell counts, glucose metabolism and expression of the protein FKBP5 – a genetic marker of GR activation. Modulating the effect of prednisone is important because it is a strong surrogate for Korlym's modulation of cortisol – the essential quality of an effective treatment for patients with Cushing syndrome.

We are developing a CLIA-validated assay to measure expression of FKBP5. We believe this assay will allow physicians to measure the degree to which their patients suffer from excess cortisol activity, which would help them more easily identify patients with Cushing syndrome and better treat those already in their care.

Oncology

Background. A range of tumor-types express GR and are potential targets for cortisol modulation therapy, among them triple-negative breast, ovarian, prostate, cervical, and pancreatic cancers, as well as sarcoma and melanoma.

Korlym to Treat Patients with Solid-Tumor Cancers. In December 2016, we announced the results of our Phase 1/2 trial of Korlym in combination with eribulin (Eisai's Inc.'s drug, Halaven®) to treat patients with metastatic triple-negative breast cancer. 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 that the addition of Korlym to chemotherapy warrants further study, such as the double-blind, placebo-controlled, multicenter, University of Chicago-led trial described above that Celgene is funding.

CORT125134 to Treat Patients with Solid-Tumor Cancers. We are conducting a Phase 1/2 trial of Abraxane (nab-paclitaxel) in combination with CORT125134 to treat any solid-tumor cancer suitable for treatment with Abraxane. Once we identify a recommended dose of this combination, we will open 20-patient cohorts to test the combination's efficacy in one or more solid-tumor cancers. Our likely initial targets will be triple-negative breast cancer and ovarian cancer. Other possible indications include pancreatic cancer, cervical cancer and sarcoma.

Results of Operations

Net Product Sales – Net product sales are gross product revenue from sales to customers less deductions for estimated government rebates and chargebacks.

For the year ended December 31, 2016, we recorded $81.3 million in net product sales, as compared to $50.3 million for the year ended December 31, 2015 and $26.6 million for the year ended December 31, 2014. The increases in net product revenue were primarily driven by increases in our sales volume and price increases.

We donate cash to the National Organization for Rare Disorders (NORD), a third-party charitable organization that helps patients with financial need pay for the treatment of Cushing syndrome, which treatment may include Korlym. We do not include as net product revenues funds we receive from this organization.

Cost of sales – Cost of sales includes the cost of manufacturing Korlym, including its active pharmaceutical ingredient (API), tableting and packaging costs, indirect personnel and overhead costs, and the cost of stability testing and distribution.

Cost of sales was $2.1 million for the year ended December 31, 2016, as compared to $1.4 million in the corresponding period in 2015. The increase was due to greater sales volumes. For the year ended December 31, 2016, cost of sales was 2.5 percent of our net product revenue, as compared to 2.7 percent in the corresponding period in 2015.

Cost of sales was $1.4 million for the year ended December 31, 2015, as compared to $0.9 million in the corresponding period in 2014. For the year ended December 31, 2015, cost of sales was 2.7 percent of our net product revenue, as compared to 3.3 percent in the corresponding period in 2014.

Cost of sales declined as a percentage of net product revenue for the years ended December 31, 2016 and 2015 due to a decline in the cost of manufacturing Korlym tablets as well as sales price increases.

Research and development expenses – Research and development expenses include the cost of (1) personnel engaged in development activities, including stock-based compensation, (2) clinical trials, including trial preparation, enrollment, site monitoring and data management and analysis expenses, (3) discovery research and pre-clinical studies, (4) acquisition of clinical trial materials and material used in registration and validation batches included in regulatory submissions prior to product approval, (5) manufacturing development, and (6) regulatory activities, including the preparation and prosecution of the regulatory submissions related to Korlym and our other product candidates.

Research and development expenses increased to $23.8 million for the year ended December 31, 2016 from $15.4 million in 2015, an increase of 54.6 percent, primarily due to increased spending on the advancement of CORT125134, which entered clinical trials in patients in the second quarter of 2016, as well as increased compensation expense due to the hiring of additional clinical development employees.

