

CORCEPT THERAPEUTICS INC

Form 10-K

March 26, 2010

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2009

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)

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Delaware

(State or other jurisdiction of incorporation or organization)

77-0487658

(I.R.S. Employer Identification No.)

149 Commonwealth Drive

Menlo Park, CA 94025

(Address of principal executive offices, including 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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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 approximately \$14,000,000 as of June 30, 2009 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.

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On March 15, 2010 there were 62,703,717 shares of common stock outstanding at a par value \$.001 per share.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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PART I

This Annual Report on Form 10-K, or 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, seeks and similar words are used to identify 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:

the progress of our research, development, clinical programs and the timing of regulatory activities;

our estimates of the dates by which we expect to report results of our clinical trials and the anticipated results of these trials;

the timing of market introduction of CORLUX® and future product candidates, including CORT 108297;

our ability to market, commercialize and achieve market acceptance for CORLUX or other future product candidates, including CORT 108297;

uncertainties associated with obtaining and enforcing patents;

our estimates for future performance; and

our estimates regarding our capital requirements and our needs for, and ability to obtain, additional financing.

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).

ITEM 1. BUSINESS

Overview

We are a pharmaceutical company engaged in the discovery and development of drugs for the treatment of severe metabolic and psychiatric disorders. Our focus is on those disorders that are associated with a steroid hormone called cortisol. Elevated levels and abnormal release patterns of cortisol have been implicated in a broad range of human disorders. Since our inception in May 1998, we have been developing our lead product, CORLUX, a potent glucocorticoid receptor II (GR-II) antagonist that blocks the activity of cortisol. We have also discovered three series of novel selective GR-II antagonists and have moved one of these compounds, CORT 108297, into development.

Cushing's Syndrome. 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.

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The Investigational New Drug application (IND) for the evaluation of CORLUX for the treatment of Cushing's Syndrome was opened in September 2007. The United States Food and Drug Administration (FDA) has indicated that our single 50-patient open-label study may provide a reasonable basis for the submission of a New Drug Application (NDA) for this indication. We expect to complete enrollment in this Phase 3 study in April, as the requisite 50 patients have now been dosed or identified. We expect to announce results of this study in the fourth quarter of this year and to submit our NDA for the use of CORLUX in Cushing's Syndrome by year-end 2010.

In July 2007, we received Orphan Drug Designation from the FDA for CORLUX for the treatment of endogenous Cushing's Syndrome. 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 in the United States. Drugs that receive Orphan Drug Designation obtain seven years of marketing exclusivity 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.

Psychotic depression. We are developing CORLUX for the treatment of the psychotic features of psychotic major depression under an exclusive patent license from Stanford University. Psychotic major depression will hereafter be referred to as psychotic depression. The FDA has granted fast track status to evaluate the safety and efficacy of CORLUX for the treatment of the psychotic features of psychotic depression.

In March of 2008, we began enrollment in Study 14, our ongoing Phase 3 trial in psychotic depression. The protocol for this trial incorporates what we have learned from our three previously completed Phase 3 trials. It attempts to address the established relationship between increased drug plasma levels and clinical response and to decrease the random variability observed in the results of the psychometric instruments used to measure efficacy. In one of the previously completed Phase 3 trials, Study 06, we prospectively tested and confirmed that patients whose plasma levels rose above a predetermined threshold statistically separated from both those patients whose plasma levels were below the threshold and those patients who received placebo; this threshold was established from data produced in earlier studies.

As expected, patients who took 1200 mg of CORLUX in Study 06 developed higher drug plasma levels than patients who received lower doses. Further, there was no discernable difference in the incidence of adverse events between patients who received placebo in Study 06 and those who received 300 mg, 600 mg or 1200 mg of CORLUX in that study. Based on this information, we are using a CORLUX dose of 1200 mg once per day for seven days in Study 14.

In addition, we also are utilizing a third party centralized rating service to independently evaluate the patients for entry into the study as well as to evaluate their level of response throughout their participation in the study. We believe the centralization of this process will improve the consistency of rating across clinical trial sites and reduce the background noise that was experienced in earlier studies and is endemic to many psychopharmacologic studies. We believe that this change in dose, as well as the other modifications to the protocol, should allow us to demonstrate the efficacy of CORLUX in the treatment of the psychotic symptoms of psychotic depression. In March 2009, we announced that, in order to conserve financial resources, we were scaling back our planned rate of spending on this trial and extended the timeline for its completion. As of early July 2009, we had completed the implementation of this strategy, which included reducing the number of clinical sites to eight.

Antipsychotic-induced Weight Gain Mitigation. In 2005, we published the results of studies in rats that demonstrated that CORLUX both reduced the weight gain associated with the ongoing use of olanzapine and mitigated the weight gain associated with the initiation of treatment with olanzapine (the active ingredient in Zyprexa). This study was paid for by Eli Lilly and Company (Eli Lilly).

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During 2007 we announced positive results from our clinical proof-of-concept study in lean healthy male volunteers evaluating the ability of CORLUX to mitigate weight gain associated with the use of Zyprexa. The results show a statistically significant reduction in weight gain in those subjects who took Zyprexa plus CORLUX compared to those who took Zyprexa plus placebo. Also, the addition of CORLUX to treatment with Zyprexa had a beneficial impact on secondary metabolic measures such as fasting insulin, triglycerides and abdominal fat, as indicated by waist circumference. Eli Lilly provided Zyprexa and financial support for this study. In January 2009 we announced positive results from a similar proof-of-concept study evaluating the ability of CORLUX to mitigate weight gain associated with the use of Johnson & Johnson's Risperdal. This study, which began in 2008, confirmed and extended the earlier results seen with CORLUX and Zyprexa, demonstrating a statistically significant reduction in weight and secondary metabolic endpoints of fasting insulin, triglycerides and abdominal fat, as indicated by waist circumference. The results from the study of CORLUX and Risperdal were presented at several scientific conferences, including the American Diabetes Association meeting in June 2009.

The combination of Zyprexa or Risperdal and CORLUX is not approved for any indication. The purpose of these studies was to explore the hypothesis that GR-II antagonists, such as CORLUX and our next generation of selective GR-II antagonists, would mitigate weight gain associated with antipsychotic medications. The group of medications known as second generation antipsychotic medication, including Zyprexa, Risperdal, Clozaril and Seroquel, 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 their labels relating to treatment emergent hyperglycemia and diabetes mellitus.

We have completed IND enabling work with CORT 108297, which included preclinical studies in the rat in antipsychotic induced weight gain, diet induced weight gain and insulin sensitivity. In February 2010, we initiated a Phase 1 study to evaluate the tolerability of this compound in healthy volunteers. CORT 108297 is the lead compound from our three series of selective GR-II antagonists. Preclinical studies of CORT 108297, presented at scientific conferences during 2009, demonstrated a statistically significant mitigation in weight gain and other metabolic effects when added to olanzapine, the active ingredient in Eli Lilly's medication Zyprexa. CORT 108297 also demonstrated the potential to mitigate weight gain caused by consumption of a high fat, high sucrose diet and improve insulin sensitivity in a preclinical mouse model.

Additional Indications. We have discovered and patented three series of next-generation selective GR-II receptor antagonists. As discussed above, the lead compound from these series, CORT 108297, is being developed for the prevention of weight gain induced by antipsychotic medication and is currently in a Phase 1 trial. There are numerous additional compounds in these three series that may be developed for weight gain mitigation or other diseases in which excess cortisol plays a role. The role of excess cortisol has been well established and documented in the scientific literature in diabetes, obesity, hypertension, osteoporosis, glaucoma, Alzheimer's disease and various other neurodegenerative diseases, in addition to antipsychotic-induced weight gain.

The Role of Cortisol in Disease

Cortisol is a steroid hormone that plays a significant role in the way the body reacts to stressful conditions and is essential for survival. Cortisol 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 edema, hypertension, fatigue and impaired glucose tolerance.

Elevated levels and abnormal release patterns of cortisol have also been linked to a broad range of metabolic and psychiatric conditions, such as weight gain, diabetes, hypertension, mood changes, psychosis and cognitive impairment.

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While excess release of cortisol may play a role in numerous diseases, Cushing's Syndrome is the fundamental disease of excess cortisol, as patients have tumors that produce excess levels of the hormone cortisol or its precursor, adrenocorticotropic hormone (ACTH). Sometimes called hypercortisolism, the body's exposure to high levels of cortisol can result in weight gain, diabetes, hypertension, infections, severe fatigue and psychosis.

Many studies have shown that patients with psychotic depression have elevated levels and abnormal release patterns of cortisol. This abnormal cortisol activity is not usually present in patients with nonpsychotic depression. More than 20 years ago, one of our scientific co-founders postulated that elevated levels of cortisol in patients with psychotic depression lead to elevated levels of dopamine, an important chemical substance found in the brain. Elevated levels of dopamine have been implicated in both delusional thinking and hallucinations. This hypothesis led to the concept that, by regulating the level and release patterns of cortisol, one could normalize dopamine levels in the brain, which may, in turn, ameliorate the symptoms of psychotic depression. In addition to cortisol's effect on dopamine levels, research has shown that prolonged elevated cortisol may also play a direct role in causing the symptoms of psychotic depression.

The challenge in regulating levels of cortisol, however, is that it is needed for natural processes in the human body. Destroying the ability of the body to make cortisol or to drastically reduce its presence would result in serious detrimental effects. To have a viable therapeutic effect, a compound must be able to selectively modulate cortisol effects.

Glucocorticoid Receptor Antagonists

Cortisol is produced by the adrenal glands and is carried via the bloodstream to the brain, where it directly influences neuronal function. In the brain, cortisol binds to two receptors, Glucocorticoid Receptor I and Glucocorticoid Receptor II, also known as GR-I and GR-II. GR-I 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-II for cortisol and its binding sites are filled with cortisol nearly all the time. In general, GR-II binding sites do not fill until levels of cortisol become elevated. Short-term activation of GR-II has benefits, which include helping the individual to be more alert and better able to function under stressful conditions. Long-term activation of GR-II, however, has been shown to have significant toxicity and appears to be linked to multiple metabolic and psychiatric disease states, such as Cushing's Syndrome and psychotic depression. The action of cortisol can be moderated by the use of blockers, or antagonists, that prevent the binding of the hormone to its receptors. These antagonists, referred to as glucocorticoid, or cortisol, receptor antagonists, may prevent the undesirable effects of elevated levels and abnormal release patterns of cortisol.

CORLUX, also known as mifepristone, works by selectively blocking the binding of cortisol to GR-II; CORLUX is neither an antagonist nor agonist of GR-I. It also blocks the progesterone receptor (PR). Because of its selective affinity, we believe that CORLUX can have a therapeutic benefit by modulating the effects of abnormal levels and release patterns of cortisol without compromising the necessary normal functions of cortisol. We have also discovered three series of additional compounds, one of which includes our lead candidate CORT 108297, which, like CORLUX, potentially block the GR-II receptor, but, unlike CORLUX, do not block the progesterone receptor.

Overview of Cushing's Syndrome

Endogenous Cushing's Syndrome is caused by prolonged exposure of the body's tissues to high levels of the hormone cortisol due to a variety of pathologic conditions. In endogenous Cushing's Syndrome, the production of excess cortisol is stimulated or directly produced by pituitary, adrenal or ectopic tumors. Cushing's Syndrome is an orphan indication which most commonly 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 over 3,000 new patients in the United States. An estimated 20,000 patients in the United States have been diagnosed with Cushing's

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Syndrome. Symptoms vary, but most people 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. There is no FDA-approved treatment for Cushing's Syndrome.

Current Treatments for Cushing's Syndrome

Current treatment depends on the specific cause of cortisol excess and may include surgery, radiation and chemotherapy. Patients sometimes may be treated with drugs that prevent the body from producing cortisol. Approximately 70% of the patients diagnosed with Cushing's Syndrome are candidates for surgery. Depending on the type of tumor there are varying rates of success and complications related to removing the tumor. If the tumor is successfully removed in its entirety, the patient is essentially cured and will not require additional treatment for Cushing's Syndrome. However, in approximately half of the patients, it is clear that surgery is not successful or, while surgery may appear to be successful initially, the patient later relapses. These patients currently have limited treatment options.

CORLUX for Cushing's Syndrome

CORLUX represents a potentially attractive treatment option with the potential for long-term oral dosing. CORLUX is a GR-II antagonist that appears to mitigate the effects of the elevated levels of cortisol in patients suffering from Cushing's Syndrome. We intend for CORLUX to be a once-daily chronic treatment in this indication. Mifepristone, the active ingredient in CORLUX, in addition to blocking GR-II, blocks the progesterone receptor and has been approved by the FDA for termination of early pregnancy.

We believe that CORLUX may significantly reduce a broad range of symptoms typically associated with Cushing's Syndrome. These symptoms can include weight gain, diabetes, hypertension, poor tissue quality, fatigue and psychosis. Cushing's Syndrome has a five-year 50% mortality rate if left untreated.

The FDA has granted Orphan Drug Designation for CORLUX for the treatment of endogenous Cushing's Syndrome. Orphan drugs receive seven years of marketing exclusivity from the date of 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.

CORLUX for Cushing's Syndrome Clinical Experience

There have been reports in the scientific literature of more than 40 Cushing's Syndrome patients who have been treated with mifepristone, the active ingredient in CORLUX. The clinical benefit supported by these data served as the rationale for our IND for CORLUX and design of our Phase 3 trial. While there have been no formal trials completed, the published results of the treatment of Cushing's Syndrome patients with mifepristone include improvement in glucose tolerance and hemoglobin A1C levels, blood pressure, depression and psychosis, and improvement in the patient's general quality of life.

CORLUX for Cushing's Syndrome Phase 3 Study

We are conducting a Phase 3 trial with CORLUX for the treatment of endogenous Cushing's Syndrome. The IND for the evaluation of CORLUX for the treatment of Cushing's Syndrome was opened in September 2007. We are conducting a single 50-patient open-label study, in which patients' dose is titrated to clinical benefit, and endpoints are focused on improvement in glucose tolerance and blood pressure, as well as broader measures of patient outcomes. The FDA has indicated that this trial may provide a reasonable basis for the submission of an NDA for this indication. We expect to complete enrollment in this Phase 3 study in April, as the requisite 50 patients have now been dosed or identified, and expect to announce results of this study in the fourth quarter of 2010.

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The primary endpoint in the trial is *either* 1) improvement in glucose tolerance (as measured by the area under the curve of an oral glucose tolerance test) at 24 weeks relative to baseline, *or* 2) if a patient is not glucose intolerant at baseline, improvement in diastolic blood pressure at 24 weeks relative to baseline. A patient in the glucose tolerance group is considered a responder if there is a 25% or greater improvement in the area under the curve of a standard oral glucose tolerance test over the 24-week course of the study. A patient in the hypertension group is considered a responder if there is a 5 millimeter or greater drop in diastolic blood pressure at 24 weeks relative to baseline. If a sufficient number of patients in *either* group are responders (such that the lower limit of the exact one-sided 95% binomial confidence interval for the responder rate is greater than 20%, or approximately 35% of the patients are responders, depending on the number of patients in each group) then the trial will have met its primary endpoint. The key secondary endpoint in the trial, global clinical improvement, is designed to capture the broader clinical benefit of CORLUX in this patient population.

Additional Trials and Preclinical Studies

In support of our planned NDA submission, we are conducting a long-term extension study in patients who completed the Phase 3 trial to assess safety of chronic dosing. We are conducting several small trials to evaluate how the drug acts on the human body, how the human body acts on the drug and the drug's safety. In addition to our clinical trials, we have completed a standard 12-month toxicology study in dogs, a carcinogenicity study in rats, and a carcinogenicity study in mice. These studies are designed to meet FDA requirements and the guidelines of an international regulatory body called the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. We anticipate completing all of the additional trials required for our NDA submission for CORLUX for the treatment of Cushing's Syndrome by the time of completion of our Phase 3 efficacy study.

Overview of Psychotic Depression

Psychotic depression is a serious psychiatric disease in which a patient suffers from severe depression accompanied by delusions, hallucinations or both. These psychotic features typically develop after the onset of a depressed mood, but may develop concurrently as well. Once psychotic symptoms occur, they usually reappear with each subsequent depressive episode. Of particular importance, when the patient's mood returns to normal the psychosis also resolves.

Data from the National Institutes of Mental Health published in 2005 indicate that depressive disorders affect an estimated 9.5% of adults in the United States, or about 19 million people each year. Of these 19 million people, many published studies show that approximately 15-20%, or about three million people, have psychotic depression. Most patients with psychotic depression suffer their first episode of major depression between the ages of 30 and 40 and the majority will experience more than one episode in their lifetime. People with psychotic depression are approximately 70 times more likely to commit suicide in their lifetime than the general population and often require lengthy and expensive hospital stays.

Current Treatments for Psychotic Depression

There are two treatment approaches for psychotic depression currently used by psychiatrists: electroconvulsive therapy ECT and combination drug therapy, which is a combination of antidepressant and antipsychotic medication. Neither of these treatments has been approved by the FDA for psychotic depression and both approaches almost always have a slow onset of action, which may result in lengthy and costly hospitalization. Each of these treatments can have debilitating side effects. Of the two treatments, ECT is generally considered to be more effective.

ECT involves passing an electrical current through the brain until the patient has a seizure. At least 100,000 patients receive ECT each year in the United States, with each patient requiring approximately six to twelve procedures over a period of three to five weeks.

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Combination drug therapy is an alternative treatment for psychotic depression that involves taking antipsychotic drugs such as olanzapine, haloperidol or chlorpromazine in combination with antidepressant drugs, such as fluoxetine, imipramine or venlafaxine. Patients on combination drug therapy often require three weeks or more to show improvement in their symptoms and treatment can take months before the symptoms are resolved entirely. Antipsychotic drugs can cause significant adverse side effects, including weight gain, diabetes, sedation, permanent movement disorders and sexual dysfunction.

CORLUX for the Psychotic Features of Psychotic Depression

We are also developing CORLUX as an oral medication to treat the psychotic features of psychotic depression. As a GR-II antagonist, CORLUX appears to mitigate the effects of the elevated and abnormal release patterns of cortisol in patients suffering from psychotic depression. We intend CORLUX to be a once-daily treatment given to patients with psychotic depression over 7 consecutive days in a controlled setting, such as a hospital or physician's office.

