CORCEPT THERAPEUTICS INC
Form 10-K
March 13, 2015

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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, 2014

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)

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(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 $184,675,000 as of June 30, 2014 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 March 2, 2015 there were 101,405,250 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 2015 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, 2014

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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 from time to time, the words "believe," "anticipate," "intend," "plan," "estimate," "expect," "may," "will," "should," "seek" and similar expressions a forward-looking statements. Such forward-looking statements are based on current expectations, but the absence of these words does not necessarily 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 dates by which we expect to report results of our clinical trials and the anticipated results of these trials;
- the progress and timing of our research, development and clinical programs and the regulatory activities associated with such programs;
- our ability to realize the benefits of Orphan Drug designation of 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 mifepristone and any compound in our families of selective glucocorticoid receptor (GR) antagonists;
- our ability to achieve marketing approval of mifepristone in the European Union (EU) (for which we have requested the brand name Corluxin®) and realize the benefits of Orphan Drug designation there;
- our ability to manufacture, market, commercialize and achieve market acceptance for our future product candidates, including mifepristone for the treatment of triple-negative breast cancer or any other indications and any compounds in our families of selective GR antagonists;
- uncertainties associated with obtaining and enforcing patents; and
- our estimates regarding our capital requirements.

Forward-looking statements are not guarantees of future performance and involve risks and uncertainties. Actual events or results may differ materially from those discussed in the forward-looking statements as a result of various factors. For a more detailed discussion of such forward-looking statements and the potential risks and uncertainties that may impact upon their accuracy, see the "Risk Factors" section of this Form 10-K and the "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. These forward-looking statements reflect our view only as of the date of this report. Except as required by law, we undertake no obligations to update any forward-looking statements. Accordingly, you should also carefully consider the factors set forth in other reports or documents that we file from time to time with the Securities and Exchange Commission (SEC).

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

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ITEM 1. BUSINESS

Overview

We are a pharmaceutical company engaged in the discovery, development and commercialization of drugs for the treatment of severe metabolic, oncologic and psychiatric disorders associated with the steroid hormone cortisol. Elevated levels and abnormal release patterns of cortisol have been implicated in a broad range of human disorders. Since our inception in 1998, we have been developing mifepristone - a potent glucocorticoid receptor (GR) antagonist that modulates the activity of cortisol - for the treatment of serious illnesses. We have also discovered three series of proprietary, next-generation selective GR antagonists.

In February 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's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. FDA approval means that we can market the drug for the approved indication in the United States. We first made Korlym available to patients in April 2012 and continue to develop the sales, marketing, medical affairs and logistical infrastructure needed to commercialize the drug.

We are conducting a Phase 1/2 trial of mifepristone (Korlym's active ingredient) in combination with the chemotherapy drug eribulin (Halaven®) to treat patients with GR-positive triple-negative breast cancer – a form of cancer with a particularly poor prognosis. We have completed the first, dose-finding portion of the study and have begun enrolling patients in the second, efficacy phase. We expect to have results by the end of 2015.

In September 2014, we began a Phase 1 clinical study of CORT 125134, one of our proprietary, selective GR antagonists, to assess its safety, tolerability and pharmacokinetics in healthy human volunteers. We expect to have results from this study in the second quarter of 2015.

On May 7, 2014, we announced the discontinuation of our Phase 3 study of mifepristone, the active ingredient in Korlym, for treatment of psychotic depression (Study 14) after receiving the report of the study's data monitoring committee that the trial was unlikely to meet its primary endpoint with statistical significance. We began this study in 2008. See further discussion under "Psychotic Depression" below.

The Role of Cortisol in Disease

Corcept is focused on the development of drugs that modulate the activity of cortisol, a steroid hormone that plays a significant role in the way the body reacts to stressful conditions. Cortisol is essential for survival. It significantly influences metabolism, exerts a clinically useful anti-inflammatory effect and contributes to emotional stability. Insufficient levels of cortisol may lead to dehydration, hypotension, shock, fatigue, low resistance to infection, trauma, stress and hypoglycemia. Excessive levels of cortisol may lead to impaired glucose tolerance, diabetes, obesity, depressed mood, psychosis, wasting of the arms and legs, edema, fatigue, hypertension and other problems. Pre-clinical and clinical data suggest that cortisol activity at GR may shield certain cancer cells from the effects of chemotherapy. Elevated levels and abnormal release patterns of cortisol have also been linked to a broad range of conditions, such as weight gain, diabetes, hypertension, mood changes, psychosis and cognitive impairment.

Cortisol binds to two receptors, the mineralocorticoid receptor and the glucocorticoid receptor, known as MR and GR, respectively. MR is a high-affinity receptor that is involved in the routine functions of cortisol in the brain. It has approximately ten times the affinity of GR for cortisol and its binding sites are filled with cortisol nearly all the time. In general, GR binding sites do not fill until levels of cortisol become elevated. Short-term activation of GR has benefits, including increased alertness and improved ability to function in stressful conditions. Long-term activation of GR, however, has been shown to have significant toxicity and appears to be linked to multiple metabolic, psychiatric and oncologic diseases, including Cushing's syndrome. Cortisol activity also appears to suppress the effect of chemotherapy in triple-negative breast cancer, ovarian cancer and prostate cancer.

