

CORCEPT THERAPEUTICS INC  
Form 10-K  
March 31, 2008  
Table of Contents

# 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, 2007

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

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(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, including zip code)

**(650) 327-3270**

(Registrant's telephone number, including area code)

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

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

**Name of Each Exchange on which Registered:**  
The NASDAQ Stock Market LLC

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

**None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15 (d) of the Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark 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, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one.)

Large Accelerated Filer

Accelerated Filer

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

Smaller reporting company

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

The aggregate market value of voting and non-voting common equity held by non-affiliates of the Registrant was approximately \$31,000,000 as of June 30, 2007 based upon the closing price on the Nasdaq Stock 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 31, 2008 there were 48,473,164 shares of common stock outstanding at a par value \$.001 per share.

**DOCUMENTS INCORPORATED BY REFERENCE**

None.

**Table of Contents**

**TABLE OF CONTENTS**

**Form 10-K**

**For the year ended December 31, 2007**

	<b>Page</b>
<b><u>PART I</u></b>	
ITEM 1. <u>Business</u>	1
ITEM 1A. <u>Risk Factors</u>	19
ITEM 1B. <u>Unresolved Staff Comments</u>	38
ITEM 2. <u>Properties</u>	38
ITEM 3. <u>Legal Proceedings</u>	38
ITEM 4. <u>Submission of Matters to a Vote of Security Holders</u>	38
<b><u>PART II</u></b>	
ITEM 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	39
ITEM 6. <u>Selected Financial Data</u>	44
ITEM 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	45
ITEM 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	57
ITEM 8. <u>Financial Statements and Supplementary Data</u>	57
ITEM 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	57
ITEM 9A (T) <u>Controls and Procedures</u>	57
ITEM 9B. <u>Other Information</u>	58
<b><u>PART III</u></b>	
ITEM 10. <u>Directors and Executive Officers and Corporate Governance</u>	59
ITEM 11. <u>Executive Compensation</u>	63
ITEM 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	73
ITEM 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	75
ITEM 14. <u>Principal Accountant Fees and Services</u>	78
<b><u>PART IV</u></b>	
ITEM 15. <u>Exhibits, Financial Statement Schedules</u>	78

---

**Table of Contents**

**PART I**

*This Annual Report on Form 10-K, or Form 10-K, contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. 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, 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 made in this Form 10-K include, but are not limited to, statements about:*

*the progress of our research, development and clinical programs and timing of the introduction of CORLUX® and future product candidates;*

*estimates of the dates by which we expect to report results of our clinical trials;*

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

*uncertainties associated with obtaining and enforcing patents;*

*our estimates for future performance; and*

*our estimates regarding our capital requirements and our needs for 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.*

**ITEM 1. BUSINESS**

**Overview**

Concept Therapeutics Incorporated is a pharmaceutical company headquartered in Menlo Park, California engaged in the development of drugs for the treatment of severe psychiatric and metabolic diseases. Our current focus is on the development of drugs for 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. Our scientific founders are responsible for many of the critical discoveries illustrating the link between psychiatric and metabolic disorders and aberrant cortisol. Since our inception in May 1998, we have been developing our lead product, CORLUX®, a glucocorticoid receptor II, or GR-II, antagonist. CORLUX modulates the effect of cortisol by selectively blocking the binding of cortisol to one of its two known receptors, the GR-II receptor, also known as the Type II or GR receptor.

*Psychotic depression.* We have an exclusive patent license from Stanford University for the use of GR-II antagonists to treat the psychotic features of psychotic major depression, hereinafter referred to as psychotic depression. The United States Food and Drug Administration (FDA) has granted fast track status to our program to evaluate the safety and efficacy of CORLUX for the treatment

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of the psychotic features of psychotic depression. Psychotic depression affects approximately three million people annually in the US. There is no FDA-approved treatment for psychotic depression. Psychiatrists currently use two approaches: electroconvulsive therapy (ECT), which involves passing an electrical

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**Table of Contents**

current through the brain until the patient has a seizure, and combination drug therapy (simultaneous use of antidepressant and antipsychotic medications). Both ECT and combination drug therapy almost always have slow onsets of action and debilitating side effects. By modifying the level and release pattern of cortisol within the human body, we believe that CORLUX may be able to treat the psychotic features of psychotic depression more quickly and effectively and with fewer side effects than is possible with currently available treatments.

Three Phase 3 clinical trials have been completed. While the response rate to medicine exceeded the response rate to placebo in each of these studies for the primary endpoint, a 50% reduction in the Brief Psychiatric Rating Scale Positive Symptom Subscale (BPRS PSS) at day 7 sustained to day 56, in none of these studies was the difference in response rate statistically significant. However a robust relationship was demonstrated between higher dosing plasma level and a higher response rate. This relationship was tested prospectively in the last of our Phase 3 trials using a predetermined plasma concentration that correlates with response and was met with statistical significance. We believe that the confirmation of a drug concentration/response correlation threshold for efficacy provides a strong basis for our next Phase 3 study.