We believe that CORLUX may significantly reduce psychotic symptoms of psychotic depression in many patients within one week and allow patients to be more easily maintained on antidepressant therapy alone without the need for ECT or antipsychotic medication. We believe that CORLUX may be superior to currently available treatments because we believe that CORLUX will enable patients with psychotic depression to improve their quality of life more quickly and with fewer side effects than with ECT or combination drug therapy.

Completed Clinical Trials of CORLUX for Psychotic Depression

We have completed seven prior clinical trials evaluating CORLUX in psychotic depression, in addition to our ongoing Phase 3 trial. The trials include three Phase 3 trials conducted from 2004 through 2007, in addition to four earlier stage clinical trials with CORLUX. These completed trials generated important data confirming the safety profile of CORLUX (alone and in combination with commonly prescribed antipsychotic and antidepressant medications), demonstrated positive efficacy trends, and provided insights into the design of future clinical trials which might improve the probability of clinical success.

Completed Phase 3 Clinical Trials. In addition to Phase 1 and 2 studies, we have completed three randomized, double-blind, placebo-controlled Phase 3 clinical trials to further assess the safety and efficacy of CORLUX for the treatment of the psychotic features of psychotic depression. Two of these trials (Study 06 and Study 07) were conducted primarily in the United States. The third trial (Study 09) was conducted in Eastern Europe.

The primary endpoint for Study 06 and Study 07 was the proportion of patients with at least a 50% improvement in the Brief Psychiatric Rating Scale Positive Symptom Subscale (BPRS PSS) at both Day 7 and Day 56. The primary endpoint for Study 09 was the proportion of patients with at least a 50% improvement in the BPRS PSS, at both Day 7 and Day 28, with day 56 as a secondary endpoint. Patients must have had at least mild psychotic symptoms (BPRS PSS \geq 12) to enter the studies and were hospitalized if clinically necessary.

Study 07: The first of these trials, which began in September 2004, enrolled 257 patients randomized one-to-one to either treatment or placebo. Patients in the treatment arm received 600 mg of CORLUX once daily for a period of seven days. Patients did not take any antidepressant or antipsychotic medication for at least one week before beginning the seven day treatment period. After the seven days of CORLUX treatment, all patients received antidepressant therapy through Day 56. Treatment with antipsychotic medications or ECT was not allowed at any time during the study.

In this study patients receiving CORLUX did not have a statistically significant difference in response rate at the primary endpoint than did the patients receiving placebo. A retrospective analysis of the data showed that patients achieving drug plasma levels higher than 1800 nanograms per milliliter (ng/ml)

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had a statistically significant greater response rate than placebo. There was also a statistically significant site by treatment effect in this trial. Among the twenty sites who participated from the trial onset, patients who were given CORLUX had a significantly higher response rate than patients who received placebo. Among the sites added later in the trial, there was no significant difference in response rate between CORLUX and placebo patients. These findings were published in 2009 by *Contemporary Clinical Trials*.

Study 09: This study, which commenced in May 2005, was a randomized, double-blind, placebo-controlled study in which 247 patients were enrolled at sites in Eastern Europe. The primary endpoint was the proportion of patients with at least a 50% improvement in the BPRS PSS score at both Day 7 and Day 28. The study did not demonstrate a significant difference in response between patients receiving CORLUX and patients receiving placebo as measured by the primary endpoint. The results at the two key secondary endpoints of Study 09 also were not statistically significant. Study 09 had an extremely high placebo response rate.

Study 06: This trial began in October 2004, and enrolled 443 patients. These patients were randomly assigned to three active dose groups (300 mg, 600 mg and 1200 mg) or a placebo group, with patients receiving once daily dosing for a period of seven days. The three dosing levels responded to the FDA's request to supplement data on a range of doses to augment the data provided by our open label dose ranging study completed in 2001.

The study did not achieve statistical significance with respect to the primary endpoint. However, there was a statistically significant correlation between plasma levels and clinical outcome achieved during treatment. Response rates for patients whose plasma levels rose above a predetermined threshold of 1661 ng/mL were statistically different than those patients whose plasma levels were below the threshold and those patients who received placebo. Further, the incidence of serious adverse events did not differ between placebo and any of the three CORLUX dose groups.

Ongoing Phase 3 trial Study 14: We believe that the confirmation of a correlation between drug concentration and clinical response, as well as other observations from Study 06 and our two other completed Phase 3 clinical trials, served as a strong basis for the design of our ongoing Phase 3 study, which commenced in March 2008. The protocol for this trial incorporates information learned from the three completed Phase 3 trials in that it addresses the established relationship between increased drug plasma levels and clinical response, and it attempts to decrease the random variability observed in the results of the psychometric instruments used to confirm diagnosis and measure efficacy.

Increased Signal: In this trial we are administering a CORLUX dose of 1200 mg once per day for seven days instead of 600 mg once per day for seven days.

Decreased Noise : We also are utilizing a third party centralized rating service to independently evaluate the patient's diagnosis prior to entry into the study as well as to assess response. We believe the centralization of this process will improve the accuracy of diagnosis and the consistency of rating across clinical trial sites and reduce the background noise that is endemic to many psychopharmacologic studies and clearly visible in our earlier studies.

We believe that these changes in the protocol should allow us to establish the efficacy of CORLUX in the treatment of the psychotic features of psychotic depression. Given the serious nature of psychotic depression, the lack of any approved drugs for the disorder and the data from our first clinical trial, the FDA granted a fast track designation for CORLUX for the treatment of the psychotic features of psychotic depression. In addition, the FDA has indicated that CORLUX will receive a priority review if no other treatment is approved for psychotic depression at the time we submit our NDA.

Clinical Trial Agreements. Many of our Phase 3 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 ongoing Phase 3 clinical

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trial, Study 14, evaluating CORLUX for the treatment of the psychotic features of psychotic depression is being conducted under an agreement with ICON Clinical Research, LP (ICON). We may terminate this agreement with 60 days notice to ICON, or sooner based on mutual agreement of the parties. In addition, we entered into an agreement with MedAvante, Inc., in March 2008, to provide the centralized psychiatric diagnosis and rating services for patients being screened and enrolled in Study 14. We may terminate this agreement with 30 days notice to MedAvante.

CORLUX for Other Metabolic Disorders

In April 2005, we announced results from two preclinical studies conducted in a rat model of olanzapine-induced weight gain. These studies demonstrated that CORLUX's GR-II antagonist action has the potential to both reduce 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 CORLUX 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 CORLUX 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 CORLUX 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 CORLUX 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 CORLUX 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 CORLUX (n=24) or CORLUX 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 CORLUX group gained an average of 4.4 pounds; which is a highly statistically significant difference ($p < .001$). Subjects in the CORLUX 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 CORLUX ($p < .01$). The study was not designed to enroll a sufficient number of patients to have statistical power to detect significant effects on metabolic measures, including waist circumference. However, 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 CORLUX. No unexpected study drug related adverse events were observed.

In the study of CORLUX 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 CORLUX (n=30) or CORLUX 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 CORLUX group. This difference was highly 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 CORLUX 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, CORLUX appeared to be well tolerated.

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The combinations of Zyprexa and CORLUX or Risperdal and CORLUX are not approved for any indication. The purpose of these studies was to explore the hypothesis that GR-II 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.

CORT 108297 for the Prevention and Reversal of Antipsychotic Induced Weight Gain

In January 2009 we announced results from two preclinical studies of our next-generation selective GR-II receptor antagonist, CORT 108297 for the prevention and reversal of weight gain associated with olanzapine, which is marketed by Eli Lilly as Zyprexa. The data demonstrated that CORT 108297 has the potential to both reduce weight gain caused by olanzapine and to prevent weight gain caused by initiation of treatment with olanzapine. The two studies were conducted in the rat model of olanzapine induced weight gain described above, in which CORLUX was tested with olanzapine.

One study evaluated the potential for CORT 108297 to reverse weight gain caused by treatment with olanzapine. In this study six groups (n = 12 per group) of rats were allowed to eat a normal diet for 56 days. Five groups were dosed orally with olanzapine daily. The sixth group received placebo. At day 35, the five groups receiving olanzapine had gained a statistically significant amount of weight compared to the group receiving placebo. The five olanzapine groups then began to receive daily oral doses either of CORT 108297 (at one of three dose levels), CORLUX or placebo through day 56. The data demonstrated that the rats administered olanzapine plus placebo continued to gain weight through day 56. In contrast, the rats given olanzapine along with CORT 108297 and those administered olanzapine with CORLUX did not. By day 56, there was a highly statistically significant difference between these groups and the group administered olanzapine plus placebo. In addition, the ameliorization of olanzapine induced weight gain by CORT 108297 was dose dependent. The rats that received the combination of olanzapine with CORT 108297, or with CORLUX, also had significantly less abdominal fat than the group dosed with olanzapine alone.

The other study evaluated the potential for CORT 108297 to prevent weight gain when administered concurrently with olanzapine. In this study six groups (n = 12 per group) of rats were allowed to eat a normal diet for 21 days. Five groups were dosed orally with olanzapine daily and one group was given placebo daily. Four of the groups that received olanzapine were also dosed orally with either CORT 108297 (at one of three dose levels) or CORLUX; one group received olanzapine plus placebo. The sixth group was dosed with only placebo. The data demonstrated that at day 21, the three groups dosed with the combination of olanzapine and CORT 108297 had gained significantly less weight compared to the group administered olanzapine alone. Rats administered olanzapine plus CORLUX also gained less weight than rats administered olanzapine alone, but this result did not reach statistical significance.

These first two studies used dose levels of 20 milligrams per kilogram (mg/kg), 60 mg/kg and 120 mg/kg of CORT 108297. Eli Lilly provided olanzapine and funded the costs of these two studies.

A third study in the rat further evaluated the dose response relationship of CORT 108297 in preventing olanzapine induced weight gain with doses from 2 mg/kg to 20 mg/kg.

In summary, these studies in the rat demonstrated a constant dose response relationship from 2 mg/kg to 120 mg/kg.

CORT 108297 has also produced statistically significant results in the prevention of weight gain and insulin insensitivity in mice fed a high fat, high sucrose diet.

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If CORT 108297 or other GR-II antagonists prove to mitigate the weight gain and metabolic disturbances associated with the use of antipsychotic medication, they could be of benefit to the millions of people currently taking this important pharmacotherapy. We advanced CORT 108297 into a Phase 1 clinical trial during the first quarter of 2010. We plan to advance the compound into a Phase 2 trial in 2011, subject to availability of funds.

GR-II Antagonist Platform

We have assembled a patent portfolio covering a broad range of uses, as well as the composition of our new chemical entities.

We have composition of matter claims on three patent families of novel selective glucocorticoid receptor (GR-II) antagonists. Applications for all of the three families have been allowed in Europe. In the United States, applications for two of the three families have been allowed. Examination has not yet begun in the United States on our third novel selective GR-II antagonist family.

We also have a portfolio of patents describing the use of drugs that block the GR-II receptor for the treatment of metabolic and psychiatric disorders. In addition to psychotic depression, we own or have exclusively licensed issued patents for the use of GR-II antagonists for treatment and / or prevention of:

weight gain following treatment with antipsychotic medication;

mild cognitive impairment;

stress disorders;

early dementia, including early Alzheimer's disease;

delirium;

gastroesophageal reflux disease;

cognitive deterioration in adults with Down's Syndrome;

psychosis associated with cocaine addiction and

increasing the therapeutic response to ECT.

Discovery Research

In 2003, we initiated a discovery research program to identify and patent selective GR-II antagonists at a contract research organization in the United Kingdom. Through the research program, we identified and filed patent applications for three distinct series of GR-II antagonists. These compounds appear to be as potent as Corcept's lead product CORLUX in blocking cortisol but, unlike CORLUX, they do not appear to block the progesterone or other steroid receptors. Currently, we are evaluating several compounds in our research programs, including CORT 108297, a lead compound from our discovery efforts. CORT 108297 has demonstrated attractive characteristics, with high plasma and brain concentrations

in an animal model and promising results in a human microdosing study, including good bioavailability and potential for once-daily dosing. CORT 108297 has also demonstrated the ability to prevent and reduce olanzapine induced weight gain in a rat model, as well as to prevent weight gain from a high fat, high sugar diet and increase insulin sensitivity in a mouse model. CORT 108297 is being evaluated in a Phase 1 study.

Research and Development

We incurred approximately \$14.4 million, \$14.2 million and \$7.9 million of research and development expenses, respectively, in the years ended December 31, 2009, 2008 and 2007, which accounted for approximately 71%, 71% and 62% of our total 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.

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Medical Education and Commercialization

We are planning for the commercialization of CORLUX. To achieve commercial success for any approved product, we must either develop a marketing and sales force or enter into arrangements with others to market and sell our products. We intend to develop our own medical affairs and commercialization infrastructure in the United States for CORLUX because we believe that the initial markets for Cushing's Syndrome and psychotic depression in the United States are highly concentrated and accessible. We intend to engage a partner to commercialize CORLUX in territories outside of the United States.

If approved, we expect to hire a small, experienced field sales force, supported by medical affairs and other infrastructure, to sell CORLUX for the treatment of Cushing's Syndrome. We intend to focus on patients who are in the care of an endocrinologist and in active treatment for their disease. We estimate that there are fewer than 1000 endocrinologists who would need to be targeted to reach the Cushing's Syndrome population in active treatment. We plan to reach out directly to patients utilizing web-based initiatives and interactions with patient groups. We expect distribution and logistical support to be provided by specialty pharmacies.

A large portion of the people who suffer from Cushing's Syndrome remain unrecognized or undertreated. We intend to develop programs to educate the medical community about early diagnosis of this Syndrome and increase awareness regarding CORLUX.

If approved for the treatment of psychotic depression, we plan to reach patients who are candidates for ECT by marketing to hospitals and psychiatrists that perform ECT. We estimate that there are approximately 900 hospitals with more than 30 in-patient psychiatric beds. Of these, we estimate that approximately 300 offer ECT. We believe that approximately 1000 psychiatrists administer most ECT procedures. Subsequently, we also intend to expand our commercialization efforts to address the larger set of patients with psychotic depression currently undergoing combination drug therapy, which would require an increase in the size of our initial sales force.

As with Cushing's Syndrome, a large portion of the people who suffer from psychotic depression remain unrecognized or undertreated. We intend to develop programs to educate the medical community about early diagnosis of psychotic depression and increase awareness regarding CORLUX as a treatment for this disorder.

Manufacturing

As a drug development entity, we intend to continue to utilize our financial resources to complete the development of CORLUX 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 manufacturing agreements with two contract manufacturers, Produits Chimiques Auxiliaires et de Synthèse SA (PCAS) and ScinoPharm Taiwan (ScinoPharm), to produce the active pharmaceutical ingredient (API) for CORLUX. The agreement with PCAS, which was executed in early November 2006, is for an initial period of five years with an automatic extension for one additional year unless either party gives twelve months prior notice that it does not want the extension. There is no guaranteed minimum purchase commitment under this agreement. If PCAS is unable to manufacture the product for a consecutive six-month period, we have the right to terminate the agreement. The agreement with ScinoPharm obligates us to purchase at least \$1,000,000 of bulk mifepristone per year following the commercial launch of CORLUX. This agreement is terminable by either party at any time. We have also entered into an agreement with another contract manufacturer, PharmaForm, L.L.C., for the production of CORLUX tablets for use in clinical activities. To date, our need for CORLUX tablets has been limited to the amounts required to support our clinical trials.

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Competition

If approved for commercial use as a treatment for Cushing's Syndrome or the psychotic features of psychotic depression, CORLUX will compete with established treatments, including other potential compounds under development for Cushing's Syndrome or, in the case of psychotic depression, with ECT and combination drug therapy.

We are aware that Laboratoire HRA Pharma has received an Orphan Drug Designation in the United States and Europe for the use of mifepristone to treat a subtype of Cushing's Syndrome and has begun a clinical trial in Europe and the United States. If this product is approved for commercialization before CORLUX, our potential future revenue could be reduced. We are also aware that Exelgyn Laboratories received Orphan Drug Designation for Cushing's Syndrome in Europe, but they have stated that they have not yet conducted any clinical trials. We may also experience competition from Novartis, which is developing a somatostatin analogue, pasireotide, that is in Phase 3 trials for various endocrine disorders, including Cushing's disease, which is a subset of the patients with Cushing's Syndrome.

ECT has been shown to be the most effective treatment for psychotic depression, but it carries the risks of general anesthesia, potential memory loss and other adverse effects as well as the stigma associated with the procedure. Use of CORLUX does not require anesthesia and, in our clinical trials conducted to date, patients treated with CORLUX have not exhibited the adverse effects associated with ECT.

Other competitors include companies that market antipsychotic drugs that are used off-label as part of combination drug therapy for psychotic depression. To reduce the psychotic features of psychotic depression, these drugs generally are taken in combination with antidepressant medication over a period of weeks to several months. Unlike the use of CORLUX, this extended course of treatment may put patients at risk of significant adverse side effects, including weight gain, diabetes, sedation, permanent movement disorders and sexual dysfunction. Antipsychotics include Bristol-Myers Squibb's Abilify, Novartis' Clozaril, Pfizer's Geodon and Navane, Ortho-McNeil's Haldol, Janssen Pharmaceutica's Risperdal, AstraZeneca's Seroquel, GlaxoSmithKline's Stelazine and Thorazine, Mylan's Mellaril, Schering Corporation's Trilafon and Eli Lilly's Zyprexa.

We are aware of one clinical trial that has taken place, conducted by the pharmaceutical division of Akzo Nobel, a division of Schering Plough, for a new chemical entity for the treatment of psychotic depression. This medicine is a GR-II antagonist, the commercial use of which would be covered by our patent. In 2004, Akzo Nobel filed an observation in our exclusively licensed European patent application with claims directed to psychotic depression, in which Akzo Nobel challenged the claims of that patent application. In 2005, we filed a rebuttal to Akzo Nobel's observation. In February 2006, the European Patent Office (EPO) allowed our patent application. In July 2006, the patent was issued. We are not aware of any public disclosures by any company, other than Akzo Nobel, regarding the development of new medicinal products to treat psychotic depression. However, other companies may be developing new drug products to treat psychotic depression and the other conditions we are exploring. Our present and potential competitors include major pharmaceutical companies, as well as specialty pharmaceutical firms. Most of our competitors have considerably greater financial, technical and marketing resources than we do. We expect competition to intensify as technical advances are made.

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 our future products either alone or through outside parties.

Table of Contents**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.