The action of cortisol can be moderated by the use of blockers, or antagonists, that compete with the hormone as it attempts to bind to its receptors. These antagonists, referred to as GR antagonists, may prevent the undesirable effects of elevated levels and abnormal release patterns of cortisol.

The challenge in regulating levels of cortisol is that cortisol is essential for life, destroying the ability of the body to make cortisol or drastically reducing its presence would cause serious harm. To have a viable therapeutic effect, a compound must be able to selectively modulate cortisol's effects without suppressing them below normal levels.

Mifepristone, the active ingredient in Korlym, works by selectively blocking the binding of cortisol to GR. It is neither an antagonist nor agonist of MR. It also blocks the binding of progesterone to the progesterone receptor (PR) and thereby terminates pregnancy. Because of its selective GR affinity, we believe that mifepristone can have a therapeutic benefit by modulating the effects

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of abnormal levels and release patterns of cortisol without compromising its necessary, normal functions. We have discovered three series of additional compounds that, while potently blocking the GR receptor, do not block the progesterone receptor, like mifepristone does, and thus do not terminate pregnancy. One of these compounds, CORT108297, has successfully completed Phase 1 trials. We expect another compound, CORT125134, to complete Phase 1 in the second quarter of 2015and we believe it is a potential therapy for several oncologic disorders and Cushing's syndrome.

Cushing's Syndrome

Background. Cushing's syndrome is a disorder caused by prolonged exposure of the body's tissues to high levels of the hormone cortisol. Sometimes called "hypercortisolism," 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's syndrome in the United States.

Symptoms vary, but most people with Cushing's 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's syndrome can affect every organ system in the body and can be lethal if not treated effectively.

The preferred treatment for Cushing's 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, either because the tumor cannot be removed completely or the disease returns.

In February 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's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. FDA approval means that we can market the drug for the approved indication in the United States.

We received Orphan Drug Designation from the FDA in 2007 and in the EU in 2011 for Korlym for the treatment of endogenous Cushing's syndrome. In the United States, Orphan Drug Designation is a special status granted by the FDA to encourage the development of treatments for diseases or conditions that affect fewer than 200,000 patients. Drugs that receive Orphan Drug Designation in the United States obtain 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. Even after an orphan drug is approved for its orphan indication, the FDA can later approve a different drug for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. In addition, the FDA may, during the orphan exclusivity period, approve the same drug for a different indication.

Orphan Drug Designation in the EU confers benefits similar to those in the United States but includes ten years of marketing exclusivity for the approved indication in all 28 Member States, free scientific advice during drug development, access to a centralized review process and a reduction or complete waiver of fees levied by the European Medicines Agency (EMA). In October 2013, we submitted a Marketing Authorization Application (MAA) to the EMA that, subject to review by the EMA, could serve as the basis for the approval of mifepristone in the EU.

Commercialization of Korlym. We first made Korlym available to patients on a commercial basis in April 2012 Physicians prescribing Korlym determine the appropriate dose for each patient by assessing tolerability and degree of improvement in manifestations of Cushing's syndrome. In the first six weeks, these manifestations may include changes in glucose control, anti-diabetic medication requirements, insulin levels and psychiatric symptoms. After two months, physicians may assess their patients for improvements in cushingoid appearance, acne, hirsutism, striae and decreased body weight, along with further changes in glucose control.

We sell Korlym using experienced sales representatives and medical science liaisons (MSLs) who target the approximately 1,500 endocrinologists who care for a large portion of the Cushing's syndrome population. 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's syndrome remain undiagnosed or inadequately treated, we have developed and continue to refine and expand programs to educate the medical community and patients about early diagnosis of this syndrome and to increase awareness regarding the role of GR antagonists to treat this syndrome.

We use a specialty pharmacy and a specialty distributor to distribute Korlym and provide logistical support.

We have also 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 the National Organization for Rare Disorders (NORD), an

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independent charitable foundation that helps Cushing's syndrome patients who satisfy its financial criteria pay for their Cushing's syndrome care.

Triple-Negative Breast Cancer.

In January 2014 we began a Phase 1/2 study of Korlym in combination with eribulin in the treatment of triple-negative breast cancer.

Triple-negative breast cancer is a form of the disease in which the three receptors that fuel most breast cancer growth – estrogen, progesterone, and the HER-2/neu gene – are not present. Because the tumor cells lack these receptors, common treatments, such as drugs that target estrogen, progesterone, and HER-2, are ineffective.

Approximately 40,000 women are diagnosed with triple-negative breast cancer each year. There is no FDA-approved treatment and neither a targeted treatment nor a preferred standard chemotherapy regimen for relapsed triple-negative breast cancer patients exists.