If we obtain FDA approval, we initially intend to market and sell CORLUX for psychotic depression in the United States directly to hospitals with in-patient psychiatric units, first focusing on those that use ECT. We then intend to expand our sales efforts to address the larger group of psychotic depression patients currently undergoing combination drug therapy. Given the concentrated nature of the initial target audience, we believe that we will be able to generate significant revenue with a relatively small, highly-focused medical education and commercialization team.

*Antipsychotic-induced Weight Gain Mitigation.* In June 2007, we announced preliminary top-line results of our proof-of-concept study evaluating the ability of CORLUX to mitigate weight gain associated with the administration of olanzapine. The top line results indicated a statistically significant reduction in weight gain in those subjects who took olanzapine plus CORLUX compared to those who took olanzapine alone. The purpose of this study was to explore the hypothesis that GR-II antagonists would mitigate weight gain associated with atypical antipsychotic medications, such as olanzapine, risperidone, clozapine and quetiapine, which 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 label relating to treatment emergent hyperglycemia and diabetes mellitus. Eli Lilly provided olanzapine and financial support for this study.

*Cushing's Syndrome.* The FDA has granted Orphan Drug Designation for CORLUX for the treatment of endogenous Cushing's Syndrome, hereinafter referred to as Cushing's Syndrome a disorder caused by prolonged exposure of the body's tissues to high levels of the hormone cortisol. Orphan drugs obtain 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. The Investigational New Drug application (IND) for the evaluation of CORLUX for the treatment of Cushing's Syndrome was opened in September 2007. The FDA has indicated that a single study may provide a reasonable basis for the submission of a New Drug Application (NDA) for this indication. This trial was opened for enrollment late in December 2007.

In addition to the above, we also own or have exclusively licensed issued patents and patent applications relating to the treatment of several disorders that we believe also result from, or are negatively affected by, prolonged exposure to elevated cortisol including increasing the therapeutic response to electroconvulsive therapy (ECT), mild cognitive impairment, stress disorders and the treatment of delirium. We also have filed patent applications for additional diseases that may benefit from treatment with a drug that blocks the GR-II receptor.

## **Table of Contents**

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

### **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 psychiatric and metabolic conditions, such as mood changes, psychosis and cognitive impairment. Cognition, including attention, concentration and memory, is impaired by elevated levels and abnormal release patterns of cortisol. Prolonged elevated levels of cortisol are neurotoxic and may accelerate the dementia process in patients with cognitive disorders such as Alzheimer's disease.

Many studies have shown that patients with psychotic depression have elevated levels and abnormal release patterns of cortisol. This abnormal cortisol pattern is not usually present in patients with nonpsychotic depression. More than 15 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 was a clinically relevant hypothesis because it led to the concept that antipsychotic medications, which act by blocking dopamine, in combination with antidepressant medications, could be useful in treating psychotic depression. The hypothesis also led to the concept that by regulating the level and release patterns of cortisol, one could normalize dopamine levels in the brain, which may, in turn, ameliorate the symptoms of psychotic depression. In addition to cortisol's effect on dopamine levels, research has shown that prolonged elevated cortisol may also play a direct role in causing the symptoms of psychotic depression.

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

### **Glucocorticoid Receptor Antagonists**

Cortisol is produced by the adrenal glands and is carried via the bloodstream to the brain, where it directly influences neuronal function. In the brain, cortisol binds to two receptors, Glucocorticoid Receptor I and Glucocorticoid Receptor II, also known as GR-I and GR-II. GR-I is a high-affinity receptor that is involved in the routine functions of cortisol. 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 psychiatric and metabolic disease states, particularly 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 receptor antagonists, may prevent the undesirable effects of elevated levels and abnormal release patterns of cortisol.

The discovery that the brain has high affinity and low affinity receptors for cortisol was critical to our scientific approach in treating the psychosis manifested by patients with psychotic depression because it allowed for a specific target for a potential medication. CORLUX, also known as mifepristone or RU-486, works by



## **Table of Contents**

selectively blocking the binding of cortisol to GR-II while not affecting GR-I. 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.

### **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.

Psychotic depression is not a simple combination of psychosis and depression, but rather a complex interaction between a predisposition to become psychotic and a predisposition to become severely depressed. In addition to psychosis, clinical features and outcomes that distinguish psychotic from nonpsychotic depression include elevated levels and abnormal release patterns of cortisol, motor abnormalities, a substantially higher suicide rate, more prominent sleep abnormalities and more potential for brain injury.

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. Psychotic depression is more prevalent than either schizophrenia or bipolar I disorder. Psychotic depression is characterized by severe depression accompanied by psychosis (delusions and/or hallucinations). 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.

We believe that people afflicted with psychotic depression are, as a group, unrecognized and undertreated because of:

reluctance on the part of patients with psychotic depression to accurately report their psychotic symptoms;

misdiagnosis of the disease by primary care physicians;

reluctance of patients and their families to be associated with the stigma of hospitalization for psychiatric care; and

adverse side effects associated with current treatments for psychotic depression.