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-II antagonists in the treatment of psychotic major depression	October 5, 2018
6,362,173	Use of GR-II antagonists in the treatment of cocaine-induced psychosis	October 5, 2018
6,369,046	Use of GR-II antagonists in the treatment of early dementia	February 4, 2019

We are required to make milestone payments and pay royalties to Stanford University on sales of products commercialized under any of the above patents. We are currently in compliance with our obligations under the agreement. 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 CORLUX for the treatment of the psychotic features of psychotic depression, cocaine-induced psychosis or early dementia.

We also own issued U.S. patents for the use of GR-II antagonists in the treatment of mild cognitive impairment, for the treatment of weight gain following treatment with antipsychotic medication, for the prevention and treatment of stress disorders, for increasing the therapeutic response to ECT, for the treatment of delirium, for the treatment of gastroesophageal reflux disease and for inhibiting cognitive deterioration in adults with Down s Syndrome.

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

patients suffering from mental disorders by optimizing mifepristone levels in plasma serum;

postpartum psychosis;

neurological damage in premature infants;

catatonia;

migraine headaches;

psychosis associated with interferon-alpha therapy;

depression in patients taking Interleukin-2 (IL-2) and

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amyotrophic lateral sclerosis (ALS).

We have composition of matter claims on three patent families of novel selective GR-II antagonists. Applications for all of the three families have been allowed in Europe. In the United States, applications for two of the three families have been allowed. Examination has not yet begun in the United States on our third novel selective GR-II antagonist family.

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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 two of our patents and one of our patent applications 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.

The patent covering the product mifepristone has expired. The only FDA-approved use of mifepristone is to terminate pregnancy. The FDA has imposed significant restrictions on the use of mifepristone to terminate pregnancy and may impose restrictions on CORLUX for the treatment of Cushing's Syndrome and the psychotic features of psychotic depression. We plan to rely on (1) the scope of our use patent, (2) the restrictions imposed by the FDA on the use of mifepristone to terminate pregnancy and (3) the different patient populations, administering physicians and treatment settings between the use of mifepristone to terminate pregnancy and to treat Cushing's Syndrome and psychotic depression.

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, 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 to any third party other than Stanford University.

In November 2003, McLean Hospital had alleged that it also had rights to the technology that led to the patent for the use of GR-II antagonists to treat the psychotic features of psychotic depression. McLean Hospital was a prior employer of one of our founders, Dr. Alan Schatzberg and it alleged that the invention of the technology underlying this patent was conceived by Dr. Schatzberg and/or Dr. Anthony Rothschild while the two were employed by McLean Hospital. We contended that the invention was actually conceived by Dr. Schatzberg and Dr. Joseph Belanoff while they were employed by Stanford University and that the patent was appropriately assigned by them to Stanford University. In October 2004, we announced a resolution of this issue in which we retained our exclusive rights under the patent and which required us to make no additional payments under the license, regardless of the resolution of the impending inventorship dispute. In January 2005, the inventorship issue was resolved in favor of Stanford University.

As discussed earlier under Competition, in 2004 Akzo Nobel filed an observation to the grant of our exclusively licensed European patent application with claims directed to psychotic depression. In February 2006, the EPO allowed our patent application. We are not aware of any other disputes related to patent issues.

License Agreement

Under our exclusive license agreement with Stanford University to patents covering the use of CORLUX to treat the psychotic features of psychotic depression and for the treatment of early dementia, we are required to pay Stanford \$50,000 annually as a nonrefundable royalty payment. This payment is creditable against future royalties. We are also obligated to pay Stanford a \$50,000 milestone upon the filing of the NDA for CORLUX.

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for the treatment of psychotic depression and a further \$200,000 milestone payment upon FDA approval of CORLUX. The milestone payments are also creditable against future royalties. This license agreement expires upon expiration of the related patents or upon notification by us to Stanford.

Government Regulation

Prescription pharmaceutical products are subject to extensive pre- and post-market 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. 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, they may grant marketing approval, request additional information or deny the application if it determines that the application does not meet regulatory approval criteria. 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-market 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

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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-market 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-market 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 trials and 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.

Approvals outside the United States. We have not started the regulatory approval process in any jurisdiction other than the United States and we are unable to estimate when, if ever, we will commence the regulatory approval process in any foreign jurisdiction. We or our 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 prices is required in most countries other than the United States. The prices approved may be too low to generate an acceptable return to us.

Orphan Drug Designation. The FDA has granted us Orphan Drug designation for CORLUX for the treatment of endogenous Cushing's Syndrome. The 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. 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.

Fast Track Designation. The FDA sometimes grants fast track status under the Food and Drug Administration Modernization Act of 1997. The fast track mechanism was created to facilitate the development and approval of new drugs intended for the treatment of life-threatening conditions for which there are no effective treatments and which demonstrate the potential to address unmet medical needs for the condition. The fast track process includes scheduling of meetings to seek FDA input into development plans, the option of submitting an NDA serially in sections rather than submitting all components simultaneously, the option to request evaluation of studies using surrogate endpoints, and the potential for a priority review.

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We have been granted fast track status for CORLUX for the treatment of the psychotic features of psychotic depression. However, the fast track designation may be withdrawn by the FDA at any time. The fast track designation does not guarantee that we will qualify for or be able to take advantage of the expedited review procedures and does not increase the likelihood that CORLUX will receive regulatory approval.

Priority Review. The FDA has indicated to us that it will grant us a priority review of our NDA of CORLUX for the treatment of the psychotic features of psychotic depression if no other medications have been approved for this indication at the time of our submission.

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, 2009, we had 16 full-time employees, three part-time employees and 11 long-term contract staff. Four of our employees are 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® and CORLUX®. 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 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 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 Our Business

We depend heavily on the success of our lead product candidate, CORLUX, currently being developed for the treatment of Cushing's Syndrome and for the treatment of the psychotic features of psychotic depression. If we are unable to commercialize CORLUX for Cushing's Syndrome or for psychotic depression, or experience significant delays in doing so, we may be unable to generate revenues and our stock price will likely decline.

We have invested a significant portion of our time and financial resources since our inception in the development of CORLUX for the treatment of Cushing's Syndrome and the psychotic features of psychotic depression. We currently do not have any commercial products and we anticipate that for the foreseeable future our ability to generate meaningful revenues and achieve profitability will be solely dependent on the successful development, approval and commercialization of CORLUX for the treatment of Cushing's Syndrome or for the psychotic features of psychotic depression. We are conducting a single Phase 3 trial in Cushing's Syndrome and a Phase 3 clinical trial in psychotic depression. We have previously completed three Phase 3 clinical trials evaluating CORLUX for psychotic depression, all of which failed to achieve statistically significant results with regard to the primary or key secondary endpoints. Many factors could harm our efforts to develop and commercialize CORLUX, including:

insufficient funding;

negative, inconclusive or otherwise unfavorable results from our pre-clinical or clinical development programs;

side effects that may be identified in the course of our clinical trials;

changes or delays in our clinical development program;

rapid technological change making CORLUX obsolete;

competition from companies with greater financial, technical and marketing resources than ours;

increases in the costs of our clinical trials;

an inability to obtain, or delay in obtaining, regulatory approval for the commercialization of CORLUX for the treatment of Cushing's Syndrome or for the treatment of the psychotic features of psychotic depression;

an inability to manufacture CORLUX or the active ingredient in CORLUX in commercial quantities and at an acceptable cost; and

political concerns relating to other uses of mifepristone, or RU-486, that could limit the market acceptance of CORLUX.

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Our clinical trials may not demonstrate that CORLUX is safe and effective. If our clinical program for CORLUX for the treatment of Cushing's Syndrome, for the treatment of the psychotic features of psychotic depression or for any other indications does not demonstrate safety and efficacy, our business will be harmed.

To gain regulatory approval from the FDA to market CORLUX, our Phase 3 clinical trials must demonstrate the safety and efficacy of CORLUX for the particular indication. Our first three Phase 3 studies evaluating CORLUX for the treatment of the psychotic features of psychotic depression did not meet their primary or key secondary endpoints. In addition to the ongoing Phase 3 clinical trials of CORLUX for the treatment of Cushing's Syndrome and for the treatment of the psychotic features of psychotic depression, we will need to conduct other studies in support of a potential NDA. Clinical development is a long, expensive and uncertain process and is subject to delays, and data obtained from clinical trials and supportive studies are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. While we obtained favorable results in our Phase 2 clinical trials in psychotic depression, these results were not replicated in a robust enough way in our completed Phase 3 clinical trials and are not sufficient to use by themselves as the pivotal clinical trials in an application for FDA approval of this indication. In addition, we cannot assure you that supportive studies and tests will produce favorable results.

The development plan for CORLUX, or any other compound, is not certain. If we decide to, or if the FDA or other regulatory agencies require us to pursue additional clinical trials or other studies, there may be a delay in the development of our compounds, which may have a negative impact on our business.

During the development of CORLUX, we have been engaged in dialogue with the FDA to determine an acceptable development plan which would enable the FDA to complete its review in a satisfactory manner. We anticipate continued dialogue with the FDA to define any additional data needed to complete an NDA.

We may decide, or the FDA or other regulatory authorities may require us, to pursue additional clinical, pre-clinical or manufacturing studies to satisfactorily complete our NDA for either Cushing's Syndrome or psychotic depression. For example, the FDA may require us to perform a bioequivalence study comparing our recently reformulated CORLUX clinical trial materials to the materials used in our earlier clinical trials in psychotic depression. Additional trials or studies will require additional funding which is not assured. Also, it is possible that additional trials or studies that we decide are necessary or desirable will delay or prevent the completion of the development of CORLUX for treating Cushing's Syndrome or the psychotic features of psychotic depression.

Many other factors could delay or result in termination of our clinical trials, including, but not limited to:

availability of funding;

negative or inconclusive results;

slow patient enrollment;

patient noncompliance with the protocol;

adverse medical events or side effects among patients during the clinical trials;

negative or problematic FDA inspections of our clinical operations or our manufacturing operations; and

real or perceived lack of effectiveness or safety of CORLUX.

Even after we conduct all of the clinical trials and supportive studies that we consider appropriate for an optimal NDA, we may not receive regulatory approval to market CORLUX.

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We will need additional capital in order to complete the development and commercialization of CORLUX and our other proprietary, selective GR-II antagonists, including CORT 108297. Additional capital may not be available to us at all or on favorable terms, which could adversely effect our business.

We may have to perform additional clinical trials prior to submission of an NDA for CORLUX for the treatment of Cushing's Syndrome and for the treatment of the psychotic features of psychotic depression. We may need to raise additional funds to complete the development of CORLUX for the treatment of Cushing's Syndrome and will need to raise additional funds to complete the development of CORLUX for the treatment of psychotic depression. In addition, we will need to raise additional funds to prepare for the commercialization of CORLUX for either of these indications, to develop a product for weight gain management associated with antipsychotic medications, and to continue and expand the development of our proprietary, selective GR-II antagonists, including CORT 108297.

We anticipate that our existing capital resources will be sufficient to fund our current operating plan into early 2011. However, our expectations are based on our currently planned clinical development and research programs for CORLUX and for certain of our proprietary, selective GR-II antagonists, including CORT 108297, which may change as a result of many factors, including:

the costs, timing of site selection and enrollment of our clinical trials;

the results of our research efforts and clinical trials;

the need to perform additional clinical trials and other supportive studies;

the need to establish a second source for CORLUX tableting;

the timing of the approval by the FDA, if any, to market CORLUX for the treatment of Cushing's Syndrome or for the treatment of the psychotic features of psychotic depression;

developments or disputes concerning patents or proprietary rights, including announcements of claims of infringement, interference or litigation against us or our licensors;

actual or anticipated fluctuations in our operating results;

changes in our growth rates;

changes in our research development plans for our proprietary, selective GR-II antagonists, including CORT 108297;

the timing of commercialization of CORLUX and future product candidates; and

changes in the reimbursement policies of third-party insurance companies or government agencies.

Consequently, we may need additional funding sooner than anticipated. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

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We cannot be certain that additional funding will be available on acceptable terms or at all. Even though we raised approximately \$18.0 million in October 2009, through a private placement of our common stock and warrants, and generated an additional \$875,000 between October 2009 and January 2010 under our Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge), a private investment group, market and economic conditions may make it difficult for us to raise any additional capital. The sales of common stock and warrants during 2009 and the first quarter of 2010 have been dilutive to stockholders and any exercise of outstanding warrants and additional equity financing will cause further dilution to stockholders. 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, including potentially our lead product candidate that we would otherwise

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seek to develop on our own. 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 losses since inception and anticipate that we will incur continued losses for at least the next few years.

We are a development stage company with no current source of product revenue. We have a limited history of operations and have focused primarily on clinical trials, and if the outcome of our clinical trials supports it, we plan to seek FDA regulatory clearance to market CORLUX for the treatment of Cushing's Syndrome and for the treatment of the psychotic features of psychotic depression. Historically, we have funded our operations primarily from the sale of our equity securities. We have incurred losses in each year since our inception in 1998. As of December 31, 2009, we had an accumulated deficit of \$150.2 million. We do not know when or if we will generate product revenue. Subject to our ability to raise additional funds, we expect our research and development expenses to increase in connection with the clinical trials and other development activities for CORLUX and for other product candidates. We expect to incur significant expenses related to the preparation for commercializing CORLUX and for the product's launch, if the FDA approves our NDA. As a result, we expect that our losses will increase at least until CORLUX is launched and commercially available to patients. We are unable to predict the extent of any future losses or whether or when we will become profitable.

The Committed Equity Financing Facility (CEFF) that we entered into with Kingsbridge in March 2008 may not be available to us at certain times, may generate a lower level of funding than we anticipate, may require us to make additional blackout or other payments to Kingsbridge, and will result in dilution to our stockholders.

Kingsbridge will not be obligated to purchase shares under the CEFF unless certain conditions are met, which include a minimum price for our common stock, currently set at \$1.50 per share and the effectiveness and continued effectiveness of the resale registration statements. The actual amount of funds that can be raised under this agreement will be dependent on the number of shares actually sold under the agreement and the market value of our stock during the pricing periods of each sale.

In June 2008, the SEC declared effective our registration statement with the SEC covering the resale of approximately 3.6 million of the shares issuable under the CEFF and the shares issuable upon the exercise of the warrant issued to Kingsbridge. This registration statement covers approximately 37% of the 9.6 million shares of our common stock issuable pursuant to the CEFF and all of the 330,000 shares of our common stock issuable upon exercise of the warrant issued to Kingsbridge. We intend to file an additional registration statement covering the resale of the remaining shares of our common stock issuable pursuant to the CEFF 60 days after Kingsbridge and its affiliates have resold substantially all of the securities covered by this initial registration statement; therefore, the timing of the submission of this subsequent registration statement is uncertain. This subsequent registration statement may be subject to review and comment by the Staff of the SEC, as well as consent by our independent registered accounting firm. We cannot assure you that these registration statements will be declared effective or, if declared effective, that they will remain continuously effective thereafter.

In addition, Kingsbridge is permitted to terminate the CEFF if it determines that a material and adverse event has occurred affecting our business, operations, properties or financial condition and if such condition continues for a period of 10 days from the date Kingsbridge provides us notice of such material and adverse event. If we are unable to access funds through the CEFF, or if the CEFF is terminated by Kingsbridge, we may be unable to access alternative capital on favorable terms or at all.

We are entitled in certain circumstances, to deliver a blackout notice to Kingsbridge to suspend the use of the resale registration statement and prohibit Kingsbridge from selling shares thereunder. If we deliver a blackout notice in the 15 trading days following the settlement of a draw down, or if the resale registration statement is not

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effective in circumstances not permitted by our agreement with Kingsbridge, then we may be required to make a payment to Kingsbridge, or issue Kingsbridge additional shares in lieu of the payment. If the trading price of our common stock declines during a suspension of the resale registration statement, the blackout or other payment could be significant.

Any shares that we may issue to Kingsbridge under the CEFF will have a dilutive effect on the holdings of our current stockholders, and may result in downward pressure on the price of our common stock. For each draw down under the CEFF, we will issue shares to Kingsbridge at a discount of up to 10% from the volume weighted average price of our common stock. If we draw down amounts under the CEFF when our share price is decreasing, we will need to issue more shares to raise the same amount than if our stock price was higher. Issuances in the face of a declining share price will have an even greater dilutive effect than if our share price were stable or increasing, and may further decrease our share price.

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

The costs required to start or continue many of the programs that our intellectual property allow 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 specific GR-II antagonists but, unlike CORLUX, do not appear to block the progesterone receptor. Further development of these proprietary compounds, including CORT 108297, or any further development stemming from our method of use patents may be delayed or cancelled if we determine that such development may jeopardize our ability to complete the clinical development of CORLUX for the treatment of Cushing's Syndrome or psychotic depression.

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

Global economic and market conditions were extremely unstable in 2009, with significantly tighter credit conditions. Any economic recovery during 2010 could be fragile and uneven. Continued concerns about the systemic impact of potential wide-spread and long-term recession, geopolitical issues, the availability and cost of credit, global financial markets and corporate, consumer and governmental debt levels have contributed to market volatility and diminished expectations for the U.S., European and other economies.

As a result of these conditions, the cost and availability of capital have been and may continue to be adversely affected. Concern about the stability of the markets generally, and the strength of counterparties specifically, has led many lenders and institutional investors to reduce, and in some cases, cease, to provide credit to businesses. Continued turbulence in the global markets and economies may adversely affect our liquidity and financial condition. If these market and economic conditions continue, they may limit our ability to fund our clinical trials and drug development programs.

In addition, our access to funds under our CEFF or any credit facility into which we may enter depends on the ability of the counterparties to such facilities to meet their funding commitments to us. We cannot assure you that continuing long-term disruptions in the global economy and tighter credit conditions will not have an adverse effect on such counterparties. If we do not have sufficient cash flow to continue operating our business and are unable to borrow funds, access our CEFF or raise equity capital, we may need to find alternative ways to increase our liquidity. Such alternatives may include, without limitation, curtailing clinical or drug development activity, which would have an adverse affect on our business and results of operation.

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We depend on clinical investigators and clinical sites to enroll patients in our clinical trials and other third parties to manage the trials and to perform related data collection and analysis, and, as a result, we may face costs and delays outside of our control.