There is substantial in vitro, in vivo and clinical evidence that it is cortisol's binding to GR – the receptor to which Korlym competitively binds – that allows triple-negative breast tumor cells to escape chemotherapy. Our research indicates that substantially more than half of patients with triple-negative breast cancer have tumors that express GR. We have developed a proprietary diagnostic test for identifying GR-positive tumors, using a laboratory that meets Clinical Laboratory Improvement Amendments (CLIA) federal regulatory standards. These standards require clinical laboratories to establish and document their own performance specifications for laboratory-developed tests to ensure accurate and precise results. Should we seek approval of Korlym or one of our selective GR antagonists to treat triple-negative breast cancer, we plan to include use of this assay in our requested label.

At the December 2013 San Antonio Breast Cancer Symposium, investigators from the University of Chicago reported the findings from their own clinical study of Korlym in combination with the chemotherapy drug nab-paclitaxel (Abraxane®) to treat triple-negative breast cancer in patients with relapsed, metastatic disease. Of the six patients in their study whose tumors were GR positive, five responded to treatment: two had a "complete response" (defined, according to the RECIST criteria, as the complete disappearance of the target tumor); two had a "partial response" (which RECIST defines as at least a 30 percent reduction in tumor size); and one had stable disease. All of the patients had previously failed chemotherapy with a taxane. (RECIST (Response Evaluation Criteria In Solid Tumors) is a set of published rules that define when tumors in cancer patients improve ("respond"), stay the same ("stabilize"), or worsen ("progress") during treatment. The criteria were published in February 2000 by an international collaboration including the European Organization for Research and Treatment of Cancer, the National Cancer

Institute of the United States, and the National Cancer Institute of Canada Clinical Trials Group.)

In January 2015, we completed the dose-finding portion of our Phase 1/2 study and have begun the efficacy phase of our study. This phase enroll 20 patients with relapsed, metastatic, GR-positive triple-negative breast cancer. These patients will receive one 300 mg Korlym tablet each day, combined with eribulin administered on days one and eight of a 21-day cycle. We expect to have efficacy results of our Phase 1/2 study by the end of 2015.

CORT125134 and Our Other Next-Generation Selective GR Antagonists

In 2003, we initiated a discovery research program to identify and patent selective GR antagonists. We have identified three distinct series of selective GR antagonists. These compounds, like Korlym, potently block GR but do not block the PR (progesterone), ER (estrogen), AR (androgen) or MR (mineralocorticoid) receptors. Both the United States Patent & Trademark Office (USPTO) and the European Patent Office (EPO) have issued to us composition of matter patents in each of the three series. One additional composition of matter patent application is pending. See “Business - Intellectual Property.”

Several of our new compounds have demonstrated positive results in animal or in vitro models in various indications, including but not limited to the following: for the prevention and reversal of alcohol dependence; amyotrophic lateral sclerosis (Lou Gehrig’s disease); Alzheimer’s disease; anti-psychotic-induced weight gain; fatty liver disease; breast, ovarian and prostate cancer (in combination with a chemotherapeutic agent); electroconvulsive-induced retrograde amnesia; metabolic syndrome; muscular dystrophy; obesity; prevention of glucocorticoid-induced neurological damage in premature infants; and post-traumatic stress disorder.

In September 2014, we commenced enrollment in a Phase 1 clinical study with CORT125134. This study will assess the safety, tolerability and pharmacokinetics of CORT125134 in healthy human volunteers. If Phase 1 results are positive, we plan to advance CORT125134 to Phase 2 for both an oncology indication and Cushing’s syndrome early next year. Another compound, CORT108297, has completed Phase 1 trials and we may explore its potential use in psychiatric and other central nervous system disorders.

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

See “Business – Intellectual Property.”

Proof-of-Concept Studies Conducted by Corcept

We have performed proof-of-concept studies using mifepristone and several of our proprietary, selective GR antagonists for the prevention and reversal of weight gain caused by the use of atypical anti-psychotic medications.

Mifepristone

In 2005, we announced results from two preclinical studies conducted in a rat model of olanzapine-induced weight gain. These studies demonstrated that mifepristone’s GR antagonist action has the potential to both reverse the weight gain associated with olanzapine and to prevent the weight gain associated with the initiation of treatment with olanzapine, which led to our studies in humans.

In 2007, we announced results of our human clinical proof-of-concept study evaluating the ability of mifepristone to mitigate weight gain associated with the administration of Eli Lilly’s Zyprexa (olanzapine). The results indicated a statistically significant reduction in weight gain in those subjects who took Zyprexa plus mifepristone compared to those who took Zyprexa plus placebo. Eli Lilly provided Zyprexa and financial support for this study. During 2009, we announced results from another proof-of-concept study evaluating the ability of mifepristone to mitigate weight gain associated with the administration of Johnson & Johnson’s Risperdal (risperidone). The results indicated a statistically significant reduction in weight gain in those subjects who took Risperdal plus mifepristone compared to those who took Risperdal plus placebo. Both Zyprexa and Risperdal are indicated for the treatment of schizophrenia and bipolar disorder.

