CORCEPT THERAPEUTICS INC Form 10-K March 15, 2011 Table of Contents

# 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, 2010

or

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

For the transition period from to

Commission File Number: 000-50679

# CORCEPT THERAPEUTICS INCORPORATED

(Exact Name of Corporation as Specified in Its Charter)

Delaware 77-0487658

(State or other jurisdiction of incorporation or organization)

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

149 Commonwealth Drive

Menlo Park, CA 94025

(Address of principal executive offices) (zip code)

(650) 327-3270

(Registrant s telephone number, including area code)

Securities registered pursuant to Section 12 (b) of the Act:

**Title of Each Class:** Common Stock, \$0.001 par value

Name of Each Exchange on which Registered: 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 x

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 x

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 x 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 and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer " Accelerated filer x Non-accelerated filer " (Do not check if a smaller reporting company) Smaller reporting company x Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes " No x

The aggregate market value of voting and non-voting common equity held by non-affiliates of the Registrant was approximately \$119,000,000 as of June 30, 2010 based upon the closing price on the Nasdaq Capital Market reported for such date. This calculation does not reflect a determination that certain persons are affiliates of the Registrant for any other purpose.

On March 8, 2011 there were 83,968,540 shares of common stock outstanding at a par value of \$0.001 per share.

## DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant s definitive proxy statement for its 2011 Annual Meeting of Stockholders are incorporated by reference in Items 10, 11, 12, 13 and 14 of Part III.

## EXPLANATORY NOTE

The Registrant meets the accelerated filer requirements as of the end of its 2010 fiscal year pursuant to Rule 12b-2 of the Securities Exchange Act of 1934, as amended. However, pursuant to Rule 12b-2 and SEC Release No. 33-8876, the Registrant (as a smaller reporting company transitioning to the larger reporting company system based on its public float as of June 30, 2010) is not required to satisfy the larger reporting company requirements until its first quarterly report on Form 10-Q for the 2011 fiscal year and is thus eligible to check the Smaller Reporting Company box on the cover of this Form 10-K.

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#### PART I

This Annual Report on Form 10-K (Form 10-K) contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act), and Section 27A of the Securities Act of 1933, as amended (Securities Act). All statements contained in this Form 10-K, other than statements of historical fact, are forward-looking statements. When used in this report or elsewhere by management from time to time, the words believe, anticipate, intend, plan, estimate, expect, may, will, should, seeks and simi 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 and timing of our research, development and clinical programs and the timing of regulatory activities, including the anticipated submission of the New Drug Application (NDA) for CORLUX for the treatment of Cushing s Syndrome to the United States Food and Drug Administration (FDA), the acceptance of that NDA for filing by the FDA and the review and approval of the NDA by the FDA;

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 and CORT 113083;

our ability to market, commercialize and achieve market acceptance for CORLUX or other future product candidates, including CORT 108297 and CORT 113083;

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, development and commercialization 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 CORT 108297, a compound from one of these series, into clinical development. Unless otherwise stated, all references in this document to we, us, our, its, Corcept, the Company and similar designations of the company and sincrease of the company and similar designations of the company an

Corcept Therapeutics Incorporated.

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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.

The Investigational New Drug application (IND) for the evaluation of CORLUX for the treatment of the signs and symptoms of Cushing s Syndrome was opened in September 2007. The United States Food and Drug Administration (FDA) 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 completed enrollment in this Phase 3 study in June 2010. This open-label Phase 3 study evaluated the response of two patient groups to CORLUX treatment: one included patients who were glucose intolerant, regardless of blood pressure level, and one included patients who had been diagnosed with hypertension but had normal glucose tolerance. The patients in both of these groups were being treated for their symptoms before study entry; CORLUX was added to their existing medications. On December 22, 2010, we announced that both groups in this study achieved their primary endpoints. After this announcement, we determined that one patient did not fully adhere to the protocol for this study and have since then revised our calculation of the percentage of patients in the hypertensive group meeting the primary endpoint. This did not impact our determination that this group achieved its primary endpoint. On January 11, 2011, we announced positive results for the key secondary endpoint of global clinical improvement. For this endpoint all of the patients in the study were included in one group.

Statistically significant improvement in the primary endpoint was achieved for each group with 60% responding in the glucose intolerant group and 38% responding in the hypertensive group. The patients in the study, whether included in the glucose intolerant group or the hypertensive group for the purpose of evaluating the primary endpoints, were evaluated as a single group on the key secondary endpoint of global clinical improvement; 87% of patients showed significant clinical improvement as evaluated by an independent board of three physicians highly experienced in the treatment of Cushing s Syndrome. An initial review of safety data indicates that CORLUX had an acceptable risk-benefit profile in this Phase 3 study. Adverse events related to treatment included signs and symptoms of adrenal insufficiency, endometrial thickening, and hypokalemia, all of which were consistent with earlier published reports. The majority of the serious adverse events (SAEs) reported in the study were not related to CORLUX treatment, as determined by the clinical investigators. All of the treatment-related SAEs resolved with clinical management. Eighty-eight percent of the patients who completed the Phase 3 study opted to enter the long-term extension study. We expect to submit our NDA for the use of CORLUX in Cushing s Syndrome by the end of the first quarter of 2011 and plan to present detailed data from the Phase 3 trial at scientific conferences during 2011.

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 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 attempts to decrease the random variability observed in the results of the psychometric instruments used to

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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 milligrams (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 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 mid-2009, in order to conserve financial resources, we reduced the number of clinical sites in this study to eight and extended the timeline for its completion.

Antipsychotic-induced Weight Gain Mitigation. In 2005, we published the results of studies in rats that demonstrated that CORLUX both reversed 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).

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 and its results were published in the journal *Advances in Therapy* in 2009. 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 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, and were published in the journal *Obesity* in 2010.

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.

Selective GR-II Receptor Antagonists. 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, like our lead product CORLUX, potently block the cortisol receptor (GR-II) but, unlike CORLUX, they do not appear to block the PR (progesterone), ER (estrogen), AR (androgen) or GR-I (mineralocorticoid) receptors. Both the United States Patent & Trademark Office (USPTO)

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and the European Patent Office (EPO) have issued to us composition of matter patents on all of the three series. A fourth composition of matter patent application is pending. See Business Intellectual Property.

CORT 108297 and CORT 113083

In 2007, we conducted a human microdosing study of one of our newly identified selective GR-II antagonists, CORT 108297, with Xceleron Limited utilizing its 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. In May 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 kilogram (mg/kg) to 50 mg/kg) 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 108297 suppresses body weight gain and improves insulin sensitivity in healthy mice fed a 60% fat diet and high sucrose liquid.

The manufacturing and preclinical development of CORT 108297 began late in 2008 and resulted in the submission of an IND to the FDA in December 2009 for the prevention of weight gain induced by antipsychotic medication. Dosing of healthy volunteers in the first Phase 1 study of CORT 108297 was completed in July 2010. A Phase 1b/2a study of this drug was initiated during the fourth quarter of 2010, with the first patients being dosed in December 2010.

During the second quarter of 2010, we selected a second new compound, CORT 113083, to advance toward an IND filing. CORT 113083 has demonstrated substantial bioavailability in animal models. During the third quarter of 2010, we commenced various manufacturing development and preclinical studies supporting an IND filing for this compound.

## 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.

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

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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 throughout the body, including 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 that, like CORLUX, potently block the GR-II receptor, but, unlike CORLUX, do not block the progesterone receptor. We have selected two compounds from one of these series for further development. CORT 108297 is now in clinical development and we are working on IND-enabling activities with CORT 113083.

## 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 Syndrome. Symptoms vary, but most people have one or more of the following manifestations: high blood sugar,

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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 excess cortisol 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 signs and symptoms typically associated with Cushing s Syndrome. These symptoms can include weight gain, diabetes, hypertension, poor tissue quality, fatigue, osteoporosis, cataracts, hirsutism, 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 50 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 we are not aware of any formal trials completed prior to the initiation of our Phase 3 trial, 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 conducted a Phase 3 trial with CORLUX for the treatment of endogenous Cushing s Syndrome. In June 2010, we completed enrollment in a single 50-patient open-label study, in which each patient s dose was titrated to clinical benefit, and the primary endpoints focused on improvement in glucose tolerance and blood pressure, while the secondary endpoints focused on 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.

As discussed above, in December 2010 we announced positive top-line results from this study, which evaluated the response of two patient groups to CORLUX treatment: one included patients who were glucose intolerant, regardless of blood pressure level, and one included patients who had been diagnosed with hypertension but had normal glucose tolerance. The primary endpoints in the trial were *either* 1) improvement in

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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 was not glucose intolerant at baseline, improvement in diastolic blood pressure at 24 weeks relative to baseline. A patient in the glucose intolerant group was considered a responder if there was 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 (or at the early termination visit) compared to baseline. A patient in the hypertension group was considered a responder if there was a 5 millimeter or greater drop in diastolic blood pressure at 24 weeks (or at the early termination visit) relative to baseline. If a sufficient number of patients in *either* group were responders, such that the lower limit of the exact one-sided 95% binomial confidence interval for the responder rate was greater than 20%, then the trial would have met its primary endpoint. The calculation, which was predetermined in the study design, was based on analyzing the response rates in a modified intention to treat group (mITT group), which was comprised of those patients who received CORLUX for at least 30 days during their participation in the study.

Statistically significant improvement in the primary endpoint was achieved for both groups: with 60% responding in the glucose intolerant group and 38% in the hypertensive group.

15 of 25, or 60%, of patients in the glucose intolerant group responded to treatment with CORLUX, significantly higher than the 20% hurdle rate (lower bound of the 95% Confidence Interval (CI) = 41.7) which equates to p<0.0001.

8 of 21, or 38%, of patients in the hypertensive group responded to treatment with CORLUX, significantly higher than the 20% hurdle rate (lower bound of the 95% CI = 20.6) which equates to p<0.05.

After our December 2010 announcement of our top-line primary endpoint results, we determined that one patient had a protocol violation that prevented an accurate efficacy assessment and subsequently revised our calculations of the percentage of patients in the hypertensive group meeting the primary endpoint. This revision is reflected in the results shown above. However, this revision did not impact our determination that statistically significant improvement was achieved for patients in the hypertensive group, as well as the glucose intolerant group.

The key secondary endpoint in the trial, global clinical improvement, was designed to capture the broader clinical benefit of CORLUX in this patient population. The patients in the study, whether included in the glucose intolerant group or the hypertensive group for the purpose of evaluating the primary endpoints, were evaluated as a single group on the key secondary endpoint of global clinical improvement. As discussed above, in January 2011, we announced that 87% of patients in this study showed a positive response to CORLUX based on global clinical improvement (lower bound of the 95% CI = 75.87) which equates to p<0.000001.

Global clinical improvement was determined by a Data Review Board (DRB), an independent three-member group of highly experienced academic physicians, expert in the evaluation and treatment of patients with Cushing's Syndrome. Each member of the DRB independently assessed all efficacy data available for each patient at each study visit beginning at the sixth week of the each patient's trial course and determined if the patient's clinical manifestations of Cushing's Syndrome had worsened, stayed the same, or improved compared to baseline. Data assessed by the DRB in determining global clinical improvement included changes in diabetes and hypertension medications, hemoglobin A1c (HgbA1c), insulin sensitivity, metabolic function, weight, body composition, Cushingoid appearance, cognitive/psychiatric evaluations, and quality of life, as well as other efficacy data collected over the course of the study. With the exception of the baseline visit, DRB members were blinded to visit sequence. At each visit, at least two of the members of the DRB had to determine that a patient had made clinically significant improvement for the patient to be deemed a responder. The key secondary endpoint was determined to have been met if the lower bound of the 95% confidence level of the response rate was greater than 30%. In fact, the response rate was 87%, giving a lower bound of 75.87% or p<0.000001.

An initial review of safety data indicates that CORLUX had an acceptable risk-benefit profile in this Phase 3 study. Although the detailed analysis of the safety data from the study has not yet been completed, the tolerability of CORLUX in the treatment of Cushing s Syndrome in the Phase 3 study met our expectations. Adverse events

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related to treatment included symptoms of adrenal insufficiency, endometrial thickening, and hypokalemia, all of which were consistent with earlier published reports. The majority of the SAEs reported in the study were not related to CORLUX treatment, as determined by the clinical investigators. Treatment related SAEs were all resolved with clinical management.

Eighty-eight percent of the 34 patients who completed the Phase 3 study opted to enter the long-term extension study.

#### **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. Under the protocol of this extension study, as originally designed, patients who had completed the initial Phase 3 study would continue to be treated with CORLUX for up to an additional year. In May 2010, in response to investigator requests, we amended the protocol of this study to allow patients to stay on the drug beyond the end of that one year period. Thirty (30) patients opted to enter the long-term extension study after having been treated with CORLUX for six months as part of our Phase 3 study. As of March 1, 2011, four of these patients have been in the extension study for over 18 months and thus have over two years of total treatment.

We have conducted 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, including drug-drug interaction studies. 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.

## 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 seven 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 312) 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 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 Proof-of-Concept Studies 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 reverse the weight gain associated with olanzapine and to prevent the weight gain associated with the initiation of treatment with olanzapine, which led to our studies in humans.

In 2007, we announced results of our human clinical proof-of-concept study evaluating the ability of 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 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; however, the effect of CORLUX in this model was greater than expected. In addition to the finding about waist circumference, notable additional non-statistically significant group differences were observed. Patients taking Zyprexa plus placebo experienced greater increases from baseline to end of study in both triglycerides and fasting insulin compared to patients taking Zyprexa plus CORLUX. No unexpected study drug related adverse events were observed. These results were published in *Advances in Therapy* in 2009.

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 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. These results were published in *Obesity* in 2010.

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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, Clozariclozapine) 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 caused by olanzapine, a medication marketed by Eli Lilly as Zyprexa. Using the same experimental rat model used previously with mifepristone, the preclinical studies demonstrated that CORT 108297 1) reversed and 2) prevented the weight gain caused by olanzapine in rats.

In the first of these two studies, seventy-two female rats (n=12 per group) were allowed to eat a normal diet for 56 days. During an induction phase of weight gain (study days 1-34), 12 rats were administered placebo, whereas 48 were administered olanzapine. Animals receiving olanzapine gained significantly more weight than animals receiving placebo (p<.00001). On Day 35, the 48 animals that had received olanzapine during the weight induction phase were randomized (n=12 per group) to receive one of the following regimens: placebo, CORT 108297 (20mg/kg), CORT 108297 (60mg/kg), CORT 108297 (120mg/kg) for the subsequent 21 days. There were robust, statistically significant, differences in weight between the olanzapine plus placebo and olanzapine plus CORT 108297 groups: Animals receiving olanzapine and placebo continued to gain significant body weight from day 35 to 56 (p<.0001) while animals receiving olanzapine plus CORT 108297 (all doses) exhibited significant weight reduction (p<.0001). At the highest dose tested (120 mg/kg), the animals weight returned to levels observed prior to initial olanzapine ingestion. The results of this first study suggest that after significant weight gain from olanzapine has already occurred, CORT 108297 can be introduced while olanzapine is continued and reverse the weight gain caused by olanzapine.

In the second study, rats (n = 96) were dosed with placebo, olanzapine (2.4 mg/kg), or, olanzapine plus CORT 108297 (2, 6, 20, 60, or 120 mg/kg) for 21 days. From baseline to day 21, rats administered olanzapine plus CORT 108297 gained significantly less weight than rats receiving olanzapine and placebo (p < .00001). Larger doses of CORT 108297 were significantly correlated with greater weight reduction (p < .00001). This second study suggests that when CORT 108297 is administered concomitantly with olanzapine, weight gain associated with the use of olanzapine can be prevented or at least attenuated.

These first two studies used dose levels of 20 mg/kg, 60 mg/kg and 120 mg/kg of CORT 108297. The results of these two experiments replicated the findings from previous animal studies of mifepristone, and were also consistent with results from randomized trials conducted in humans. These studies were recently published in the peer-reviewed journal *Diabetes Obesity Metabolism* in 2010. 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. These data were presented at the 2009 Annual Meeting of American Diabetes Association.

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The manufacturing and preclinical development of CORT 108297 began late in 2008 and resulted in the submission of an IND to the FDA in December 2009. Dosing of healthy volunteers in the first Phase 1 study of CORT 108297 was completed in July 2010. This initial study was a single dose escalation study in healthy volunteers. A Phase 1b/2a study of this drug was initiated during the fourth quarter of 2010, with the first healthy volunteers being dosed in December 2010. The trial is evaluating CORT 108297 in models of antipsychotic induced weight gain and changes in biomarkers induced by prednisone, a steroid.

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 potentially be of benefit to the millions of people currently taking this important pharmacotherapy.

## **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 three families have been allowed or issued in both the United States and Europe. A fourth composition of matter patent application is pending.

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
See	Business	increasing the therapeutic response to ECT.  Intellectual Property.

## **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 and CORT 113083. CORT 108297 has demonstrated attractive characteristics, with high plasma and brain concentrations in an animal model and promising results in a human microdosing study and Phase 1 studies, including good bioavailability and potential for once-daily dosing. CORT 108297 has also demonstrated the ability to prevent and reverse 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 1b/2a study. We plan to submit an IND for CORT 113083 this year.

## **Research and Development**

We incurred approximately \$18.9 million, \$14.4 million and \$14.2 million of research and development expenses in the years ended December 31, 2010, 2009 and 2008, respectively, which accounted for approximately 69%, 71% and 71% of our total operating expenses in these respective fiscal years. For a further discussion, see Part II, Item 7, Management s Discussion and Analysis of Financial Conditions and Results of Operations Results of Operations.

#### **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 commercial 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 1,000 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 plan to execute agreements with specialty pharmacies to distribute CORLUX and provide logistical support.

A large portion of the people who suffer from Cushing s Syndrome remain undiagnosed or inadequately treated. We intend to develop programs to educate the medical community about early diagnosis of this syndrome and to increase awareness regarding the role of GR-II antagonists for this syndrome.

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 1,000 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 undiagnosed or inadequately treated. We intend to develop programs to educate the medical community about early diagnosis of psychotic depression and increase awareness regarding the role of GR-II antagonists for this disorder.

## **Manufacturing of CORLUX**

As a drug discovery, development and commercialization entity, we intend to continue to utilize our financial resources to complete the development and commercialization 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 a manufacturing agreement with one contract manufacturer, Produits Chimiques Auxiliaires et de Synthese SA (PCAS), to produce the active pharmaceutical ingredient (API) for CORLUX. We plan to submit a request for approval for commercial use of material produced by PCAS as part of our NDA submission for CORLUX for the treatment of Cushing s Syndrome. The agreement with PCAS, which was executed in November 2006, is for an initial period of five years with an automatic extension for one additional year and we

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intend to pursue discussions for further extensions. There is no guaranteed minimum purchase commitment under this agreement until NDA approval. After the NDA approval, we agree to purchase from PCAS 100% of our requirements for six months after the approval and 75% of our requirements from six months through 18 months after approval for the initial five year term of the 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. We also have a memorandum of understanding with ScinoPharm Taiwan (ScinoPharm). Pursuant to that memorandum of understanding, ScinoPharm agrees to manufacture API and we agree to purchase at least \$1,000,000 of bulk mifepristone per year following the commercial launch of CORLUX. ScinoPharm is considered to be a potential secondary site for the manufacture of the API. However, no activities are currently being conducted at this site to develop or qualify the manufacturing processes or facilities and we do not plan to include a request for approval of material produced by ScinoPharm when we submit our NDA for Cushing s Syndrome planned for the first quarter of 2011.

We have also entered into an agreement with another contract manufacturer, PharmaForm, L.L.C. (PharmaForm), for the production of CORLUX tablets. To date, our need for CORLUX tablets has been limited to the amounts required to support our clinical trials and the registration batches needed to support our anticipated NDA filing for CORLUX for the treatment of Cushing s Syndrome. The agreement with PharmaForm was executed in December 2006 and will expire upon the completion of the development program for CORLUX, but may be extended. There are no minimum purchase amounts under this agreement.