We rely on clinical investigators and clinical sites to enroll patients and other third parties to manage our trials and to perform related data collection and analysis. However, we may not be able to control the timing of identification and selection of appropriate sites for our planned trials and the amount and timing of resources that the clinical sites that conduct the clinical testing may devote to our clinical trials. If our clinical investigators and clinical sites fail to enroll a sufficient number of patients in our clinical trials or fail to enroll them on our planned schedules, we will be unable to complete our trials or to complete them as planned, which could delay or prevent us from completing the clinical development of CORLUX or other development programs.

We have an agreement with a contract research organization (CRO) that is conducting our ongoing Phase 3 trial evaluating CORLUX for the treatment of the psychotic features of psychotic depression, Study 14, to supervise and monitor clinical site performance and to perform investigator supervision, data collection and analysis for this trial. We may not be able to maintain relationships with this or other CROs or with the clinical investigators and the clinical sites through the completion of all trial activities without delays in anticipated timing of trial activities or excessive expenditures. Our agreements place substantial responsibilities on these parties, which could result in excessive expenditures for our clinical trials if these parties fail to perform as expected. For example, if any of our clinical trial sites fail to comply with FDA-approved good clinical practices, we may be unable to use the data gathered at those sites. If these CROs, clinical investigators, clinical sites or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, we may be unable to obtain regulatory approval for, or successfully commercialize, CORLUX.

The conduct of any future clinical trials will likely also be conducted through the use of CROs and clinical research sites. The conduct, timing and cost of these trials will be subject to the same kinds of risks as discussed above.

Our use of MedAvante to provide centralized psychiatric rating services in Study 14, our ongoing clinical trial evaluating CORLUX for the psychotic features of psychotic depression, may not result in any improvement in the accuracy and consistency of the psychiatric assessments and may continue to slow the pace of enrollment in Study 14.

In connection with our ongoing Phase 3 trial evaluating CORLUX for the psychotic features of psychotic depression, Study 14, we engaged MedAvante to provide centralized psychiatric rating services. MedAvante is providing centralized psychometric assessments via high resolution video-conferencing. The use of MedAvante's centralized rating services is expected to increase the accuracy and consistency of the psychiatric assessments.

MedAvante has provided similar centralized rating services to companies conducting clinical studies in various psychiatric disorders. However, they have not previously provided centralized rating services to any study in patients with psychotic depression. Although Corcept and MedAvante conducted a small pilot evaluation in patients with psychotic depression to assess patient receptivity, we cannot be certain that centralized rating will be successful in the patients enrolled in our study.

If patients are uncomfortable or unwilling to participate in the centralized rating process or if MedAvante is unable to provide services in a satisfactory manner over the course of the trial, we may not see any improvement in the accuracy or reliability of the psychiatric assessments. Such a result might diminish the likelihood of a successful trial or a definitive demonstration of the efficacy of CORLUX in treating the psychotic features of psychotic depression.

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During screening for Study 14, we have seen a higher than anticipated incidence of potential patients who do not meet appropriate criteria for entrance into the trial for diagnostic and other clinical reasons. We believe that this is the result of improved accuracy in the screening process resulting from the use of the MedAvante centralized rating services as an additional step in the selection of patients appropriate for inclusion in the study. In addition, in March 2009, we announced that, in order to lower variable and fixed expenses and to conserve financial resources, we scaled back our planned rate of spending on this trial and extended the timeline for its completion. We are currently using eight clinical sites in order to conserve capital. A continued lower enrollment rate could result in delays in the timing of anticipated completion of the trial and increased study costs over the longer term.

If we are unable to obtain or maintain regulatory approval, we will be limited in our ability to commercialize our product candidates, including CORLUX, and our business will be harmed.

The research, testing, manufacturing, selling and marketing of product candidates are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, in which regulations differ from country to country. Obtaining and maintaining regulatory approval typically is an uncertain process, is costly and takes many years. In addition, failure to comply with the FDA and other applicable foreign and U.S. regulatory requirements may subject us to administrative or judicially imposed sanctions. These include warning letters, civil and criminal penalties, injunctions, product seizure or detention, product recalls, total or partial suspension of production, and refusal to approve pending NDAs, or supplements to approved NDAs.

Regulatory approval of an NDA or NDA supplement is never guaranteed. Despite the time, resources and effort expended, failure can occur at any stage. The FDA has substantial discretion in the approval process for human medicines. The FDA can deny, delay or limit approval of a product candidate for many reasons including:

the FDA may not find that the candidate is safe;

the FDA may not find data from the clinical or preclinical testing to be sufficient; or

the FDA may not approve our or our third party manufacturers' processes or facilities.

Future governmental action or changes in FDA policy or personnel may also result in delays or rejection of an NDA in the United States. In addition, because the only currently FDA-approved use of mifepristone is the termination of pregnancy, we expect that the label for CORLUX will include some limitations, including a warning that it should not be used by pregnant women or women seeking to become pregnant.

If we receive regulatory approval for our product candidates, including CORLUX, we will also 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 obligations. If we are not able to maintain regulatory compliance, we may not be permitted to market our product candidates.

Any regulatory approvals that we receive for our 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. In addition, if the FDA approves any of our product candidates, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping for the medicine will be subject to extensive regulatory requirements. The subsequent discovery of previously unknown problems with the medicine, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the medicine, and could include withdrawal of the medicine from the market.

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

We intend to commercialize our product candidates in international markets with the help of one or more partners. Outside the United States, we can commercialize a product only if we receive a marketing authorization and, in some cases, pricing approval, from the appropriate regulatory authorities. This foreign regulatory approval process includes 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. We have not taken any actions to obtain foreign approvals. We may not develop our product candidates in the clinic in order to obtain foreign regulatory approvals on a timely basis, if at all.

Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our product candidates in any market.

The Orphan Drug Designation for CORLUX for the treatment of endogenous Cushing's Syndrome may not provide protection from competition and other benefits as anticipated.

In July 2007, we received Orphan Drug Designation from the FDA for CORLUX for the treatment of endogenous Cushing's Syndrome. Although we have received Orphan Drug Designation from the FDA, we cannot be assured that we will recognize the potential benefits of this designation.

For example, we are aware that Laboratoire HRA Pharma has received an Orphan Drug Designation in the United States and Europe for the use of mifepristone to treat a subtype of Cushing's Syndrome and has begun a Phase 2 clinical trial in Europe and the United States for this indication. We are also aware that Exelgyn Laboratories recently received a recommendation for Orphan Drug Designation for Cushing's Syndrome in Europe, but they have stated that they have not yet conducted any clinical trials.

If another drug is approved for this indication before CORLUX, we may not garner the seven years of marketing exclusivity from the date of drug approval and other benefits that we anticipate.

The fast track designation for the development program of CORLUX for the treatment of the psychotic features of psychotic depression may not lead to a faster development or regulatory review or approval process.

If a human medicine is intended for the treatment of a serious or life-threatening condition and the medicine demonstrates the potential to address unmet medical needs for this condition, the sponsor of an IND may apply for FDA fast track designation for a particular indication. Marketing applications submitted by sponsors of product candidates in fast track development may qualify for expedited FDA review under the policies and procedures offered by the FDA, but the fast track designation does not assure any such qualification. Although we have obtained a fast track designation from the FDA for CORLUX for the treatment of the psychotic features of psychotic depression, we may not experience a faster development process, review or approval compared to applications considered for approval under conventional FDA procedures. In addition, the FDA may withdraw our fast track designation at any time. If we lose our fast track designation, the approval process may be delayed. In addition, our fast track designation does not guarantee that we will qualify for or be able to take advantage of the expedited review procedures and does not increase the likelihood that CORLUX will receive regulatory approval for the treatment of the psychotic features of psychotic depression.

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Even if we receive approval for the marketing and sale of CORLUX for the treatment of Cushing's Syndrome and / or psychotic depression, CORLUX may never be accepted as a treatment for the approved indications, which would adversely effect our financial results.

Many factors may affect the market acceptance and commercial success of CORLUX for the treatment of Cushing's Syndrome and / or the psychotic features of psychotic depression or for any other approved indication.

Even if the FDA approves CORLUX for the treatment of Cushing's Syndrome, for the treatment of the psychotic features of psychotic depression, or for any other indication, physicians may not adopt CORLUX. Physicians will recommend the use of CORLUX only if they determine, based on experience, clinical data, side effect profiles and other factors, that it is preferable to other products or treatments then in use. Acceptance of CORLUX among influential practitioners may be essential for market acceptance of CORLUX.

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

the effectiveness of CORLUX, including any side effects, as compared to alternative treatment methods;

the product labeling or product insert required by the FDA for CORLUX;

the cost-effectiveness of CORLUX and the availability of third-party insurance coverage and reimbursement, in particular from government payors such as Medicare and Medicaid, for patients using CORLUX;

the timing of market entry of CORLUX relative to competitive products;

the intentional restriction of distribution of CORLUX to physicians treating the target patient population;

the extent and success of our sales and marketing efforts;

the rate of adoption of CORLUX by physicians and by target patient population; and

negative publicity concerning CORLUX, RU-486 or mifepristone.

The failure of CORLUX to achieve market acceptance would prevent us from generating meaningful product revenue.

Public perception of the active ingredient in CORLUX, mifepristone or RU-486, may limit our ability to market and sell CORLUX.

The active ingredient in CORLUX, mifepristone (RU-486) is used to terminate 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 CORLUX by patients and physicians. Even though we intend to create measures to minimize the likelihood of the prescribing of CORLUX to a pregnant woman, physicians may decline to prescribe CORLUX to a woman simply to avoid altogether any risk of unintentionally terminating a pregnancy. We intend to create measures for controlling the distribution of CORLUX to reduce the potential for diversion. However, controlled distribution may negatively impact sales of CORLUX.

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We have no manufacturing capabilities and we currently depend on third parties to manufacture the active ingredient and the tablets for CORLUX. The tablet manufacturer is a single source supplier. If these suppliers are unable to continue manufacturing CORLUX and we are unable to contract quickly with alternative sources, our business will be harmed.

We currently have no experience in, and we do not own facilities for, nor do we plan to develop facilities for, manufacturing any products. We have agreements with two manufacturers of the active pharmaceutical ingredient (API) of mifepristone and an agreement with a tablet manufacturer for development quantities of CORLUX. The tablet manufacturer is a single source supplier to us. Our current arrangements with these manufacturers are terminable by either party at any time. Although we anticipate engaging our current tablet supplier to produce commercial quantities of CORLUX, we cannot guarantee that we will enter into an agreement with them on terms acceptable to us. If we are unable, for whatever reason, to obtain the active pharmaceutical ingredient or CORLUX tablets from our contract manufacturers, we may not be able to manufacture our required quantities or identify alternate manufacturers of mifepristone or CORLUX tablets in a timely manner or on reasonable terms, if at all.

If our third-party manufacturers of CORLUX fail to comply with FDA regulations or otherwise fail to meet our requirements, our product development and commercialization efforts may be delayed.

We depend on third party manufacturers to supply the active pharmaceutical ingredient in CORLUX and to manufacture CORLUX tablets. These suppliers and manufacturers must comply with the FDA's current Good Manufacturing Practices (cGMP) regulations and guidelines. Our suppliers and manufacturers may encounter difficulties in achieving quality control and quality assurance and may experience shortages of qualified personnel. Their failure to follow cGMP or other regulatory requirements and to document their compliance with cGMP may lead to significant delays in the availability of products for commercial use or clinical study or the termination or hold on a clinical study, or may delay or prevent filing or approval of marketing applications for CORLUX.

Failure of our third party suppliers and manufacturers or us to comply with applicable regulations could result in sanctions being 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, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could harm our business. If the operations of any current or future supplier or manufacturer were to become unavailable for any reason, commercialization of CORLUX could be delayed and our revenue from product sales could be reduced.

We may use a different third-party manufacturer to produce commercial quantities of CORLUX than we are using in our clinical trials. The FDA may require us to conduct a study to demonstrate that the tablets used in our clinical trials are equivalent to the final commercial product. If we are unable to establish that the tablets are equivalent or if the FDA disagrees with the results of our study, commercial launch of CORLUX would be delayed.

If we or others identify side effects after our product candidates are on the market, we may be required to perform lengthy additional clinical trials, change the labeling of our future products or withdraw our future products from the market, any of which would hinder or preclude our ability to generate revenues.

If we or others identify side effects after any of our product candidates are on the market:

regulatory authorities may withdraw their approvals;

we may be required to reformulate our future products, conduct additional clinical trials, make changes in labeling of such products or implement changes to or obtain re-approvals of our manufacturing facilities;

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we may experience a significant drop in the sales of the affected products;

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 the affected products or could increase the costs and expenses of commercializing and marketing these product candidates.

If CORLUX 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.

Our success depends in part on our ability to obtain and maintain adequate patent protection for the use of CORLUX for the treatment of the psychotic features of psychotic depression and other potential uses of GR-II antagonists. If we do not adequately protect our intellectual property, competitors may be able to use our intellectual property and erode our competitive advantage.

To date, we own seven issued U.S. method of use patents and have exclusively licensed three issued U.S. method of use patents, with a number of corresponding foreign patents or patent applications. We have eight U.S. method of use patent applications for GR-II antagonists. We own two composition of matter patents and have one composition of matter patent application covering specific GR-II antagonists pending in the U.S. We have applied, and will continue to apply, for patents covering our product candidates as we deem appropriate.

We have exclusively licensed three issued U.S. patents from Stanford University for the use of GR-II antagonists in the treatment of psychotic major depression, which is commonly referred to as psychotic depression, cocaine-induced psychosis and early dementia, including early Alzheimer's disease. We bear the costs of protecting and defending the rights to 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 Stanford University. We are currently in compliance with our obligations under this agreement. If we become noncompliant, we may lose the right to commercialize CORLUX for the treatment of psychotic depression, cocaine-induced psychosis and early dementia and our business would be materially harmed. In addition, if Stanford University were to terminate our CORLUX license due to breach of the license on our part, we would not be able to commercialize CORLUX for the treatment of the psychotic features of psychotic depression, cocaine-induced psychosis or early dementia.

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. For example, in 2004, Akzo Nobel, which was subsequently acquired by Schering Plough, filed an observation challenging the claims of our exclusively licensed European patent application with claims directed to psychotic depression. In 2005, we filed a rebuttal to the EPO that responded to the points raised by Akzo Nobel. In February 2006, the EPO allowed our patent application and in July 2006, this patent was issued. In April 2007 we received notification that there will be no opposition proceedings in Europe in regards to this patent.

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. For example, the arguments presented by Akzo Nobel could be raised in the United States either before the U.S. Patent and Trademark Office or in a court of law. Furthermore, the claims in patents which have been issued to us, or which may be issued to us in the future, may not be sufficiently broad to prevent third parties from producing competing products. In addition, the laws of various foreign countries in which we 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, which would impair our ability to compete.

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If a third party were successful in asserting an infringement claim against us, we could be forced to pay damages and prevented from developing, manufacturing or marketing our potential products. We do not have liability insurance for patent infringements. A third party could require us to obtain a license to continue to use their intellectual property, and we may not be able to do so on commercially acceptable terms, or at all. We believe that significant litigation will continue in our industry regarding patent and other intellectual property rights. If we become involved in litigation, it could consume a substantial portion of our resources. Regardless of the merit of any particular claim, defending a lawsuit takes significant time, is expensive and diverts management's attention from other business.

If we are unable to protect our trade secrets and proprietary information, our ability to compete in the market could be diminished.

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 adequately protect our trade secrets or other proprietary information. If they do not adequately protect our rights, third parties could use our proprietary information, which could 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 through means not currently foreseen. Notwithstanding our efforts to protect our trade secrets and proprietary information, our competitors may independently develop similar or alternative products that are equal or superior to our product candidates without infringing on any of our proprietary information or trade secrets.

Our licensed patent covering the use of mifepristone to treat psychotic depression is a method of use patent rather than a composition of matter patent, which increases the risk that physicians will prescribe another manufacturer's mifepristone for the treatment of Cushing's Syndrome or psychotic depression rather than CORLUX or patients may acquire mifepristone from other sources, such as the internet or black market.

We have an exclusive license from Stanford University to a patent covering the use of GR-II antagonists, including mifepristone, for the treatment of psychotic depression. A method of use patent covers only a specified use of a particular compound, not a particular composition of matter. Ten of our 12 U.S. issued patents and eight of our nine U.S. patent applications are method of use patents. Because none of our issued patents covers the composition of mifepristone, we cannot prevent others from commercializing mifepristone in indications not covered by our method of use patents. If others receive approval to manufacture and market mifepristone or any other GR-II antagonist, physicians could prescribe mifepristone or any other GR-II antagonist for patients with psychotic depression instead of CORLUX. Although any such off-label use would violate our licensed patent, effectively monitoring compliance with our licensed patent may be difficult and costly. In addition, if others develop a treatment for psychotic depression that works through a mechanism which does not involve the GR-II receptor, physicians could prescribe that treatment instead of CORLUX.

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 black 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's Syndrome patients may not be able to obtain mifepristone from this source.

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The composition of matter patents on our families of novel selective glucocorticoid antagonists may not be issued and we would not be able to prevent competition from others.

We have filed composition of matter patent claims on three families of novel selective glucocorticoid antagonists but not all of these have been issued. Applications for all of the three families have been allowed in Europe. In the United States, applications for two of the three families have been allowed. Examination has not yet begun in the United States on our third novel selective GR-II family. We cannot be certain that these patents will be issued to us. If these patents are not issued we may not be able to prevent others from developing competing compounds. The competing products could be prescribed by physicians instead of those developed by us.

Our efforts to discover, develop and commercialize new product candidates beyond CORLUX are at a very early stage. If we fail to identify and develop additional uses for GR-II antagonists, we may be unable to market additional products.

To develop additional potential sources of revenue, we believe that we must identify and develop additional product candidates. We own or have exclusively licensed issued U.S. patents covering the use of GR-II antagonists to treat psychotic depression, mild cognitive impairment, weight gain due to treatment with antipsychotic medication, stress disorders, early dementia, delirium, gastroesophageal reflux disease, Down's Syndrome and psychosis associated with cocaine addiction, and to increase the therapeutic response to ECT. In addition, we have eight U.S. method of use patent applications covering GR-II antagonists for the treatment of a number of other metabolic and psychiatric disorders and three U.S. composition of matter patent applications covering specific GR-II antagonists. We have also filed patent applications in all of the major international markets.