In the study of mifepristone and Zyprexa, 57 lean, healthy men (body mass index of 25 or less) were randomized to receive either Zyprexa plus placebo (n=22), Zyprexa plus mifepristone (n=24) or mifepristone plus placebo (n=11). This study took place in an institutional setting where daily weights were recorded and a range of metabolic parameters were measured. In the two week study, subjects in the Zyprexa plus placebo group gained an average of 7.0 pounds and subjects in the Zyprexa plus mifepristone group gained an average of 4.4 pounds; which is a

statistically significant difference (p<.001). Subjects in the mifepristone plus placebo group gained an average of 4.4 pounds. The difference in weight gain trajectory was apparent in the first days of the study, reaching statistical significance during the first week. The increase in waist circumference, a surrogate for abdominal fat, in subjects who received Zyprexa plus placebo was also significantly greater than subjects who received Zyprexa plus mifepristone (p<.01). The study was not designed to enroll a sufficient number of patients to have statistical power to detect significant effects on metabolic measures; however, the effect of mifepristone in this model was greater than expected. In addition to the finding about waist circumference, notable additional non-statistically significant group differences were observed. Patients taking Zyprexa plus placebo experienced greater increases from baseline to end of study in both triglycerides and fasting insulin compared to patients taking Zyprexa plus mifepristone. No unexpected study drug related adverse events were observed. These results were published in Advances in Therapy in 2009.

In the study of mifepristone and Risperdal, 75 lean, healthy men (body mass index of 23 or less) were randomized to receive either Risperdal plus placebo (n=30), Risperdal plus mifepristone (n=30) or mifepristone plus placebo (n=15). This study also took place in an institutional setting where daily weights were recorded and a range of metabolic parameters were measured. In this four-week randomized double-blind controlled study, subjects in the Risperdal plus placebo group gained an average of 9.2 pounds, compared to a gain of 5.1 pounds in the Risperdal plus mifepristone group. This difference was statistically significant (p<0.0001). Additional important metabolic parameters, including fasting insulin, triglycerides and abdominal fat, as reflected by waist circumference, were also measured. The addition of mifepristone to Risperdal resulted in a statistically significant reduction in fasting insulin levels, triglyceride levels, and abdominal fat (as measured by waist circumference). Consistent with prior studies, mifepristone appeared to be well tolerated. These results were published in Obesity in 2010.

The combinations of Zyprexa and mifepristone or Risperdal and mifepristone are not approved for any indication. The purpose of these studies was to explore the hypothesis that GR antagonists would mitigate weight gain and other metabolic effects associated with antipsychotic medications. The group of medications sometimes referred to as “atypical antipsychotics,” including Zyprexa, Risperdal, Clozaril (clozapine) and Seroquel (quetiapine), are widely used to treat schizophrenia and bipolar disorder. All medications in this group are associated with treatment-emergent weight gain of varying degrees and carry a warning in the label relating to treatment-emergent hyperglycemia and diabetes mellitus.

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Our Proprietary Selective GR Antagonist, CORT108297

In January 2009, we announced results from two preclinical studies of our next-generation selective GR receptor antagonist, CORT108297, for the prevention and reversal of weight gain caused by olanzapine, a medication marketed by Eli Lilly as Zyprexa. Using the same experimental rat model used previously with mifepristone, the preclinical studies demonstrated that CORT 108297 (i) reversed and (ii) prevented the weight gain caused by olanzapine in rats. Eli Lilly provided olanzapine and funded the cost of the studies. The results of these two experiments replicated the findings from previous animal studies of mifepristone, and were also consistent with results from randomized trials conducted in humans. The results were published in the peer-reviewed journal, Diabetes Obesity and Metabolism in 2010. A third study in the rat further evaluated the dose response relationship of CORT108297 in preventing olanzapine induced weight gain with doses from 2 mg/kg to 20 mg/kg.

At the American Diabetes Association conference in 2009 there was a presentation of preclinical data from a study which demonstrated that CORT108297 suppresses body weight gain and improves insulin sensitivity in healthy mice fed a 60% fat diet and high sucrose liquid. In 2011, these study results were published in the peer-reviewed publication, The Journal of Nutrition and Metabolism.

Studies by Independent Investigators

We have collaborated with independent academic researchers investigating the utility of our proprietary selective GR antagonists in pre-clinical studies in a wide range of disorders, including Cushing's syndrome, alcoholism, post-traumatic stress disorder, Alzheimer's disease, amyotrophic lateral sclerosis (ALS), muscular dystrophy, the metabolic syndrome, ovarian cancer, castration-resistance prostatic cancer, fatty liver disease and triple-negative breast cancer.

We have also collaborated with researchers investigating the utility of mifepristone in pre-clinical and human proof-of-concept studies in a wide range of disorders, including alcoholism, post-traumatic stress disorder, Alzheimer's disease, central serous chorioretinopathy, triple-negative breast cancer, castration resistant prostatic cancer, and ovarian cancer.