## 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, which operates as a subsidiary of Medi Challenge (Pty) Ltd., received Orphan Drug Designation for endogenous 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. Novartis completed its Phase 3 trial of pasireotide in Cushing s disease and has stated it plans to submit an NDA to the FDA in the first half of 2011. Novartis filed for regulatory approval of pasireotide in Cushing s disease in the European Union in October 2010.

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.

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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.

#### **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	<b>Expiration Date</b>
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

The corresponding foreign patents expire in 2018.

We are required to make milestone payments and pay royalties to Stanford University on sales of products commercialized under any of the above patents. 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. The expiration dates of these patents and their foreign counterparts range from 2020 to 2025.

In addition, we have seven 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;

neurological damage in premature infants;

catatonia;

migraine headaches;

psychosis associated with interferon-alpha therapy;

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

amyotrophic lateral sclerosis (ALS).

The expiration dates of these patents and their foreign counterparts range from 2023 to 2029.

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 both the United States and Europe. The expiration dates of these U.S. and European patents range from 2025 to 2026. A fourth composition of matter patent application is pending.

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

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

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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 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. See Intellectual Property.

## **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

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any time for various reasons, including a belief that the subjects are being exposed to an unacceptable health risk. The FDA may also require that additional studies be conducted, such as studies demonstrating that the drug being tested does not cause cancer.

After Phase 3 trials are completed, drug developers submit the results of preclinical studies, clinical trials, formulation studies and data supporting manufacturing to the FDA in the form of an NDA for approval to commence commercial sales. The FDA reviews all NDAs submitted before it accepts them for filing. The FDA may request additional information rather than accept an NDA for filing. If the FDA accepts an NDA for filing, it may grant marketing approval, request additional information or deny the application if it determines that the application does not meet regulatory approval criteria. 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 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

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disease or condition providing that the product meets certain criteria. Orphan designation qualifies the sponsor of the product for the tax credit and marketing incentives of the Orphan Drug Act, including seven years of exclusive marketing rights for the specific drug for the orphan indication. 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.

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.* We plan to request a priority review for the NDA for Cushing s Syndrome when it is submitted. 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.

## **Executive Officers**

The following table sets forth, as of December 31, 2010, information about our executive officers:

Name	Age	Position
Joseph K. Belanoff, M.D.	53	Chief Executive Officer and Director
Robert L. Roe, M.D.	70	President and Secretary
Caroline M. Loewy	44	Chief Financial Officer
Steven Lo	43	Vice President of Commercial Operations
Anne M. LeDoux	63	Vice President, Controller and Chief Accounting 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.

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 Allergenics, 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.

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Caroline M. Loewy joined us as Chief Financial Officer in November 2008. From 2006 to 2008, Ms. Loewy served as Chief Financial Officer of Poniard Pharmaceuticals, a publicly traded biopharmaceutical company. From 2004 to 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 to 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 received her B.A. degree from the University of California, Berkeley, and her MBA/MS degree from Carnegie Mellon University.

Steven Lo joined us as Vice President of Commercial Operations in September 2010. Mr. Lo brings 15 years of commercial experience in the pharmaceutical and biotechnology industry. From 1997 to 2010, Mr. Lo held various positions in marketing, sales and managed markets at Genentech, Inc., a biotechnology company that became a member of the Roche Group in March in 2009, most recently as Franchise Head, leading that company s endocrinology marketing and sales organization. Mr. Lo received his B.S. degree from the University of California, Davis and his Master of Health Administration from the University of Southern California.

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 20 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 B.A. degree in Business from the University of Massachusetts and her law degree from Western New England College, School of Law.

#### **Employees**

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

As of December 31, 2010, we had 19 full-time employees, four part-time employees and 12 long-term contract staff. Four of our employees and two of our contractors have M.D.s. We consider our employee relations to be good. None of our employees is covered by a collective bargaining agreement.

## General

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

## **Available Information**

We are subject to the information requirements of the Securities Exchange Act of 1934, as amended, and we therefore file periodic reports, proxy statements and other information with the SEC relating to our business, financial statements and other matters. The reports, proxy statements and other information we file may be inspected and copied at prescribed rates at the SEC s Public Reference Room, 100 F Street, N.E., Washington, D.C. 20549, on official business days during the hours of 10:00 A.M. to 3:00 P.M. You may obtain information on the operation of the SEC s Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site that contains reports, proxy statements and other information regarding issuers like us

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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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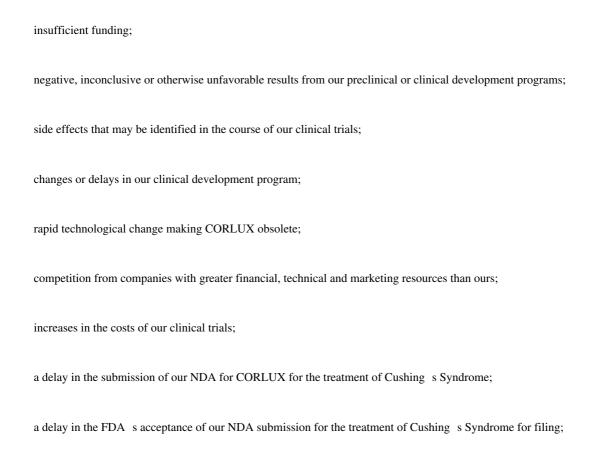
#### ITEM 1A. RISK FACTORS

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 have completed patient treatment in our Phase 3 trial in Cushing s Syndrome and are preparing an NDA in that indication for submission to the FDA. We are also conducting 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:



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. The FDA has indicated that our single 50-patient open-label study may provide a reasonable basis for the submission of an NDA for this indication. However, the FDA may determine that the results of our Phase 3 trial in Cushing s Syndrome, while meeting its primary and key seconday endpoints, do not sufficiently demonstrate safety and/or efficacy. The ongoing Phase 3 clinical trial of CORLUX for the treatment of the psychotic features of psychotic depression, may not demonstrate safety or efficacy results sufficient for approval, and we may need to conduct other studies in support of a potential NDA in that indication. 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.

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, preclinical or manufacturing studies to satisfactorily complete our NDA for either Cushing s Syndrome or 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:

æ	availability of funding;
r	negative or inconclusive results;
s	slow patient enrollment;
I	patient noncompliance with the protocol;
ε	adverse medical events or side effects among patients during the clinical trials;
I	negative or problematic FDA inspections of our clinical operations or our manufacturing operations; and
Even after w	real or perceived lack of effectiveness or safety of CORLUX. we conduct all of the clinical trials and supportive studies that we consider appropriate for an optimal NDA, we may not receive pproval to market CORLUX.

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 and CORT 113083. Additional capital may not be available to us at all or on

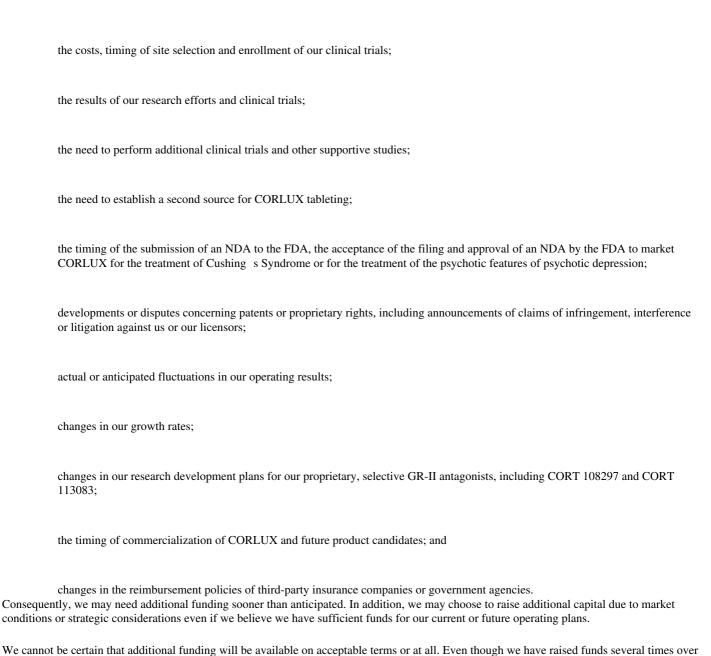
## favorable terms, which could adversely affect our business.

We may have to perform additional clinical trials prior to the approval of an NDA for CORLUX for the treatment of Cushing  $\,$ s Syndrome and for the treatment of the psychotic features of psychotic depression. We

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may need to raise additional funds to complete the development of CORLUX for the treatment of Cushing s Syndrome or for the treatment of psychotic depression. In addition, we will need to raise additional funds 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 and CORT 113083 in various indications.

We anticipate that our existing capital resources will be sufficient to fund our current operating plan into the third quarter of 2012. 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 and CORT 113083, which may change as a result of many factors, including:



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

the past twelve months, market and economic conditions may make it difficult for us to raise any or sufficient additional capital. The sales of common stock and warrants during 2010 and through January 2011 have been dilutive to stockholders and any exercise of outstanding warrants

to our technologies or product candidates, including our lead product candidate, which 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.

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

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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, 2010, we had an accumulated deficit of \$176.2 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, and will require the consent of our independent registered public 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 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 during the eight-day trading period following the issuance of the draw down

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notice. 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 and CORT 113083, 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 activities necessary for the submission of our NDA for CORLUX for the treatment of Cushing s Syndrome, the support of this NDA through its successful approval, the commercialization of this product for this indication or to complete the clinical development of CORLUX for the treatment of psychotic depression.

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

Global economic and market conditions have been volatile since the fall of 2008, with significantly tighter credit conditions. 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.

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 recent 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, or limiting our commercial efforts, product manufacturing or sales and marketing support, which would have an adverse affect on our business and results of operations.

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 a contract research organization, Octagon Research Solutions, Inc., that is managing our data and statistical analysis for our Phase 3 trial of CORLUX for the treatment of Cushing s Syndrome. They may be

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unable to collect, process or analyze the trial data in a timely manner or may fail to process the data appropriately, which could delay or prevent us from producing data which may be submitted to the FDA as part of our NDA.

We have an agreement with a clinical 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.

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. Although 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, MedAvante s diagnostic screening has resulted in slower patient enrollment and may not actually improve trial performance. In addition, in mid-2009, in order to lower 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 a reduced total of eight clinical sites in order to conserve capital. This strategy may result in increased total study costs over the longer term.

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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.

The Food and Drug Administration Amendments Act of 2007 gave the FDA the authority to require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks. A REMS program may include a medication guide, a patient package insert, a plan for communicating risks to health care providers or other elements that the FDA deems necessary to assure the safe use of the drug. We are working with a vendor to assist in development of our REMS program, a plan for which will be submitted to the FDA as part of our NDA for CORLUX for the treatment of Cushing s Syndrome.

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;

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

the FDA may not find that our REMS program is adequate to address the risks associated with our product candidate. 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 and/or may be subject to product recalls or seizures.

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.

## 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, whose approval processes 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. 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. 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, which operates as a subsidiary of Medi Challenge (Pty) Ltd., received 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 with the same active ingredient is approved for this indication before CORLUX, we will not garner the seven years of marketing exclusivity from the date of drug approval in the U.S. and other benefits that we anticipate. If CORLUX is the first drug approved by the FDA for this indication, any delay in our commercialization of the product, may have a negative impact on the revenue that we might be able to realize from the exclusivity provided during those seven years.

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.

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 affect 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 efforts to manufacture, commercialize, market, distribute and sell CORLUX;

the rate of adoption of CORLUX by physicians and by target patient populations; 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 choose not 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. 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. Our 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 an agreement with one manufacturer of the active pharmaceutical ingredient (API) of mifepristone which we expect to include in our initial NDA submission. We have a memorandum of understanding with a second API manufacturer. However, there are no activities currently being conducted at this site to develop or qualify the manufacturing processes or facilities and we do not plan to include a request for approval of material produced by this second manufacturer when we submit our NDA for Cushing s Syndrome.

We have an agreement with a tablet manufacturer to be included in our initial NDA submission. The tablet manufacturer is a single source supplier to us. If this single source supplier were to cease manufacturing tablets for us or fail to manufacture tables on a timely basis, we might be required to qualify an alternate supplier and we would likely experience a lengthy delay in our manufacturing processes. We cannot assure you that our single source supplier will be able or willing to meet our future demands.

Our current arrangements with these manufacturers are terminable by such manufacturers. We anticipate engaging some or all of the suppliers to produce commercial quantities of CORLUX, however 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.

If we, or our third party suppliers and manufacturers fail to comply with applicable regulations, sanctions could be imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, 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 future 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, which could result in increased costs and a delay in the commercial launch of CORLUX. If we are unable to establish that the tablets are equivalent or if the FDA disagrees with the results of our study, a commercial launch of CORLUX could be delayed and we may incur additional costs.

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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;

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 Cushing s Syndrome or 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. We have seven U.S. method of use patent applications for GR-II antagonists. We own three composition of matter patents and have one composition of matter patent application pending. We have applied, and will continue to apply, for patents covering our product candidates as we deem appropriate. We have also filed, where we deemed appropriate, foreign patent applications corresponding to our U.S. patents and applications.

We have exclusively licensed three issued U.S. patents from Stanford University for the use of 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 which was then subsequently acquired by Merck & Co., filed an observation challenging the claims of our exclusively licensed European patent application with claims directed to psychotic depression. In this instance, the patent later issued and, in 2007, we received notice that there will be no opposition proceedings in Europe in regard to this patent.

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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.

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. 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

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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.

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 electroconvulsive therapy (ECT). In addition, we have seven U.S. method of use patent applications covering GR-II antagonists for the treatment of a number of other metabolic and psychiatric disorders, three U.S. composition of matter patents covering specific GR-II antagonists, and a fourth U.S. composition of matter patent is pending. 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. 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. The compounds developed pursuant to our early clinical, preclinical and discovery research programs, including CORT 108297 and CORT 113083, 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.

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

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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, clinicians using the medicine in our clinical trials and, if approved by the FDA, physicians prescribing the medicine to women with childbearing potential, must take necessary and strict precautions 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 and recent healthcare legislation may limit our future revenues. Our near-term dependence on the commercial success of CORLUX makes us particularly susceptible to any such 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. In addition, we may need to obtain approvals from hospital formularies to receive wide-spread third-party coverage and reimbursement for those situations where our products may be needed during in-patient treatment. If we fail to obtain such approvals, this will reduce the level of revenues that we are able to attain.

In some foreign markets, pricing and profitability of prescription pharmaceuticals are subject to government control. In the United States, we expect that there will continue to be federal and state proposals for similar controls. Also, the trends toward managed health care in the United States and recent laws and legislation intended to reduce the cost of government insurance programs could significantly influence the purchase of health care services and products and may result in lower prices for our future products or the exclusion of such products from reimbursement programs.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively referred to as the PPACA, was passed. The PPACA includes, among other things, the following measures:

Annual, non-deductible fees on any entity that manufactures or imports certain prescription drugs and biologics;

Increases in Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program for both branded and generic drugs;

A new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical research;

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New requirements for manufacturers to discount drug prices to eligible patients by 50 percent at the pharmacy level and for mail order services in order for their outpatient drugs to be covered under Medicare Part D;

An increase in the number of entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and

Establishment of a licensure framework for follow-on biologic products.

The PPACA provisions on comparative clinical effectiveness research extend the initiatives of the American Recovery and Reinvestment Act of 2009, also known as the stimulus package, which included \$1.1 billion in funding to study the comparative effectiveness of health care treatments. This stimulus funding was designated for, among other things, conducting, supporting or synthesizing research that compares and evaluates the risks and benefits, clinical outcomes, effectiveness and appropriateness of products. The PPACA also appropriates additional funding to comparative clinical effectiveness research. Although Congress has indicated that this funding is intended to improve the quality of health care, it remains unclear how the research will impact current Medicare coverage and reimbursement or how new information will influence other third-party payor policies. We expect that the PPACA and regulations and policies implementing this legislation, as well as other healthcare reform measures that may be adopted in the future, may have a material adverse effect on our industry generally and on our ability to successfully develop and commercialize our products.

If we market products in a manner that violates health care fraud and abuse laws, we may be subject to civil or criminal penalties.

In the United States, we will be subject to health care fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business once we commercialize. The laws that may affect our ability to operate include:

the federal health care programs Anti-Kickback Law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal health care programs such as the Medicare and Medicaid programs;

federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;

the federal Health Insurance Portability and Accountability Act of 1996, (HIPAA), which created federal criminal laws that prohibit executing a scheme to defraud any health care benefit program or making false statements relating to health care matters;

federal sunshine laws that require transparency regarding financial arrangements with health care providers, such as the reporting and disclosure requirements imposed by PPACA on drug manufacturers regarding any transfer of value made or distributed to prescribers and other health care providers; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Some states, such as California, Massachusetts and Vermont, mandate implementation of commercial compliance programs to ensure compliance with these laws.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Moreover, recent health care reform legislation has strengthened these laws. For example, the

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recently enacted PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes; a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from governmental health care programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

We may face competition from other companies who attempt to develop mifepristone or other compounds 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 and has reported results from a Phase 3 trial for 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 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 which was then subsequently acquired by Merck & Co. Organon s new chemical entity is a GR-II antagonist; we believe that its commercial use would be covered by our patent. 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.

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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.

## 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 will need to develop sales and marketing capabilities to successfully commercialize CORLUX and any future uses of GR-II antagonists.

A limited number of our employees have experience in marketing or selling pharmaceutical products. 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. 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.

#### 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 8, 2011, our average daily trading volume has been approximately 180,000 shares and the intra-day sales prices per share of our common stock on the NASDAQ Capital Market has ranged from \$2.52 to \$4.70. As of March 8, 2011, our officers, directors and principal stockholders control approximately 40% 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.  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

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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 statement 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 specified deadlines, or failed to maintain the effectiveness of such registration statement (subject to limited permissible suspension 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

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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 liquidated damages of approximately \$1.3 million in 2008 to the investors in this financing. 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 8, 2011, our officers, directors and principal stockholders control approximately 40% 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, have and will likely continue to result in increased costs to us as we respond to their requirements. We are investing resources to comply with evolving laws and regulations, and this investment may result in increased 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 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 first applies to this annual report on Form 10-K for our fiscal year ended 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 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 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 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 a revised standard related to stock-based compensation. This standard, which we adopted in 2006, requires the recording of expense for stock options granted using fair-value-based measurements. 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 using fair-value-based measurements, 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. Any such changes could result in corresponding changes to the amounts of assets, liabilities, revenues, expenses and income. Any such changes could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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 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.

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## 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 August 12, 2010, we renewed our lease for office space for a one-year term commencing on January 1, 2011. 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)

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#### 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
2010	111911	Dow
First Quarter	\$ 3.22	\$ 2.50
Second Quarter	\$ 3.93	\$ 2.56
Third Quarter	\$ 4.33	\$ 2.76
Fourth Quarter	\$ 4.70	\$ 3.34
	High	Low
2009	9	
First Quarter	\$ 1.46	\$ 0.75
Second Quarter	\$ 1.29	\$ 0.73
Third Quarter	\$ 1.65	\$ 0.75
Fourth Quarter	\$ 3.10	\$ 1.36

## Stockholders of Record and Dividends

As of March 8, 2011, we had 83,968,540 shares of common stock outstanding held by 133 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, 2010 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 and development activities including clinical trials, commercialization and administrative activities, as well as for general corporate purposes, including working capital.

## Repurchases of Securities

None.

#### **Market Performance Graph**

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

The rules of the SEC require that we include a 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

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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, 2005 including reinvestment of dividends. Fiscal year ended December 31.

## Securities Authorized for Issuance under Equity Compensation Plans

The information required by this Item concerning our equity compensation plans will be included in the section captioned Equity Compensation Plans contained in our Definitive Proxy Statement to be filed related to the 2011 Annual Meeting of Stockholders and is incorporated herein by reference.