### **Current Treatments for Psychotic depression**

There are two treatment approaches for psychotic depression currently used by psychiatrists: ECT and combination drug therapy. Neither of these treatments has been approved by the FDA for psychotic depression and both approaches almost always have slow onsets of action and 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. ECT is administered while the patient is under general anesthesia and the procedure requires the use of an operating room, as well as the participation of a psychiatrist, an anesthesiologist and a nurse. General anesthesia and paralytic agents are necessary to avoid fractures of the spine

## **Table of Contents**

that otherwise could result from the seizures caused by ECT. Although ECT provides a reduction in depressive and psychotic symptoms, the procedure can result in cognitive impairment, including permanent memory loss, cardiovascular complications, headache, muscle ache and nausea, in addition to complications related to general anesthesia.

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 medication. Patients on combination drug therapy often require three weeks or more to show improvement in their symptoms and treatment can take months to complete. Antipsychotic drugs can cause significant adverse side effects, including weight gain, diabetes, sedation, permanent movement disorders and sexual dysfunction.

Because a therapeutic response to ECT and combination drug therapy does not occur for several weeks, neither approach prevents lengthy and expensive hospital stays in patients who are seriously ill. Consequently, a significant need exists for a medication that provides rapid relief from the psychotic symptoms of psychotic depression, as such a medication would substantially reduce the length of suffering associated with the illness. We believe that people suffering from psychotic depression would prefer a treatment that did not involve the risks of anesthesia, adverse side effects and stigma associated with ECT or the slow onset of action associated with both ECT and combination drug therapy. If an alternative treatment was approved by the FDA and had secured third-party reimbursement, we believe that many patients with psychotic depression would choose that alternative.

### **CORLUX for the Psychotic Features of Psychotic Depression**

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

### **CORLUX for Psychotic Depression Clinical Trials**

*Psychiatric Rating Scales.* In our clinical trials, we assess the efficacy of CORLUX utilizing psychiatric rating scales commonly used to support regulatory approval of new antipsychotic and antidepressant medications. These scales include the:

**BPRS:** The Brief Psychiatric Rating Scale (BPRS) is an 18-item instrument to assess psychopathology. It incorporates a range of psychiatric symptoms, including anxiety, depression, guilt, hostility and suicidality. Each of the 18 symptoms is scored on a numeric scale ranging from 1 (not present) to 7 (extremely severe).

**BPRS Positive Symptom Subscale (BPRS PSS):** This subscale, which is based on four items of the BPRS, assesses a patient's psychotic features by measuring the patient's conceptual disorganization, suspiciousness, hallucinatory behavior and unusual thought content.

**HAM-D:** The Hamilton Depression Scale (HAM-D) is a 24-item instrument designed to measure the severity of a number of depressive symptoms such as insomnia, depressed mood, concentration, ability

**Table of Contents**

to experience pleasure, and agitation. Each question has 3 to 5 possible responses, with associated scores ranging from 0 to 4. The total score is calculated from all items.

*Clinical Trials.* We initiated two Phase 3 trials in the United States in September 2004 (Study 07) and October 2004 (Study 06) and an additional Phase 3 trial in Eastern Europe in the second quarter of 2005 (Study 09) to evaluate the safety and efficacy of CORLUX. These three studies have been completed. The details of the results of these trials are discussed below. Prior to initiating these trials, we completed the following four clinical trials with CORLUX for the treatment of psychotic features of psychotic depression:

In 2001, we completed our first trial, an open label dose finding clinical trial with 30 patients evaluating the efficacy, tolerability and dose response of CORLUX for the treatment of the psychotic features of psychotic depression. After one week of treatment, approximately two-thirds of the patients in the two higher dosage groups experienced clinically meaningful reductions in psychosis, as measured by the BPRS PSS. A clinically meaningful reduction in psychosis represents a reduction of symptoms that are readily recognizable by patients and physicians.

Later in 2001, we initiated two clinical trials designed to evaluate the safety and efficacy of CORLUX for the treatment of the psychotic features of psychotic depression. The two trials, which we call Study 02 and Study 03, were double-blind, placebo-controlled safety and efficacy studies.

Study 02, in which 208 patients were enrolled, showed that CORLUX was well tolerated and that there were no discernable problems with drug interactions between CORLUX and commonly prescribed antipsychotic and antidepressant medications.

Study 03, in which 221 patients were enrolled, demonstrated with statistical significance that patients in the CORLUX group were more likely to achieve a rapid and sustained reduction in psychotic symptoms than patients in the control group, as measured by a 30% reduction in the BPRS at 7 days sustained to 28 days (p value = 0.01) and a 50% reduction in the BPRS PSS at 7 days sustained to 28 days (p value = 0.01). The term *p value* is a statistical term that indicates the probability that an observed result is random. A p value of 0.05 or less is considered statistically significant. All p values for Study 03 are based on an observed cases, per protocol analysis, which takes into account only those patients who received at least 6 doses of study medication, had the BPRS assessed at day 0 and day 7 and had no major violations of the inclusion/exclusion criteria or other protocol specified criteria.