Termination of Our Phase 3 Trial of Mifepristone to Treat Psychotic Depression

In May 2014, we discontinued our Phase 3 study of mifepristone, the active ingredient in Korlym, for the treatment of psychotic depression after the study's data monitoring committee informed us that the trial had failed to meet its primary endpoint – a rapid and sustained reduction in the patients' psychotic symptoms – with statistical significance. The committee based its conclusion on an analysis of data from the first 226 patients to enroll in the study. The committee also advised us that continuing the study to its full enrollment of 450 patients would be unlikely to generate a statistically significant result. We terminated it to redeploy resources to more promising programs.

Clinical Trial Agreements

Many of our clinical trials are conducted through the use of clinical research organizations (CROs.) At our request, these organizations oversee clinical trials at various institutions to test the safety and efficacy of our product candidates for the targeted indications. Our Phase 1/2 trial for the study of mifepristone in the treatment of triple-negative breast cancer is being conducted under an agreement with Chiltern International Limited (Chiltern), formerly known as Ockham Development Group Inc. This agreement may be terminated by us with 60 days notice to Chiltern or sooner if the parties agree to do so. Our Phase 1 trial of CORT125134 is being conducted under an agreement with Quotient Clinical Limited and may be terminated by us with 30 days notice to Quotient.

Research and Development

We incurred $18.4 million, $20.5 million and $14.1 million of research and development expenses in the years ended December 31, 2014, 2013 and 2012, respectively, which accounted for 34%, 39% and 36% of our total operating expenses in these respective fiscal years. For a further discussion, see Part II, Item 7, Management's Discussion and Analysis of Financial Conditions and Results of Operations – Results of Operations.

Manufacturing Korlym

As a drug discovery, development and commercialization company, we intend to continue to utilize our financial resources to commercialize Korlym and advance other product candidates rather than diverting resources to establishing our own manufacturing facilities.

We intend to continue to rely on experienced contract manufacturers to produce our product candidates. We have entered into a manufacturing agreement with one contract manufacturer, Produits Chimiques Auxiliaires et de Synthese SA (PCAS), to produce the active pharmaceutical ingredient (API) for Korlym. The FDA approved our commercial use of material produced by PCAS as part of

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our NDA submission for Korlym. In March 2014, we entered into a new long-term manufacturing and supply agreement with PCAS for the manufacture of mifepristone, the active pharmaceutical agreement in Korlym. We have agreed to purchase a minimum percentage of our mifepristone requirements from PCAS; the amount of the commitment will depend on our future needs. The initial term of the agreement is five years, with an automatic extension of one year unless either party gives 12 months' prior written notice that it does not want an extension. We have the right to terminate the agreement if PCAS is unable to manufacture the product for a consecutive nine-month period.

We have one tablet manufacturer for Korlym – AAI Pharma Services Corp. (AAI) - which was approved by the FDA in November 2012 for the manufacture of our commercial tablets. In April 2014, we entered into a new manufacturing agreement with AAI for the manufacture and package Korlym tablets. The initial term of this agreement is a period of three years, with consecutive automatic extensions of two years unless either party gives written notice - in the case of AAI Pharma, 18 months prior to the end of the applicable term, and in our case 12 months prior to the end of the applicable term - that it does not want such an extension. We have the right to terminate the agreement if AAI Pharma is unable to manufacture the product for a consecutive four-month period or if the product is withdrawn from the market. There are no minimum purchase obligations under this agreement.

Competition for Korlym

Korlym competes with established treatments, including surgery, radiation and approved medicines prescribed "off-label." Korlym also competes with Novartis' drug, Signifor® (pasireotide) Injection, which the FDA approved in December 2012 for the treatment of adult patients with Cushing's disease (a subset of Cushing's syndrome) who are not candidates for pituitary surgery or for whom surgery did not work. In April 2012, Signifor received marketing approval in the EU. It has Orphan Drug designation in the United States and the EU. Signifor is a somatostatin analogue that inhibits ACTH production by the pituitary, which leads to reduced cortisol production in some patients. In the Phase 3 study that served as the basis for Novartis' NDA, the drug normalized cortisol levels in 26 percent of patients. Sixty-seven percent of patients developed hyperglycemia or diabetes. Signifor must be taken twice daily, by injection. Novartis has also announced that it is undertaking an investigational study of an experimental compound (LC1699) to determine whether it can safely reduce the level of urinary free cortisol in patients with Cushing's disease.

Korlym may also experience competition from compounds under development for Cushing's syndrome. We are aware that Laboratoire HRA Pharma (HRA) has received an Orphan Drug Designation in the United States and EU for the use of mifepristone to treat a subtype of Cushing's syndrome. HRA began a Phase 2 trial in Europe and the United States for this indication, which has been terminated. We are also aware that Exelgyn Laboratories, which operates as a subsidiary of Medi Challenge (Pty) Ltd., received Orphan Drug Designation for endogenous Cushing's syndrome in the EU, but they have stated that they have not yet conducted any clinical trials.