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## ITEM 6. SELECTED FINANCIAL DATA

## SELECTED FINANCIAL DATA

## (in thousands, except per share data)

The selected financial data set forth below are derived from our financial statements. The statement of operations data for the years ended December 31, 2010, 2009 and 2008 and for the period from inception (May 13, 1998) to December 31, 2010 and the balance sheet data as of December 31, 2010 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, 2007 and 2006, and the balance sheet data as of December 31, 2008, 2007 and 2006 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		
	2010	2009	2008 (In thousands	<b>2007</b> s, except per sh	<b>2006</b> are data)	De	cember 31, 2010
Statement of Operations Data:			· ·		,		
Collaboration revenue	\$	\$ 29	\$ 209	\$ 482	\$ 294	\$	1,014
Operating expenses:							
Research and development*	18,949	14,402	14,152	7,860	20,834		133,161
General and administrative*	8,488	5,877	5,746	4,867	5,042		49,249
Total operating expenses	27,437	20,279	19,898	12,727	25,876		182,410
Loss from operations	(27,437)	(20,250)	(19,689)	(12,245)	(25,582)		(181,396)
Non-operating income (expense), net	1,471	84	(372)	672	709		5,191
Net loss	\$ (25,966)	\$ (20,166)	\$ (20,061)	\$ (11,573)	\$ (24,873)	\$	(176,205)
Net loss per share:							
Basic and diluted	\$ (0.38)	\$ (0.38)	\$ (0.43)	\$ (0.34)	\$ (1.09)		
Weighted average shares basic and diluted	68,336	52,443	46,721	34,251	22,841		
* Includes non-cash stock-based compensation, net of recoveries, of the following:							
Research and development	\$ 219	\$ 263	\$ 268	\$ 213	\$ 535	\$	5,495
General and administrative	1,896	1,552	1,360	846	1,013		11,458
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Total non-cash stock-based compensation	\$ 2,115	\$ 1,815	\$ 1,628	\$ 1,059	\$ 1,548	\$	16,953

	As of December 31,				
	2010	2009	2008	2007	2006
	(In thousands)				
Balance Sheet Data:					
Cash, cash equivalents and investments	\$ 24,578	\$ 23,867	\$ 18,309	\$ 17,366	\$ 9,456
Working capital	21,136	22,001	16,717	14,662	6,286

Total assets	25,104	24,511	19,775	17,744	9,902
Long-term liabilities			6	16	29
Total stockholders equity	21,244	22,092	16,907	14,734	6,360

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.

# 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, including the anticipated submission of the New Drug Application (NDA) for CORLUX for the treatment of Cushing s Syndrome to the United States Food and Drug Administration (FDA), the acceptance of that NDA for filing by the FDA and the review and approval of the NDA by the FDA:

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 the market introduction of CORLUX® and future product candidates, including CORT 108297 and CORT 113083;

our ability to market, commercialize and achieve market acceptance for CORLUX or other future product candidates, including CORT 108297 and CORT 113083;

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, development and commercialization 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 CORT 108297, a compound from one of these series, into clinical development. Unless otherwise stated, all references in this document to we, us, our, its, Corcept, the Company and similar designations of Corcept Therapeutics Incorporated.

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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.

The Investigational New Drug application (IND) for the evaluation of CORLUX for the treatment of the signs and symptoms of Cushing s Syndrome was opened in September 2007. The United States Food and Drug Administration (FDA) 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 completed enrollment in this Phase 3 study in June 2010. This open-label Phase 3 study evaluated the response of two patient groups to CORLUX treatment: one included patients who were glucose intolerant, regardless of blood pressure level, and one included patients who had been diagnosed with hypertension but had normal glucose tolerance. The patients in both of these groups were being treated for their symptoms before study entry; CORLUX was added to their existing medications. On December 22, 2010, we announced that both groups in this study achieved their primary endpoints. After this announcement, we determined that one patient did not fully adhere to the protocol for this study and have since then revised our calculation of the percentage of patients in the hypertensive group meeting the primary endpoint. This did not impact our determination that this group achieved its primary endpoint. On January 11, 2011, we announced positive results for the key secondary endpoint of global clinical improvement. For this endpoint all of the patients in the study were included in one group.

Statistically significant improvement in the primary endpoint was achieved for each group with 60% responding in the glucose intolerant group and 38% responding in the hypertensive group. The patients in the study, whether included in the glucose intolerant group or the hypertensive group for the purpose of evaluating the primary endpoints, were evaluated as a single group on the key secondary endpoint of global clinical improvement; 87% of patients showed significant clinical improvement as evaluated by an independent board of three physicians highly experienced in the treatment of Cushing s Syndrome. An initial review of safety data indicates that CORLUX had an acceptable risk-benefit profile in this Phase 3 study. Adverse events related to treatment included signs and symptoms of adrenal insufficiency, endometrial thickening, and hypokalemia, all of which were consistent with earlier published reports. The majority of the serious adverse events (SAEs) reported in the study were not related to CORLUX treatment, as determined by the clinical investigators. All of the treatment-related SAEs resolved with clinical management. Eighty-eight percent of the patients who completed the Phase 3 study opted to enter the long-term extension study. We expect to submit our NDA for the use of CORLUX in Cushing s Syndrome by the end of the first quarter of 2011 and plan to present detailed data from the Phase 3 trial at scientific conferences during 2011.

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 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 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

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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 milligrams (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 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 mid-2009, in order to conserve financial resources, we reduced the number of clinical sites in this study to eight and extended the timeline for its completion.

Antipsychotic-induced Weight Gain Mitigation. In 2005, we published the results of studies in rats that demonstrated that CORLUX both reversed 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).

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 and its results were published in the journal *Advances in Therapy* in 2009. 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 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, and were published in the journal *Obesity* in 2010.

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.

Selective GR-II Receptor Antagonists. 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, like our lead product CORLUX, potently block the cortisol receptor (GR-II) but, unlike CORLUX, they do not appear to block the PR (progesterone), ER (estrogen), AR (androgen) or GR-I (mineralocorticoid) receptors. Both the United States Patent & Trademark Office (USPTO) and the European Patent Office (EPO) have issued to us composition of matter patents on all of the three series. A fourth composition of matter patent application is pending. See Business Intellectual Property.

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CORT 108297 and CORT 113083

In 2007, we conducted a human microdosing study of one of our newly identified selective GR-II antagonists, CORT 108297, with Xceleron Limited utilizing its 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. In May 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 kilogram (mg/kg) to 50 mg/kg) 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 108297 suppresses body weight gain and improves insulin sensitivity in healthy mice fed a 60% fat diet and high sucrose liquid.

The manufacturing and preclinical development of CORT 108297 began late in 2008 and resulted in the submission of an IND to the FDA in December 2009 for the prevention of weight gain induced by antipsychotic medication. Dosing of healthy volunteers in the first Phase 1 study of CORT 108297 was completed in July 2010. A Phase 1b/2a study of this drug was initiated during the fourth quarter of 2010, with the first patients being dosed in December 2010.

During the second quarter of 2010, we selected a second new compound, CORT 113083, to advance toward an IND filing. CORT 113083 has demonstrated substantial bioavailability in animal models. During the third quarter of 2010, we commenced various manufacturing development and preclinical studies supporting an IND filing for 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

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of December 31, 2010, we had an accumulated deficit of \$176.2 million. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for CORLUX and CORT 108297, 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 few years as we continue our CORLUX and CORT 108297 clinical development programs, apply for regulatory approvals, initiate development of CORT 113083 or other 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 and CORT 108297 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-Antipsychotic-Induced Weight Gain Mitigation. 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 were rendered in accordance with the agreements.

During the years ended December 31, 2009 and 2008, we recognized approximately \$29,000 and \$209,000, respectively, under these agreements. We did not recognize any revenue under the agreements during the year ended December 31, 2010 and none will be recognized in the future as all of the activities relating to these agreements 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 32% to \$18.9 million for the year ended December 31, 2010 from \$14.4 million for the year ended December 31, 2009. Clinical trial cost increases during 2010, as compared to 2009, included approximately \$405,000 related to the clinical trials with CORLUX for the treatment of Cushing s Syndrome, \$3.4 million related to other NDA-supportive studies with CORLUX and approximately \$1.8 million related to the Phase 1a study with CORT 108297. These increases were partially offset by decreases of approximately \$1.8 million related to scaling back our Phase 3 study with CORLUX for the treatment of psychotic depression, and approximately \$420,000 related to the study for the mitigation of weight gain caused by Risperdal, which was completed in 2009.

During 2010, as compared to 2009, there were also increases of approximately \$1.0 million in research work with our proprietary, selective new GR-II antagonists, including CORT 113083, and approximately \$665,000 in CORLUX manufacturing costs related to the acquisition of active pharmaceutical ingredient and the manufacture of clinical trial materials and registration batches to be used for the NDA. There was also an increase of approximately \$800,000 related to the start of manufacturing of clinical trial material for use in the Phase 1b/2a study with CORT 108297. During 2010, we recorded an aggregate amount of approximately \$340,000, related to

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bonuses awarded to employees working in research and development functions in recognition of significant company accomplishments during 2010. Bonus amounts during 2009 were negligible. In addition, consultancy and staffing costs increased approximately \$920,000 during 2010 as compared to 2009, due to the additional resources necessary to assist in the management of the research and development activities, and to commence activities toward a submission of an NDA for CORLUX for the treatment of Cushing s Syndrome by the end of the first quarter of 2011. During 2010 as compared to 2009, there was also a decrease of approximately \$2.7 million, related to the preclinical and IND-enabling work on CORT 108297, which entered a Phase 1a study in February 2010.

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 carcogenicity 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 discussed above included stock based compensation charges related to option grants to individuals performing these functions of approximately \$220,000, \$263,000 and \$268,000, respectively, for the years ended December 31, 2010, 2009 and 2008. The decrease in expense between years was primarily the result of the completion of vesting of earlier grants to employees in these functions with higher exercise prices and fair values not being fully offset by the costs related to more recent option grants to existing and new employees in these functions.

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

	Year Ended				
Project	2010	December 31, 2009 (in thousands)	2008		
CORLUX					
Cushing s Syndrome	\$ 5,075	\$ 2,952	\$ 2,316		
Psychotic Depression	2,567	5,030	5,948		
Weight Gain Mitigation	11	565	1,588		
Selective GR-II antagonists	5,089	3,940	2,186		
Unallocated activities, including NDA supportive studies and manufacturing, regulatory and					
pre-clinical activities	5,987	1,652	1,846		
Stock-based compensation	220	263	268		
Total research and development expense	\$ 18,949	\$ 14,402	\$ 14,152		

We expect that research and development expenditures will increase during 2011 as compared to 2010 due to the preparation and support of our NDA filing for CORLUX for the treatment of Cushing s Syndrome, increased manufacturing activities for pre-validation and validation batches of CORLUX, continuation of our long-term extension study in Cushing s Syndrome, continuation of our Phase 3 study of CORLUX for the treatment of psychotic depression, and the continued development of CORT 108297, CORT 113083 and our

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other proprietary selective GR-II antagonists, which costs will be only partially offset by decreases in the costs related to the completion of our Phase 3 study in Cushing s Syndrome. Research and development expenses in 2012 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, 2010, general and administrative expenses increased 44% to \$8.5 million from \$5.9 million for the year ended December 31, 2009. During 2010, we recorded an aggregate amount of \$1.3 million related to bonuses awarded to our officers and employees working in general and administrative functions in recognition of significant company accomplishments during 2010. We did not award bonuses for 2009 performance to any officer or employee in these functions. In addition, during 2010, as compared to 2009, staffing and consultancy costs increased approximately \$885,000 due primarily to additional resources necessary to engage in planning for the potential commercialization of CORLUX for Cushing s Syndrome, approximately \$345,000 of which represented increases in noncash stock-based compensation costs related to stock options granted to employees, directors and consultants. There was also an increase in legal costs related to patents and other corporate matters during 2010, as compared to 2009, of approximately \$150,000.

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 reflected 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 included a net increase in stock-based compensation of \$180,000 that reflected 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 included stock-based compensation expense related to option grants to individuals performing these functions of approximately \$1.9 million, \$1.5 million and \$1.4 million for the years ended December 31, 2010, 2009 and 2008, respectively.

We expect that general and administrative expenses will increase in 2011 as compared to 2010 in regard to activities directly associated with preparations for potential product commercialization and the need to increase our administrative infrastructure to support these activities. The amount of general and administrative expenses in 2012 and future years will be largely dependent on our assessment of the staff necessary to support expected product commercialization and our continued clinical development activities 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 \$1.5 million for the year ended December 31, 2010 as compared to \$101,000 for the same period in 2009 and \$945,000 in 2008. Other income in 2010 included \$750,000 in connection with the favorable

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settlement of a lawsuit brought on our behalf against an individual for defamation and harassment and approximately \$733,438 in grants from the United States Treasury s Therapeutic Discovery Project Grant program. Interest income in 2009 and 2008 included approximately \$60,000 and \$410,000, respectively, related to the note receivable in connection with our March 2008 financing, which was collected in February 2009. In 2009, there were also decreases in yields and balances of invested funds as compared to 2008.

Other expense Other expense for the year ended December 31, 2010 was approximately \$25,000 as compared to \$17,000 in 2009 and \$1.3 million in 2008. 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 our 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, 2010, we had a deficit accumulated during the development stage of \$176.2 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, 2010, we had cash and cash equivalents of \$24.6 million, compared to \$23.9 million at December 31, 2009. Net cash used in operating activities for the years ended December 31, 2010, 2009 and 2008 was \$22.3 million, \$18.0 million and \$18.4 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 2010, we issued common stock upon the exercise of warrants that had been issued in a private placement transaction in October 2009 and sold new warrants to the same investors, generating gross proceeds of approximately \$7.7 million and sold common stock in an underwritten public offering, generating gross proceeds of approximately \$15.0 million. We also sold common stock to Kingsbridge Capital Limited (Kingsbridge), a private investment group, under a Committed Equity Financing Facility (CEFF) generating gross proceeds of approximately \$1.6 million. Issuance costs for these transactions collectively totaled approximately \$1.4 million. The net proceeds of all these transactions have been, or will be, used for general corporate purposes.

In January 2011, we sold 11.5 million shares of our common stock in an underwritten public offering at a price to the public of \$3.90 per share for aggregate gross proceeds of approximately \$44.9 million, which resulted in net proceeds of approximately \$41.9 million after deducting the underwriter's discount and commissions and other expenses related to this offering.

We expect cash used in operating activities to increase during 2011 as compared to spending levels in 2010 due to the preparation and support of our NDA filing for CORLUX for the treatment of Cushing s Syndrome, increased manufacturing activities for pre-validation and validation batches of CORLUX, commercialization planning activities, continuation of the long-term extension study of CORLUX for Cushing s Syndrome and the continued development of our selective GR-II antagonists, including CORT 108297 and CORT 113083. We expect our funding requirements for operating activities may increase during later years as costs associated with 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 may be only partially offset by revenues from sales of CORLUX once approval for marketing has been received from the FDA.

We believe that we have sufficient capital resources to maintain our operations into the third quarter of 2012, including the planned continuation of our long-term extension study of CORLUX for the treatment of Cushing s Syndrome, the planned submission of an NDA and commercialization activities for CORLUX, the Company s lead product, for this indication, the continuation of enrollment in our Phase 3 psychotic depression

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trial, the completion of a Phase 1b/2a multi-dose safety and proof of concept clinical study for CORT 108297, one of our proprietary, selective GR-II antagonists, and research and pre-clinical activities related to additional selective GR-II antagonists, including the submission of an Investigational New Drug (IND) application for CORT 113083.

We will need to raise additional funds to support the potential commercialization of CORLUX for the treatment of Cushing s Syndrome, continue the development of CORLUX for the treatment of the psychotic features of psychotic depression and continue and expand the development of our proprietary selective GR-II antagonists beyond mid-2012.

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 2.6 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 December 31, 2010, we have raised a total of approximately \$2.6 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 8, 2011, the maximum amount of additional funds that could be raised under the CEFF is approximately \$26 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.

While we monitor the cash balance in our checking account and transfer the funds in only as needed, these cash balances and our money market fund could be impacted if the underlying financial institution were to fail or could be subject to other adverse conditions in the financial markets. To date, we have experienced no loss or lack of access to cash in our checking accounts or money market fund.

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.

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#### **Contractual Obligations and Commercial Commitments**

The following table presents our estimates of obligations under contractual agreements as of December 31, 2010:

Contractual Obligations	Less than 1 Year	1-3 Years	3-5 Years housands)	More than 5 Years
Research and development studies (1) through (5)	\$ 5,358	\$ 6,058	\$	\$
Commercialization planning activities (6)	1,100			
Operating lease (7)	231			
Minimum royalty payments (8)	50	100	100	50 per year
Total	\$ 6,739	\$ 6,158	\$ 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, 2010.
- During 2008, we entered into 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 \$8.0 million of these costs were expensed through December 31, 2010, 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.
- (3) During 2010, we entered into agreements for the conduct of the initial clinical trials using CORT 108297. The total commitment under these agreements is approximately \$2.3 million. Approximately \$1.3 million of costs under these agreements have been incurred as of December 31, 2010, with the remainder expected to be incurred during 2011.
- (4) In June 2010, we entered into agreements with the vendor that provides manufacturing services for materials to be used in development work for CORT 108297 and CORT 113083 in the aggregate amount of \$1.6 million. Approximately \$1.2 million has been incurred under these agreements through December 31, 2010, with the remainder to be incurred during 2011.
- (5) During the period from September to December 2010, we entered into purchase orders for the acquisition of mifepristone, the active pharmaceutical ingredient (API) in CORLUX, to be delivered during 2011 for aggregate commitments of approximately \$1.8 million.
- (6) In August 2010, we entered into an agreement with United Biosource Corporation (UBC) to assist us in developing our Risk Evaluation and Mitigation Strategy (REMS), a plan for which will be submitted to the FDA as part of our NDA for CORLUX for the treatment of Cushing s Syndrome. The financial commitment under the initial set-up phase of this agreement is approximately \$1.2 million; approximately \$105,000 of which cost was incurred during 2010 with the remainder expected to be incurred during 2011. See discussion below regarding potential contingent future obligations under this agreement after approval of CORLUX by the FDA for marketing.
- (7) In August 2010, we renewed the operating lease agreement for our office facility for a one-year term commencing on January 1, 2011.
- (8) 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.

We also have other contractual payment obligations and purchase commitments, the timing of which are 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.

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- Pursuant to our memorandum of understanding with ScinoPharm, ScinoPharm agrees to manufacture API for CORLUX and we agree to purchase at least \$1,000,000 bulk mifepristone per year following the commercial launch of CORLUX. ScinoPharm is considered to be a potential secondary site for the manufacture of the API. However, no activities are currently being conducted at this site to develop or qualify the manufacturing processes or facilities and we do not plan to include a request for approval of material produced by ScinoPharm when we submit our NDA for Cushing s Syndrome.
- (d) In November 2006, we entered into an agreement with PCAS for the manufacture of mifepristone, the API 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. We intend to pursue discussions for further extensions. There is no guaranteed minimum purchase commitment under this agreement until NDA approval. After NDA approval, we agree to purchase from PCAS 100% of our requirements for six months after the approval and 75% of our requirements from six months through 18 months after the approval for the initial five year term of the 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.
- (e) See discussion in footnote 6 above regarding the agreement with UBC for development of the REMS system which would require future obligations for use of the system following the FDA approval of our NDA for CORLUX for the treatment of Cushing s Syndrome. The majority of such costs are variable and dependent on patient utilization of our drug.

In February 2011, we amended our agreement with Argenta Discovery 2009 Limited (Argenta) for the continuation of research services regarding new proprietary selective GR-II antagonists through September 30, 2011 for an additional commitment of approximately \$840,000.