Research and development expenses decreased to $15.4 million for the year ended December 31, 2015 from $18.4 million in 2014, a decline of 16.1 percent, due to the discontinuation of our Phase 3 clinical trial of Korlym to treat psychotic depression in May 2014, which reduced our research and development expenses in the year ended December 31, 2015 by $3.9 million, partially offset by $0.9 million in spending on our Phase 1/2 study in triple-negative breast cancer, an FDA-required drug-drug interaction study and the development of new selective cortisol modulators.

Below is a summary of our research and development expenses by major project:

	Year Ended December 31,		
	2016	2015	2014
Project	(in thousands)		
Development programs:			
Oncology	$4,592	$3,494	$2,455
Cushing syndrome	3,739	811	2,157
Psychotic depression	—	190	5,971
Pre-clinical selective cortisol modulators	10,393	7,431	5,607
Unallocated activities, including pre-clinical, manufacturing and regulatory activities	3,808	2,654	1,459
Stock-based compensation	1,312	839	723
Total research and development expense	$23,844	$15,419	$18,372

We expect research and development expenditures in 2017 to be higher than they were in 2016, as we hire more clinical staff, our research and development programs advance and their costs increase. Research and development expenses in 2017 and beyond will depend on the outcomes of our current trials and future development plans.

Many factors affect the cost and timing of our trials, including inconclusive results requiring more clinical trials, slow patient enrollment, adverse side effects in study patients, insufficient supplies of medicine for our clinical trials and real or perceived lack of effectiveness or safety of the product candidate. The cost and timing of development of our selective cortisol modulators will depend on the success of our efforts and any difficulties we encounter. In addition, the development of our product candidates is subject to extensive governmental regulation. These factors make it difficult for us to predict the timing and costs of developing and securing approval of our product candidates.

Selling, general and administrative expenses – Selling, general and administrative expenses include (1) the cost of personnel, consultancy and contractors engaged in administrative and commercial activities, including stock-based compensation, (2) expenses of third-party vendors used in our commercial activities related to Korlym, including sales, marketing and promotion, pharmacy costs, market research, reimbursement support services, pharmacovigilance, distribution of marketing materials, and logistical requirements and (3) legal, accounting and other professional fees.

Selling, general and administrative expenses for the year ended December 31, 2016 increased 22.4 percent to $45.2 million, from $36.9 million for the comparable period in 2015. The increases were driven primarily by increased compensation expense due to additional hiring, bonus expense, and commissions related to increased sales.

Selling, general and administrative expenses for the year ended December 31, 2015 increased 5.8 percent to $36.9 million, from $34.9 million for the comparable period in 2014. The increases were primarily due to the growth of our sales organization.

We expect that selling, general and administrative expenses will be higher in 2017 than in 2016 due to increased sales of Korlym. The level of selling, general and administrative activities and related expenses in 2017 and future years will be dependent on our assessment of the staff and other services necessary to support our commercial efforts and our continued clinical development activities.

See also, “Liquidity and Capital Resources.”

Interest and other expense – Interest and other expense for the year ended December 31, 2016 was $2.0 million, as compared to $3.0 million for the year ended December 31, 2015 and $3.8 million for the year ended December 31, 2014. These amounts consisted primarily of interest expense related to our Financing Agreement with

Biopharma, which we entered into in August 2012. Interest expense for 2017 will decrease as our quarterly payments reduce the outstanding obligation. We expect to make our final payment under the Financing Agreement in 2017.

Non-GAAP Financial Measures

Our financial statements and footnotes thereto are prepared in accordance with U.S. Generally Accepted Accounting Principles (GAAP) and are included in Part IV, Item 15 of this Annual Report on Form 10-K. To supplement our financial results presented on a GAAP basis, we use non-GAAP measures of net income (loss) and net income (loss) per share that exclude non-cash expenses related to stock-based compensation expense and the accretion of interest expense under our capped royalty financing transaction. We use these non-GAAP measures to manage our business and believe that they may help investors better evaluate our past financial performance and potential future results. Non-GAAP measures should not be considered in isolation or as a substitute for comparable GAAP accounting and investors should read them in conjunction with our financial statements and notes thereto prepared in accordance with GAAP. The non-GAAP measures of net income (loss) and net income (loss) per share we use may be different from, and not directly comparable to, similarly titled measures used by other companies.