We may not develop or continue to develop product candidates for any of the indications or compounds covered by our patents and patent applications. Typically, there is a high rate of attrition for product candidates in preclinical and clinical trials, so our product development efforts may not lead to commercially viable products. The use of GR-II antagonists may not be effective to treat these conditions or any other indications. In addition, we could discover that the use of GR-II antagonists in these patient populations has unacceptable side effects or is otherwise not safe.

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 CORLUX and we may determine that CORLUX is not desirable for uses other than for the treatment of Cushing's Syndrome or the treatment of the psychotic features of psychotic depression. In that event, we would have to identify and may need to secure rights to a different GR-II antagonist. For example, we do not intend to develop CORLUX for mitigation of the weight gain associated with the use of Zyprexa, Risperdal or other atypical antipsychotics, even though we have reported positive results in the proof of concept studies described elsewhere in this Annual Report on Form 10-K. We are pursuing other GR-II antagonists for this use and may pursue additional compounds. The compounds developed pursuant to our preclinical and discovery research programs, including CORT 108297, may fail to generate commercially viable product candidates in spite of the resources we may dedicate to the program. Even if product candidates are identified, we may abandon further development efforts before we reach clinical trials or after expending significant expense and time conducting clinical trials due to financial constraints, concerns over safety, efficacy of the product candidates or for 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 GR-II antagonists, we may be unable to generate sufficient revenue to support our operations.

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We may have substantial exposure to product liability claims and may not have adequate insurance to cover those claims.

We may be subject to product liability or other claims based on allegations that the use of our products has resulted in adverse effects or that our product candidates are not effective, whether by participants in our clinical trials for CORLUX or other product candidates, or by patients using our future products. A product liability claim may damage our reputation by raising questions about our product candidates' safety or efficacy 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 CORLUX is used to terminate pregnancy. Therefore, necessary and strict precautions must be taken by clinicians using the medicine in our clinical trials and, if approved by the FDA, physicians prescribing the medicine to women with childbearing potential, to insure that the medicine is not administered to pregnant women. The failure to observe these precautions could result in significant product claims.

We have only limited product liability insurance coverage, with limits that we believe to be customary for a development stage company. We intend to expand our product liability insurance coverage to any product candidates for which we obtain marketing approval. However, this insurance may be 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 our product candidates. Defending a lawsuit could be costly and significantly divert management's attention from conducting our business. If a third party successfully sues us for any injury caused by our product candidates, our liability could exceed our total assets.

If CORLUX is approved and we are unable to obtain acceptable prices or adequate coverage and reimbursement for it from third-party payors, we will be unable to generate significant revenues.

There is significant uncertainty related to the availability of third-party insurance coverage and reimbursement for newly approved medications. The commercial success of our potential medications in both domestic and international markets is dependent on whether third-party coverage and reimbursement is available for them. Government payors, including Medicare and Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new medicines, and, as a result, they may not cover or provide adequate payment for our medications. The continuing efforts of government and other third-party payors to contain or reduce the costs of health care may limit our revenues. Our dependence on the commercial success of CORLUX alone makes us particularly susceptible to any cost containment or reduction efforts. Accordingly, even if CORLUX or future product candidates are approved for commercial sale, unless government and other third-party payors provide adequate coverage and reimbursement for our future products, physicians may not prescribe them. We intend to sell CORLUX directly to hospitals if we receive FDA approval. As a result, we will need to obtain approval from hospital formularies to receive wide-spread third-party coverage and reimbursement. If we fail to obtain that approval, we will be unable to generate significant 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 proposed 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 our future products or the exclusion of such products from reimbursement programs.

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We may face competition from other companies who attempt to develop mifepristone for the treatment of Cushing's Syndrome, which could limit our future revenues from the commercialization of CORLUX for the treatment of that disorder and which could have a negative impact on future revenues from the commercialization of CORLUX for any indication.

As discussed above in the risk related to Orphan Drug Designation, we are aware that Laboratoire HRA Pharma has begun a Phase II clinical trial in Europe and the United States evaluating the use of mifepristone to treat a subtype of Cushing's Syndrome. We are also aware that Novartis is developing a somatostatin analogue that is in Phase 3 trials for various endocrine disorders, including Cushing's disease, which is a subset of the patients with Cushing's Syndrome. If a product for treatment of Cushing's Syndrome is approved for commercialization before CORLUX, our potential future revenue could be reduced.

We face competition from companies with substantial financial, technical and marketing resources, which could limit our future revenues from the commercialization of CORLUX for the treatment of psychotic depression or for other indications.

If approved for commercial use, CORLUX as a treatment for psychotic depression will compete with established treatments, including ECT and combination medicinal therapy.

Combination medicinal therapy consists of the use of antipsychotic and antidepressant medicines, not currently approved for the treatment of psychotic depression. The antipsychotics are prescribed for off-label use by physicians to treat the psychotic features of psychotic depression, which is the clinical target of CORLUX. Antipsychotics include Bristol-Myers Squibb's Abilify, Novartis' Clozaril, Pfizer's Geodon and Navane, Ortho-McNeil's Haldol, Janssen Pharmaceutica's Risperdal, AstraZeneca's Seroquel, GlaxoSmithKline's Stelazine and Thorazine, Mylan's Mellaril, Schering Corporation's Trilafon and Eli Lilly's Zyprexa. CORLUX may not compete effectively with these established treatments. We are aware of one clinical trial conducted by Organon, for a new chemical entity for the treatment of psychotic depression. Organon was the pharmaceutical division of Akzo Nobel, which was purchased by Schering Plough. Organon's new chemical entity is a GR-II antagonist, the commercial use of which would be covered by our patent. As discussed above, in 2004, Akzo Nobel filed an observation in our exclusively licensed European patent application with claims directed to psychotic depression, in which it challenged the claims of that patent application. In 2005, we filed a rebuttal to the EPO that responded to the points raised by Akzo Nobel. In February 2006, the EPO allowed our patent application. In July 2006, the patent was issued. As of the time of filing of this report, we are not aware of any other public disclosures by any company, regarding the development of new products to treat psychotic depression.

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, either alone or with collaborative parties, may succeed with the development and commercialization of medicinal products that are superior to and more cost-effective than CORLUX. Many of our competitors and related private and public research and academic institutions have greater experience, more financial 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 developing human medicines, obtaining regulatory approvals, manufacturing and commercializing products.

Accordingly, CORLUX may not be an effective competitor against established treatments and our present or potential competitors may succeed in developing medicinal products that are superior to CORLUX or render CORLUX obsolete or non-competitive. If we are unable to establish CORLUX as a superior and cost-effective treatment for psychotic depression, or any future use, we may be unable to generate the revenues necessary to support our business.

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Rapid technological change could make our product candidates obsolete.

Pharmaceutical technologies have undergone rapid and significant change and we expect that they will continue to do so. Our future will depend in large part on our ability to maintain a competitive position with respect to these technologies. Any products and processes that we develop may become obsolete or uneconomical before we recover any or all expenses incurred in connection with their development. Rapid technological change could make our product candidates obsolete or uneconomical, which could materially adversely affect our business, financial condition and results of operations.

We have no sales staff and limited marketing activities and will need to develop sales and marketing capabilities to successfully commercialize CORLUX and any future uses of GR-II antagonists.

Our employees have limited experience in marketing or selling pharmaceutical products and we currently have no sales staff and limited marketing activities. To achieve commercial success for any approved product, we must either develop a sales and marketing force or enter into arrangements with others to market and sell our future products. We currently plan to establish small, specialty sales forces to market and sell CORLUX in the United States for the treatment of Cushing's Syndrome and for the treatment of the psychotic features of psychotic depression, as each indication is approved for marketing by the FDA. However, our sales and marketing efforts may not be successful or cost-effective. In the event that the commercial launch of CORLUX is delayed due to FDA requirements or other reasons, we may establish a sales and marketing force too early relative to the launch of CORLUX. This may be expensive, and our investment would be lost if the sales and marketing force could not be retained. If our efforts to develop a sales and marketing force are not successful, cost-effective and timely, we may not achieve profitability.

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

As we expand our research and development efforts and develop a sales and marketing organization, we expect to experience growth, which may strain our operations, product development and other managerial and operating resources. Future 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, including a number of part-time contributors. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to manage any future growth effectively.

To that end, we must be able to:

manage our research and development efforts effectively;

manage our clinical trials effectively;

integrate additional management, clinical development, administrative and sales and marketing personnel;

expand the size and composition of our management team;

develop our administrative, accounting and management information systems and controls; and

hire and train additional qualified personnel.

We may not be able to accomplish these tasks, and our failure to accomplish any of them could harm our business.

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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.

We depend substantially on the principal members of our management and scientific staff, including Joseph K. Belanoff, M.D., our Chief Executive Officer, and Robert L. Roe, M.D., our President. 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.

Our ability to operate successfully and manage our potential future growth depends significantly upon retaining key research, technical, sales, marketing, managerial and financial personnel, and attracting and retaining additional highly qualified personnel in these areas. We face intense competition for such personnel from numerous companies, as well as universities and nonprofit research organizations in the highly competitive northern California business 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 result in delays in the research, development and commercialization of our potential products.

If we acquire other GR-II antagonists 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 become available, we may attempt to acquire other GR-II antagonists, particularly GR-II antagonists that do not terminate pregnancy. We may also be able to acquire other technologies or potential products that are complementary to our operating plan. We currently have no commitments, agreements or plans for any acquisitions. The process of acquiring rights to another GR-II antagonist or any other 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.

The occurrence of a catastrophic disaster or other similar events could cause damage to our or our manufacturers' facilities and equipment, which could require us to cease or curtail operations.

Because our executive offices are located in the San Francisco Bay Area and some of our current manufacturers are located in earthquake-prone areas, 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. 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 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.

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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 of the Company or factors influencing the stock market and opportunities for sale at any given time may be limited.

We cannot assure you 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 March 15, 2010, our average daily trading volume has been approximately 36,000 shares and the intra-day sales prices per share of our common stock on the NASDAQ Capital Market has ranged from \$0.73 to \$3.22. As of March 15, 2010, our officers, directors and principal stockholders control approximately 60% 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:

our cash and short-term investment position;

actual or anticipated timing and results of our clinical trials;

actual or anticipated regulatory approvals of our product candidates or of competing products;

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;

actual or anticipated variations in quarterly operating results;

announcements of technological innovations by us, our collaborators or our competitors;

new products or services introduced or announced by us or our competitors;

general market and economic conditions, including those seen as a result of the recent worldwide financial credit crisis;

changes in financial estimates or recommendations by securities analysts;

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;

developments concerning collaborations;

trading volume of our common stock;

limited number of shares of our common stock held by our non-affiliates;

maintaining compliance with the listing requirements of the stock exchange on which we are listed;

announcement of, or expectation of, additional financing efforts; and

sales of our common stock by us or our stockholders.

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In addition, the stock market in general, the Nasdaq Capital Market 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 those companies. These broad market and industry factors 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.

If we fail to continue to meet all applicable Nasdaq Capital Market requirements, our stock could be delisted by the Nasdaq Capital Market. If delisting occurs, it would adversely affect the market liquidity of our common stock and harm our business.

If we are unable to meet any of the Nasdaq listing requirements in the future, including, for example, if the closing bid price for our common stock is below \$1 per share for 30 consecutive trading days, the Nasdaq Capital Market staff could determine to delist our common stock, the delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease. Such delisting could also adversely affect our ability to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees.

Securities analysts may not continue to provide or initiate coverage of our common stock or may issue negative reports, and this may have a negative impact on our common stock's market price.

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. 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 would likely decline rapidly and significantly. If one or more of these analysts ceases coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline. In addition, rules mandated by the Sarbanes-Oxley Act of 2002, and a global settlement reached in 2003 between the SEC, other regulatory analysts and a number of investment banks have led to a number of fundamental changes in how analysts are reviewed and compensated. In particular, many investment banking firms are required to contract with independent financial analysts for their stock research. It may be difficult for companies such as ours with smaller market capitalizations to attract independent financial analysts that will cover our common stock. This could have a negative effect on our market price.

A 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, the supply of our common stock will increase, which could decrease the price. Substantially all of the shares of our common stock are eligible for sale, subject to applicable volume and other resale restrictions.

We may be required to pay significant amounts if we are not able to meet our obligations under our outstanding registration rights agreements.

The registration rights agreement covering the approximately 8.9 million shares of our common stock issued in a private offering in March 2008 and an additional approximately 4.5 million shares of common stock underlying warrants issued in connection with the offering provided that if we failed to file or cause to be declared effective the registration statement covering the resale of these shares prior to a specified deadline, or failed to maintain the effectiveness of such registration statement (subject to limited permissible suspension

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periods), we would be required to pay the holders of such shares and warrants liquidated damages at the rate of 1% of the purchase price of these shares and warrants per month, up to a total of 10%. The registration statement covering the resale of the shares and shares underlying the warrants sold in this transaction was declared effective by the SEC in November 2008. Since this registration statement was not declared effective within the time frame specified in the registration rights agreement, we became obligated to pay the investors in this financing liquidated damages of approximately \$1.3 million in 2008. As noted above, if we fail to maintain the effectiveness of this registration statement, we may be obligated to pay additional liquidated damage amounts in the future.

See the discussion above under **Risks Related to our Business** regarding risks associated with the CEFF, including the risks regarding registration rights under that agreement.

If we are required to pay significant amounts under these or future registration rights agreements, it could have a material adverse effect on our financial condition and ability to finance our operations.

Our officers, directors and principal stockholders acting as a group, will be able to significantly influence corporate actions.

As of March 15, 2010, our officers, directors and principal stockholders control approximately 60% 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 result in increased costs to us, which may harm our financial results.

New laws and regulations, as well as changes to existing laws and regulations, affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted by the SEC and by The Nasdaq Capital Market, would likely 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 general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities.

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. 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.

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

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 impose comprehensive reporting and disclosure requirements, set stricter independence and financial expertise standards for audit committee members, and impose civil and criminal penalties for companies, their chief executive officers, principal financial officers and directors for

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securities law violations. These requirements have increased and will continue to increase our legal compliance costs, increase the difficulty and expense in obtaining director and officer liability insurance, and make it harder for us to attract and retain qualified members of our Board of Directors and/or qualified executive officers. Such developments could harm our results of operations and divert management's attention from business operations.

In addition, as directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the company's internal control over financial reporting in their annual reports on Form 10-K. This requirement first applied to our annual report on Form 10-K for the year ended December 31, 2007. This same legislation 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. The SEC postponed the initial compliance date for this requirement for smaller reporting companies such that the requirement for the auditor's attestation and report will first apply to our annual report on Form 10-K for our fiscal year ending December 31, 2010. Uncertainty exists regarding our ability to comply with these requirements by applicable deadlines and to maintain compliance in future years. If we are unable to complete the required assessment as to the adequacy of our internal control over financial reporting in 2009 or in future years 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 as of the required deadline in 2010 and as of future year ends, 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, including policies regarding are subject to continual review, interpretation and guidance from relevant accounting authorities, including the SEC. For example, in December 2004, the Financial Accounting Standards Board adopted Financial Accounting Standard 123R, Share Based Payment. This statement, which we adopted in 2006, requires the recording of expense for the fair value of stock options granted. As a result, our operating expenses have increased and are likely to continue to increase. We rely heavily on stock options to compensate existing employees and attract new employees. Because we are now required to expense stock options on a fair-value basis, we may choose to reduce our reliance on stock options as a compensation tool. If we reduce our use of stock options, it may be more difficult for us to attract and retain qualified employees. 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.

Anti-takeover provisions in our charter and bylaws and under Delaware law may make an acquisition of us or a change in our management more 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 divide our board into three classes with only a portion of our directors subject to election at each annual meeting, 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 is appointed by our board of directors. 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% or more of our outstanding voting stock, from merging or combining with us. These provisions in our charter, bylaws and

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under Delaware law could reduce the price that investors might be willing to pay for shares of our common stock in the future and result in the market price being lower than it would be without these provisions.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We lease approximately 7,700 square feet of office space in Menlo Park, California for our corporate facilities. On October 20, 2008, we renewed our lease for office space for a two-year term commencing on January 1, 2009. The new lease provides us an option to extend the lease for an additional year upon 180 days notice. We expect that these facilities will accommodate our operations for the next year.

ITEM 3. LEGAL PROCEEDINGS

We are not currently involved in any material legal proceedings.

ITEM 4. (Removed and Reserved)

Table of Contents**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.

	High	Low
2009		
First Quarter	\$ 1.46	\$ 0.75
Second Quarter	\$ 1.29	\$ 0.73
Third Quarter	\$ 1.65	\$ 0.75
Fourth Quarter	\$ 3.10	\$ 1.36
	High	Low
2008		
First Quarter	\$ 3.50	\$ 2.25
Second Quarter	\$ 4.29	\$ 1.85
Third Quarter	\$ 2.43	\$ 1.19
Fourth Quarter	\$ 1.90	\$ 0.80

Stockholders of Record and Dividends

As of March 15, 2010, we had 62,703,717 shares of common stock outstanding held by 144 stockholders of record. We have never declared or paid cash dividends on our capital stock. 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.

Sale of Unregistered Securities

All sales of unregistered securities during the year ended December 31, 2009 have previously been disclosed in filings with the SEC. We have used, or will use, the net proceeds from these transactions to fund our research, development, and administrative activities, as well as for general corporate purposes, including working capital.

Sales and Repurchases of Securities

See Item 12, "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" for information with respect to our compensation plans under which equity securities are authorized for issuance.

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.

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The rules of the SEC require that we include a line-graph comparing cumulative stockholder returns on our common stock with the NASDAQ Composite Index (which tracks the aggregate price performance of equity securities of companies traded on NASDAQ) 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 approximately 130 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 CAPITAL MARKET (U.S.) INDEX
AND THE NASDAQ BIOTECHNOLOGY INDEX

* \$100 invested on December 31, 2004 including reinvestment of dividends. Fiscal year ending December 31.

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The selected financial data set forth below are derived from our financial statements. The statement of operations data for the years ended December 31, 2007, 2008 and 2009 and for the period from inception (May 13, 1998) to December 31, 2009 and the balance sheet data as of December 31, 2008 and 2009 are derived from our audited financial statements included in this Annual Report on Form 10-K (Form 10-K). The statements of operations data for the years ended December 31, 2005 and 2006, and the balance sheet data as of December 31, 2006, 2005 and 2004 have been derived from our audited financial statements, which are not included in this Form 10-K. 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 Form 10-K.