Many colleges, universities and public and private research organizations are also active in the human health care field. While these entities focus on education, they may develop or acquire proprietary technology that we may require for the development of our product candidates. We may attempt to obtain licenses to this proprietary technology.

Our ability to compete successfully will be based on our ability to develop proprietary products, attract and retain scientific personnel, obtain patent or other protection for our product candidates, obtain required regulatory approvals and manufacture and successfully market Korlym and our future products either alone or through outside parties.

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 previously 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 and EU, (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’s syndrome and (4) our method of use patents described below.

Oncology

Under an agreement with University of Chicago, we have licensed exclusive rights to U.S. Patent No. 8,710,035 “Methods and Compositions Related to Glucocorticoid Receptor Antagonists and Breast Cancer.”

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In the event any products are commercialized under any of the claims contained in this patent, we would be required to make milestone payments and pay royalties to the University of Chicago on sales of such products. If the University of Chicago were to terminate any of our exclusive licenses due to breach of the license on our part, we would not be able to commercialize mifepristone for the treatment of triple-negative breast cancer.

Proprietary GR Antagonists

We also own issued U.S. patents for the use of GR antagonists in the treatment of mild cognitive impairment, the treatment of weight gain following treatment with antipsychotic medication, the prevention and treatment of stress disorders, improving the therapeutic response to ECT, the treatment of delirium, the treatment of catatonia, the treatment of gastroesophageal reflux disease, the treatment of migraine headaches, the treatment of psychosis with Interferon-Alpha therapy, the treatment of neurological damage in premature infants, the treatment of diseases using combination steroid and GR antagonist therapy and for inhibiting cognitive deterioration in adults with Down's Syndrome. We also own a method of use patent for optimizing mifepristone levels in plasma serum in patients suffering from mental disorders. The expiration dates of these patents and their foreign counterparts range from 2020 to 2034.

In addition, we have three U.S. method-of-use applications covering certain GR antagonists, including the treatment of:

- patients suffering from mental disorders by optimizing mifepristone absorption;
- muscular dystrophy; and
- amyotrophic lateral sclerosis (ALS).

The approximate expiration dates of the patents that could issue from these applications and their foreign counterparts range from 2029 to 2032.

We have eight U.S. composition of matter patents containing claims relating to three distinct series of novel selective GR antagonists. Four of these patents have issued in Europe, with applications for two more 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. However, 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 will

not successfully challenge or circumvent our patents if they are issued.

Although eight of our patents have claims directed to the composition of compounds, we do not have a patent with claims directed to the composition of mifepristone. Our rights under our issued patents related to mifepristone cover only the use of that compound in the treatment of specific diseases.

Psychotic Depression

Under an agreement with Stanford University, we have licensed exclusive rights to the following issued U.S. patents and any corresponding foreign patents:

U.S. Patent Number	Subject Matter	Expiration Date
6,150,349	Use of GR antagonists in the treatment of psychotic major depression	October 5, 2018
6,362,173	Use of GR antagonists in the treatment of cocaine-induced psychosis	October 5, 2018
6,369,046	Use of GR antagonists in the treatment of early dementia	February 4, 2019

The corresponding foreign patents expire in 2018.

We are required to make milestone payments and pay royalties to Stanford University on sales of products commercialized under any of the above patents. If Stanford University were to terminate any of our exclusive licenses due to breach of the license on our part, we would not be able to commercialize mifepristone for the treatment of the psychotic features of psychotic depression, cocaine-induced psychosis or early dementia.

Competition

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 we infringe on the products or proprietary rights of others. If it is determined that our drug candidates infringe on others' patent rights,

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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 to any third party other than Stanford University and The University of Chicago.

License Agreements

Under our exclusive license agreement with Stanford University to patents covering the use of mifepristone to treat the psychotic features of psychotic depression, early dementia and cocaine-induced psychosis, we are required to make milestone payments and pay royalties to Stanford University on sales of products commercialized under any of the above patents. These milestone payments are creditable against future royalties. This license agreement expires upon expiration of the related patents or upon notification by us to Stanford. See "Intellectual Property."

In November 2013, we licensed from the University of Chicago exclusive rights to the University's U.S. Patent No. 8,710,035 "Methods and Compositions Related to Glucocorticoid Receptor Antagonists and Breast Cancer". In exchange for the license, we have agreed to pay the University customary milestone fees and royalties on sales of any products commercialized under any of the claims. We have recently begun a Phase 1 study of mifepristone in combination with the chemotherapy drug eribulin in the treatment of triple-negative breast cancer.