#### **Net Operating Loss Carryforwards**

At December 31, 2010 we had net operating loss carryforwards available to offset any future taxable income that we may generate for federal income tax purposes of approximately \$94.0 million, which expire in the years 2019 through 2030, and California net operating loss carryforwards of approximately \$94.6 million, which expire in the years 2012 through 2030. We also had federal and California research and development tax credits of approximately \$10.2 million and \$1.5 million, respectively. The federal research credits will expire in the years 2019 through 2030 and the California research credits have no expiration date. Our deferred tax assets have been offset by a full valuation allowance as the realization of such assets is uncertain. Utilization of our net operating losses and tax credit carryforwards may be subject to substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code and similar state provisions. Such limitations could result in the expiration of the net operating losses and tax credit carryforwards before utilization.

#### **Off-Balance Sheet Arrangements**

None.

### **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 \$815,000 and \$710,000 as of

December 31, 2010 and 2009, 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:

- 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.
- For service-based awards, expense is recognized over the requisite service period. For options with performance-based vesting criteria, expense will be recognized at such time as there is a high degree of probability (i.e., greater than 70%) of achieving the required vesting criteria.
- 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.
- 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:

- 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.
- 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.

For all options granted prior to January 1, 2006, we continued to utilize the graded-vesting attribution method for amortization of the relevant compensation amounts until these grants were fully vested in 2010.

Since we have a limited employee base and have experienced minimal turnover, 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.

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As of December 31, 2010, we had approximately \$4.0 million of unrecognized compensation expense for employee and director options outstanding as of that date. Approximately \$3.3 million of the unrecognized compensation relates to option grants with service-based vesting criteria, which had a remaining weighted-average vesting period of 2.4 years. Approximately \$637,000 of the unrecognized compensation relates to option grants with performance-based vesting criteria; as this amount will be expensed based on the high probability of success of the performance criteria, it is not possible to estimate the timing of recognition of this expense.

#### Non-employees

All stock option grants to consultants vest solely based upon continuing service, with the exception of a performance-based award granted during 2010, in the amount of 50,000 shares. Stock-based compensation related to service-based option grants to non-employees is charged to expense on a straight line basis over the vesting period of the options, which approximates the period over which the related services are rendered, based on the fair value of the options 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. The grant with performance-based vesting criteria awarded in 2010 will vest in its entirety upon the filing by the FDA of the Company s NDA for CORLUX for the treatment of Cushing s Syndrome. The fair value of the grant as of the date of vesting, as determined using the Black-Scholes option pricing model, will be charged to expense at that time.

#### Recently Adopted Accounting Standards

On March 31, 2010, the Financial Accounting Standards Board ratified the conclusions reached by its Emerging Issues Task Force that the milestone method of revenue recognition is a valid application of the proportional performance model when applied to research or development arrangements. Accordingly, the guidance states that an entity can make an accounting policy election to recognize a payment that is contingent upon the achievement of a *substantive* milestone in its entirety in the period in which the milestone is achieved. The milestone method is not required and is not the only acceptable method of revenue recognition for milestone payments.

This guidance also indicates that, in order to recognize the revenue, certain criteria must be met, including the requirement that the activities leading up to the achievement of the milestone must be conducted by the entity. A milestone is defined in the guidance as an event: (a) that can only be achieved based in whole or in part on either (1) the entity s performance or (2) on the occurrence of a specific outcome resulting from the entity s performance, (b) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (c) that would result in additional payments being due to the entity. Therefore, a milestone does not include events for which the occurrence is contingent solely on the passage of time or solely on a customer s performance.

The new guidance was effective for fiscal years that began on or after June 15, 2010 and interim periods within those years. The adoption of the new standard on January 1, 2011 did not have any effect on our financial statements as we do not currently have any arrangements to which the standard would apply.

# 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, 2010, our cash and cash equivalents consisted primarily of money market funds maintained at

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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, 2010.

#### 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. CONTROLS AND PROCEDURES

#### (a) 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, 2010, 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 srules 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.

There were no changes in our internal controls over financial reporting during the quarter ended December 31, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### (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

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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.

Our management, including our Chief Executive Officer, Chief Financial Officer and Chief Accounting Officer, 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 this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2010.

Our independent registered public accounting firm has issued an attestation report on our internal control over financial reporting as included below.

#### (c) Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Corcept Therapeutics Incorporated

We have audited Corcept Therapeutics Incorporated s internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Corcept Therapeutics Incorporated s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management s Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Corcept Therapeutics Incorporated maintained, in all material respects, effective internal control over financial reporting as of December 31, 2010, based on the COSO criteria.

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We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Corcept Therapeutics Incorporated (a development stage company) as of December 31, 2010 and 2009, and the related statements of operations, convertible preferred stock and stockholders equity (net capital deficiency), and cash flows for each of the three years in the period ended December 31, 2010, and for the period from inception (May 13, 1998) to December 31, 2010 of Corcept Therapeutics Incorporated (a development stage company), and our report dated March 15, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California

March 15, 2011

ITEM 9B. OTHER INFORMATION

None.

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#### PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K because we expect to file with the U.S. Securities and Exchange Commission, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, a definitive proxy statement (the Proxy Statement), pursuant to Regulation 14A in connection with the solicitation of proxies for our 2011 Annual Meeting of Stockholders, and certain information included therein is incorporated herein by reference.

#### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Except as disclosed below, the information required by this Item will be included in the Proxy Statement and is incorporated herein by reference.

#### **Executive Officers**

The information required by this Item concerning our executive officers is set forth in Part I of this Annual Report on Form 10-K.

#### **Code of Ethics**

We have adopted a Code of Ethics that applies to all officers and employees, including our principal executive officer, principal financial officer and controller. The Code of Ethics is publicly available on our website at <a href="https://www.corcept.com">www.corcept.com</a>. 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. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of our Code of Ethics by posting such information on our website, at the address and location specified above and, to the extent required by the listing standards of The NASDAQ Stock Market, by filing a Current Report on Form 8-K with the SEC, disclosing such information.

#### ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item will be included in the Proxy Statement and is incorporated herein by reference.

# ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item will be included in the Proxy Statement and is incorporated herein by reference.

## ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item will be included in the Proxy Statement and is incorporated herein by reference.

#### ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item will be included in the Proxy Statement and is incorporated herein by reference.

#### PART IV

## ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this Form 10-K

#### (1) Financial Statements:

Pag	
F-	Report of Independent Registered Public Accounting Firm
	Audited Financial Statements
F-	Balance Sheets
F-	Statements of Operations
F-	Statement of Convertible Preferred Stock and Stockholders Equity (Net Capital Deficiency)
F-1	Statements of Cash Flows
F-1	Notes to Financial Statements

## (2) Financial Statement Schedules:

All schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

## (3) Exhibits:

Item 601 of Regulation S-K requires the exhibits listed below. Each management contract or compensatory plan or arrangement required to be filed as an exhibit to this Form 10-K has been identified.

#### (A) EXHIBITS

Exhibit	
Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the registrant s Registration Statement on Form S-1/A (File No. 333-112676) filed on March 19, 2004).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the registrant s Current Report on Form 8-K filed on September 27, 2007).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the registrant s Registration Statement on Form S-1 (Registration No. 333-112676) filed on February 10, 2004).
4.2	Amended and Restated Information and Registration Rights Agreement by and among Corcept Therapeutics Incorporated and certain holders of preferred stock, dated as of May 8, 2001 (incorporated by reference to Exhibit 4.2 to the registrant s Registration Statement on Form S-1 (Registration No. 333-112676) filed on February 10, 2004).
4.3	Amendment No. 1 to Amended and Restated Information and Registration Rights Agreement by and among Corcept Therapeutics Incorporated and certain holders of preferred stock, dated as of March 16, 2004 (incorporated by reference to Exhibit 4.3 to the registrant s Registration Statement on Form S-1/A (File No. 333-112676) filed on March 19, 2004).
4.4	Registration Rights Agreement by and among Corcept Therapeutics Incorporated and the investors signatory thereto, dated March 14, 2008 (incorporated by reference to Exhibit 10.25 to the registrant s Annual Report on Form 10-K filed on March 31, 2008).

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Exhibit Number	Description of Document
4.5	Registration Rights Agreement by and between Corcept Therapeutics Incorporated and Kingsbridge Capital Limited, dated as of March 25, 2008 (incorporated by reference to Exhibit 10.27 to the registrant s Annual Report on Form 10-K filed on March 31, 2008).
4.6	Amendment to Registration Rights Agreement by and among Corcept Therapeutics Incorporated and the investors signatory thereto, dated November 11, 2008 (incorporated by reference to Exhibit 10.30 to the registrant s Annual Report on Form 10-K filed on March 31, 2009).
4.7	Registration Rights Agreement by and among Corcept Therapeutics Incorporated and the investors signatory thereto, dated October 12, 2009 (incorporated by reference to Exhibit 4.2 to the registrant s Quarterly Report on Form 10-Q filed on November 12, 2009).
4.8	Registration Rights Agreement dated as of April 21, 2010 by and among Corcept Therapeutics Incorporated and the investors signatory thereto (incorporated by reference to Exhibit 4.2 to the registrant s Current Report on Form 8-K filed on April 23, 2010).
10.1*	2000 Stock Option Plan (incorporated by reference to Exhibit 10.1 to the registrant s Registration Statement on Form S-1 (Registration No. 333-112676) filed on February 10, 2004).
10.2*	Promissory Note and Pledge Agreement by and between Corcept Therapeutics Incorporated and Robert L. Roe, M.D., dated as of October 22, 2001 (incorporated by reference to Exhibit 10.4 to the registrant s Registration Statement on Form S-1 (Registration No. 333-112676) filed on February 10, 2004).
10.3#	License Agreement by and between The Board of Trustees of the Leland Stanford Junior University and Corcept Therapeutics Incorporated, dated as of July 1, 1999 (incorporated by reference to Exhibit 10.6 to the registrant s Registration Statement on Form S-1 (Registration No. 333-112676) filed on February 10, 2004).
10.4#	Memorandum of Understanding, Supply and Services Agreement, by and between Corcept Therapeutics Incorporated and ScinoPharm Taiwan, dated as of June 12, 2000 (incorporated by reference to Exhibit 10.9 to the registrant s Registration Statement on Form S-1/A (File No. 333-112676) filed on March 19, 2004).
10.5	Master Services Agreement by and between Corcept Therapeutics Incorporated and PPD Development, LP, dated as of January 17, 2003 (incorporated by reference to Exhibit 10.12 to the registrant s Registration Statement on Form S-1/A (File No. 333-112676) filed on March 19, 2004).
10.6##	Manufacturing Agreement with Produits Chimiques Auxiliaires et de Synthese SA, dated November 8, 2006 (incorporated by reference to Exhibit 10.15 to the registrant s Annual Report on Form 10-K filed on April 2, 2007).
10.7	Common Stock Purchase Agreement by and among Corcept Therapeutics Incorporated and each of the Purchasers listed on Exhibit A thereto, dated November 14, 2006 (incorporated by reference to Exhibit 10.1 to the registrant s Current Report on Form 8-K filed on November 16, 2006).
10.8	Common Stock Purchase Agreement by and among Corcept Therapeutics Incorporated and each of those persons and entities listed on the Schedule of Purchasers thereto, dated as of March 30, 2007 (incorporated by reference to Exhibit 10.1 to the registrant s Current Report on Form 8-K filed on April 3, 2007).
10.9	Common Stock Purchase Agreement by and among Corcept Therapeutics Incorporated and each of those persons and entities listed on the Schedule of Purchasers thereto, dated as of August 16, 2007 (incorporated by reference to Exhibit 10.1 to the registrants Current Report on Form 8-K filed on August 21, 2007).

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Exhibit Number	Description of Document
10.10*	Form of Indemnification Agreement for directors and officers approved by the Board of Directors on September 24, 2007 (incorporated by reference to Exhibit 10.7 to the registrant s Quarterly Report on Form 10-Q filed on November 14, 2007).
10.11	Securities Purchase Agreement by and among Corcept Therapeutics Incorporated and the purchasers named therein, dated March 14, 2008 (incorporated by reference to Exhibit 10.24 to the registrant s Annual Report on Form 10-K filed on March 31, 2008).
10.12	Form of Warrant issued in connection with the Securities Purchase Agreement by and among Corcept Therapeutics Incorporated and the purchasers named therein, dated March 14, 2008 (incorporated by reference to Exhibit 4.4 to the registrant s Annual Report on Form 10-K filed on March 31, 2008).
10.13	Common Stock Purchase Agreement by and between Kingsbridge Capital Limited and Corcept Therapeutics Incorporated dated as of March 25, 2008 (incorporated by reference to Exhibit 10.26 to the registrant s Annual Report on Form 10-K filed on March 31, 2008).
10.14	Warrant, dated March 25, 2008 issued to Kingsbridge Capital Limited (incorporated by reference to Exhibit 4.5 to the registrant s Annual Report on Form 10-K filed on March 31, 2008).
10.15#	Master Service Agreement by and among Corcept Therapeutics Incorporated and ICON Clinical Research, L.P., signed on June 4, 2008 (incorporated by reference to Exhibit 10.5 to the registrant s Quarterly Report on Form 10-Q filed on August 14, 2008).
10.16*	Amended and Restated Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and Joseph K. Belanoff, M. D., dated September 19, 2008 (incorporated by reference to Exhibit 10.25 to the registrant s Annual Report on Form 10-K filed on March 31, 2009).
10.17*	Amended and Restated Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and Robert L. Roe, M. D., dated September 19, 2008 (incorporated by reference to Exhibit 10.26 to the registrant s Annual Report on Form 10-K filed on March 31, 2009).
10.18*	Amended and Restated Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and Anne M. LeDoux, dated September 19, 2008 (incorporated by reference to Exhibit 10.27 to the registrant s Annual Report on Form 10-K filed on March 31, 2009).
10.19*	Amended and Restated Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and James N. Wilson, dated September 19, 2008 (incorporated by reference to Exhibit 10.28 to the registrant s Annual Report on Form 10-K filed on March 31, 2009).
10.20*	Employment offer letter to Caroline M. Loewy, dated October 21, 2008 (incorporated by reference to Exhibit 10.29 to the registrant s Annual Report on Form 10-K filed on March 31, 2009).
10.21*	Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and Caroline M. Loewy, dated November 28, 2008 (incorporated by reference to Exhibit 10.31 to the registrant s Annual Report on Form 10-K filed on March 31, 2009).
10.22	Form of Warrant issued in connection with the Securities Purchase Agreement by and among Corcept Therapeutics Incorporated and the purchasers named therein, dated October 12, 2009 (incorporated by reference to Exhibit 4.1 to the registrant s Quarterly Report on Form 10-Q filed on November 12, 2009).

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Exhibit Number	Description of Document
10.23	Securities Purchase Agreement by and among Corcept Therapeutics Incorporated and the purchasers named therein, dated October 12, 2009 (incorporated by reference to Exhibit 10.1 to the registrant s Quarterly Report on Form 10-Q filed on November 12, 2009).
10.24*	Amended and Restated 2004 Equity Incentive Plan (incorporated by reference to the registrant s Proxy Statement on Schedule 14A filed on May 7, 2009).
10.25*	Form of Option Agreement
10.26	Warrant Purchase Agreement dated as of April 21, 2010 by and among Corcept Therapeutics Incorporated and the purchasers named therein (incorporated by reference to Exhibit 10.1 to the registrant s Current Report on Form 8-K filed on April 23, 2010).
10.27	Form of Warrant issued in connection with the Warrant Purchase Agreement dated as of April 21, 2010 by and among Corcept Therapeutics Incorporated and the purchasers named therein (incorporated by reference to Exhibit 4.1 to the registrant s Current Report on Form 8-K filed on April 23, 2010).
10.28##	Development Agreement by and between Corcept Therapeutics Incorporated and Formulation Technologies L.L.C. d/b/a PharmaForm, dated as of December 14, 2006.
10.29##	Master Services Agreement by and between Corcept Therapeutics Incorporated and United BioSource Corporation, dated as of June 29, 2010.
10.30*	Employment offer letter to Steven Lo, dated August 9, 2010 (incorporated by reference to Exhibit 10.1 to the registrant s Quarterly Report on Form 10-Q filed on November 12, 2010).
10.31*	Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and Steven Lo, dated September 15, 2010 (incorporated by reference to Exhibit 10.2 to the registrant s Quarterly Report on Form 10-Q filed on November 12, 2010).
14.1	Code of Ethics (incorporated by reference to Exhibit 99.1 to the registrant s Registration Statement on Form S-1/A (File No. 333-112676) filed on March 19, 2004).
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (See signature page)
31.1	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Joseph K. Belanoff, M.D.
31.2	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Caroline M. Loewy
32.1	Certification pursuant to 18 U.S.C. Section 1350 of Joseph K. Belanoff, M.D.
32.2	Certification pursuant to 18 U.S.C. Section 1350 of Caroline M. Loewy

Confidential treatment granted Confidential treatment requested

Management contract or compensatory plan or arrangement

#### **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

#### CORCEPT THERAPEUTICS INCORPORATED

By: /s/ Joseph K. Belanoff, M.D.,

**Chief Executive Officer** 

Date: March 15, 2011

#### POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Joseph K. Belanoff and Caroline M. Loewy, and each of them acting individually, as his or her true and lawful attorneys-in-fact and agents, each with full power of substitution, for him or her in any and all capacities, to sign any and all amendments to this report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, with full power of each to act alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Exchange Act, this Annual Report on Form 10-K has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Joseph K. Belanoff	Chief Executive Officer and Director (Principal Executive Officer)	March 15, 2011
Joseph K. Belanoff, M.D.		
/s/ Caroline M. Loewy	Chief Financial Officer (Principal Financial Officer)	March 15, 2011
Caroline M. Loewy		
/s/ Anne M. Ledoux	Vice President and Controller (Principal Accounting Officer)	March 15, 2011
Anne M. LeDoux	,	
/s/ James N. Wilson	Director and Chairman of the Board of Directors	March 15, 2011
James N. Wilson		
/s/ G. Leonard Baker, Jr.	Director	March 15, 2011
G. Leonard Baker, Jr.		
/s/ Joseph C. Cook, Jr.	Director	March 15, 2011

Joseph C. Cook, Jr.

/s/ Patrick G. Enright Director March 15, 2011

Patrick G. Enright

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Signature		Title	Date
/s/ James A. Harper	Director		March 15, 2011
James A. Harper			
/s/ David L. Mahoney	Director		March 15, 2011
David L. Mahoney			
/s/ Joseph L. Turner	Director		March 15, 2011
Joseph L. Turner			

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## CORCEPT THERAPEUTICS INCORPORATED

## (A DEVELOPMENT STAGE COMPANY)

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#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Corcept Therapeutics Incorporated

We have audited the accompanying balance sheets of Corcept Therapeutics Incorporated (a development stage company) as of December 31, 2010 and 2009, and the related statements of operations, convertible preferred stock and stockholders—equity (net capital deficiency), and cash flows for each of the three years in the period ended December 31, 2010, and for the period from inception (May 13, 1998) to December 31, 2010. These financial statements are the responsibility of the Company—s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States.) Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Corcept Therapeutics Incorporated (a development stage company) at December 31, 2010 and 2009, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2010 and for the period from inception (May 13, 1998) to December 31, 2010, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Corcept Therapeutics Incorporated s internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 15, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California

March 15, 2011

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## CORCEPT THERAPEUTICS INCORPORATED

## (A DEVELOPMENT STAGE COMPANY)

#### **BALANCE SHEETS**

(in thousands, except per share amounts)

	December 31, 2010 2009		-	
Assets				
Current assets:				
Cash and cash equivalents	\$	24,578	\$	23,867
Prepaid expenses and other current assets		418		553
Total current assets		24,996		24,420
Property and equipment, net of accumulated depreciation		4		10
Other assets		104		81
Total assets	\$	25,104	\$	24,511
Liabilities and Stockholders Equity				
Current liabilities:				
Accounts payable	\$	817	\$	1,270
Accrued clinical expenses		815		709
Accrued compensation		1,806		210
Obligations under capital lease				6
Other liabilities		422		224
Total current liabilities		3,860		2,419
Commitments				
Stockholders equity:				
Preferred stock, \$0.001 par value, 10,000 shares authorized and no shares outstanding at December 31, 2010 or 2009				
Common stock, \$0.001 par value, 140,000 shares authorized and 72,404 and 62,475 shares issued and				
outstanding at December 31, 2010 and 2009, respectively		72		62
Additional paid-in capital		197,473		172,369
Notes receivable from stockholders		(97)		(101)
Deficit accumulated during the development stage	(	(176,204)	(	(150,238)
Total stockholders equity		21,244		22,092
Total liabilities and stockholders equity	\$	25,104	\$	24,511

See accompanying notes.