In our fourth trial, we evaluated the safety of retreatment in patients with a favorable response to treatment in Study 02 and Study 03, and our analysis indicates that patients tolerated their retreatment well.

*Dose Finding Study.* In January 2001, we concluded our first study, which was an open-label study designed to measure clinically meaningful reductions in the psychiatric rating scales. The 33 patients with psychotic depression enrolled in the study were randomly assigned to receive daily doses of 50 mg, 600 mg, or 1200 mg of CORLUX orally for 7 days. There was no placebo control group. After 7 days of treatment, clinically meaningful reductions in the psychiatric rating scales were observed for patients in the 600 mg and 1200 mg treatment groups, as summarized below.

	50 mg Dose Group	600 mg Dose Group	1200 mg Dose Group	600 mg and 1200 mg Dose Groups Combined
30% or greater reduction in BPRS	4/11 (36)%	7/10 (70)%	6/9 (67)%	13/19 (68)%
50% or greater reduction in positive symptom subscale of BPRS	3/11 (27)%	6/10 (60)%	6/9 (67)%	12/19 (63)%
50% or greater reduction in Ham-D scale	2/11 (18)%	5/10 (50)%	3/9 (33)%	8/19 (42)%

Results were similar in the 600 mg and 1200 mg dose groups, but there was an apparent dose-response relationship when the results of the 50 mg group were compared to the two higher dose groups. Sixty-eight

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**Table of Contents**

percent of patients in the higher dose groups (600 mg and 1200 mg combined) had a clinically meaningful 30% or greater reduction in the BPRS, compared to 36% in the 50 mg group. The items in the BPRS that are most specific to psychotic depression are contained in the BPRS PSS. Every patient with psychotic depression experiences one or more of these subscale symptoms. More than 60% of patients in the higher dosage groups had a 50% or greater reduction in the BPRS PSS within one week of treatment. Each of the reductions in the psychiatric rating scales that the study measured is a clinically meaningful reduction in symptoms that would be readily recognized by patients, family members, physicians and hospital staff. None of the patients in the trial experienced clinically consequential side effects and none dropped out of the trial due to side effects.

*Double-blind Clinical Trials.* In June and July 2001, we initiated two double-blind, randomized clinical trials, Study 02 and Study 03, each of which was designed to enroll 200 patients and to evaluate the safety and efficacy of CORLUX in patients with psychotic depression. In each study, patients received either CORLUX or placebo. Both studies were designed and powered to test the hypothesis that the group of patients treated with CORLUX would be superior to the control group in achieving a rapid (within 7 days) and sustained (to 28 days) reduction in their BPRS score of at least 30%.

The two studies were identical in design except for one of the key entry criteria. Patients enrolled in Study 02 were allowed to receive any antipsychotic or antidepressant medications deemed appropriate by their treating physicians prior to entry into the study and throughout the week of administration of the study drugs, CORLUX or placebo. Therefore, in Study 02, patients received their usual treatment plus CORLUX or placebo. In Study 03, patients were not allowed to receive any antipsychotic or antidepressant medication for at least 7 days prior to administration of the study drug or during the week of study drug administration. All patients enrolled in the studies were treated in the hospital. After day 7, while the studies remained blinded, each treating physician was allowed to add any additional treatment, including ECT or antipsychotic, antidepressant or other psychotropic medications.

*Study 02*

The results of Study 02 indicated that CORLUX was well tolerated and that there were no discernable problems with clinical drug interactions when CORLUX was taken in combination with other antipsychotic or antidepressant medications. The median number of psychotropic medications that patients in Study 02 were receiving in addition to CORLUX was four. Although patients in the usual treatment plus CORLUX group more frequently achieved the study's primary endpoint, a rapid and sustained reduction in psychotic symptoms as measured by a 30% decline in the BPRS at Day 7 sustained to Day 28, than did patients in the usual treatment plus placebo group, the difference between the groups was not statistically significant. The study did demonstrate with statistical significance (p value = 0.02) that the usual treatment plus placebo group required ECT or more antipsychotic medication between Day 7 and Day 28 and was less likely to be discharged from the hospital during the week of dosing (p value = 0.05) relative to the usual treatment plus CORLUX group. Post-hoc analysis of Study 02 data further revealed that patients in the usual treatment plus CORLUX group were more likely than patients in the usual treatment plus placebo group to achieve a rapid and sustained asymptomatic condition, as measured by a BPRS score of 25 or less. Although the number of patients achieving this result was small, the difference between the usual treatment plus CORLUX group and the usual treatment plus placebo group was statistically significant (p value = 0.01). All p values for Study 02 are based on an intent-to-treat analysis, which takes into account patients in the trial who received at least one dose of study medication.