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 will 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 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 or biologic's intended use; and, in the case of a new drug, approval by the FDA of an NDA. The process of complying with these and other federal and state statutes and regulations in order to obtain the necessary approvals and subsequently complying with 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, maximum tolerated dose and pharmacokinetics of the product candidate in human volunteers.
- Phase 2. Clinical trials are conducted with groups of patients afflicted with a specific disease to determine preliminary efficacy, optimal dosages and expanded evidence of safety.
- Phase 3. Large-scale, multi-center, comparative trials are conducted with patients afflicted with a target disease to establish the overall risk/benefit ratio of the drug and to provide enough data to demonstrate with substantial evidence the efficacy and safety of the product, as required by the FDA.

The FDA and the Institutional Review Boards closely monitor the progress of each of the three phases of clinical trials that are conducted in the United States and may reevaluate, alter, suspend or terminate the testing at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable health risk. The FDA may also require that additional studies be conducted, such as studies demonstrating that the drug being tested does not cause cancer.

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 an NDA for approval to commence commercial sales. The FDA reviews all NDAs submitted before it accepts them for filing. The FDA 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 regulatory approval criteria. 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 6 months for priority review if a sponsor shows

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that its drug candidate provides a significant improvement 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. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-approval regulatory standards is not maintained. The drug developer must submit periodic reports to the FDA. Adverse experiences with the product must be reported to the FDA and could result in the imposition of marketing restrictions through labeling changes or product removal. Product approvals may be withdrawn if problems with safety or efficacy occur after the product reaches the marketplace. 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 used to manufacture drugs are subject to periodic inspection by the FDA and other authorities where applicable, and must comply with current Good Manufacturing Practices regulations (cGMP). Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product or voluntary recall of a product.

With respect to post-approval product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among others, standards and regulations for direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving the Internet. The FDA has very broad enforcement authority under the Federal Food, Drug and Cosmetic Act, and failure to abide by these 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 investigations and prosecutions.

In addition to studies requested by the FDA after approval, a drug developer may conduct other studies to explore use of the approved compound for treatment of new indications. The purpose of these trials and studies and related publications is to broaden the application and use of the drug and its acceptance in the medical community. Data supporting the use of a drug for these new indications must be submitted to the FDA in a new or supplemental NDA that must be approved by the FDA before the drug can be marketed for the new indications.

Orphan Drug Designation. We have received Orphan Drug designation for Korlym for the treatment of endogenous Cushing's syndrome in both the United States and the EU. In the United States, Orphan Drug designation provides special status to a product to treat a rare disease or condition providing that the product meets certain criteria. 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 by the applicable regulatory authority.

Benefits of Orphan Drug Designation in the EU are similar to those in the U.S., but include ten years of marketing exclusivity in all 28 Member States, free scientific advice during drug development, access to a centralized review process and a reduction or complete waiver of fees levied by the European Medicines Agency (EMA).

Approvals outside the United States. Other than applying for and receiving Orphan Drug Designation for Korlym for Cushing's syndrome in the EU and submitting our MAA for that indication, we have not started the regulatory approval process in any jurisdiction other than the United States. We, or our potential future partners, will have to complete an approval process similar to the U.S. approval process in foreign target markets for our product candidates before we can commercialize our product candidates in those countries. The approval procedure and the time required for approval vary from country to country and can involve additional testing. 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 to us.

Coverage and Reimbursement. Sales of our products will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health care programs, 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.

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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 throughout the country, for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected 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 a recent trend of 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 are required to and submit reports

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.

Executive Officers

The following table sets forth, as of March 3, 2015, information about our executive officers:

Name	Age	Position
Joseph K. Belanoff, M.D.	57	Chief Executive Officer, President and Director
G. Charles Robb	52	Chief Financial Officer and Secretary
Steven Lo	47	Senior Vice President , Oncology
Anne M. LeDoux	67	Vice President, Controller and Chief Accounting Officer

Joseph K. Belanoff, M.D. is a co-founder of our company, has served as a member of our Board and as our Chief Executive Officer since 1999 and as our President since January 2014. Dr. Belanoff is currently a clinical faculty member and has held various positions in the Department of Psychiatry and Behavioral Sciences at Stanford University since 1992. Dr. Belanoff received his B.A. from Amherst College and his M.D. from Columbia University’s College of Physicians & Surgeons. Our Board selected Dr. Belanoff

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to serve as a director because, as our Chief Executive Officer, he brings expertise and knowledge regarding our business and operations to our Board of Directors. Dr. Belanoff also has expertise in clinical medicine and psychopharmacology.

G. Charles Robb has served as Chief Financial Officer since September 2011 and as our Secretary since January 2014. Mr. Robb has more than 25 years of experience in executive management, operations and finance. From April 2005 through August 2011 Mr. Robb served as the Senior Vice President of Operations, Administration and Finance of Fitness Anywhere, Inc. (FAI), a private fitness equipment and training company with operations in the United States, Europe and Asia. From 2003 to 2005, Mr. Robb was engaged in the private practice of law. From 2000 to 2002 he was Senior Vice President of Citadon, Inc. He also held positions in business development for Normura Asset Capital Corporation from 1998 to 1999 and in sales and marketing for Legal Research Network, Inc. from 1996 to 1998. From 1992 to 1996 Mr. Robb practiced law at Howard, Rice, Nemerovski, Canady, Falk & Rabkin. Mr. Robb earned a B.A. in English and Political Philosophy from Yale and a J.D. from Harvard Law School, where he was a member of the Harvard Law Review.