## CORCEPT THERAPEUTICS INCORPORATED

## (A DEVELOPMENT STAGE COMPANY)

#### STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

	Year Ended December 31,			Period From Inception (May 13, 1998) to December 31,	
C-11-h	2010	2009	2008	2010	4
Collaboration revenue	\$	\$ 29	\$ 209	\$ 1,014	+
Operating expenses:					
Research and development*	18,949	14,402	14,152	133,161	l
General and administrative*	8,488	5,877	5,746	49,249	)
Total operating expenses	27,437	20,279	19,898	182,410	)
	,	,	,	,	
Loss from operations	(27,437)	(20,250)	(19,689)	(181,396	5)
Interest and other income, net	1,496	101	944	6,822	2
Other expense	(25)	(17)	(1,316)	(1,630	))
•					
Net loss	\$ (25,966)	\$ (20,166)	\$ (20,061)	\$ (176,204	4)
	1 ( 2 ) 2 2 7	1 ( 2, 22)	. ( -, ,	( , , , ,	
Basic and diluted net loss per share	\$ (0.38)	\$ (0.38)	\$ (0.43)		
Basic and diluted liet loss per share	\$ (0.36)	Ψ (0.36)	Φ (0.43)		
Charac used in computing basis and diluted not loss nor share	68,336	52,443	46,721		
Shares used in computing basic and diluted net loss per share	08,330	32,443	40,721		
* Includes non-cash stock-based compensation of the following:					
Research and development	\$ 220	\$ 263	\$ 268	\$ 5,495	5
General and administrative	1,896	1,552	1,360	11,458	
	,	, <del>-</del>	,	-,	
Total non-cash stock-based compensation	\$ 2,116	\$ 1,815	\$ 1,628	\$ 16,953	3
Total non-cash stock-based compensation	Ψ 2,110	Ψ 1,015	Ψ 1,020	Ψ 10,935	,

See accompanying notes.

## CORCEPT THERAPEUTICS INCORPORATED

## (A DEVELOPMENT STAGE COMPANY)

## STATEMENT OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (NET CAPITAL DEFICIENCY)

(in thousands, except per share amounts)

		ertible ed Stock	Comn Stoc	ek	Additional Paid-in	Notes Receivable from		the	Total d Stockholders Accumulated Equity Other (Net 6mprehensive Capital
	Shares	Amount	Shares	Amount			Compensation		ncome (Loss Deficiency)
Balance at inception (May 13, 1998)		\$		\$	\$	\$	\$	\$	\$ \$
Issuance of common stock to directors for cash in June and July 1998			7,500	8	(5)				3
Issuance of common stock to a director for cash in May 1999			1,771	2	63				65
Issuance of common stock to Stanford and directors in conjunction with a license			·						
agreement in October 1999			30		1				1
Issuance of Series A convertible preferred stock to institutional and individual investors at \$1.08 per share for cash and conversion of notes payable, net of issuance costs									
of \$34 in May 1999	608	623							
Common stock issued to attorneys and consultants in exchange for services in May 1999			49		2				2
Issuance of common stock upon option exercise			60						
Repurchase of common stock held by director in March 1999			(750)	(1)					(1)
Deferred compensation related to options granted to non-employees					65		(65)		
Amortization of deferred compensation							7		7
Net loss from inception to December 31, 1999								(321)	(321)
Balance at December 31, 1999 Issuance of Series B convertible preferred stock to institutional and individual investors at \$3.00 per share for cash, net of issuance costs	608	623	8,660	9	126		(58)	(321)	(244)
of \$19 in January 2000	400	1,180							
Deferred compensation related to options granted to an employee and non-employees					248		(248)		
Amortization of deferred					270		` '		
compensation							91	(1.046)	91
Net loss								(1,846)	(1,846)
Balance at December 31, 2000	1,008 12	1,803 205	8,660	9	374		(215)	(2,167)	(1,999)

Issuance of Series B convertible preferred stock to consultants in exchange for services in January and April 2001									
Issuance of Series BB convertible preferred stock to institutional and individual investors at \$4.033 per share upon conversion of									
promissory notes in May 2001 Issuance of Series C convertible preferred stock to institutional and individual investors at \$7.066 per share for cash, net of issuance costs of approximately \$95 in May and	268	1,081							
June 2001	3,807	26,805							
Issuance of Series C convertible preferred stock to consultants in exchange for services in October 2001	1	20,003							
Issuance of common stock to a	1	20							
consultant for cash below fair value									
in April 2001			50		50				50
Issuance of common stock upon									
option exercises			768		438	(438)			
Issuance of common stock in									
conjunction with a license			1		1.5				1.5
agreement Deferred compensation related to			1		15				15
options granted to employees and									
non-employees					10,226		(10,226)		
Amortization of deferred					,		(-0,0)		
compensation							1,849		1,849
Net loss								(7,454)	(7,454)
Balance at December 31, 2001									
(carried forward)	5,096	29,914	9,479	9	11,103	(438)	(8,592)	(9,621)	(7,539)

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## CORCEPT THERAPEUTICS INCORPORATED

## (A DEVELOPMENT STAGE COMPANY)

# STATEMENT OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (NET CAPITAL DEFICIENCY), (Continued)

(in thousands, except per share amounts)

		ertible ed Stock	Com Sto		Additional Paid-in	Notes   Receivable   from		During	ccumulate <b>&amp;</b> tocl Other E omprehensive	Equity
	Shares	Amount	Shares	Amount			Compensation	•		apitai ficiency)
Balance at December 31, 2001 (brought forward)	5,096	\$ 29,914	9,479	\$ 9	\$ 11,103	\$ (438)	•	_	\$ \$	(7,539)
Issuance of Series C convertible preferred stock to institutional and individual investors at \$7.066 per share for cash, net of issuance costs of approximately \$19 in December 2002	1,673	11,802								
Issuance of common stock upon option exercises			62							
Amortization of deferred compensation							4.085			4.085
Reduction of deferred compensation related to the unamortized portion of deferred stock compensation							1,003			1,000
related to a terminated employee					(239)	)	239			
Reversal of previously expensed deferred compensation related to a terminated employee based on the straight line method					(50)					(50)
Stock-based compensation related					(30)					(30)
to lapsing repurchase right of stock held by a non-employee					68					68
Net loss								(18,504)		(18,504)
Balance at December 31, 2002	6,769	41,716	9,541	9	10,882	(438)	(4,268)	(28,125)		(21,940)
Deferred compensation related to options granted to employees and										
non-employees Amortization of deferred					1,159		(1,159)			
compensation Reduction of deferred compensation							1,559			1,559
related to the unamortized portion of deferred stock compensation					(4.500)		4.500			
related to terminated employees Reversal of previously expensed					(1,588)	)	1,588			
deferred compensation related to terminated employees					(1,384)	)				(1,384)
Repurchase of common stock and reduction of note payable upon termination of employees			(206)		(155)	) 155				
Repayment of note receivable from stockholder			, ,			37				37
Stock-based compensation related to lapsing repurchase right of stock held by a non-employee					68					68

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Net loss								(9,812)		(9,812)
Unrealized loss on short-term investments									(1)	(1)
Total comprehensive loss										(9,813)
Balance at December 31, 2003 (carried forward)	6,769	41,716	9,335	9	8,982	(246)	(2,280)	(37,937)	(1)	(31,473)

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## CORCEPT THERAPEUTICS INCORPORATED

## (A DEVELOPMENT STAGE COMPANY)

# STATEMENT OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (NET CAPITAL DEFICIENCY), (Continued)

(in thousands, except per share amounts)

		ertible ed Stock	Commo	n Stock	Additiona Paid-in	l Rec		Deferred	Deficit Accumulated During the Co	Other omprehensi	Equity
	Shares	Amount	Shares	Amoun	t Capital	Stock	kholdeCx	ompensatio	n Stage	(Loss)	Deficiency)
Balance at December 31, 2003 (brought forward)	6,769	\$ 41,716	9.335	\$ 9	\$ 8,982	. \$	(246)	\$ (2.280)	\$ (37,937)	<b>\$</b> (1)	\$ (31,473)
Sale of Shares in IPO at \$12.00 per	.,	, ,,	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		, -,	•	( -/	, (,,,,,	( ( ) )	. ()	( ( , , , , , , )
share for cash, net of issuance costs of approximately \$4,974			4,500	5	49,020						49,025
Conversion of preferred shares in IPO	(6,769)	(41,716)	8,807	9	41,707						41,716
Conversion of note payable Issuance of common stock upon			45		534						534
option exercises			7		1						1
Deferred compensation related to options granted to employees and non-employees					1,447			(1,447)			
Amortization of deferred					1,44/			(1,447)			
compensation								1,854			1,854
Reduction of deferred compensation											
related to the unamortized portion of deferred stock compensation related											
to terminated employees and											
consultants					(155	)		155			
Reversal of previously expensed deferred compensation related to											
employees terminated or converted to consultant					(243	)					(243)
Repayment of note receivable from					(213	,					(213)
stockholder							62				62
Stock-based compensation related to											
lapsing repurchase right of stock					68						68
held by a non-employee Net loss					08				(15,535)		(15,535)
Change in unrealized loss on									(13,333)		(13,333)
investments										(61)	(61)
Total comprehensive loss											(15,596)
Balance at December 31, 2004			22,694	23	101,361		(184)	(1,718)	(53,472)	(62)	45,948
Issuance of common stock upon											
option exercise for cash in June 2005 at a price of \$0.10 per share			9		1						1
Deferred compensation related to			9		1						1
options granted to employees and											
non-employees					(94	)		94			
Amortization of deferred								04.5			o .=
compensation					35 (109			912 109			947
					(109	,		109			

Reduction of deferred compensation related to the unamortized portion of deferred stock compensation related to unvested shares at termination of employees								
Reversal of previously expensed deferred compensation related to employees terminated or converted								
to consultant			(250)					(250)
Repayment of note receivable from stockholder				16				16
Stock-based compensation related to lapsing repurchase right of stock								
held by a non-employee			68					68
Issuance of common stock for								
services	1		2					2
Net loss						(20,093)		(20,093)
Change in unrealized loss on								
investments							(46)	(46)
Total comprehensive loss								(20,139)
Balance at December 31, 2005								
(carried forward)	22,704	23	101,014	(168)	(603)	(73,565)	(108)	26,593

## CORCEPT THERAPEUTICS INCORPORATED

## (A DEVELOPMENT STAGE COMPANY)

# STATEMENT OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (NET CAPITAL DEFICIENCY), (Continued)

(in thousands, except per share amounts)

	Convertible Preferred Stock	Common	n Stock	Additional Paid-in	Notes Receivabl from		Deficit Accumulated During the C Development	Other comprehensiv	Equity
	SharesAmount	Shares	Amount			enSompensati	•	(Loss)	Deficiency)
Balance at December 31, 2005 (brought		22.704	Ф. 22	Ф 101 014	Φ (160	- (CO2)		Φ (100)	Ф. 26.502
forward) Sale of common stock in December	\$	22,704	\$ 23	\$ 101,014	\$ (168	(603)	\$ (73,565)	\$ (108)	\$ 26,593
2006 at \$1.00 per share for cash, net of									
issuance costs of approximately \$83		3,000	3	2,914					2,917
Issuance of common stock upon option									
exercises at various times for cash at									
weighted-average exercise price of									
\$0.73 per share		26		19					19
Issuance of common stock at various									
times for services in lieu of cash									
compensation at an average value of		_							
\$4.93 per share		2		12					12
Amortization of deferred compensation									
related to options granted to employees prior to the IPO						375			375
Stock-based compensation related to						313			313
employee and director options granted									
after the IPO				1,118					1.118
Stock-based compensation related to				-,					-,
options to consultants				75					75
Reversal of previously expensed									
compensation related to employees									
terminated or converted to consultant				(50)					(50)
Repayments of notes receivable from									
stockholders in October and December									
of 2006					43				43
Stock-based compensation related to									
lapsing repurchase right of stock held by	У			23					22
a non-employee Net loss				23			(24,873)		23 (24,873)
Change in unrealized loss on							(24,073)		(24,673)
investments								108	108
m Counciles								100	100
Total comprehensive loss									(24,765)
Tom completionsive 1055									(24,703)
Balance at December 31, 2006 (carried									
forward)		25,732	26	105,125	(125	(228)	(98,438)		6,360
101.1144)		23,732	20	103,123	(123	, (220)	(50,150)		0,500

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## CORCEPT THERAPEUTICS INCORPORATED

## (A DEVELOPMENT STAGE COMPANY)

# STATEMENT OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (NET CAPITAL DEFICIENCY), (Continued)

(in thousands, except per share amounts)

	Convertible Preferred Stock	Commo	n Ste	ock	Additional Paid-in	Re	Notes eceivable from	Deferred	Deficit Accumula During t Developm	itedAcc	umulated Other	(Net
	SharesAmount	Shares	Am	ount		Sto		ompensatio				Deficiency)
Balance at December 31, 2006 (brought					•			•	Ü			•
forward)	\$	25,732	\$	26	\$ 105,125	\$	(125)	\$ (228)	\$ (98,4	38) \$		\$ 6,360
Sale of common stock in March 2007 at												
\$1.00 per share for cash, net of issuance												
costs of approximately \$151		9,000		9	8,840							8,849
Sale of common stock in August &												
September 2007 at \$2.10 per share for												
cash, net of issuance costs of				_								
approximately \$64		4,790		5	9,991							9,996
Issuance of common stock upon option												
exercises at various times for cash at												
weighted-average exercise price of \$0.79	)	2.										
per share		26			21							21
Amortization of deferred compensation												
related to options granted to employees								96				06
prior to the IPO Stock-based compensation related to								90				96
employee and director options granted												
after the IPO					1,334							1,334
Stock-based compensation related to					1,334							1,334
options to consultants					48							48
Reduction of deferred compensation					40							70
related to the unamortized portion of												
deferred stock compensation related to												
unvested shares at termination of												
employees					(119)	)		119				
Reversal of previously expensed												
compensation related to employees												
terminated					(418)	)						(418)
Repayments of notes receivable from												
stockholders in March and October 2007	1						18					18
Net loss									(11,5	73)		(11,573)
Change in unrealized gain on investment	ts										3	3
Net comprehensive loss												(11,570)
Balance at December 31, 2007 (carried												
forward)		39,548		40	124,822		(107)	(13)	(110,0	11)	3	14,734

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## CORCEPT THERAPEUTICS INCORPORATED

## (A DEVELOPMENT STAGE COMPANY)

# STATEMENT OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (NET CAPITAL DEFICIENCY), (Continued)

(in thousands, except per share amounts)

	Convertible Preferred Stock	Commo	n Stock	Additional Paid-in	Notes Receivable from	Deferred	Accumulated During theCo Development	Other	Capital
	SharesAmount	Shares	Amount	Capital	Stockholder	Compensatio	n Stage	(Loss)	Deficiency)
Balance at December 31, 2007 (brough									
forward)	\$	39,548	\$ 40	\$ 124,822	\$ (107)	\$ (13)	\$ (110,011)	\$ 3	\$ 14,734
Sale of common stock and issuance of									
warrants in March 2008 at \$2.83 per	,								
unit for cash and note receivable, net of		8,924	9	24,783	(6,000)				18,792
issuance costs of approximately \$382 Sales of common stock in August and		0,924	9	24,763	(0,000)				10,792
September 2008 under Committed									
Equity Financing Facility (CEFF), at ar	1								
average discounted price of \$1.85 per	•								
share, net of costs associated with the									
registration of shares under the CEFF									
of \$216		405		533					533
Issuance of common stock in									
November 2008 in settlement of									
liquidated damages, net of issuance									
costs of \$5		883	1	1,274					1,275
Issuance of common stock upon option									
exercise in September 2008 for cash at									
exercise price of \$1.50 per share		2		4					4
Issuance of common stock in February									
for services in lieu of cash									
compensation at a value of \$2.73 per		1		4					4
share		1		4					4
Amortization of deferred compensation									
related to options granted to employees prior to the IPO						13			13
Stock-based compensation related to						13			13
employee and director options granted									
after the IPO				1,580					1,580
Stock-based compensation related to				1,000					1,500
options to consultants				31					31
Repayment of note receivable from									
stockholder in May 2008					6				6
Net loss							(20,061)		(20,061)
Change in unrealized loss on									
investments								(4)	(4)
Total comprehensive loss									(20,065)
-									, ,
Balance at December 31, 2008		49,763	50	153,031	(6,101)		(130,072)	(1)	16,907
Sale of common stock and issuance of		12,703	50	155,051	(0,101)		(130,072)	(1)	10,707
warrants in October 2009 at \$1.43 per									
unit for cash, net of issuance costs of									
approximately \$720		12,597	12	17,280					17,292
**									

Sales of common stock in October 2009 under CEFF, at an average						
discounted price of \$2.45 per share, net	100		242			2.42
of issuance costs of approximately \$7	102		243			243
Issuance of common stock in August October 2009 for services in lieu of						
cash compensation at an average value	12		16			16
of \$1.22 per share	13		16			16
Stock-based compensation related to			700			1 700
employee and director options			,789			1,789
Stock-based compensation related to			10			10
options to consultants			10			10
Repayment of note receivable from						
stockholder in February 2009			6,000			6,000
Net loss				(20,166)		(20,166)
Change in unrealized loss on						
investments					1	1
Total comprehensive loss						(20,165)
•						
Balance at December 31, 2009 (carried						
	62 175	62 172	260 (101)	(150 229)		22,002
forward)	62,475	02 1/2	2,369 (101)	(150,238)		22,092

# CORCEPT THERAPEUTICS INCORPORATED

# (A DEVELOPMENT STAGE COMPANY)

# STATEMENT OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (NET CAPITAL DEFICIENCY), (Continued)

(in thousands, except per share amounts)

	Convertible Preferred Stock	Commo	n Stock	Additional Paid-in	Notes Receivable from		Deficit A Accumulated During theCo	Other	Total Estockholders Equity ve (Net Capital
	SharesAmount	Shares	Amount	Capital	Stockholde	sompensatio	on Stage	(Loss)	Deficiency)
Balance at December 31, 2009 (brought forward)	\$	62,475	\$ 62	\$ 172,369	\$ (101)	\$	\$ (150,238)	\$	\$ 22,092
Sales of common stock in January and October 2010 under CEFF, at an average discounted price of \$3.13 per share, net	:								
of issuance costs of approximately \$15		519	1	1,609					1,610
Issuance in April 2010 of common stock upon exercise of warrants at \$1.66 per share and issuance of new warrants at \$0.125 per share for cash, net of issuance									
costs of approximately \$168		4,286	4	7,480					7,484
Sale of common stock in June 2010 at \$3.00 per unit for cash, net of issuance costs of approximately \$1,247		5,000	5	13,748					13,753
Issuance of common stock upon option exercise for cash at exercise prices ranging from \$0.10 to \$2.23 per share		124		151					151
Stock-based compensation related to employee and director options		124		1,947					1,947
Stock-based compensation related to an option to a consultant				169					169
Repayment of note receivable from stockholder in January 2010					4				4
Net loss and comprehensive loss							(25,966)		(25,966)
Balance at December 31, 2010	\$	72,404	\$ 72	\$ 197,473	\$ (97)	\$	\$ (176,204)	\$	\$ 21,244

See accompanying notes.