*Study 03*

The results of Study 03 indicated that CORLUX was well tolerated as demonstrated by the finding that there was no statistically significant difference in adverse events observed between the CORLUX group and the placebo group. Study 03 also demonstrated with statistical significance (p value = 0.01) that patients who received CORLUX were more likely than patients who received placebo to achieve a rapid and sustained reduction in psychosis as measured by the study's original primary endpoint, a 30% reduction in the BPRS at

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**Table of Contents**

Day 7 sustained to Day 28. Study 03 also showed with statistical significance ( $p$  value = 0.01) that patients in the CORLUX group were more likely than patients in the placebo group to achieve a 50% reduction in the BPRS PSS at Day 7 sustained to Day 28. In addition, patients in the placebo group were more likely than patients in the CORLUX group to receive antipsychotic medication between Day 7 and Day 28, although this difference was not statistically significant. All  $p$  values for Study 03 are based on an observed cases, per protocol analysis, which takes into account only those patients who received at least 6 doses of study medication, had the BPRS assessed at Day 0 and Day 7 and had no major violations of the inclusion/exclusion criteria or other protocol specified criteria.

At the request of the FDA, we followed the last third of patients enrolled in this trial to Day 56. Of those patients who exhibited at least mild psychotic symptoms on Day 0 (score  $\geq 12$  on the BPRS PSS), Study 03 showed with statistical significance that patients receiving CORLUX were more likely than patients receiving placebo to achieve a 50% reduction in the BPRS PSS at Day 7 sustained to Day 56 ( $p$  value = 0.03).

We indicated to the FDA shortly before the study concluded that we would use as our primary endpoint for the study the number of patients who became asymptomatic at the end of one week as measured by the BPRS, a differentiating characteristic that we had noted in post-hoc Study 02 analysis. In Study 03, as in Study 02, only a small number of patients became asymptomatic at the end of one week and, in Study 03, there was no statistically significant difference between the CORLUX and placebo groups.

Of the approximately 480 patients who were enrolled in these completed Phase 2 studies, over 240 individuals were treated with CORLUX. The drug seemed to be well tolerated by these patients, with a low incidence of adverse events. In Studies 02 and 03, the most commonly reported adverse events were headache, dizziness, nausea and sedation. The incidence of these adverse events was similar in the control and CORLUX groups. In Study 02, rash was the only adverse event where there was a statistically significant difference ( $p$  value = 0.05) between groups: 4% occurrence in the CORLUX group compared to no occurrences in the control group. In Study 03, there was no statistically significant difference in the occurrence of any adverse event.

We have also conducted a small open label study to evaluate the safety of retreatment in patients who had a favorable response to treatment in Study 02 and Study 03. Twenty-eight patients completed the study. Our analysis indicates that patients tolerated their retreatment well.

*Phase 3 Clinical Trials.* 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 design of all three trials was based on the design of Study 03, described above.

The primary endpoint for Study 06 and Study 07 was the proportion of patients with at least a 50% improvement in the BPRS PSS at both Day 7 and Day 56. This type of endpoint is known as a categorical endpoint. Patients must have had at least mild psychotic symptoms (BPRS PSS  $\geq 12$ ) to enter the studies and were hospitalized if clinically necessary. BPRS PSS assessments were also be made at Days 14, 28 and 42. 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. A secondary endpoint of Study 09 was the same as the primary endpoint for Study 06 and Study 07.

#### *Study 07*

The first of these trials, Study 07, which began in September 2004, enrolled 257 patients at 25 sites in the United States and Europe with a randomized one-to-one distribution into either a treatment or a placebo arm. 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

## **Table of Contents**

treatment period. After the seven days of CORLUX treatment, all patients received antidepressant therapy through Day 56. Treatment with antipsychotic medications or electroconvulsive therapy was not allowed at any time during the study.

In August 2006 we announced the results of Study 07. In this study 30.5% of the patients receiving CORLUX and 28.6% of the patients receiving placebo met the primary endpoint. This was not a statistically significant difference in response rate. The two key secondary endpoints of Study 07 also failed to achieve statistical significance. There was an unusually high placebo response rate in this trial. At Day 56, for example, approximately 80% of the patients in both of the arms of the study were responders as measured by a 50% improvement in BPRS PSS score.

Even though Study 07 did not meet its primary endpoint, an analysis of the data from this clinical trial revealed some items of interest that helped us to determine the direction for the continued development of CORLUX for treating psychotic depression including the fact that patients with higher plasma levels of CORLUX separated from patients who took placebo with statistical significance.

An item of interest in Study 07 was a statistically significant site by treatment effect. A site by treatment analysis is conducted for all clinical trials to know if the results seen at one site are generalizable to patients seen at another site. A statistically significant site by treatment effect indicates that the effect of treatment with a drug is not uniform at the various clinical sites participating in the clinical trial. One site may have a large difference in the response rate favoring the drug group and another site may have a large difference in the response rate favoring the comparator group. When a site by treatment interaction is statistically significant, it is not possible to know which sites represent the true activity of the drug.

Another interesting observation from Study 07 was that patient enrollment did not have an even pace. 150 patients were enrolled in the first 480 days of the study (September 2004 through December 2005) and 107 patients in the last 120 days. An analysis of the results of the first 150 patients revealed a statistically significant difference on the primary endpoint favoring patients who took CORLUX compared to those who did not. Most of the clinical sites enrolling patients during this time had participated in the conduct of Study 02 and Study 03.