	Year Ended December 31,					Period from inception (May 13, 1998) to December 31, 2009
	2009	2008	2007	2006	2005	
Statement of Operations Data:						
Collaboration revenue	\$ 29	\$ 209	\$ 482	\$ 294	\$	\$ 1,014
Operating expenses:						
Research and development*	14,402	14,152	7,860	20,834	17,074	114,211
General and administrative*	5,877	5,746	4,867	5,042	4,084	40,762
Total operating expenses	20,279	19,898	12,727	25,876	21,158	154,973
Loss from operations	(20,250)	(19,689)	(12,245)	(25,582)	(21,158)	(153,959)
Non-operating income (expense), net	84	(372)	672	709	1,065	3,721
Net loss	\$ (20,166)	\$ (20,061)	\$ (11,573)	\$ (24,873)	\$ (20,093)	\$ (150,238)
Net loss per share:						
Basic and diluted	\$ (0.38)	\$ (0.43)	\$ (0.34)	\$ (1.09)	\$ (0.89)	
Weighted average shares basic and diluted	52,443	46,721	34,251	22,841	22,608	
* Includes non-cash stock-based compensation (recovery) of the following:						
Research and development	\$ 263	\$ 268	\$ 213	\$ 535	\$ (26)	\$ 5,276
General and administrative	1,552	1,360	846	1,013	799	9,562
Total non-cash stock-based compensation	\$ 1,815	\$ 1,628	\$ 1,059	\$ 1,548	\$ 773	\$ 14,838

	As of December 31,				
	2009	2008	2007	2006	2005
Balance Sheet Data:					
Cash, cash equivalents and investments	\$ 23,867	\$ 18,309	\$ 17,366	\$ 9,456	\$ 29,619
Working capital	22,001	16,717	14,662	6,286	25,984

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Total assets	24,511	19,775	17,744	9,902	30,156
Long-term liabilities		6	16	29	42
Total stockholders' equity	22,092	16,907	14,734	6,360	26,593

See our financial statements and related notes for a description of the calculation of the net loss per share and the weighted-average number of shares used in computing the per share amounts.

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ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS **Forward-Looking Statements**

This Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements within the meaning of Section 21E of the Exchange Act and Section 27A of the Securities Act and should be read in conjunction with the Risk Factors section of Part I of this Form 10-K. 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, may, will, should, seeks and similar expressions are 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 may include, but are not limited to, statements about:

the progress and timing of our research, development and clinical programs and the timing of regulatory activities;

the timing of the market introduction of CORLUX® and future product candidates, including CORT 108297;

estimates of the dates by which we expect to report results of our clinical trials and the anticipated results of these trials;

our ability to market, commercialize and achieve market acceptance for CORLUX or other future product candidates, including CORT 108297;

uncertainties associated with obtaining and enforcing patents;

our estimates for future performance; and

our estimates regarding our capital requirements and our needs for, and ability to obtain, additional financing.

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 Risk Factors included in Part I 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. 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 SEC.

Overview

We are a pharmaceutical company engaged in the discovery and development of drugs for the treatment of severe metabolic and psychiatric disorders. Since our inception in May 1998, we have been developing our lead product, CORLUX, a potent glucocorticoid receptor II (GR-II) antagonist. We are also developing three series of novel selective GR-II antagonists.

Cushing's Syndrome

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

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year, which equates to approximately 3,000 new patients in the United States. This results in an estimated prevalence of 20,000 patients with Cushing's Syndrome in the United States.

The Investigational New Drug application (IND) for the evaluation of CORLUX for the treatment of Cushing's Syndrome was opened in September 2007. The United States Food and Drug Administration (FDA) has indicated that our single 50-patient open-label study may provide a reasonable basis for the submission of a New Drug Application (NDA) for this indication. We expect to complete enrollment in this Phase 3 study in April, as the requisite 50 patients have now been dosed or identified. We expect to announce results of this study in the fourth quarter of this year and to submit our NDA for the use of CORLUX in Cushing's Syndrome by year-end 2010.

In July 2007, we received Orphan Drug Designation from the FDA for CORLUX for the treatment of endogenous Cushing's Syndrome. 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 in the United States. Drugs that receive Orphan Drug Designation obtain seven years of marketing exclusivity 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.

Psychotic Depression

We are also developing CORLUX for the treatment of the psychotic features of psychotic major depression under an exclusive patent license from Stanford University. Psychotic major depression will hereinafter be referred to as psychotic depression. The FDA has granted fast track status to evaluate the safety and efficacy of CORLUX for the treatment of the psychotic features of psychotic depression.

In March 2008, we commenced enrollment in Study 14, our ongoing Phase 3 trial in psychotic depression. The protocol for this trial incorporates what we have learned from our three previously completed Phase 3 trials to address the established relationship between increased drug plasma levels and clinical response and attempts to decrease the random variability observed in the results of the psychometric instruments used to measure efficacy. In one of the previously completed Phase 3 trials, Study 06, we prospectively tested and confirmed that patients whose plasma levels rose above a predetermined threshold statistically separated from both those patients whose plasma levels were below the threshold and those patients who received placebo; this threshold was established from data produced in earlier studies. As expected, patients who took 1200 mg of CORLUX in Study 06 developed higher drug plasma levels than patients who received lower doses. Further, there was no discernable difference in the incidence of adverse events between placebo and any of the three CORLUX dose groups in Study 06. Based on this information, we are using a CORLUX dose of 1200 mg once per day for seven days in Study 14. In addition, we also are utilizing a third party centralized rating service to independently evaluate the patients for entry into the study as well as for their level of response. We believe the centralization of this process will improve the consistency of rating across clinical trial sites and reduce the background noise that was illustrated in earlier studies and is endemic to many psychopharmacologic studies. We believe that this change in dose, as well as the other modifications to the protocol, should allow us to demonstrate the efficacy of CORLUX in the treatment of the psychotic symptoms of psychotic depression. In March 2009, we announced that, in order to lower variable and fixed expenses and to conserve financial resources, we were scaling back our planned rate of spending on this trial and extended the timeline for its completion. As of early July 2009, we completed the implementation of this strategy, which included reducing the number of clinical sites to eight.

Management of Weight Gain Induced by Antipsychotics

In 2005, we published the results of studies in rats that demonstrated that CORLUX both reduced the weight gain associated with the ongoing use of olanzapine and mitigated the weight gain associated with the initiation of treatment with olanzapine (the active ingredient in Zyprexa). This study was paid for by Eli Lilly and Company (Eli Lilly.)

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During 2007 we announced positive results from our clinical proof-of-concept study in lean healthy male volunteers evaluating the ability of CORLUX to mitigate weight gain associated with the use of Zyprexa. The results show a statistically significant reduction in weight gain in those subjects who took Zyprexa plus CORLUX compared to those who took Zyprexa plus placebo. Also, the addition of CORLUX to treatment with Zyprexa had a beneficial impact on secondary metabolic measures such as fasting insulin, triglycerides and abdominal fat, as indicated by waist circumference. Eli Lilly provided Zyprexa and financial support for this study. In January 2009 we announced positive results from a similar proof-of-concept study evaluating the ability of CORLUX to mitigate weight gain associated with the use of Johnson & Johnson's Risperdal. This study, which began in 2008, confirmed the earlier results seen with CORLUX and Zyprexa, demonstrating a statistically significant reduction in weight and secondary metabolic endpoints of fasting insulin, triglycerides and abdominal fat, as indicated by waist circumference. The results from the study of CORLUX and Risperdal were presented at several scientific conferences, including the American Diabetes Association meeting in June 2009.

The combination of Zyprexa or Risperdal and CORLUX is not approved for any indication. The purpose of these studies was to explore the hypothesis that GR-II antagonists would mitigate weight gain associated with atypical antipsychotic medications. The group of medications known as atypical antipsychotics, including Zyprexa, Risperdal, Clozaril and Seroquel, 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.

Research

In 2003, we initiated a discovery research program to identify and patent selective GR-II antagonists to develop a pipeline of products for proprietary use. Three distinct series of GR-II antagonists were identified. These compounds appear to be as potent as our lead product CORLUX in blocking cortisol but, unlike CORLUX, they do not appear to block the PR (progesterone), ER (estrogen), AR (androgen) or GR-I (mineralocorticoid) receptors. Composition of matter patents on all of the three series have been granted in Europe. The patent on two series have issued in the United States. Examination has not yet begun in the United States on the third.

New Chemical Entity CORT 108297

In 2007, we commenced a human microdosing study of one of our newly identified selective GR-II antagonists, CORT 108297, with Xceleron Limited utilizing their Accelerator Mass Spectrometry technology. In this microdosing study, we evaluated CORT 108297, a compound which develops particularly high plasma and brain concentrations in an animal model. On May 1, 2008, we announced the results from this study, which demonstrated that CORT 108297 was extremely well absorbed, demonstrated good bioavailability and had a half-life that appears compatible with once-a-day oral dosing. In addition, further pharmacokinetic testing of CORT 108297 in a rat model indicated that a ten-fold increase in oral dose (5 milligrams per kilograms to 50 milligrams per kilograms) led to a proportional increase in the amount of compound detected in plasma.

In September 2008, we signed a second agreement with Eli Lilly, under which Eli Lilly agreed to provide funding and provide olanzapine for two studies to test the effectiveness of CORT 108297 in rat models of olanzapine induced weight gain. In January 2009 we announced top-line results from these studies of CORT 108297 and olanzapine. The results from the studies of both the prevention and reversal of antipsychotic-induced weight gain were positive and statistically significant. The results of these studies were presented at the International Society of Psychoneuroendocrinology and the World Congress of Biological Psychiatry conferences in July 2009.

At the American Diabetes Association conference in June 2009 there was also a presentation of preclinical data from another study of CORT 108297 conducted at Stanford University. This study demonstrated that CORT

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108297 suppresses body weight gain and improves insulin sensitivity in healthy mice fed a 60% fat diet and high sucrose liquid.

The manufacturing and pre-clinical development of CORT 108297 began late in 2008 and continued through 2009 as preparatory steps to the submission of an IND with the FDA, which we submitted in December 2009. On February 22, 2010, we began dosing patients in the Phase 1 study with this compound.

General

Our activities to date have included:

product development;

designing, funding and overseeing clinical trials;

regulatory affairs; and

intellectual property prosecution and expansion.

Historically, we have financed our operations and internal growth primarily through private placements of our preferred and common stock and the public sale of common stock rather than through collaborative or partnership agreements. Therefore, we have no research funding or collaborative payments payable to us, except for the limited revenue that has been collected under the agreements with Eli Lilly discussed above.

We are in the development stage and have incurred significant losses since our inception. We have not generated any revenue other than the revenue under the agreements with Eli Lilly, and do not expect to generate significant revenue until CORLUX has been approved by the FDA for marketing in the United States, if at all. As of December 31, 2009, we had an accumulated deficit of \$150.2 million. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for CORLUX, discovery research, non-clinical activities such as toxicology and carcinogenicity studies, manufacturing process development and regulatory activities, as well as general and administrative expenses. We expect to continue to incur net losses over at least the next several years as we continue our CORLUX clinical development program, apply for regulatory approvals, initiate development of newly identified GR-II antagonists for various indications, continue our discovery research program, acquire and develop treatments in other therapeutic areas, establish sales and marketing capabilities and expand our operations.

Our business is subject to significant risks, including the risks inherent in our research and development efforts, the results of our CORLUX clinical trials, uncertainties associated with securing financing, uncertainties associated with obtaining and enforcing patents, our investment in manufacturing set-up, the lengthy and expensive regulatory approval process and competition from other products. Our ability to successfully generate revenues in the foreseeable future is dependent upon our ability, alone or with others, to finance our operations and develop, obtain regulatory approval for, manufacture and market our lead product.

Results of Operations

Collaboration revenue. Collaboration revenue relates to services rendered in connection with our agreements with Eli Lilly discussed above under the caption Overview-Management of Weight Gain induced by Antipsychotics. Under these agreements, Eli Lilly agreed to supply the Zyprexa and olanzapine and pay for the costs of the studies. We were required to perform development activities as specified in the agreements and we were reimbursed based on the costs associated with the conduct of the trial and the preparation and packaging of clinical trial materials. Revenue was recognized as the services are rendered in accordance with the agreements.

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During the years ended December 31, 2009, 2008 and 2007, we recognized approximately \$29,000, \$209,000 and \$482,000, respectively, under these agreements. There will be no revenue under the agreements in the future as all of the activities were completed by mid-2009.

Research and development expenses. Research and development expenses include the personnel costs related to our development activities, including facilities costs and non-cash stock-based compensation, as well as the costs of discovery research, pre-clinical studies, clinical trial preparations, enrollment and monitoring expenses, regulatory costs, the costs of manufacturing development and the costs of manufacture and / or acquisition of clinical trial materials.

Research and development expenses increased 2% to \$14.4 million for the year ended December 31, 2009 from \$14.2 million for the year ended December 31, 2008. During 2009, as compared to 2008, there were increases of approximately \$1.9 million in costs related to research, manufacturing and IND-enabling work with our selective GR-II antagonist, CORT 108297, \$830,000 related to the Phase 3 trial and the long-term extension study in Cushing's Syndrome, \$242,000 related to the conduct of other NDA-supportive studies, \$260,000 in staffing costs, \$130,000 of consulting expenses and \$90,000 related to the cost of a carcinogenicity study. Offsetting these increases were decreases of approximately \$1.5 million in manufacturing expenses related to CORLUX due to the acquisition and manufacture during 2008 of the initial supply of materials for the CORLUX clinical trials and completion of certain manufacturing process development activities related to CORLUX, \$840,000 related to the scaling back of our Phase 3 trial of CORLUX in psychotic depression that was announced in March 2009, \$610,000 in basic research on our selective GR-II antagonists as CORT 108297 moved into the IND-enabling phase and \$210,000 related to our clinical trial of CORLUX for the mitigation of weight gain caused by Risperdal that was completed early in 2009.

Research and development expenses increased 80% to \$14.2 million for the year ended December 31, 2008, from \$7.9 million for the year ended December 31, 2007. The increase in expenses reflects clinical trial cost increases of approximately \$5.1 million related to trials in psychotic depression, Cushing's Syndrome and the mitigation of weight gain caused by Risperdal that commenced in 2008, which were partially offset by decreases of approximately \$3.1 million due to the completion of our earlier Phase 3 clinical trials for psychotic depression, our cardiac study and our earlier human proof of concept study in the mitigation of Zyprexa induced weight gain in 2007. During 2008, we also performed two smaller clinical studies to test formulation development and drug-drug interaction at a cost of approximately \$705,000. During the year ended December 31, 2008 as compared to 2007, there were also increases in contract research expenses of approximately \$750,000 due to basic research work on new chemical compounds, approximately \$495,000 related to other research and preclinical work with our selective new GR-II antagonist, CORT 108297, and approximately \$209,000 of costs associated with the rat studies using this compound in combination with olanzapine, which was conducted in connection with the agreement with Eli Lilly discussed above. In addition, during the year ended December 31, 2008, there was an increase in manufacturing expenses of approximately \$925,000 due to the acquisition and manufacture of materials for the clinical trials and manufacturing process development. There were also increases of approximately \$565,000 in staffing costs, \$530,000 in consulting expenses, \$135,000 in travel costs and \$115,000 in the allocation of facilities costs during 2008 as compared to 2007.

Research and development expenses discussed above included stock based compensation charges related to option grants to individuals performing these functions of approximately \$265,000, \$270,000 and \$240,000, respectively, for the years ended December 31, 2009, 2008 and 2007. The increase in expense between years was primarily the result of expense related to new option grants calculated on a straight-line basis, which was partially offset by the decrease of expense due to the declining scale of expense related to earlier option grants that were being expensed using the graded vesting method. In addition, during 2007, upon the termination of an employee who worked in a development function, we recorded a reversal of approximately \$25,000 of previously reported stock-based compensation expense, which represents the difference between the expense recorded and the expense that would have been recorded based upon the rights to options that vested during the service of these individuals as employees. There were no terminations or conversions to consultant during 2008 or 2009.

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

Project	Year Ended December 31,		
	2009	2008*	2007*
	<i>(in thousands)</i>		
CORLUX			
Psychotic Depression	\$ 5,030	\$ 5,948	\$ 2,993
Cushing's Syndrome	2,952	2,316	553
Weight Gain Mitigation	565	1,588	677
Selective GR-II antagonists	3,940	2,186	917
Unallocated activities, including NDA supportive studies and manufacturing, regulatory, pre-clinical activities	1,652	1,846	2,507
Stock-based compensation	263	268	213
Total research and development expense	\$ 14,402	\$ 14,152	\$ 7,860

* The data in the table above for the years ended December 31, 2007 and 2008 has been reorganized to be consistent with the presentation for 2009 to recognize that certain costs such as NDA supportive studies, some manufacturing activities, regulatory and pre-clinical activities are not readily allocable to any one product or indication as these activities benefit multiple products and/or indications.

We expect that research and development expenditures will increase during 2010 as compared to 2009 due to the continuation of our Phase 3 studies in Cushing's Syndrome and psychotic depression, and the continued development of CORT 108297 and our other proprietary selective GR-II antagonists. Research and development expenses in 2011 and future years will be largely dependent on the availability of additional funds to finance clinical development plans. See also, Liquidity and Capital Resources .

Many factors can affect the cost and timing of our trials including inconclusive results requiring additional clinical trials, slow patient enrollment, adverse side effects in study patients, insufficient supplies for our clinical trials and real or perceived lack of effectiveness or safety of the drug in our trials. The cost and timing of development of our selective GR-II antagonists will be dependent on our success in the effort and any difficulties that may be encountered. In addition, the development of all of our product candidates will be subject to extensive governmental regulation. These factors make it difficult for us to predict the timing and costs of the further development and approval of our product candidates.

General and administrative expenses. General and administrative expenses consist primarily of the costs of administrative personnel and related facility costs along with legal, accounting and other professional fees.

For the year ended December 31, 2009, general and administrative expenses increased 2% to \$5.9 million from \$5.7 million for the year ended December 31, 2008. This increase reflects higher staffing costs of approximately \$445,000, due primarily to the recruitment of our new chief financial officer during the fourth quarter of 2008, which includes a net increase in stock-based compensation of \$180,000 that reflects the expense related to stock options granted to our new chief financial officer, other employees and directors late in 2008 and during 2009. During this period, there were also increases in professional fees and consultancy costs of approximately \$195,000, primarily related to the costs associated with periodic filings with the SEC and the preparations for the initial year of auditor attestation under SOX section 404, which requirement was deferred until 2010 by the SEC in a ruling announced in October 2009. These increases were partially offset by a decrease of approximately \$575,000 in legal expenses due primarily to the reduction in patent related legal costs in 2009 as compared to the prior year.