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# CORCEPT THERAPEUTICS INCORPORATED

# (A DEVELOPMENT STAGE COMPANY)

# STATEMENTS OF CASH FLOWS

(in thousands)

	Year	Period f incepti (May 1 1998) Decembe	ion 13, to		
	2010	2009	2008	2010	,
Operating activities					
Net loss	\$ (25,966)	\$ (20,166)	\$ (20,061)	\$ (176	,204)
Adjustments to reconcile net loss to net cash used in operations:					
Depreciation and amortization of property and equipment	6	10	12		116
Stock-based compensation, net of recoveries	2,116	1,799	1,624	16	,579
Expense related to stock issued for services		16	4		64
Settlement of liquidated damages in stock			1,281	1	,281
Expense related to stock issued in conjunction with license agreement					31
Expense related to stock issued below fair value					522
Interest accrued on convertible promissory notes					104
Changes in operating assets and liabilities:					
Prepaid expenses and other current assets	135	717	(980)		(418)
Other assets	(23)	95	(113)		(104)
Accounts payable	(453)	(34)	189		817
Accrued clinical expenses	106	(280)	110		815
Accrued compensation and other liabilities	1,794	(125)	(428)	2	2,228
Net cash used in operating activities	(22,285)	(17,968)	(18,362)	(154	,169)
Investing activities					
Purchases of property and equipment			(7)		(61)
Purchases of short-term and long-term investments			(3,594)	(118	3,320)
Maturities of short-term investments		3,594	5,930	118	3,320
Net cash provided by (used in) investing activities		3,594	2,329		(61)
Financing activities					
Proceeds from issuance of common stock and warrants, including collection					
of stockholder notes receivable, net of cash paid for issuance costs	23,002	23,535	19,329		,946
Proceeds from issuance of convertible notes				1	,543
Principal payments of obligations under capital leases	(6)	(10)	(13)		(59)
Proceeds from issuance of convertible preferred stock, net of cash paid for					
issuance costs				40	),378
Net cash provided by financing activities	22,996	23,525	19,316	178	3,808
Net increase in cash and cash equivalents	711	9,151	3,283	24	,578
Cash and cash equivalents at beginning of period	23,867	14,716	11,433		,
Cash and cash equivalents at end of period	\$ 24,578	\$ 23,867	\$ 14,716	\$ 24	,578

Supplemental disclosure of cash flow information

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Interest paid	\$ \$	1 \$	5	\$ 16
Supplemental disclosure of non-cash financing activities				
Conversion of convertible promissory notes and accrued interest				
to convertible preferred stock	\$ \$	\$		\$ 1,111
to common stock	\$ \$	\$		\$ 534
Issuance of warrant in connection with financing agreement	\$ \$	\$	653	\$ 653
Issuance of common stock in settlement of liquidated damages	\$ \$	\$	1,281	\$ 1,281
Purchase of equipment under capital leases	\$ \$	\$		\$ 59

See accompanying notes.

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#### CORCEPT THERAPEUTICS INCORPORATED

#### (A DEVELOPMENT STAGE COMPANY)

#### NOTES TO FINANCIAL STATEMENTS

# 1. Basis of Presentation and Summary of Significant Accounting Policies

#### **Description of Business**

Corcept Therapeutics Incorporated was incorporated in the state of Delaware on May 13, 1998, and its facilities are located in Menlo Park, California. Corcept is a pharmaceutical company engaged in the discovery, development and commercialization of drugs for the treatment of severe metabolic and psychiatric diseases. Our most advanced program is for the use of CORLUX, our lead product, for the treatment of the signs and symptoms of endogenous Cushing s Syndrome, for which we have completed treatment and reported top-line results of our Phase 3 trial and are preparing for the submission of a New Drug Application (NDA) to the United States Food and Drug Administration (FDA) late in the first quarter of 2011. We have another clinical program for the use of CORLUX for the treatment of psychotic depression, where we are engaged currently in a Phase 3 study. Unless otherwise stated, all references in these financial statements to we, us, our, its, Corcept, the Company and similar designations refer to Corcept Therapeutics Incorporated.

Our activities since incorporation have been establishing our offices, recruiting personnel, conducting research and development, performing business and financial planning, raising capital, overseeing clinical trials, and preparing for potential commercialization. Accordingly, we are considered to be in the development stage.

# **Management Plans Regarding Liquidity**

In the course of our development activities, we have sustained operating losses and expect such losses could continue into the future. We plan to continue to finance our operations through the sale of our equity and/or debt securities or by engaging in strategic relationships with potential partners. Our ability to continue our operations through the complete development and commercialization of our products is dependent upon the successful execution of our financing and/or any partnership strategies.

As reflected in the accompanying financial statements as of December 31, 2010, we had cash and cash equivalents of \$24.6 million, working capital of \$21.1 million and an accumulated deficit of \$176.2 million. In January 2011, we sold additional shares of our common stock for net proceeds of approximately \$41.9 million. (See Note 14 Subsequent Events.) We believe that we have sufficient funds to maintain our operations into the third quarter of 2012.

#### **Use of Estimates**

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ materially from those estimates. Any changes in estimates are recorded in the period of the change.

Cost accruals for clinical trials are based upon estimates of work completed under service agreements, milestones achieved, patient enrollment and past experience with similar contracts. Our estimates of work completed and associated cost accruals include our assessments of information received from third-party contract research organizations and the overall status of clinical trial activities. The estimates are updated on a recurring basis as new information becomes available.

# **Cash and Cash Equivalents**

We invest our excess cash in bank deposits, money market accounts, corporate debt securities, and obligations of the U.S. government and U.S. government sponsored entities. We consider all highly liquid

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investments purchased with maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents are carried at fair value, which approximates cost and, as of December 31, 2010 and 2009, consist of money market funds maintained at major U.S. financial institutions. As of December 31, 2010 and 2009, all of our funds were invested in cash and cash equivalents.

#### **Credit Risks and Concentrations**

Our concentration of credit risk relate to our cash and cash equivalents. We are exposed to credit risk in the event of default by the financial institutions holding these funds to the extent of the amount recorded on the balance sheet. This risk is mitigated by investing in securities with high credit ratings from the major rating services and by limiting the amount of investment in any one issuer. As of December 31, 2010 and 2009, we had no investments in mortgage-backed securities or auction rate securities. For the years ended December 31, 2010, 2009 and 2008, we experienced no loss or lack of access to cash and cash equivalents in our operating or investment accounts.

We also have a concentration of risk in regard to the manufacture of our product. As of December 31, 2010, we had one pre-existing supplier for our tablet manufacture and had negotiated a contract with a second tablet manufacturer with whom we have not yet completed process transfer or test manufacture. If we are not able to qualify our second tablet manufacturer or if our pre-existing supplier is unable to prepare the CORLUX tablets in the quantities and time frame required, we may not be able to manufacture our product in a timely manner.

#### **Fair Value Measurements**

Financial instruments are categorized in a fair value hierarchy that prioritizes the information used to develop assumptions for measuring fair value. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets or liabilities (Level 1 input), then to quoted prices (in non-active markets or in active markets for similar assets or liabilities), inputs other than quoted prices that are observable for the asset or liability, and inputs that are not directly observable, but that are corroborated by observable market data for the asset or liability (Level 2 input), then the lowest priority to unobservable inputs, for example, our own data about the assumptions that market participants would use in pricing an asset or liability (Level 3 input). Fair value is a market-based measurement, not an entity-specific measurement, and a fair value measurement should therefore be based on the assumptions that market participants would use in pricing the asset or liability.

No assets or liabilities in our financial statements are required to be measured at fair value other than the Company s investment portfolio.

# **Revenue Recognition**

Collaboration revenue relates to services rendered in connection with agreements signed with Eli Lilly and Company (Eli Lilly), in which Eli Lilly agreed to support certain of our pre-clinical and clinical proof-of-concept studies evaluating the ability of our product candidates to mitigate or prevent weight gain associated with the use of Zyprexa (olanzapine), an atypical antipsychotic medication. Under the agreements, Eli Lilly agreed to supply the Zyprexa and olanzapine and pay for the studies. We were required to perform development activities as specified in these agreements and 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 services were rendered in accordance with the agreements.

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#### **Research and Development**

Research and development expenses consist of costs incurred for Company-sponsored research and development activities. These costs include direct expenses (including nonrefundable payments to third parties) and research and development-related overhead expenses, as well as the cost of funding clinical trials, pre-clinical studies, manufacturing development and the development of second-generation compounds, and are expensed as incurred. Costs to acquire technologies and materials that are utilized in research and development and that have no alternative future use are expensed when incurred (see Note 2).

#### **Segment Reporting**

Operating segments are determined based on the way we organize our business for making operating decisions and assessing performance. We have only one operating segment, which is involved in the development of pharmaceutical products.

#### **Property and Equipment**

Property and equipment are stated at cost less accumulated depreciation and amortization. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets, ranging from three to five years. Assets acquired under capital leases were amortized over the term of their useful lives or the lease period, whichever is shorter.

### **Stock-Based Compensation**

Stock-based compensation for employee and director options

Since January 1, 2006, we have accounted for stock-based compensation related to option grants to employees and directors under the fair value method, based on the fair value-based measurement of the award at the grant date except that, for option awards granted prior to our initial public offering (IPO), we calculated stock-based compensation expense based on the intrinsic value method. For service awards, expense is recognized over the requisite service period. For options with performance-based vesting criteria, expense will be recognized at such time as there is a high degree of probability (i.e., greater than 70%) of achieving the vesting criteria.

Stock-based compensation expense related to non-employees

Expense is recognized for options granted to non-employees based on the fair-value based measurement of the option grants at the time of vesting. For service-based awards, expense is recognized over the requisite service period. For options with performance-based vesting criteria, expense is recognized based on the minimum number of shares that will vest over time as the criteria are met based on the Black-Scholes valuation of the vested shares.

See Note 9 for a detailed discussion of stock-based compensation expense.

# **Income Taxes**

Deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates that will be in effect when the differences are expected to reverse. A valuation allowance is recorded when it is more likely than not that the deferred tax asset will not be realized.

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No amounts have been recognized as interest or penalties on income tax related matters. The determination of an accounting policy as to the classification of such costs has been deferred until such time as any such costs are incurred.

## **Recently Adopted Accounting Standards**

Milestone Method of Revenue Recognition

On March 31, 2010, the Financial Accounting Standards Board ratified the conclusions reached by its Emerging Issues Task Force that the milestone method of revenue recognition is a valid application of the proportional performance model when applied to research or development arrangements. Accordingly, the guidance states that an entity can make an accounting policy election to recognize a payment that is contingent upon the achievement of a *substantive* milestone in its entirety in the period in which the milestone is achieved. The milestone method is not required and is not the only acceptable method of revenue recognition for milestone payments.

This guidance also indicates that, in order to recognize the revenue, certain criteria must be met, including the requirement that the activities leading up to the achievement of the milestone must be conducted by the entity. A milestone is defined in the guidance as an event: (a) that can only be achieved based in whole or in part on either (1) the entity s performance or (2) on the occurrence of a specific outcome resulting from the entity s performance, (b) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (c) that would result in additional payments being due to the entity. Therefore, a milestone does not include events for which the occurrence is contingent solely on the passage of time or solely on a customer s performance.

The new guidance was effective for fiscal years that began on or after June 15, 2010 and interim periods within those years and allowed prospective or retrospective adoption. The adoption of the new standard on January 1, 2011 on a prospective basis did not have any effect on our financial statements as we do not currently have any arrangements to which the standard would apply.

# 2. Significant Agreements

### **Stanford License Agreements**

In October 1998, we entered into an agreement with The Board of Trustees of Leland Stanford Junior University (Stanford) in which Stanford granted us an exclusive option to acquire an exclusive license for inventions and patents related to Mifepristone for Psychotic Major Depression and Mifepristone and Alzheimer s Disease owned by Stanford.

In October 1999, we exercised our option to acquire an exclusive license to patents covering the use of glucocorticoid receptor antagonists for the treatment of psychotic major depression, early dementia, and cocaine-induced psychosis, as specified in the license agreement. This license agreement expires upon the expiration of the related patents or upon notification by us to Stanford. In exchange for the license, we paid Stanford \$47,000 and immediately issued 30,000 shares of our common stock to Stanford. We are further required to pay Stanford \$50,000 per year as a nonrefundable royalty payment. The annual royalty payments are creditable against future royalties. We are also obligated to pay a \$50,000 milestone upon filing of the first NDA by FDA for CORLUX in one of the indications covered by the license and a \$200,000 milestone upon FDA approval of the related drug. The milestone payments are also creditable against future royalties. We have expensed the \$47,000 payment made up front, the \$50,000 annual nonrefundable royalty payments and the value of the common stock issued to Stanford as research and development costs.

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# **Manufacturing Agreements**

On November 8, 2006, we signed an agreement with Produits Chimiques Auxiliaires et de Synthese SA (PCAS) for the manufacture of the active pharmaceutical ingredient (API) 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 and we intend to pursue discussions for further extensions. If PCAS is unable to manufacture the product for a consecutive six-month period, we have the right to terminate the agreement, without penalty. During the period from September through December 2010, we signed purchase orders for the acquisition of API to be delivered during 2011 for aggregate commitments of approximately \$1.8 million. There is no guaranteed minimum purchase commitment under this agreement until after approval of the NDA.

We also have a memorandum of understanding with ScinoPharm Taiwan (ScinoPharm). Pursuant to that memorandum of understanding, ScinoPharm agrees to manufacture API and we agree to purchase at least \$1,000,000 of bulk mifepristone per year following the commercial launch of CORLUX. ScinoPharm is considered to be a potential secondary site for the manufacture of the API. However, no activities are currently being performed at this site to develop or qualify the manufacturing processes or facilities and we do not plan to include a request for approval of material produced by ScinoPharm when we submit our NDA for Cushing s Syndrome planned for the first quarter of 2011.

We have also entered into an agreement with another contract manufacturer, PharmaForm, L.L.C. (PharmaForm), for the production of CORLUX tablets. To date, our need for CORLUX tablets has been limited to the amounts required to support our clinical trials and the registration batches needed to support our anticipated NDA filing for CORLUX for the treatment of Cushing s Syndrome. The agreement with PharmaForm was executed in December 2006 and will expire upon the completion of the development program for CORLUX, but may be extended. There are no minimum purchase amounts under this agreement. The agreement with PharmaForm may be terminated by either party upon 180 days written notice; we may terminate projects initiated under this agreement with 30 days written notice.

In June 2010, we signed agreements with a vendor that provides manufacturing services for materials to be used in development work for CORT 108297 and CORT 113083 in the aggregate amount of \$1.6 million. Approximately \$1.2 million has been incurred under these agreements through December 31, 2010, with the remainder to be incurred in 2011.

#### **Research and Development Agreements**

In 2003, we entered into a contract research agreement with Argenta Discovery Limited (Argenta) in which Argenta agreed to conduct research toward identifying a novel small molecule glucocorticoid receptor antagonist for the treatment of psychotic depression, Alzheimer's disease, and other metabolic and psychiatric disorders. The project was expected to last at least two years, during which time we would make payments to Argenta based upon the number of FTEs (full-time equivalents) that we have working on our projects. By December 31, 2008, work under the initial agreement with Argenta and major subsequent amendments had been concluded. We continue our relationship with Argenta, requesting them to conduct research projects on a regular basis. Under the agreements with Argenta, 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 us or any future licensees reach \$5,000,000. These obligations remain in force after the conclusion of work under the agreement. During 2010, we expensed a \$100,000 payment to Argenta upon the initiation of the Phase 1 clinical trial with CORT 108297 as a research and development expense. See footnote 14 regarding the signing of an amendment under this agreement.

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In 2008, we executed a Master Service Agreement (MSA) and a Project Contract (Contract), with ICON Clinical Research, L.P. (ICON) to assist us in various clinical trial activities, including the selection of clinical sites, supervision and monitoring of clinical site performance, data collection and analysis in connection with Study 14, our current Phase 3 trial to confirm the utility of CORLUX for the treatment of the psychotic features of psychotic depression. In June 2009, we amended our agreements with this vendor to reduce the amounts of commitments under these agreements in accordance with the reduction in the near-term scope of activities in 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, assuming the availability of sufficient capital for this purpose. The total commitment under this agreement, including amendments executed through 2010 is estimated to be approximately \$12.3 million over the course of the trial. Approximately \$5.3 million of costs under this agreement have been expensed through December 31, 2010. The actual amount and timing of expense recognition and payments will depend upon various factors, including the timing of site initiation, the pace of patient enrollment, the fees negotiated with site investigators, the timing of other trial activities and the timing of payments of pass-through costs, such as grants to investigators and laboratory services. The Contract may be terminated by us at any time upon sixty days written notice, or sooner based on mutual agreement of the parties. Upon termination, we would be obligated to pay ICON for services performed and pass-through costs incurred to the date of termination plus a cancellation fee to compensate the CRO for staff reallocation costs.

We entered into an agreement with MedAvante, Inc. (MedAvante), effective March 17, 2008, under which MedAvante will provide centralized psychiatric rating services of patients to be screened and enrolled in Study 14. In June 2009, we amended our agreements with this vendor to reduce the amounts of commitments under these agreements in accordance with the reduction in the near-term scope of activities in 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, assuming the availability of sufficient capital for this purpose. The total commitment under this agreement, including amendments executed through 2010, is approximately \$4.0 million. Approximately \$2.7 million of costs under this agreement have been expensed through December 31, 2010, with the remainder of any actual costs to be incurred over the remainder of the course of the trial. We may terminate this agreement with 30 days notice to MedAvante. In the event of termination, we are obligated to pay certain costs including costs incurred to date, costs associated with any non-cancellable commitments for video service connectivity and costs of staff assigned to the project for a period of three months or until such time as they can be assigned to other projects, whichever is less.

During 2010, we signed agreements for the conduct of the initial clinical trials using CORT 108297. The total commitment under these agreements is approximately \$2.3 million. Approximately \$1.3 million of costs under these agreements have been incurred as of December 31, 2010, with the remainder expected to be incurred during 2011.

See footnote 14 Subsequent Events for discussion of agreements signed during the first quarter of 2011.

#### Other Agreements

In August 2010, we entered into an agreement with United Biosource Corporation (UBC) to assist us in developing our Risk Evaluation and Mitigation Strategy (REMS), a plan for which will be submitted to the FDA as part of our NDA for CORLUX for the treatment of Cushing s Syndrome. The financial commitment under the initial set-up phase of this agreement is approximately \$1.2 million; approximately \$105,000 of which cost was incurred during 2010 with the remainder expected to be incurred during 2011. Commitments for any future phases of the agreement will not be effective until after the FDA approval of our NDA; the majority of such costs will be variable and dependent on patient utilization of our drug. We may terminate this agreement at

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any time upon 30 days written notice. The agreement may be terminated by UBC for any reason upon 120 days written notice. In the event of termination, we are obligated to compensate UBC for any actual costs and any uncancellable obligations incurred prior to the date of termination.

#### 3. Fair Value

As of December 31, 2010 and 2009, our financial assets were invested in a money market fund, which can be converted to cash at par on demand. These funds, which totaled \$23.9 and \$23.0 million, respectively, were measured at fair value as of December 31, 2010 and 2009 and were classified as Level 1 assets in the fair value hierarchy for financial assets.

All cash equivalents and short-term investments held as of December 31, 2010 and 2009 and 2008 were in active markets and valued based upon their quoted prices.

#### 4. Financial Instruments

The following tables present a summary of cash and cash equivalents. All amounts are in thousands.