The sites that had enrolled the first 150 patients continued enrolling patients until the trial was fully enrolled at the end of April 2006. By the end of the study this group of sites had enrolled a total of 215 patients, approximately the same total number of patients enrolled in Study 03. The primary endpoint was also met with statistical significance with these 215 patients. After January 1, 2006, in order to increase the speed of enrollment we added eight additional sites. These sites had not participated previously in clinical trials sponsored by Corcept. The eight sites that joined the trial in 2006 enrolled a total of 42 patients. In this group of 42 patients, those who took placebo had a substantially higher response rate on the primary endpoint than those who took CORLUX. The disparate outcome between the group of 215 patients and the group of 42 patients resulted in a statistically significant site by treatment effect.

An important teaching from Study 07 derives from an analysis of the relationship between the concentration of CORLUX in patients' blood on Day 7 and the likelihood that patients meet the response criteria of the primary endpoint. Patients with CORLUX plasma levels higher than 1650 nanograms per milliliter had statistically significant greater response rates observed than did patients who received placebo.

### *Study 09*

Study 09 was a randomized, double-blind, placebo-controlled study in which 247 patients were enrolled at 17 sites. The primary endpoint, a responder analysis, was the proportion of patients with at least a 50% improvement in the BPRS PSS score at both Day 7 and Day 28. We announced the results of this study in September 2006. The study revealed no meaningful separation in response between patients receiving CORLUX and patients receiving placebo on the primary endpoint. The two key secondary endpoints of Study 09 also failed

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**Table of Contents**

to achieve statistical significance. Study 07 had an extremely high placebo response rate; the magnitude of the placebo response rate in Study 09 was unprecedented. At Day 56, for example, approximately 95% of the patients in both of the arms of the study were responders as measured by a 50 percent improvement in BPRS PSS score. Although not the primary or a key secondary endpoint, it is interesting to note that there was a statistically significant separation between the CORLUX group and the comparator group on their change from baseline to Day 56 on the BPRS PSS scale. Change from baseline to study end is an endpoint commonly used to measure the efficacy of antipsychotic and antidepressant medications. However, because of the already high degree of response in the comparator group, it is difficult to determine how much additional clinical utility is conferred by this finding. We do not expect to be able to use Study 09 as one of the two positive efficacy trials required by the FDA for a fileable NDA.

*Study 06*

Study 06, which began in October 2004, enrolled 443 patients at 45 sites in the United States and Europe. These patients were evenly distributed among three active dose groups (300 mg, 600 mg and 1200 mg) and a placebo group, with patients receiving once daily dosing for a period of seven days. The three dosing levels respond 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. Patients in the study did not take any antidepressant and antipsychotic medication for at least one week before the seven day treatment period and received antidepressant therapy starting on Day 1 through Day 56. As with Study 07, treatment with antipsychotic medications or electroconvulsive therapy was not allowed at any time during this study.

We reported the initial results of this trial in March 2007. These results indicated that this 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. 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. In particular, those patients in Study 06 who achieved a predetermined level of 1661 nanograms of CORLUX per milliliter of plasma separated from the placebo group with statistical significance. At substantially lower plasma levels, there was no distinguishable difference in response rates between patients who received CORLUX and those receiving placebo. This study confirms our previous similar finding in Study 07 that at higher plasma levels the drug candidate is able to demonstrate desired clinical effects. Further, the incidence of serious adverse events did not differ between placebo and any of the three CORLUX dose groups.

*Fourth 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 recently completed Phase 3 clinical trials, serves as a strong basis for our next Phase 3 study which commenced in March 2008. The protocol for this trial incorporates the learnings from the three completed trials that 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. We have met with the FDA to discuss and seek their input concerning the design of this trial. In this trial we will use a CORLUX dose of 1200 mg once per day for seven days because, as expected, at this dose more patients achieved the predetermined plasma concentration in Study 06. In Study 06, 80% of the patients who took 1200 mg of CORLUX achieved a drug plasma level sufficient to separate responders from non-responders. We believe that this change in dose as well as other modifications to the protocol should allow us to determine the efficacy of CORLUX in the treatment of the psychotic features of psychotic depression. In addition, in our initial review of a summary of the safety data, we have seen no difference between any of the dose levels used in Study 06.

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 has 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

## **Table of Contents**

priority review if no other treatment is approved for psychotic depression at the time we submit our New Drug Application, or NDA.

*Additional Non-Efficacy Trials and Pre-clinical Studies.* In support of an eventual NDA submission, we plan to conduct additional clinical trials to assess the safety of retreatment of patients with CORLUX. We also plan to conduct several small trials to evaluate how the drug acts on the human body, how the human body acts on the drug and the drug's safety. In addition to our clinical trials, we have completed a standard 12-month toxicology study in the dog and a carcinogenicity study in the rat. A second carcinogenicity study in the mouse is underway. 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.