Steven Lo, our Senior Vice President, Oncology, joined us as Vice President of Commercial Operations in September 2010 to develop our program for the commercialization of Korlym. In November 2013, Mr. Lo was promoted to the position of Senior Vice President and Chief Commercial Officer and, in February 2015, he took responsibility for planning the potential commercialization of our product into the treatment of oncology. Mr. Lo has more than 20 years of commercial experience in the pharmaceutical and biotechnology industry. From 1997 to 2010, Mr. Lo held various positions in marketing, sales and managed markets at Genentech, Inc., a biotechnology company that became a member of the Roche Group in March 2009, most recently as Franchise Head, leading that company's endocrinology marketing and sales organization. Mr. Lo received his B.S. degree from the University of California, Davis and his Master of Health Administration degree from the University of Southern California.

Anne M. LeDoux, our Vice President, Controller and Chief Accounting Officer, joined us as Controller in 2004 and was promoted to her current position in April 2007. Ms. LeDoux has over 25 years of financial and accounting management experience with public pharmaceutical and biotechnology companies. Prior to joining Corcept in 2004, Ms. LeDoux served in various financial positions at Aviron, Roche Biosciences and Syntex Corporation. She was also Vice President and Chief Financial Officer at the Northern California Health Center and Vice President, Finance for the Children’s Hospital of San Francisco. Ms. LeDoux is a Certified Public Accountant with over 13 years of experience in public accounting, primarily at Coopers and Lybrand. Ms. LeDoux received her Bachelor of Arts degree in Business from the University of Massachusetts and a law degree from Western New England College, School of Law.

Employees

We are managed by a core group of experienced pharmaceutical executives with a track record of bringing new drugs to market. To facilitate advancement of development programs, we also enlist the expertise of associates and advisors with extensive pharmaceutical development experience.

As of December 31, 2014, we had 50 full-time employees, seven part-time employees, a contracted sales force of 21 sales representatives and 14 long-term contract staff. Three of our employees have M.D.s. We consider our employee relations to be good. None of our employees is covered by a collective bargaining agreement.

General

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. 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.

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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 you decide to invest 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 trading 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 also become important factors that may harm our business. Except as required by law, we undertake no obligations to update any risk factors.

Risks Related to the Commercialization of Korlym

and Development of Mifepristone and Our Proprietary GR Antagonists

We depend heavily on the success of Korlym, which we began to sell in the United States in April 2012. If we are unable to increase revenues of Korlym to the levels that 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 revenues and achieve profitability will be solely dependent on the successful commercialization of Korlym. Many factors could harm our efforts to commercialize Korlym, including:

- an inability to generate meaningful revenue due to low product usage, inadequate insurance coverage and reimbursement or other factors;
- competition from Novartis's Signifor and from other companies with greater financial, technical and marketing resources than ours;
- an inability to manufacture Korlym or the active ingredient in Korlym in commercial quantities and at an acceptable cost;
- the cost-effectiveness of Korlym and the availability of third-party insurance coverage and reimbursement, in particular from government payors such as Medicare and Medicaid, for patients using Korlym;
- political concerns relating to other uses of mifepristone, or RU-486, that could limit the market acceptance of Korlym;
- negative, inconclusive or otherwise unfavorable results from any post-approval studies we conduct;
- previously unknown, serious side effects that may be identified; and
- rapid technological change making Korlym obsolete.

Even if we commercialize Korlym successfully, we cannot predict the rate at which success will occur.

As our current ability to generate revenue is wholly dependent upon the commercialization of Korlym, its rate of sale will directly and materially affect our results of operations. There are inherent difficulties in predicting the volumes of Korlym that will be sold, which are heightened by our limited experience commercializing Korlym or other products. Failure of our revenue to meet the expectations of investors could cause our stock price to decline. See also the discussion below under "If our operating and financial performance in any given period does not meet the guidance that we provide to the public, estimates published by research analysts or other investor expectations, our stock price may decline."

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

Even though the FDA has approved Korlym, physicians may not adopt it as a treatment for their eligible patients. Physicians will prescribe Korlym only if they determine, based on experience, clinical data, side effect profiles and other factors, that it is preferable to other products or treatments currently in use, even if those products are not approved for Cushing's syndrome. Because Cushing's 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 a newer treatment, such as Korlym, even with clinical trial results that suggest it may be a compelling treatment for them to consider.

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

- the effectiveness of Korlym, including any side effects, as compared to alternative treatment methods;
- the rate of adoption of Korlym by physicians and by target patient populations;
- the possible preference of some physicians for more familiar, long-standing off-label treatments for Cushing's syndrome or for Novartis' drug, Signifor, for the treatment of Cushing's disease;