The following table reflects the reconciliation of GAAP net income (loss) and net income (loss) per share to non-GAAP net income (loss) and net income (loss) per share for the periods presented.

	Year Ended December 31,		
	2016	2015	2014
	(in thousands, except for per share data)		
GAAP net income (loss)	$8,140	$(6,408)	$(31,383)
Non-cash expenses:			
Stock-based compensation	7,058	6,013	5,201
Accretion of interest expense related to long-term obligation	1,929	2,848	3,678
Non-GAAP net income (loss), as adjusted for non-cash expenses	$17,127	$2,453	$(22,504)
Basic and diluted net income (loss) per share	$0.07	$(0.06)	$(0.31)
Non-GAAP basic and diluted net income (loss) per share, as adjusted for non-cash expenses	$0.15	$0.02	$(0.22)
Weighted average shares outstanding shares used in computing net income (loss) per share			
Basic	110,566	106,883	100,978
Diluted	116,139	106,883	100,978

Liquidity and Capital Resources

Until the year ended December, 31, 2016, we had incurred operating losses since inception. At December 31, 2016, we had an accumulated deficit of $322.3 million. Since 2012, we have relied primarily on revenues from the sale of Korlym, and proceeds from the sale of our common stock and our Financing Agreement with Biopharma to fund our operations.

Based on our current plans, which include funding our Cushing syndrome commercial operations, conducting Phase 2 trials of CORT125134 in both Cushing syndrome and solid tumor cancers and advancing to the clinic CORT125281 and CORT118335, we expect to fund our operations without needing to raise additional funds. We may choose to raise additional funds to finance our strategic priorities, however, if we are able to do so on acceptable terms. Any additional equity financing may be dilutive to stockholders. Any debt financing, if available,

may involve restrictive covenants. If we obtain funds through collaborations with others, these arrangements may be on unfavorable terms or may require us to relinquish certain rights to our technologies or product candidates that we would otherwise seek to develop on our own.

At December 31, 2016, we had cash and cash equivalents of $51.5 million, compared to $40.4 million at December 31, 2015. Net cash provided by operating activities for the year ended December 31, 2016 and December 31, 2015 was $18.4 million and $3.1 million, respectively, primarily due to greater sales volumes. Net cash used in operating activities for the year ended December 31, 2014 was $27.4 million, primarily to fund the commercialization of Korlym and for research and development. Net cash provided by stock option exercises was $7.7 million, $5.2 million, and $1.8 million during the years ended December 31, 2016, 2015, and 2014, respectively. In addition, we made payments under the Biopharma Financing Agreement of $14.8 million, $9.2 million, and $4.9 million during the years ended December 31, 2016, 2015 and 2014, respectively.

We are required to make aggregate payments under the Biopharma Financing Agreement of $45.0 million, with $29.9 million paid through December 31, 2016 and an additional payment of $4.8 million made in February 2017. We will make additional quarterly repayments in 2017 based on the level of our Korlym sales, and expect to fully repay the obligation in 2017.

While we monitor the cash balance in our checking account and transfer the funds into it only as needed, these cash balances and our money market fund could be affected if the underlying financial institution were to fail or were subject to other adverse conditions in the financial markets. We have never experienced a loss or lack of access to cash in our checking account or money market fund.

Contractual Obligations and Commercial Commitments

The following table presents our estimates of obligations under contractual agreements as of December 31, 2016.

Contractual Obligations	Total	Less than 1 year	2-3 Years	4-5 Years	More than 5 Years
	(in thousands)				
Long-term obligation [1]	$14,664				
Other contractual obligations:					
Research and development studies [2 to 3]	$8,537	$ 5,355	$3,182	$ —	$ —
Operating lease [4]	2,331	937	1,394	—	—
Minimum royalty and license fee payments [5]					