*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. The preparation for our fourth Phase 3 clinical trial, Study 14, evaluating CORLUX for the treatment of the psychotic features of psychotic depression is being conducted under a Letter of Intent with ICON Clinical Research, LP (ICON) and we are in negotiations with ICON regarding an agreement for the conduct of the full trial activities. In addition, we entered into an agreement with MedAvante, Inc., effective March 17, 2008, to provide centralized psychiatric rating services of patients to be screened and enrolled in Study 14. This agreement may be terminated by Corcept with 30 days notice to MedAvante.

The previous three Phase 3 trials for CORLUX for this indication were conducted under clinical development agreements with other CROs that will be responsible for the completion of final reporting under these trials.

## **GR-II Antagonist Platform**

We have assembled a patent portfolio covering the treatment of psychiatric and metabolic disorders that may benefit from drugs that block the GR-II receptor. In addition to psychotic depression, we own or have exclusively licensed issued patents for the use of GR-II antagonists for the prevention and treatment of stress disorders, for increasing the therapeutic response to ECT and for the treatment of :

weight gain following treatment with antipsychotic medication,

early dementia, including early Alzheimer's disease;

mild cognitive impairment;

gastroesophageal reflux disease;

cognitive deterioration in adults with Down's Syndrome;

delirium; and

psychosis associated with cocaine addiction.

We believe that cortisol plays a role in a variety of other diseases. We have eight pending U.S. method of use patent applications covering GR-II antagonists for the treatment of various diseases.

## **Clinical Trials in Other Psychiatric and Metabolic Disorders.**



## Edgar Filing: CORCEPT THERAPEUTICS INC - Form 10-K

*Cushing's Syndrome.* In July 2007, the FDA granted Orphan Drug Designation for CORLUX for the treatment of Cushing's Syndrome a disorder caused by prolonged exposure of the body's tissues to high levels of the hormone cortisol. Sometimes called hypercortisolism, it is relatively rare. An estimated 10 to 15 of every one million people are affected each year. It most commonly affects adults aged 20 to 50.

## **Table of Contents**

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. Orphan drugs obtain 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.

In September 2007, the Investigational New Drug application (IND) for the evaluation of CORLUX for the treatment of Cushing's Syndrome was opened. The FDA has indicated that a single 50-patient open label study defined by the protocol submitted with the application for the IND may provide a reasonable basis for the submission of an NDA for this indication. This trial was opened for enrollment late in December of 2007.

*Antipsychotic-induced Weight Gain Mitigation.* In June 2007, we announced top-line results of our proof-of-concept study evaluating the ability of CORLUX to mitigate weight gain associated with the administration of olanzapine. The results indicated a statistically significant reduction in weight gain in those subjects who took olanzapine plus CORLUX compared to those who took olanzapine alone. The purpose of this study was to explore the hypothesis that GR-II antagonists would mitigate weight gain associated with atypical antipsychotic medications, such as olanzapine, risperidone, clozapine and quetiapine, which 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 label relating to treatment emergent hyperglycemia and diabetes mellitus. Eli Lilly provided olanzapine and financial support for this study.

In this study, 57 lean, healthy men (body mass index of 25 or less) were randomized to receive either olanzapine plus placebo (n=22), olanzapine 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 olanzapine alone group gained an average of 2.5 pounds more than subjects in the olanzapine plus CORLUX group and 2.2 pounds more than subjects in the CORLUX alone group, which are highly statistically significant differences (p<.001). 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 in subjects who received olanzapine alone was also significantly greater than subjects who received olanzapine plus CORLUX (p<.01). The study was not designed to have statistical power to detect significant effects or metabolic measures, however, notable non-statistically significant group differences were observed. Compared to patients taking olanzapine plus CORLUX, patients taking olanzapine plus placebo experienced greater increases from baseline to end of study in both triglycerides and fasting insulin. No unexpected study drug related adverse events were observed.

The combination of olanzapine and CORLUX is not approved for any indication. The purpose of this study was to explore the hypothesis that GR-II antagonists would mitigate weight gain associated with atypical antipsychotic medications. The group of medications known as atypical antipsychotics, including olanzapine, risperidone, clozapine and 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 label relating to treatment emergent hyperglycemia and diabetes mellitus.

In April 2005, we announced results from two preclinical studies conducted in a rat model of olanzapine-induced weight gain. These studies demonstrated that CORLUX's GR-II antagonist action has the potential to both reduce the weight gain associated with olanzapine and to prevent the weight gain associated with the initiation of treatment with olanzapine.

## **Discovery Research**

In early 2003, we initiated a discovery research program to identify and patent more selective GR-II antagonists in order to develop a pipeline of products for proprietary use. Our discovery chemistry was conducted 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

## **Table of Contents**

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 one compound identified under our research program, which develops particularly high plasma and brain concentrations in an animal model, in a human microdosing study using Xceleron's Accelerator Mass Spectrometry technology under an agreement signed in July 2007.