General and administrative expenses increased 18% to \$5.7 million for the year ended December 31, 2008 from \$4.9 million for the year ended December 31, 2007. The increase in costs between years was primarily an

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increase of approximately \$510,000 of legal costs related to patent activities and combined increases in staffing and consultancy costs of approximately \$415,000. The changes in staffing costs include increases in non-cash stock-based compensation of approximately \$510,000 and in recruiting costs of approximately \$130,000, which were partially offset by a decrease of approximately \$320,000 related to bonus compensation. The increase in stock-based compensation was the net result of approximately \$315,000 of costs associated with additional stock options being expensed under the straight-line method, decreases of approximately \$200,000 associated with the declining scale of expense of options accounted for under the graded vesting method and the inclusion in 2007 of a reversal of approximately \$395,000 of stock-compensation expense in connection with the resignation of an officer, which represented the excess of expense under the graded vesting method as compared with the expense associated with stock options that actually vested prior to this termination.

General and administrative expenses included stock-based compensation expense related to option grants to individuals performing these functions of approximately \$1.5 million, \$1.4 million and \$1.2 million, respectively, for the years ended December 31, 2009, 2008 and 2007.

The amount of general and administrative expenses in 2010 and future years will be largely dependent on our assessment of the staff necessary to support our continued clinical development activities, potential product commercialization support and the availability of additional funds. See also, Liquidity and Capital Resources .

Interest and other income, net. Interest and other income, net of investment management fees, was approximately \$101,000 for the year ended December 31, 2009 as compared to \$945,000 for the same period in 2008 and \$690,000 in 2007. Interest income in 2009 and 2008 included approximately \$60,000 and \$410,000, respectively, related to the note receivable in connection with the March 2008 Financing, which was collected in February 2009. In addition, there were also decreases in yields and balances of invested funds as compared to 2008. The increase in net interest income in 2008 as compared to 2007 is the net result of the interest on this note being partially offset by decreased yields and balances of invested funds as compared to 2007.

Other expense. Other expense for the year ended December 31, 2009 was approximately \$17,000 as compared to \$1.3 million in 2008 and \$15,000 in 2007. The other expense for 2008 was primarily related to the cost of liquidated damages due to the delay in the effectiveness of the registration statement of the securities sold in the March 2008 Financing. Other expense includes interest expense on capitalized leases and state tax on capital, which is based on our capital and asset positions as of each year-end.

Liquidity and Capital Resources

We have incurred operating losses since inception, and at December 31, 2009, we had a deficit accumulated during the development stage of \$150.2 million. Since our inception, we have relied primarily on the proceeds from public and private sales of our equity securities to fund our operations.

At December 31, 2009, we had cash, cash equivalents and investments balances of \$23.9 million, compared to \$18.3 million at December 31, 2008. Net cash used in operating activities for the years ended December 31, 2009, 2008 and 2007, was \$18.0 million, \$18.4 million and \$11.0 million, respectively. The use of cash in each period was primarily a result of our research and development activities and amounts incurred to develop our administrative infrastructure.

During 2009 we sold common stock and warrants in a private placement generating gross proceeds of approximately \$18.0 million and we sold common stock to Kingsbridge Capital Limited (Kingsbridge), a private investment group, under a Committed Equity Financing Facility (CEFF) generating an additional \$250,000. Issuance costs for these transactions totaled approximately \$725,000. In February 2009, we collected a note receivable of \$6.0 million that had been issued in March 2008 in connection with the March 2008 Financing. In January 2010, we sold additional stock to Kingsbridge under the CEFF for proceeds of \$625,000. The net proceeds of all these transactions have been, or will be, used for general corporate purposes.

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We expect cash used in operating activities to increase during 2010 as the increased spending on the continuation of our Cushing's Syndrome study and the development of our selective GR-II antagonists, including CORT 108297, is expected to be only partially offset by the decreased spending on psychotic depression, as compared to spending levels during 2009. We expect our funding requirements for operating activities will increase during later years due to the continuation and expansion of our development programs for Cushing's Syndrome, psychotic depression and our selective GR-II antagonists, research activities, commercialization activities and general and administrative expenses.

We believe that we have sufficient capital resources to maintain our operations into early 2011, including the planned completion of enrollment of our Phase 3 Cushing's Syndrome trial, continuation of our long-term extension study in this indication, and other activities in preparation of the submission of an NDA for CORLUX for the treatment of Cushing's Syndrome, the continuation of enrollment in our Phase 3 psychotic depression trial, the early clinical development of CORT 108297, one of our proprietary, selective GR-II antagonists, and research activities aimed at the selection of additional compounds for further study.

We will need to raise additional funds to continue the development of CORLUX for the treatment of Cushing's Syndrome or the psychotic features of psychotic depression beyond early 2011, to prepare for the commercialization of CORLUX for either of these indications and to continue and expand the development of our proprietary selective GR-II antagonists.

We cannot be certain that additional funding will be available on acceptable terms or at all. Further, any additional equity financing may be dilutive to stockholders, and 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, including potentially our lead product candidate that we would otherwise seek to develop on our own. 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.

In March 2008, we entered into a CEFF with Kingsbridge. Under the terms of the agreement, Kingsbridge committed to provide up to \$60 million of capital in exchange for newly-issued shares of our common stock for a period of up to three years after the SEC declares effective the registration statements filed by us covering the resale of the shares of common stock issuable in connection with the CEFF and the shares of common stock underlying the warrant issued to Kingsbridge. In June 2008, the SEC declared effective our registration statement with the SEC covering the resale of approximately 3.6 million of the shares issuable under the CEFF and the shares issuable upon the exercise of the warrant issued to Kingsbridge. This registration statement covers approximately 37% of the 9.6 million shares of our common stock issuable pursuant to the CEFF and all of the 330,000 shares of our common stock issuable upon exercise of the warrant issued to Kingsbridge. As of the filing of this report, approximately 2.9 million shares remain available for sale under the initial registration statement. We intend to file an additional registration statement covering the resale of the remaining 6.0 million shares of our common stock issuable pursuant to the CEFF approximately 60 days after Kingsbridge and its affiliates have resold substantially all of the securities registered for sale under this initial registration statement.

Under the terms of the agreement, the determination of the exact timing and amount of any CEFF financings will be made solely by us, subject to certain conditions. The agreement currently requires a minimum stock price of \$1.50 per share to allow us to issue shares to Kingsbridge under the CEFF. Through January 2010, we have raised a total of approximately \$1.6 million from the sales of stock under the CEFF. Based on the volume weighted average price on the NASDAQ Capital Market for our common stock for the period from March 25, 2008, the date of the signing of the Kingsbridge CEFF, through March 15, 2010, the maximum amount of additional funds that could be raised under the CEFF is approximately \$16 million. The actual amount of funds that can be raised under this agreement will be dependent on the number of shares actually sold under the agreement and the market value of our stock during the pricing periods of each sale.

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While we monitor the cash balance in our checking account and transfer the funds in only as needed, these cash balances could be impacted if the underlying financial institution were to fail or could be subject to other adverse conditions in the financial markets. On October 23, 2008, the Federal Deposit Insurance Corporation implemented its Temporary Liquidity Guarantee Program. Under this program, non-interest bearing commercial accounts are insured to an unlimited amount through June 30, 2010, thus mitigating our exposure to any possible bank failure. To date, we have experienced no loss or lack of access to cash in our checking accounts.

As a result of volatile market conditions, the cost and availability of capital has been and may continue to be adversely affected by illiquid capital markets. Concern about the stability of the markets generally and the strength of counterparties specifically has led many lenders and institutional investors to reduce, and in some cases, cease to provide credit to businesses and consumers. Continued turbulence in the U.S. and international markets and economies and prolonged declines in business consumer spending may adversely affect our liquidity and financial condition, including our ability to access the capital markets to meet liquidity needs.

Contractual Obligations and Commercial Commitments

The following table presents our estimates of obligations under contractual agreements as of December 31, 2009:

Payments Due by Period	Less	1-3	3-5	More than
	than 1	Years	Years	5 Years
	year			
	<i>(in thousands)</i>			
Research and development studies ^{(1) through (4)}	\$ 4,156	\$ 7,894	\$	\$
Operating lease ⁽⁵⁾	241			
Capital leases ⁽⁶⁾	6			
Minimum royalty payments ^{(7) (8)}	150	100	100	50 per year
Total	\$ 4,553	\$ 7,994	\$ 100	\$ 50 per year

- (1) Amounts reflected for research and development studies exclude amounts included in accounts payable and accrued clinical costs reflected on the balance sheet as of December 31, 2009.
- (2) During 2007 and 2008, we signed agreements for services in connection with our trials for CORLUX for the treatment of Cushing's Syndrome. The total commitment under these agreements is approximately \$2.1 million. Approximately \$900,000 of costs under these agreements have been expensed as of December 31, 2009, with the remainder to be expensed over the remainder of the trials. Under the master agreement with these vendors, the agreements may be terminated upon sixty days notice to the vendors. If terminated early, we would be responsible for the costs incurred by the vendor through the effective date of the termination plus cancellation charges as stipulated in the various agreements.
- (3) During 2008, we signed agreements for services in connection with our ongoing Phase 3 trial to confirm the utility of CORLUX for the treatment of the psychotic features of psychotic depression. The total commitment under these original agreements was approximately \$21.1 million. In June 2009, we amended these agreements to reduce the amounts of commitments with these organizations by approximately \$5.0 million in accordance with the reduction in the near-term scope of activities under this trial. However, we view the reduction in these commitments as a temporary measure as it is our intent to continue the conduct of this trial to its conclusion, when sufficient capital is available for this purpose. Approximately \$7.0 million of these costs was expensed through December 31, 2009, with the remainder to be incurred over the course of the trial. Under the master services agreements with these vendors, the project contracts may be terminated upon thirty to sixty day's notice. If terminated early, we would be responsible for the costs incurred by the vendors through the effective date of termination plus cancellation charges as stipulated in the agreements.
- (4) During the period from October to December 2009, we signed agreements with contract research organizations and other vendors for the conduct of four of the NDA-supportive studies for aggregate commitments of approximately \$2.2 million. Approximately \$870,000 of costs under these agreements has been expensed as of December 31, 2009, with the remainder to be incurred during 2010.
- (5) In October 2008, we renewed the operating lease agreement for our office facility for a two-year term commencing on January 1, 2009. The new lease provides us an option to extend the lease for an additional year upon 180 days notice.
- (6) During 2005, we entered into capital leases for the acquisition of certain pieces of office furniture. The obligations under these leases will be fully satisfied during 2010.
- (7) Under our cancellable license agreement with Stanford University, we are obligated to make nonrefundable minimum royalty payments of \$50,000 annually for as long as we maintain our licenses with Stanford; however, these payments are creditable against future royalties.

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(8) Under the agreement with our contract research company, we are obligated to make a payment of \$100,000 related to the commencement in February 2010 of the Phase 1 clinical trial evaluating CORT 108297.

We also have other contractual payment obligations, the timing of which is contingent on future events.

- (a) Under our license agreement with Stanford University related to the patent covering the use of GR-II antagonists to treat the psychosis associated with psychotic depression and early dementia, we are obligated to make milestone payments to Stanford of \$50,000 upon filing of an NDA covering the licensed product and \$200,000 upon FDA approval of the licensed product. The milestone payments payable to Stanford under these licenses are creditable against future royalties.
- (b) Under the agreement with our contract research company we may be obligated to make milestone payments upon the occurrence of certain events, including: (i) patent filings in connection with the project; (ii) entries into Phase 1 clinical trials; and (iii) national regulatory approval of each product arising from work performed under the agreement, provided that sales of the product by the Company or any future licensees reach \$5,000,000. These obligations remain in force after the conclusion of work under the agreement. There are no royalty obligations associated with this contract.
- (c) Our agreement with ScinoPharm Taiwan that provides for the manufacture and supply of the active pharmaceutical ingredient for CORLUX includes a minimum purchase commitment of \$1,000,000 per year following the commercial launch of CORLUX. This agreement may be terminated by us at any time without penalty.
- (d) On November 8, 2006, we signed an agreement with Produits Chimiques Auxiliaires et de Synthèse SA (PCAS), for the manufacture of mifepristone, the active pharmaceutical ingredient in CORLUX, for our development and commercial needs for an initial period of five years. The agreement provides for an automatic extension for one additional year unless either party gives twelve months prior notice that it does not want the extension. There is no guaranteed minimum purchase commitment under this agreement. If PCAS is unable to manufacture the product for a consecutive six-month period, we have the right to terminate the agreement without penalty.
- In February 2010, we signed an agreement with a clinical research organization for the conduct of a Phase 1 clinical study to evaluate CORT 108297 for a commitment of approximately \$690,000 and, in March 2010, we signed agreements with two contract research organizations and a clinical research site for the conduct of two NDA-supportive studies for CORLUX for aggregate commitments of approximately \$1.2 million. All of these amounts are expected to be expended in 2010.

Net Operating Loss Carryforwards

At December 31, 2009 we had approximately \$76.4 million of federal net operating loss carryforwards and approximately \$4.9 million in federal research and development tax credit carryforwards, as well as approximately \$76.7 million of California net operating loss carryforwards and approximately \$1.3 million in California research and development tax credit carryforwards, available to offset any future taxable income we may generate. The federal and California net operating loss and tax credit carryforwards will expire beginning in 2019 and 2012, respectively. Our deferred tax assets have been offset by a full valuation allowance as the realization of such assets is uncertain. The Internal Revenue Code of 1986, as amended, places certain limitations on the annual amount of net operating loss and tax credit carryforwards that can be utilized in any particular year if certain changes in our ownership occur.

Off-Balance Sheet Arrangements

None.

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Critical Accounting Policies and Estimates

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Accruals of Research and Development Costs. We recorded accruals for estimated costs of research, pre-clinical and clinical studies, and manufacturing development of approximately \$710,000 and \$990,000 as of December 31, 2009 and 2008, respectively. These costs are a significant component of our research and development expenses. We make significant judgments and estimates in determining the accrual balance in each reporting period. Accrued clinical trial costs are based on estimates of the work completed under the service agreements, milestones achieved, patient enrollment and past experience with similar contracts and service providers. Our estimate of the work completed, and associated costs to be accrued, includes our assessment of the information received from our third-party contract research organizations and the overall status of our clinical trial activities. In the past, we have not experienced any material deviations between accrued clinical trial expenses and actual clinical trial expenses. However, actual services performed, number of patients enrolled and the rate of patient enrollment may vary from our estimates, resulting in adjustments to clinical trial expense in future periods.

Stock-based compensation. Stock-based compensation arises from the granting of stock options to employees and directors, as well as to non-employees.

Employees and directors

Our accounting practices and the estimates and judgments that are considered in determining fair value in regard to stock option grants to employees and directors are as follows:

Options granted subsequent to January 1, 2006:

- i The grant date fair value for all new grants issued after January 1, 2006 is being amortized to expense using the straight-line method over the vesting period of the options.
- i The expected term used in determining the fair value for options is based on the simplified method prescribed by the SEC that considers the weighted average of the vesting period and contractual life of the options. There has been no adjustment made to the expected term to adjust for employees' expected exercise and expected post-vesting termination behavior because we have a limited employee base and do not have sufficient historical information to determine such an adjustment.
- i The expected volatility of our common stock used in determining the fair value of option grants is based on a weighted-average combination of the volatility of our own stock price and that of a group of peer companies since we do not have sufficient historical data from which to base an appropriate volatility assumption.

Options granted prior to January 1, 2006:

- i For options granted prior to our initial public offering (IPO) in 2004, we have continued to account for the portion of these grants that were non-vested as of January 1, 2006 based on the intrinsic value of these grants.

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For the options granted after the IPO, we began, as of January 1, 2006, to record non-cash stock-based compensation expense in the financial statements in amounts that represent the remaining fair value of the non-vested portion of these grants.

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- i For all options granted prior to January 1, 2006, we are continuing to utilize the graded-vesting attribution method for amortization of the relevant compensation amounts.

Since we have a limited employee base, we do not have sufficient historical information to determine a reasonable forfeiture rate for options that might not vest because of employee terminations and, therefore, do not apply a forfeiture rate. When an employee terminates, we will record a change in accounting estimate that represents the difference between the expense recorded in the financial statements and the expense that would have been recorded based upon the rights to options that vested during the individual's service as an employee.

As of December 31, 2009, the Company had approximately \$4.1 million of unrecognized compensation expense for employee options outstanding as of that date, which had a remaining weighted-average vesting period of 2.3 years.

Non-employees

Stock-based compensation related to option grants to non-employees is charged to expense on a straight line basis over the vesting period of the options, based on the fair value of the options, which approximates the period over which the related services are rendered, using the Black-Scholes option pricing model. The assumptions used in these calculations are similar to those used for the determination of fair value for options granted to employees, with the exception that, for non-employee options, we are required to use the remaining contractual term as the life of the option and the fair value related to unvested non-employee options is re-measured quarterly, based on the then current stock price as reflected on the Nasdaq Capital Market.

Recently Adopted Accounting Standards

In October 2009, the Financial Accounting Standards Board (FASB) adopted a change in the accounting standards applicable to revenue arrangements with multiple deliverables. This change eliminates the residual method of allocation and the requirement to use the relative selling price method when allocating revenue in a multiple deliverable arrangement. When applying the relative selling price method, the selling price for each deliverable needs to be determined using vendor specific objective evidence of selling price, if it exists, otherwise third-party evidence of selling price. If neither vendor specific objective evidence nor third-party evidence of selling price exists for a deliverable, it is permissible to use the best estimate of the selling price for that deliverable when applying the relative selling price method. This change is to be applied on a prospective basis for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, with earlier application permitted. As the Company does not have any such agreements at this time, this change is not expected to have an impact on our financial statements.