	Cost	Unrealized Gain	Unrealized Loss	Fair Value
December 31, 2010	Cost	Guiii	2005	Tun vuide
Cash	\$ 662	\$	\$	\$ 662
Money market fund	23,916			23,916
	\$ 24,578	\$	\$	\$ 24,578
Reported as:				
Cash and cash equivalents	\$ 24,578	\$	\$	\$ 24,578

	Cost	Unrealized Gain	Unrealized Loss	Fa	ir Value
December 31, 2009					
Cash	\$ 887	\$	\$	\$	887
Money market fund	22,980				22,980
•	\$ 23,867	\$	\$	\$	23,867
Reported as:					
Cash and cash equivalents	\$ 23,867	\$	\$	\$	23,867

As of December 31, 2010 and 2009, all cash and cash equivalents were classified as available-for-sale securities. There were no mortgage-backed securities and no auction rate securities in the portfolio at any time during 2010 or 2009.

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The net realized loss on sales of available-for-sale investments was not material for any period presented.

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# 5. Property and Equipment

Property and equipment, including assets purchased under capitalized leases, consists of the following:

	Decen	nber 31,
	2010	2009
	(in the	ousands)
Furniture and equipment	\$ 51	\$ 51
Less: accumulated depreciation and amortization	(47)	(41)
	\$ 4	\$ 10

Amortization expense related to assets under capital lease was approximately \$4,000, \$9,000 \$12,000 and \$59,000 for the years ended December 31, 2010, 2009 and 2008 and the period from inception (May 13, 1998) to December 31, 2010, respectively. During 2009, we returned to the lessor a piece of equipment that had been financed under one of the capital leases and wrote-off both the \$15,000 capitalized value of the asset and the accumulated amortization. During 2010, we acquired title to furniture with a capitalized asset value of approximately \$44,000 that had been acquired under the remaining capital lease.

# 6. Other Liabilities

Other liabilities consisted of the following:

	Decen	nber 31,
	2010	2009
	(in the	ousands)
Accrued professional fees	\$ 224	\$ 186
Accrued legal fees	135	
Other	63	38
	\$ 422	\$ 224

# 7. Lease Obligations

On August 12, 2010, we renewed our lease for office space for a one-year term commencing on January 1, 2011 at a monthly cost of approximately \$19,000 plus operating expenses. At December 31, 2010, the remaining minimum rental payments under this operating lease were approximately \$230,000.

Rent expense amounted to approximately \$250,000, \$240,000, \$265,000 and \$2.2 million for the years ended December 31, 2010, 2009 and 2008, and the period from inception (May 13, 1998) to December 31, 2010, respectively.

# 8. Related Party Transactions

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See discussion below in Note 9, **Preferred Stock and Stockholders Equity, Stockholder Notes Receivable**, regarding and, in **Common Stock**, regarding the sale of securities in April 2010 to various investors, including members of the Board of Directors, and a Note Receivable from an officer of the company.

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#### NOTES TO FINANCIAL STATEMENTS, Continued

See discussion under Note 14, **Subsequent Events**, regarding the participation of an entity affiliated with one of the members of our Board of Directors in a financing transaction in January 2011.

### 9. Preferred Stock and Stockholders Equity

#### Preferred Stock

The board of directors is authorized, subject to any limitations prescribed by law, without stockholder approval, to issue up to an aggregate of 10,000,000 shares of preferred stock at \$0.001 par value in one or more series and to fix the rights, preferences, privileges and restrictions granted to or imposed upon the preferred stock, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences. The rights of the holders of common stock will be subject to the rights of holders of any preferred stock that may be issued in the future.

As of December 31, 2010 and 2009, we had no outstanding shares of preferred stock.

#### Common Stock

Our authorized capital stock includes 140,000,000 shares of common stock at \$0.001 par value. Holders of common stock are entitled to one vote per share on all matters to be voted upon by our stockholders.

On April 21, 2010, we issued approximately 4.3 million shares of our common stock upon the exercise of warrants that had been issued in a private placement transaction in October 2009 at their exercise price of \$1.66 per share and sold new warrants to the same investors to purchase a total of approximately 4.3 million shares of our common stock, which we refer to as the April 2010 Warrant Exchange. The new warrants are exercisable through April 21, 2013 at an exercise price of \$2.96 per share. The total net proceeds generated in this transaction were approximately \$7.5 million, after the deduction of issuance costs. Approximately 40% of the securities sold in this transaction were purchased by venture capital funds, trusts and other entities affiliated with members of our Board of Directors, with the remainder being purchased by other qualified investors.

On June 30, 2010, we sold 5.0 million shares of our common stock in an underwritten public offering at a price to the public of \$3.00 per share for aggregate net proceeds of approximately \$13.8 million after deducting the underwriter s discount and commissions and other expenses of the offering. See the discussion in Note 14, **Subsequent Events**, regarding an additional public offering in January 2011.

During 2010, we also sold an aggregate of 518,639 shares of common stock to Kingsbridge under the Committed Equity Financing Facility (CEFF) at an average price of \$3.13 per share, for net proceeds of approximately \$1.6 million. There were no underwriting discounts or commissions paid in connection with the CEFF sales and the transaction costs were immaterial.

Under the terms of the CEFF, which was executed in March 2008, Kingsbridge has committed to provide up to \$60 million of capital in exchange for newly-issued shares of Corcept s common stock for a period of up to three years after the SEC declares effective the registration statement covering the resale of the shares of common stock issuable in connection with the CEFF and the shares of common stock underlying the warrant discussed below. The maximum number of shares that we can sell to Kingsbridge under this agreement is approximately 9.6 million shares. Through December 31, 2010, approximately 1.0 million shares of common stock had been sold to Kingsbridge under this CEFF, for aggregate gross proceeds of approximately \$2.6 million. Based on the volume weighted average price on the NASDAQ Capital Market for our common stock for the

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period from March 25, 2008, the date of the signing of the Kingsbridge CEFF, through March 8, 2011, the maximum amount of additional funds that could be raised under the CEFF is projected to be approximately \$26 million. 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 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 common stock during the pricing periods of each sale.

Certain details of the CEFF are as follows:

We can access capital under the CEFF in tranches of up to 1.25% of our market capitalization at the time of the initiation of the draw down period, or, at our option, the lesser of (a) 2.5% of our market capitalization at the time of the initiation of the draw down period, and (b) an alternative draw down amount as defined in the agreement; provided, however, that in no event may the maximum draw down amount exceed \$10 million per tranche, subject to certain conditions.

Each tranche will be issued and priced over an eight-day pricing period. Kingsbridge will purchase shares of common stock pursuant to the CEFF at discounts ranging from 6% to 10%, depending on the volume weighted average price of our common stock during the eight-day pricing period, provided that the minimum acceptable purchase price for any shares to be issued to Kingsbridge during the eight-day period is determined by the higher of \$1.50 or 90% of our common stock closing price the day before the commencement of each draw down.

Throughout the term of the agreement, Kingsbridge has agreed it will not, and will not cause any other person to, enter into or execute a short sale of any of our securities.

We are not obligated to utilize any of the \$60 million initially available under the CEFF and there are no minimum commitments or minimum use penalties. The CEFF agreement does not contain any restrictions on our operating activities, automatic pricing resets or minimum market volume restrictions.

The agreement does not prohibit us from conducting additional debt or equity financings, other than financings similar to the CEFF and other future priced securities.

In connection with the CEFF, we issued a warrant to Kingsbridge to purchase up to 330,000 shares of common stock at an exercise price of \$3.525 per share, which represents 125% of the average of the closing bid prices of our common stock during the 5 trading days preceding the signing of the agreement. The warrant became exercisable on September 25, 2008 and will remain exercisable, subject to certain exceptions, until five years after that date. The warrant was valued at approximately \$653,000 using the Black-Scholes pricing model using the following assumptions: a contractual term of five and one-half years, risk-free interest rate of 2.71%, volatility of 89%, and the closing price of our stock price on the Nasdaq Capital Market on the date of signing the commitment, March 25, 2008, of \$2.84 per share. The warrant value was recorded in Additional Paid In Capital with an offsetting amount recorded as issuance cost in Additional Paid In Capital.

At the time of the signing of the CEFF agreements, the warrant issued to Kingsbridge and the shares of common stock issuable under the CEFF, and the shares issuable upon the exercise of the warrant, were not registered under the Securities Act, or state securities laws, and could not be offered or sold in the United States without being registered with the SEC or through an applicable exemption from SEC registration

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requirements. On June 10, 2008, the SEC declared effective our initial registration statement covering the resale of approximately 3.9 million shares, which includes approximately 3.6 million of the shares issuable under the CEFF and the shares issuable upon the exercise of the warrant. This registration statement covers approximately

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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 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 the initial registration statement.

In March 2008, we sold approximately 8.9 million shares of our common stock and warrants to purchase approximately 4.5 million shares of our common stock in a private placement (the March 2008 Financing). The registration rights agreement covering securities issued in the March 2008 Financing provides that if we failed to file or cause to be declared effective the registration statement or registration statements covering the resale of these shares prior to specified deadlines, or fail to maintain the effectiveness of such registration statements (subject to limited permissible suspension periods), we may be required to pay the holders of such shares and warrants liquidated damages at the rate of 1% per month of the purchase price of these shares and warrants, up to a total of 10%. We filed the registration statement covering the resale of the shares sold and shares underlying the warrants sold in this transaction with the Securities and Exchange Commission (SEC) on April 11, 2008, within the time period required by the agreement. However, this registration statement was not declared effective by the SEC until November 10, 2008. During 2008, we recorded approximately \$1.3 million in liquidated damages to other non-operating expense because of the delay in the effectiveness of the registration statement, which represented approximately 5% of the purchase price.

No dividends have been declared or paid by us.

Shares of common stock reserved for future issuance as of December 31, 2010 are as follows:

	(in thousands)
Common stock:	
Exercise of outstanding options	7,961
Exercise of warrants	9,200
Shares available for grant under stock option plans	1,949
	19,110

In November 2010, our Board of Directors authorized an increase in the shares available under the 2004 Equity Incentive Plan (the 2004 Plan) to be effective on January 1, 2011, equivalent to 4% of the shares of our common stock outstanding as of December 31, 2010, pursuant to the terms of the 2004 Plan. Accordingly, the shares available under the 2004 Plan have been increased by a total of 2,896,155 shares as of January 1, 2011.

#### **Stock Option Plans**

In October 2000, we adopted the 2000 Stock Option Plan (the 2000 Plan), which was amended in May 2001 to provide for the issuance of option grants for up to 2,000,000 shares of our common stock to eligible participants. Under the 2000 Plan, options to purchase common stock could be granted at no less than 100% of fair value on the date of grant for incentive stock options and 85% of fair value on the date of grant for nonqualified options, as determined by the board of directors. Options became exercisable at such times and under such conditions as determined by the board of directors. As of December 31, 2010, all option grants under this plan were fully vested, with grants covering approximately 317,000 shares remaining outstanding with contractual lives expiring in 2011 through 2014. Vested shares under this plan that are not exercised within the remaining contractual life will expire on that date and not be added to the pool of shares available for future grant.

#### CORCEPT THERAPEUTICS INCORPORATED

# (A DEVELOPMENT STAGE COMPANY)

#### NOTES TO FINANCIAL STATEMENTS, Continued

In 2004, our board of directors and stockholders approved the 2004 Plan, which became effective upon the completion of our IPO, after which time, no additional options have been or will be issued under the 2000 Plan. Under the 2004 Plan, options, stock purchase and stock appreciation rights and restricted stock awards can be issued to our employees, officers, directors and consultants. The 2004 Plan provides that the exercise price for incentive stock options will be no less than 100% of the fair value of the Company s common stock, as of the date of grant. Options granted under the 2004 Plan vest over periods ranging from one to five years. The vesting period of the options is generally equivalent to the requisite service period.

Upon exercise, new shares are issued.

In December 2009, the Board of Directors authorized an increase of 2,498,987 shares in the shares available under the 2004 Plan to be effective on January 1, 2010, which amount was based on 4% of the shares of our common stock outstanding as of December 31, 2009, pursuant to the terms of the 2004 Plan. As of December 31, 2010, the total number of shares authorized for issuance under the 2004 Plan was 9,707,805, of which 1,948,907 shares remained available for future grants. See discussion above under **Common Stock** regarding an additional increase to the shares available for grant under the 2004 Plan that was authorized by the Board of Directors in November 2010 and effective as of January 1, 2011.

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# CORCEPT THERAPEUTICS INCORPORATED

# (A DEVELOPMENT STAGE COMPANY)

# NOTES TO FINANCIAL STATEMENTS, Continued

Option activity during 2008, 2009 and 2010

The following table summarizes all stock plan activity:

		a.		Outsta	nding Options Weighted		
	Shares Available For Future Grants	Shares Subject to Options Outstanding	Weighted- Average Exercise Price		Average Remaining Contractual Life	Ir	ggregate ntrinsic Value
	thousands)	thousands)			(in years)	(in t	thousands)
Balance at December 31, 2007	887	3,891	\$	3.10		\$	3,819
Increase in shares authorized under 2004 Plan	791						
Shares granted	(1,273)	1,273	\$	1.48			
Shares exercised	` ' '	(2)	\$	1.50			
Shares issued for services	(1)	` '	\$	2.73			
Shares cancelled and forfeited under 2004							
Plan	30	(30)	\$	2.70			
Balance at December 31, 2008	434	5,132	\$	2.70		\$	31
Increase in shares authorized under 2004	1.005						
Plan	1,995	2 200	¢.	1.26			
Shares granted	(2,300)	2,300	\$	1.36			
Shares issued for services	(13)		\$	1.17			
Shares cancelled and forfeited under 2004	0.7	(0.5)	Φ.	0.60			
Plan	85	(85)	\$	2.62			
Balance at December 31, 2009	201	7,347	\$	2.28		\$	7,933
Increase in shares authorized under 2004							
Plan	2,499						
Shares granted	(838)	838	\$	3.40			
Shares exercised		(124)	\$	1.22			
Shares cancelled and forfeited under 2000		,					
Plan		(13)	\$	15.00			
Shares cancelled and forfeited under 2004 Plan	87	(87)	\$	2.26			
D. 1 01 2010			*	2.40			1.1.20.5
Balance at December 31, 2010	1,949	7,961	\$	2.40	7.1	\$	14,306
Options exercisable at December 31, 2010		5,020	\$	2.70	6.3	\$	8,478

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Options fully vested and expected to vest at December 31, 2010

7,211 \$ 2.51

7.0 \$

\$ 12,389

All stock option grants vest solely based upon continuing service, with the exception of an award with performance-based vesting criteria that was granted during 2010 to a consultant in the amount of 50,000 shares that will vest in its entirety on the filing by the FDA of our NDA for CORLUX for the treatment of Cushing s Syndrome, and awards with performance-based vesting criteria that were granted during 2009 to Joseph K. Belanoff, our Chief Executive Officer, and Robert L. Roe, our President, in the amounts of 500,000 shares and

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#### CORCEPT THERAPEUTICS INCORPORATED

## (A DEVELOPMENT STAGE COMPANY)

#### NOTES TO FINANCIAL STATEMENTS, Continued

200,000 shares, respectively, that will vest in their entirety upon the approval of the NDA for the Company s first product by the FDA.

The total intrinsic value of options exercised during the years ended December 31, 2010 and 2008 was approximately \$250,000 and \$1,000, respectively, based on the difference between the closing price of our common stock on the date of exercise of the options and the exercise price. There were no exercises of options during the year ended December 31, 2009.

The following table presents the total fair value of options to employees and directors that vested during the years ended December 31, 2010, 2009 and 2008. All amounts are in thousands.

	Year e	Year ended December 31,			
	2010	2009	2008		
Pre-IPO options, using minimum value method	\$	\$	\$ 197		
Options granted after IPO through 2005, using fair value	34	318	475		
Options granted after January 1, 2006, using fair values	1,858	1,849	1,330		
Total	\$ 1,892	\$ 2,167	\$ 2,002		

As of December 31, 2010, we had approximately \$4.0 million of unrecognized compensation expense for employee and director options outstanding as of that date. Approximately \$3.3 million of the unrecognized compensation relates to option grants with service-based vesting criteria, which had a remaining weighted-average vesting period of 2.4 years. Approximately \$637,000 of the unrecognized compensation relates to option grants with performance-based vesting criteria; as this amount will be expensed based on the high probability of success of the performance criteria, it is not possible to estimate the timing of recognition of this expense.

The following is a summary of options outstanding and options exercisable at December 31, 2010.

		Options ( Weighted	Outsta	nding			(	Option	ıs Exerci	sable	
	Number of Shares	Average Remaining Contractual Life	Av Ex	ighted erage ercise Price	Ii	ggregate ntrinsic Value	Options Exercisable (in	Av Ex	eighted verage ercise Price	In	gregate trinsic Value
	(in thousands)	(in years)			(in 1	housands)	thousands)			(in t	housands)
\$ 0.10 - \$ 1.19	2,660	8.1	\$	1.12	\$	7,281	1,022	\$	1.08	\$	2,844
\$ 1.50 - \$ 3.47	3,479	7.1	\$	1.89		6,852	2,672	\$	1.75		5,634
\$ 3.51 - \$ 5.00	1,295	6.9	\$	4.07		173	799	\$	4.41		
\$ 5.70 - \$ 14.50	527	3.0	\$	8.06			527	\$	8.06		
	7,961	7.1	\$	2.40	\$	14,306	5,020	\$	2.70	\$	8,478

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value that option holders would have received had all option holders exercised their options on December 31, 2010. The aggregate intrinsic value is the difference between our closing stock price on December 31, 2010 and the exercise price, multiplied by the number of in-the-money options.

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#### CORCEPT THERAPEUTICS INCORPORATED

## (A DEVELOPMENT STAGE COMPANY)

#### NOTES TO FINANCIAL STATEMENTS, Continued

#### Stock-Based Compensation related to Employee and Director Options

Accounting Practices

For options granted prior to our initial public offering (IPO) in 2004, we accounted for options granted to employees and directors based on the intrinsic value of these grants. This treatment was followed even after the change in accounting pronouncements affecting stock-based compensation in January 2006 because we had used the minimum value method for these options for purposes of pro-forma disclosure under the previous guidance. During the period from inception (May 13, 1998) to September 30, 2008, we recorded \$10.1 million in deferred compensation for employee stock options to purchase common stock granted at exercise prices deemed to be below the fair value of common stock at the date of grant. We amortized the deferred stock-based compensation to expense utilizing the graded-vesting method over the vesting periods of the applicable stock options, generally five years. As of September 30, 2008, the deferred compensation related to these options was fully amortized.

For options granted after the IPO, we began, as of January 1, 2006, to account for stock-based compensation related to option grants to employees and directors under the fair value method. Following is a synopsis of our accounting practices in regard to these stock option grants:

Options granted after the IPO but prior to January 1, 2006:

- Prior to January 1, 2006, we had accounted for employee options under the intrinsic value method, which did not require the recognition of any compensation expense as the grants had been issued at the market value on the date of grant.
- We began, as of January 1, 2006, to record non-cash stock-based compensation expense related to these grants in the financial statements based on the remaining fair value, as of January 1, 2006, of the non-vested portion of these grants, utilizing the assumptions and fair value per share information as of the original grant date that we had been using for pro forma disclosure purposes. We continued to utilize the graded-vesting attribution method for amortization of the relevant compensation amounts, which were fully expensed early in 2010.

Options granted on or after January 1, 2006:

- Compensation expense is being recorded in the financial statements based on the fair value on the date of grant.
- For service based awards, the grant date fair value being amortized to expense using the straight-line attribution method over the vesting period of the options, which is commensurate with the service period.
- For awards with performance-based vesting criteria, expense will be recognized at such time as there is a high degree of probability (i.e., greater than 70%) of achieving the vesting criteria.

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#### CORCEPT THERAPEUTICS INCORPORATED

## (A DEVELOPMENT STAGE COMPANY)

#### NOTES TO FINANCIAL STATEMENTS, Continued

Assumptions used in determining fair value for options granted to employees and directors

The following table summarizes the weighted-average assumptions and resultant fair value for options granted to employees and directors.