Recently Issued Accounting Standards

In September 2009, the Emerging Issues Task Force of the Financial Accounting Standards Board (EITF) discussed possible changes to the standard regarding the milestone method of revenue recognition. Under the milestone method, the additional consideration earned from achievement of the milestone is viewed as being indicative of the value provided to the customer through either (a) the efforts performed by the vendor or (b) a specific outcome resulting from the vendor's performance to achieve that specific milestone. Under the milestone method an entity recognizes contingent arrangement consideration earned from the achievement of a milestone in its entirety in the period in which the milestone is achieved. The proposed model requires that a milestone be substantive before this method can be applied; that is, there is a substantial uncertainty about the achievement of the milestone, substantive effort is required to achieve the milestone, and none of the payment for the milestone is refundable. The EITF did not reach a consensus on this issue. The task force will continue deliberations on this issue at future meetings. The adoption of such a standard is not expected to have an impact on our financial statements as we currently have no such arrangements.

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ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Quantitative and Qualitative Disclosures About Market Risk

Market Risk

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk of loss. As of December 31, 2009, our cash and cash equivalents consisted primarily of money market funds maintained at major U.S. financial institutions. To minimize our exposure to interest rate risk, we have limited the maturities of our investments to less than two years with an average maturity not to exceed one year. Due to the short-term nature of these instruments, a 1% increase or decrease in market interest rates would not have a material impact on the total value of our portfolio as of December 31, 2009.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this item are set forth beginning at page F-1 of this report and are incorporated herein by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A(T). CONTROLS AND PROCEDURES

(a) Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Evaluation of disclosure controls and procedures. We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and discussed with our management, including our Chief Executive Officer, Chief Financial Officer and Chief Accounting Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As of December 31, 2009, our Chief Executive Officer, Chief Financial Officer and Chief Accounting Officer have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) which were designed to ensure that the information required to be disclosed by us in this Annual Report on Form 10-K was recorded, processed, summarized and reported within the time periods specified in the SEC's rules and Form 10-K. Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met. Based on the evaluation, our Chief Executive Officer, Chief Financial Officer and Chief Accounting Officer have concluded that our disclosure controls and procedures are effective.

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(b) Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control system is designed to provide reasonable assurance regarding the preparation and fair presentation of financial statements for external purposes in accordance with generally accepted accounting principles. All internal control systems, no matter how well designed, have inherent limitations and can provide only reasonable assurance that the objectives of the internal control system are met.

Under the supervision and with the participation of our management, including our Chief Executive Officer, Chief Financial Officer and Chief Accounting Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on our evaluation, we concluded that our internal control over financial reporting was effective as of December 31, 2009.

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report on internal controls over financial reporting was not subject to attestation by our independent registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only management's report in this annual report.

(c) *Changes in internal controls.* There were no changes in our internal controls over financial reporting during the quarter ended December 31, 2009 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

Table of Contents**PART III****ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE****Board of Directors**

The following table sets forth, as of December 31, 2009, the name, age and occupation of each member of our Board of Directors:

Name	Age	Occupation
James N. Wilson ⁽³⁾	66	Chairman of the Board of the Company
Joseph K. Belanoff, M.D.	52	Chief Executive Officer of the Company
G. Leonard Baker, Jr. ⁽²⁾	67	Venture Capitalist
Joseph C. Cook, Jr. ⁽¹⁾⁽³⁾	67	Investor
Patrick G. Enright ⁽¹⁾	48	Venture Capitalist
James A. Harper ⁽²⁾	62	Retired Pharmaceutical Executive
David L. Mahoney ⁽¹⁾⁽²⁾	55	Private Equity Investor
Edward E. Penhoet, Ph. D. ⁽⁴⁾	69	Venture Capitalist

(1) Member of audit committee

(2) Member of compensation committee

(3) Member of nominating and corporate governance committee

(4) Dr. Penhoet resigned from our Board of Directors, effective January 5, 2010

The directors are elected at each annual meeting of stockholders, or special meeting in lieu thereof. The directors serve for a one-year term until the next annual meeting of stockholders and until their successors are elected and qualified. In addition to the information presented below regarding each director's specific experience, qualifications, attributes and skills that led our Board to the conclusion that each individual should serve as a director, we also believe that all of our director nominees have a reputation for integrity, honesty and adherence to high ethical standards. They each have demonstrated business acumen and an ability to exercise sound judgment, as well as a commitment of service to us and our Board of Directors. The Board of Directors believes that the backgrounds and qualifications of the directors, considered as a group, provides a significant composite mix of experience, knowledge and abilities that allows the Board of Directors to fulfill its responsibilities.

James N. Wilson has served as a director and as Chairman of the Board since 1999. In addition, since 2005, Mr. Wilson has been the Chairman of the Board of NuGEN Technologies, Inc., a provider of systems for genomic analysis. From 2002 to 2009, he served as a director of Amylin Pharmaceuticals, Inc., a biopharmaceutical company, and from 1996 to 2001 Mr. Wilson was Chairman of the Board of Amira Medical, Inc., which was acquired by Hoffmann-La Roche A.G. From 1991 to 1994, he was Chief Operating Officer of Syntex Corporation, which was acquired by Roche Holding, Ltd. From 1989 to 1990, Mr. Wilson was Chairman and Chief Executive Officer of Neurex Corporation, which was acquired by Elan Corporation plc, and from 1982 to 1988, Mr. Wilson was Chief Executive Officer of LifeScan, Inc., which was acquired by Johnson & Johnson Company. Mr. Wilson received his B.A. and M.B.A. from the University of Arizona. Mr. Wilson brings to the Board of Directors extensive experience in the biotechnology industry, evidenced by nearly 30 years of representing biotechnology companies as a director or officer.

Joseph K. Belanoff, M.D. is a co-founder and has served as a member of the Board and as our Chief Executive Officer since 1999. 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. From 1997 to 2001, he served as the Director of Psychopharmacology at the outpatient division of the Palo Alto Veterans Affairs Hospital. Dr. Belanoff received his B.A. from Amherst College and his M.D. from Columbia University's College of Physicians & Surgeons. As our Chief Executive Officer, Dr. Belanoff brings expertise and knowledge regarding our business and operations to our Board of Directors. Dr. Belanoff also has expertise in clinical medicine and psychopharmacology.

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G. Leonard Baker, Jr. has served as a member of the Board of Directors since 1999. Since 1973, Mr. Baker has been a Managing Director of the General Partner of Sutter Hill Ventures, a venture capital firm. Mr. Baker currently serves on the boards of a number of private companies. Mr. Baker received his B.A. from Yale University and his M.B.A. from Stanford University. Mr. Baker has broad experience in advising companies, including expertise in capital raising, strategic transactions and operations.

Joseph C. Cook, Jr. has served as a member of the Board of Directors since 2002. Mr. Cook served as Chairman of the Board of Amylin Pharmaceuticals, Inc. from 2003 to 2009 and as its Chief Executive Officer from 1998 to 2003. Mr. Cook is a founder and currently serves as Chairman of the Board of Ironwood Pharmaceuticals, Inc. Mr. Cook is an officer of Mountain Ventures, Inc. and a founder of Clinical Products, Inc. and Mountain Group Capital, LLC. Mr. Cook also serves as a director of Mercy Ministries International and as a member and past Chairman of the University of Tennessee College of Engineering Advisory Board. Mr. Cook retired as Group Vice President of Eli Lilly in 1993 after more than 28 years of service. Mr. Cook received his B.S. from the University of Tennessee. Mr. Cook brings to our Board of Directors extensive experience in the pharmaceutical industry.

Patrick G. Enright has served as a member of the Board of Directors since April 2008. He is a founder of Longitude Capital Management Co., LLC, a venture capital firm focused on investments in biotechnology and has served as its Managing Director since 2006. From 2002 through 2006, Mr. Enright was a Managing Director of Pequot Ventures where he co-led the life sciences investment practice. Prior to Pequot, he was a Managing Member responsible for the Delta Opportunity Fund, where he invested in privately-held and publicly-traded biotechnology companies, such as SUGEN, Inc. and Cephalon, Inc. Mr. Enright began his investment career at PaineWebber Development Corporation, a direct investment group focused primarily on biotechnology companies. Mr. Enright also has significant life sciences operations experience. He was CFO and Senior Vice President Business Development of Valentis, Inc. (now Urigen Pharmaceuticals, Inc.) and Senior Vice President Finance and Business Development of Boehringer Mannheim Pharmaceuticals (now Hoffmann-La Roche). Mr. Enright began his life sciences career 23 years ago at Sandoz (now Novartis). He currently serves on the boards of Corcept and a number of privately-held companies. Mr. Enright has served within the last five years, on the Board of Directors of Infacare Pharmaceuticals, Xanodyne Pharmaceuticals, Jazz Pharmaceuticals, Threshold Pharmaceuticals, Sequenom and Valentis. Mr. Enright holds an M.B.A. from the Wharton School of Business at the University of Pennsylvania and a B.S. in Biological Sciences from Stanford University. Mr. Enright has extensive knowledge of finance and experience in the biotechnology industry.

James A. Harper has served as a member of the Board of Directors since October 2004. Mr. Harper held various positions with Eli Lilly, from which he retired in 2004. Mr. Harper served as Group Vice President and Chief Marketing Officer from 2001 to 2004 and as President, Diabetes and Growth Disorders Business Unit / Product Group from 1994 to 2001. He was a Vice President, Global Pharmaceutical Marketing, from 1993 to 1994 and was President and CEO, Advanced Cardiovascular Systems, Inc. from 1991 to 1993. Mr. Harper also serves on the Board of Directors of Zymogenetics, Inc., including membership on the Audit and Compensation Committees, and the Board of Directors of Phenomix Corporation, where he serves as the Chairman of the Board and a member of the Compensation Committee. Zymogenetics, Inc. and Phenomix Corporation are both biotechnology companies. Mr. Harper served on the Board of Directors of Anesiva, Inc., a biotechnology company, from 2007 through 2008, including as a member of the Compensation Committee. He is also an advisor for Nomura Phase4 Ventures. Mr. Harper received his B.A. from Vanderbilt University and his M.B.A. from The Wharton School of Business. He has spent over 30 years in the pharmaceutical and healthcare industries and expertise in marketing,

David L. Mahoney is a private equity investor who has served as a member of the Board since July 2004. From 1999 to 2001, Mr. Mahoney served as co-CEO of McKesson HBOC, Inc., a healthcare supply management and information technology company and as CEO of iMcKesson LLC, a healthcare management and connectivity company. He joined McKesson Corporation in 1990 as Vice President for Strategic Planning. Prior to joining McKesson, Mr. Mahoney was a principal with McKinsey & Company where he worked from 1981 to 1990. He also serves on the Board of Directors of Symantec Corporation, Adamas Pharmaceuticals,

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San Francisco Museum of Modern Art, Mercy Corps and NCPB, Inc., a public television and radio operator. Mr. Mahoney served on the Board of Directors of Tercica, Inc., a pharmaceutical company, from 2004 through 2008, including as a member of the Audit and Compensation committees. Tercica was acquired by the Ipsen Group in 2008. Mr. Mahoney received his B.A. from Princeton University and his M.B.A. from Harvard University. Mr. Mahoney brings to our Board of Directors extensive experience in operating and advising technology companies.

Edward E. Penhoet served as a member of the Board from June 2008 to January 2010. He has served as a Director of Alta Partners, LLP, a venture capital firm, since 2000. He is a member of the Boards of Directors of ChemoCentryx, Chimerix, Immune Design Corp, Scynexis, and ZymoGenetics, and serves as the Chairman of the Board for Metabolex. A co-founder of Chiron, he served as the company's President and Chief Executive Officer from its formation in 1981 until April 1998. Dr. Penhoet is a member of the Independent Citizens Oversight Committee for the California Institute of Regenerative Medicine (CIRM), and recently served as the President of the Gordon and Betty Moore Foundation. For 10 years prior to founding Chiron, he was a faculty member of the Biochemistry Department of the University of California, Berkeley. Dr. Penhoet is the immediate past Dean of the School of Public Health at the University of California, Berkeley. He is a member of the Institute of Medicine of the National Academy of Sciences and has co-authored more than 50 scientific articles and papers. Dr. Penhoet was recently appointed to President Obama's Council of Advisors on Science and Technology (PCAST). Due to time pressures from this appointment to PCAST, Dr. Penhoet resigned from our Board of Directors, effective January 5, 2010,

There are no family relationships among any of our directors or executive officers.

Executive Officers

The following table sets forth, as of December 31, 2009, information about our executive officers:

Name	Age	Position
Joseph K. Belanoff, M.D.	52	Chief Executive Officer and Director
Robert L. Roe, M.D.	69	President and Secretary
Caroline M. Loewy	43	Chief Financial Officer
Anne M. LeDoux	62	Vice President, Controller and Chief

Accounting Officer

Joseph K. Belanoff, M.D.'s background is discussed above.

Robert L. Roe, M.D. joined us as President in October 2001. Dr. Roe has spent more than 30 years in the pharmaceutical and biotechnology industries. From 1999 to 2001, he served as President and Chief Executive Officer of Allergan, Inc. From 1996 to 1999, he was Executive Vice President, Chief Operating Officer and a director of Cytel Corporation. From 1995 to 1996, he was Executive Vice President, Chief Operating Officer and a director of Chugai Biopharmaceuticals, Inc. From 1992 to 1995, Dr. Roe served as President of the Development Research Division and Senior Vice President of Syntex Corporation. Dr. Roe received his B.A. from Stanford University and his M.D. from the University of California, San Francisco.

Caroline M. Loewy joined us as Chief Financial Officer in November 2008. From 2006-2008, Ms. Loewy served as Chief Financial Officer of Poniard Pharmaceuticals, a publicly traded biopharmaceutical company. From 2004-2006 she acted as an independent consultant to a variety of biopharmaceutical companies advising on corporate strategy, business development, and financing. Ms. Loewy spent 14 years in equity research and corporate finance. From 2000-2004 she was an Executive Director in biotechnology equity research at Morgan Stanley, providing fundamental analysis and recommendations to investors, as well as strategic advisory services to corporate clients. She was also a Managing Director in biotechnology equity research at Prudential Securities and held positions in corporate finance at BankAmerica. Ms. Loewy holds a BA degree from the University of California, Berkeley, and an MBA/MS degree from Carnegie Mellon University.

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Anne M. LeDoux joined the company as Controller in 2004 and was promoted to the position of Vice President, Controller and Chief Accounting Officer in April 2007. Ms. LeDoux has over 15 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 and has 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.

Board Meetings and Committees

The Board met five times during 2009. The Audit Committee met four times and the Compensation Committee met twice. The Nominating and Corporate Governance Committee did not meet during 2009. Each member of the Board attended 75% or more of the total number of Board meetings and meetings of Board committees on which such Board member served.

The Board has standing Audit, Compensation and Nominating and Corporate Governance Committees as described below.

Audit Committee. The Audit Committee currently consists of David L. Mahoney (chairman), Joseph C. Cook, Jr. and Patrick G. Enright. The Board has determined that all members of the Audit Committee are independent directors under the rules of the Nasdaq Capital Market and each of them is able to read and understand fundamental financial statements. In addition, the Board has determined that each member of the Audit Committee also satisfies the independence requirements of Rule 10A-3(b)(1) of the Exchange Act. The Board has determined that David L. Mahoney qualifies as an Audit Committee financial expert as defined by Item 407(d)(5) of Regulation S-K of the Securities Act and the Exchange Act. The purpose of the Audit Committee is to oversee the accounting and financial reporting processes and financial statements audits. The responsibilities of the Audit Committee include appointing and providing the compensation of the independent accountants to conduct the annual audit of our accounts, reviewing the scope and results of the independent audits, reviewing and evaluating internal accounting policies, and approving all professional services to be provided to us by our independent auditors.

Compensation Committee. The Compensation Committee currently consists of G. Leonard Baker, Jr. (chairman), James A. Harper and David L. Mahoney. Allen Andersson was also a member of this committee until his term as a director was concluded at the Annual Meeting on June 11, 2009. The Board has determined that all members of the Compensation Committee are independent directors under the rules of the Nasdaq Capital Market. The Compensation Committee administers our benefit plans, reviews and administers all compensation arrangements for executive officers, and establishes and reviews general policies relating to the compensation and benefits of our officers and employees.

Nominating and Corporate Governance Committee. Our Nominating and Corporate Governance Committee consists of Joseph C. Cook, Jr. (chairman), and James N. Wilson. The Nominating and Governance Committee is responsible for identifying individuals qualified to serve as members of the Board, recommending to the independent members of the Board nominees for election as our directors and providing oversight with respect to corporate governance and ethical conduct. Although Mr. Wilson is our employee and therefore not an independent director for NASDAQ purposes, our director nomination process meets applicable NASDAQ requirements because our director nominees are selected by the independent members of the Board.

Communications with Directors

Stockholders or other interested parties may communicate with any director or committee of the Board by writing to them c/o Secretary, Corcept Therapeutics, 149 Commonwealth Drive, Menlo Park, California 94025.

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Comments or questions regarding our accounting, internal controls or auditing matters will be referred to members of the Audit Committee. Comments or questions regarding the nomination of directors and other corporate governance matters will be referred to members of the Nominating and Governance Committee.

We encourage our directors to attend the annual stockholder meetings. Seven of our directors attended the 2009 annual meeting.

Code of Ethics

We have adopted a code of ethics that applies to all officers and employees, including its principal executive officer, principal financial officer and controller. This code of ethics has been filed as Exhibit 14.1 to our Registration Statement on Form S-1/A (Registration No. 333-112676) filed with the SEC on March 19, 2004. We will also deliver a copy of our code of ethics to any stockholder, without charge, upon written request to Corcept Therapeutics, 149 Commonwealth Drive, Menlo Park, California 94025, Attention: Secretary, or upon oral request by calling (650) 327-3270.

Section 16(a) Beneficial Ownership Reporting Compliance

Under Section 16(a) of the Exchange Act and SEC rules, our directors, executive officers and beneficial owners of more than 10% of any class of equity security are required to file periodic reports of their ownership, and changes in that ownership, with the SEC. Based solely on our review of copies of these reports and representations of such reporting persons, we believe that during 2009, such SEC filing requirements were satisfied

ITEM 11. EXECUTIVE COMPENSATION Compensation Discussion and Analysis

Compensation Objectives

For Joseph K. Belanoff, M.D., our Chief Executive Officer, Robert L. Roe, M.D., our President, Caroline M. Loewy, our Chief Financial Officer, and Anne LeDoux, our Vice President and Controller (Chief Accounting Officer), our named executive officers (NEOs), compensation is intended to be performance-based, with the exception of such NEOs' base salary. The Compensation Committee believes that compensation paid to NEOs should be closely aligned with our performance on both a short-term and long-term basis, linked to specific, measurable results intended to create value for stockholders, and that such compensation should assist us in attracting and retaining key executives critical to our long-term success.