	Ye	ar Ended December 31,	
	2010	2009	2008
Weighted average assumptions for stock options granted:			
Risk-free interest rate	1.83%	2.24%	2.63%
Expected term	5.9 years	6.0 years	6.0 years
Expected volatility of stock price	96.3%	94.2%	90.6%
Dividend rate	0%	0%	0%
Weighted average grant date fair value	\$ 2.68	\$ 1.05	\$ 1.12

The expected term for options granted since January 1, 2006 is based on the simplified method prescribed by the SEC, and 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.

The expected volatility of our stock used in determining the fair value of option grants to employees and directors prior to April 2010 has been 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 valuation assumption for a period of time equivalent to the expected term of the option. For stock options granted to employees and directors after April 2010, the volatility is based on historical data of the price for our common stock since the date of our IPO as the expected term of these option grants has been covered by this period.

Since we have a limited employee base and have experienced minimal turnover, we do not have sufficient historical information to determine a reasonable forfeiture rate for options that might not vest because of employee terminations and does not, therefore, 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.

Summary of compensation expense related to employee and director options

Compensation expense of approximately \$1.9 million, \$1.8 million, \$1.6 million and \$15.5 million was recognized for employee and director options during the years ended December 31, 2010, 2009 and 2008 and for the period from inception (May 13, 1998) to December 31, 2010, respectively, net of recoveries.

# **Stock Options to Consultants**

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, which approximates the period over which the related services are rendered, based on the fair value of the options 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

#### CORCEPT THERAPEUTICS INCORPORATED

# (A DEVELOPMENT STAGE COMPANY)

#### NOTES TO FINANCIAL STATEMENTS, Continued

employees and directors, with the exception that, for non-employee options, the remaining contractual term is utilized as the expected term 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.

All stock option grants to consultants vest solely based upon continuing service, with the exception of an award with performance-based vesting criteria that was granted during 2010, in the amount of 50,000 shares. This performance-based grant will vest in its entirety upon the filing by the FDA of the Company s NDA for CORLUX for the treatment of Cushing s Syndrome. The fair value of the grant as of the date of vesting, as determined using the Black-Scholes option pricing model, will be charged to expense at that time.

The Company recorded charges in the statement of operations for stock options granted to consultants using the straight-line vesting method of approximately \$169,000, \$11,000, \$30,000 and \$1.1 million for the years ended December 31, 2010, 2009 and 2008 and for the period from inception (May 13, 1998) to December 31, 2010, respectively. The straight-line method is commensurate with the services being provided by such consultants.

As of December 31, 2010, all options that had been granted to consultants were fully vested, with the exception of the performance-based grant discussed above.

### Stockholder Notes Receivable

In 2001, we recorded notes receivable from stockholders in the aggregate amount of \$438,165 in connection with the exercise of options issued under the 2000 Plan to purchase 585,000 shares of common stock. The notes are secured by the related shares of common stock and are full recourse notes, with interest compounded annually at the rate of 6.5% per year. The notes mature ten years from the date of issuance. As of December 31, 2010, the amounts outstanding under these notes included principal in the amount of approximately \$97,000 and interest in the amount of approximately \$70,000.

#### Warrants

On April 21, 2010, we sold warrants to purchase approximately 4.3 million shares of our common stock in the April 2010 Warrant Exchange. See discussion above under the caption Common Stock.

Outstanding warrants at December 31, 2010 were as follows:

	Number of shares	<b>Exercise Price</b>	<b>Expiration Date</b>
March 2008 Financing	4,461,599	\$ 2.77	3/25/15
Kingsbridge CEFF	330,000	\$ 3.525	9/25/13
October 2009 Financing	122,378	\$ 1.66	10/16/12
April 2010 Warrant Exchange	4,286,395	\$ 2.96	4/21/13

# 10. Other Income

In June 2010, we received a payment of \$750,000 in connection with the favorable settlement of a lawsuit brought on our behalf against an individual for defamation and harassment. This is the full amount due to us in settlement of this claim.

#### CORCEPT THERAPEUTICS INCORPORATED

## (A DEVELOPMENT STAGE COMPANY)

#### NOTES TO FINANCIAL STATEMENTS, Continued

In November 2010, we received grants totaling \$733,438 from the United States Treasury s Therapeutic Discovery Project Grant program. This included the maximum available grant of \$244,479 for each of our three clinical programs CORLUX for the treatment of Cushing s Syndrome, CORLUX for the treatment of psychotic depression, and CORT 108297 for the treatment of antipsychotic induced weight gain.

#### 11. Net Loss Per Share

Basic and diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding during the period less outstanding shares subject to repurchase. The computation of net loss per share for each period, including the number of weighted-average shares outstanding, is shown on the face of the statements of operations.

We have excluded the impact of common stock equivalents from the calculation of diluted net loss per common share because all such securities are antidilutive for all periods presented. In addition, for all periods presented, we excluded additional shares that might have been issued under stock option grants.

The following table presents information on securities outstanding as of the end of each period that could potentially dilute the per share data in the future.

	December 31,		
	2010	<b>2009</b> (in thousands)	2008
Stock options outstanding	7,961	7,347	5,132
Warrants outstanding	9,200	9,200	4,792
Total	17,161	16,547	9,924

# 12. Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets are as follows:

	Decem	December 31,	
	2010	2009	
	(in thou	isands)	
Deferred tax assets:			
Federal and state net operating losses	\$ 37,466	\$ 30,463	
Capitalized research and patent costs	23,397	22,734	
Stock-based compensation costs	2,195	1,756	
Research credits	11,149	5,743	
Total deferred tax assets	74,207	60,696	
Valuation allowance	(74,207)	(60,696)	

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Net deferred tax assets \$

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#### CORCEPT THERAPEUTICS INCORPORATED

## (A DEVELOPMENT STAGE COMPANY)

#### NOTES TO FINANCIAL STATEMENTS, Continued

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by \$13.5 million, \$8.4 million and \$8.9 million for the years ended December 31, 2010, 2009 and 2008, respectively.

At December 31, 2010 we had net operating loss carryforwards available to offset any future taxable income that we may generate for federal income tax purposes of approximately \$94.0 million, which expire in the years 2019 through 2030, and California net operating loss carryforwards of approximately \$94.6 million, which expire in the years 2012 through 2030. We also had federal and California research and development tax credits of approximately \$10.2 million and \$1.5 million, respectively. The federal research credits will expire in the years 2019 through 2030 and the California research credits have no expiration date. Our deferred tax assets have been offset by a full valuation allowance as the realization of such assets is uncertain. Utilization of our net operating losses and tax credit carryforwards may be subject to substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code and similar state provisions. Such limitations could result in the expiration of the net operating losses and tax credit carryforwards before utilization.

All tax years from inception remain open to examination by the Internal Revenue Service and the California Franchise Tax Board until such time as the net operating losses and research credits are either fully utilized or expire.

A reconciliation from the statutory federal income tax rate to the effective rate is as follows:

	Year ended December 31,		
	2010	2009	2008
		(in thousands)	
U.S. federal taxes (benefit) at statutory rate	\$ (8,828)	\$ (6,856)	\$ (6,821)
State tax			
Unutilized, net operating loss	7,208	5,955	6,294
Non-deductible offset of Orphan Drug Credit	1,671	694	303
Non-deductible stock based compensation	189	207	168
Research & Development grants under Section 48D	(249)		
Other	9		56
Total	\$	\$	\$

#### 13. Commitments

We have entered into a number of agreements to conduct clinical trials and pre-clinical studies for further development of our lead product, CORLUX, and our proprietary, selective GT-II antagonists. See the discussion in Note 2 **Significant Agreements** for further discussion regarding the commitments under these agreements.

In the ordinary course of our business, we make certain indemnities, commitments and guarantees under which we may be required to make payments in relation to certain transactions. These include indemnities of clinical investigators and contract research organizations involved in the development of our clinical stage product candidates, indemnities of contract manufacturers and indemnities to our directors and officers to the maximum extent permitted under the laws of the State of Delaware. The duration of these indemnities, commitments and guarantees varies, and in certain cases, is indefinite. The majority of these indemnities, commitments and guarantees do not provide for any limitation of the maximum potential future payments that we

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#### CORCEPT THERAPEUTICS INCORPORATED

## (A DEVELOPMENT STAGE COMPANY)

#### NOTES TO FINANCIAL STATEMENTS, Continued

could be obligated to make. We have not recorded any liability for these indemnities, commitments and guarantees in the accompanying balance sheets. However, we would accrue for losses for any known contingent liability, including those that may arise from indemnification provisions, when future payment is probable. No such losses have been recorded to date.

#### 14. Subsequent Events

On January 26, 2011, we sold 11.5 million shares of our common stock in an underwritten public offering at a price to the public of \$3.90 per share for aggregate net proceeds of approximately \$41.9 million after deducting the underwriter s discount and commissions and other expenses of the offering. Longitude Venture Partners, LP purchased approximately 750,000 (approximately 6.5%) of the shares sold in this transaction. Patrick Enright, who is a member of our board of directors, is a managing member of Longitude Capital Partners, LLC, the general partner of Longitude Venture Partners, LP.

In February 2011, we amended our agreement with Argenta Discovery 2009 Limited (Argenta) for the continuation of research services regarding new proprietary selective GR-II antagonists through September 30, 2011 for an additional commitment of approximately \$840,000.

#### 15. Quarterly Financial Data (Unaudited)

The following table is in thousands, except per share amounts:

Quarter Ended	March 31	June 30	September 30	December 31
2010				
Net revenue	\$	\$	\$	\$
Net loss	\$ (6,073)	\$ (5,695)	\$ (7,104)	\$ (7,094)
Basic and diluted net loss per share	\$ (0.10)	\$ (0.09)	\$ (0.10)	\$ (0.10)
2009				
Net revenue	\$ 24	\$ 5	\$	\$
Net loss	\$ (5,450)	\$ (4,877)	\$ (4,668)	\$ (5,170)
Basic and diluted net loss per share	\$ (0.11)	\$ (0.10)	\$ (0.09)	\$ (0.09)

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# **Exhibit Index**

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the registrant s Registration Statement on Form S-1/A (File No. 333-112676) filed on March 19, 2004).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the registrant s Current Report on Form 8-K filed on September 27, 2007).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the registrant s Registration Statement on Form S-1 (Registration No. 333-112676) filed on February 10, 2004).
4.2	Amended and Restated Information and Registration Rights Agreement by and among Corcept Therapeutics Incorporated and certain holders of preferred stock, dated as of May 8, 2001 (incorporated by reference to Exhibit 4.2 to the registrant s Registration Statement on Form S-1 (Registration No. 333-112676) filed on February 10, 2004).
4.3	Amendment No. 1 to Amended and Restated Information and Registration Rights Agreement by and among Corcept Therapeutics Incorporated and certain holders of preferred stock, dated as of March 16, 2004 (incorporated by reference to Exhibit 4.3 to the registrant s Registration Statement on Form S-1/A (File No. 333-112676) filed on March 19, 2004).
4.4	Registration Rights Agreement by and among Corcept Therapeutics Incorporated and the investors signatory thereto, dated March 14, 2008 (incorporated by reference to Exhibit 10.25 to the registrant s Annual Report on Form 10-K filed on March 31, 2008).
4.5	Registration Rights Agreement by and between Corcept Therapeutics Incorporated and Kingsbridge Capital Limited, dated as of March 25, 2008 (incorporated by reference to Exhibit 10.27 to the registrant s Annual Report on Form 10-K filed on March 31, 2008).
4.6	Amendment to Registration Rights Agreement by and among Corcept Therapeutics Incorporated and the investors signatory thereto, dated November 11, 2008 (incorporated by reference to Exhibit 10.30 to the registrant s Annual Report on Form 10-K filed on March 31, 2009).
4.7	Registration Rights Agreement by and among Corcept Therapeutics Incorporated and the investors signatory thereto, dated October 12, 2009 (incorporated by reference to Exhibit 4.2 to the registrant s Quarterly Report on Form 10-Q filed on November 12, 2009).
4.8	Registration Rights Agreement dated as of April 21, 2010 by and among Corcept Therapeutics Incorporated and the investors signatory thereto (incorporated by reference to Exhibit 4.2 to the registrant s Current Report on Form 8-K filed on April 23, 2010).
10.1*	2000 Stock Option Plan (incorporated by reference to Exhibit 10.1 to the registrant s Registration Statement on Form S-1 (Registration No. 333-112676) filed on February 10, 2004).
10.2*	Promissory Note and Pledge Agreement by and between Corcept Therapeutics Incorporated and Robert L. Roe, M.D., dated as of October 22, 2001 (incorporated by reference to Exhibit 10.4 to the registrant s Registration Statement on Form S-1 (Registration No. 333-112676) filed on February 10, 2004).
10.3#	License Agreement by and between The Board of Trustees of the Leland Stanford Junior University and Corcept Therapeutics Incorporated, dated as of July 1, 1999 (incorporated by reference to Exhibit 10.6 to the registrant s Registration Statement on Form S-1 (Registration No. 333-112676) filed on February 10, 2004).
10.4#	Memorandum of Understanding, Supply and Services Agreement, by and between Corcept Therapeutics Incorporated and ScinoPharm Taiwan, dated as of June 12, 2000 (incorporated by reference to Exhibit 10.9 to the registrant s Registration Statement on Form S-1/A (File No. 333-112676) filed on March 19, 2004).

Exhibit Number	Description of Document
10.5	Master Services Agreement by and between Corcept Therapeutics Incorporated and PPD Development, LP, dated as of January 17, 2003 (incorporated by reference to Exhibit 10.12 to the registrant s Registration Statement on Form S-1/A (File No. 333-112676) filed on March 19, 2004).
10.6##	Manufacturing Agreement with Produits Chimiques Auxiliaires et de Synthese SA, dated November 8, 2006 (incorporated by reference to Exhibit 10.15 to the registrant s Annual Report on Form 10-K filed on April 2, 2007).
10.7	Common Stock Purchase Agreement by and among Corcept Therapeutics Incorporated and each of the Purchasers listed on Exhibit A thereto, dated November 14, 2006 (incorporated by reference to Exhibit 10.1 to the registrant s Current Report on Form 8-K filed on November 16, 2006).
10.8	Common Stock Purchase Agreement by and among Corcept Therapeutics Incorporated and each of those persons and entities listed on the Schedule of Purchasers thereto, dated as of March 30, 2007 (incorporated by reference to Exhibit 10.1 to the registrant s Current Report on Form 8-K filed on April 3, 2007).
10.9	Common Stock Purchase Agreement by and among Corcept Therapeutics Incorporated and each of those persons and entities listed on the Schedule of Purchasers thereto, dated as of August 16, 2007 (incorporated by reference to Exhibit 10.1 to the registrants Current Report on Form 8-K filed on August 21, 2007).
10.10*	Form of Indemnification Agreement for directors and officers approved by the Board of Directors on September 24, 2007 (incorporated by reference to Exhibit 10.7 to the registrant s Quarterly Report on Form 10-Q filed on November 14, 2007).
10.11	Securities Purchase Agreement by and among Corcept Therapeutics Incorporated and the purchasers named therein, dated March 14, 2008 (incorporated by reference to Exhibit 10.24 to the registrant s Annual Report on Form 10-K filed on March 31, 2008).
10.12	Form of Warrant issued in connection with the Securities Purchase Agreement by and among Corcept Therapeutics Incorporated and the purchasers named therein, dated March 14, 2008 (incorporated by reference to Exhibit 4.4 to the registrant s Annual Report on Form 10-K filed on March 31, 2008).
10.13	Common Stock Purchase Agreement by and between Kingsbridge Capital Limited and Corcept Therapeutics Incorporated dated as of March 25, 2008 (incorporated by reference to Exhibit 10.26 to the registrant s Annual Report on Form 10-K filed on March 31, 2008).
10.14	Warrant, dated March 25, 2008 issued to Kingsbridge Capital Limited (incorporated by reference to Exhibit 4.5 to the registrant s Annual Report on Form 10-K filed on March 31, 2008).
10.15#	Master Service Agreement by and among Corcept Therapeutics Incorporated and ICON Clinical Research, L.P., signed on June 4, 2008 (incorporated by reference to Exhibit 10.5 to the registrant s Quarterly Report on Form 10-Q filed on August 14, 2008).
10.16*	Amended and Restated Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and Joseph K. Belanoff, M. D., dated September 19, 2008 (incorporated by reference to Exhibit 10.25 to the registrant s Annual Report on Form 10-K filed on March 31, 2009).
10.17*	Amended and Restated Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and Robert L. Roe, M. D., dated September 19, 2008 (incorporated by reference to Exhibit 10.26 to the registrant s Annual Report on Form 10-K filed on March 31, 2009).
10.18*	Amended and Restated Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and Anne M. LeDoux, dated September 19, 2008 (incorporated by reference to Exhibit 10.27 to the registrant s Annual Report on Form 10-K filed on March 31, 2009).

Exhibit Number	Description of Document
10.19*	Amended and Restated Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and James N. Wilson, dated September 19, 2008 (incorporated by reference to Exhibit 10.28 to the registrant s Annual Report on Form 10-K filed on March 31, 2009).
10.20*	Employment offer letter to Caroline M. Loewy, dated October 21, 2008 (incorporated by reference to Exhibit 10.29 to the registrant s Annual Report on Form 10-K filed on March 31, 2009).
10.21*	Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and Caroline M. Loewy, dated November 28, 2008 (incorporated by reference to Exhibit 10.31 to the registrant s Annual Report on Form 10-K filed on March 31, 2009).
10.22	Form of Warrant issued in connection with the Securities Purchase Agreement by and among Corcept Therapeutics Incorporated and the purchasers named therein, dated October 12, 2009 (incorporated by reference to Exhibit 4.1 to the registrant s Quarterly Report on Form 10-Q filed on November 12, 2009).
10.23	Securities Purchase Agreement by and among Corcept Therapeutics Incorporated and the purchasers named therein, dated October 12, 2009 (incorporated by reference to Exhibit 10.1 to the registrant s Quarterly Report on Form 10-Q filed on November 12, 2009).
10.24*	Amended and Restated 2004 Equity Incentive Plan (incorporated by reference to the registrant s Proxy Statement on Schedule 14A filed on May 7, 2009).
10.25*	Form of Option Agreement
10.26	Warrant Purchase Agreement dated as of April 21, 2010 by and among Corcept Therapeutics Incorporated and the purchasers named therein (incorporated by reference to Exhibit 10.1 to the registrant s Current Report on Form 8-K filed on April 23, 2010).
10.27	Form of Warrant issued in connection with the Warrant Purchase Agreement dated as of April 21, 2010 by and among Corcept Therapeutics Incorporated and the purchasers named therein (incorporated by reference to Exhibit 4.1 to the registrant s Current Report on Form 8-K filed on April 23, 2010).
10.28##	Development Agreement by and between Corcept Therapeutics Incorporated and Formulation Technologies L.L.C. d/b/a PharmaForm, dated as of December 14, 2006.
10.29##	Master Services Agreement by and between Corcept Therapeutics Incorporated and United BioSource Corporation, dated as of June 29, 2010.
10.30*	Employment offer letter to Steven Lo, dated August 9, 2010 (incorporated by reference to Exhibit 10.1 to the registrant s Quarterly Report on Form 10-Q filed on November 12, 2010).
10.31*	Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and Steven Lo, dated September 15, 2010 (incorporated by reference to Exhibit 10.2 to the registrant s Quarterly Report on Form 10-Q filed on November 12, 2010).
14.1	Code of Ethics (incorporated by reference to Exhibit 99.1 to the registrant s Registration Statement on Form S-1/A (File No. 333-112676) filed on March 19, 2004).
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (See signature page)
31.1	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Joseph K. Belanoff, M.D.
31.2	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Caroline M. Loewy

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# **Table of Contents**

Exhibit	
Number	Description of Document
32.1	Certification pursuant to 18 U.S.C. Section 1350 of Joseph K. Belanoff, M.D.
32.2	Certification pursuant to 18 U.S.C. Section 1350 of Caroline M. Loewy

- # Confidential treatment granted
  ## Confidential treatment requested
- \* Management contract or compensatory plan or arrangement