### **Medical Education and Commercialization**

We intend to develop our own medical education and commercialization infrastructure in the United States for CORLUX because we believe that the initial market for psychotic depression in the United States is highly concentrated and accessible. We anticipate that this will include hiring a small, experienced field sales force of up to approximately 35 people. We intend to focus initially on patients who are candidates for ECT by marketing to hospitals and psychiatrists that perform ECT. We estimate that there are approximately 900 hospitals with more than 30 in-patient psychiatric beds. Of these, we estimate that approximately 300 offer ECT. We believe that approximately 1000 psychiatrists administer most ECT procedures. Subsequently, we also intend to expand our commercialization efforts to address the larger set of patients with psychotic depression currently undergoing combination drug therapy, which would require an increase in the size of our initial sales force.

We believe that a significant opportunity exists to further expand the market for the treatment of the psychotic features of psychotic depression beyond patients currently treated by ECT and combination drug therapy. A large portion of the people who suffer from psychotic depression remain unrecognized and undertreated. We intend to develop medical educational programs to alert the medical community about early diagnosis of psychotic depression and increase awareness regarding CORLUX.

We are planning for the commercialization of CORLUX. 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 products.

### **Manufacturing**

As a drug development entity, we intend to continue to utilize our financial resources to complete the development of CORLUX and advance other product candidates rather than diverting resources to establishing our own manufacturing facilities.

We intend to continue to rely on experienced contract manufacturers to produce our product candidates. We have entered into manufacturing agreements with two contract manufacturers, Produits Chimiques Auxiliaires et de Synthese SA (PCAS) and ScinoPharm Taiwan (ScinoPharm), to produce the active pharmaceutical ingredient, or API, for CORLUX. The agreement with PCAS is for an initial period of five years with an automatic extension for one additional year unless either party gives twelve months prior notice that it does not want the extension. There is no guaranteed minimum purchase commitment under this agreement. If PCAS is unable to manufacture the product for a consecutive six-month period, we have the right to terminate the agreement. The agreement with ScinoPharm obligates us to purchase at least \$1,000,000 of bulk mifepristone per year following the commercial launch of CORLUX. This agreement is terminable by either party at any time. We have also entered into an agreement with another contract manufacturer, PharmaForm, L.L.C., for the production of CORLUX tablets for use in clinical activities. In the event we are unable, for whatever reason, to obtain mifepristone or CORLUX from our contract manufacturers, we may not be able to identify alternate manufacturers able to meet our needs on commercially reasonable terms and in a timely manner, or at all. To date, our need for CORLUX tablets has been limited to the amounts required to support our clinical trials.

### **Competition**

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

## **Table of Contents**

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

Other competitors include companies that market antipsychotic drugs that are used off-label as part of combination drug therapy for psychotic depression. To reduce the psychotic features of psychotic depression, these drugs generally are taken in combination with antidepressant medication over a period of weeks to several months. Unlike the use of CORLUX, this extended course of treatment may put patients at risk of significant adverse side effects, including weight gain, diabetes, sedation, permanent movement disorders and sexual dysfunction.

Antipsychotics include Bristol-Myers Squibb's Abilify, Novartis' Clozaril, Pfizer's Geodon and Navane, Ortho-McNeil's Haldol, Janssen Pharmaceutica's Risperdal, AstraZeneca's Seroquel, GlaxoSmithKline's Stelazine and Thorazine, Mylan's Mellaril, Schering Corporation's Trilafon and Eli Lilly's Zyprexa.

We are aware of one clinical trial that has taken place, conducted by the pharmaceutical division of Akzo Nobel, for a new chemical entity for the treatment of psychotic depression. This new 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, or 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 specialized 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.

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 if there is off-label use of mifepristone for psychotic depression or for Cushing's Syndrome that cannot be protected by our intellectual property.

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.

**Table of Contents**

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

<b>U.S. Patent Number</b>	<b>Subject Matter</b>	<b>Expiration Date</b>
U.S. Pat. No. 6,150,349	Use of GR-II antagonists in the treatment of psychotic major depression	October 5, 2018
U.S. Pat. No. 6,362,173	Use of GR-II antagonists in the treatment of cocaine-induced psychosis	October 5, 2018
U.S. Pat. No. 6,369,046	Use of GR-II antagonists in the treatment of early dementia	February 4, 2019

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

We also own issued U.S. patents for the use of GR-II antagonists in the treatment of mild cognitive impairment, for the treatment of weight gain following treatment with antipsychotic medication, for the prevention and treatment of stress disorders, for the treatment of delirium, the treatment of gastroesophageal reflux disease, for inhibiting cognitive deterioration in adults with Down's Syndrome and for increasing the therapeutic response to ECT. In addition, we have three U.S. composition of matter patent applications covering specific GR-II antagonists and eight U.S. method of use patent applications covering certain GR-II antagonists, including the treatment of:

catatonia;

neurological damage in premature infants;

migraine, headache;

postpartum psychosis, and

psychosis associated with interferon-alpha therapy.

We are also considering, where appropriate, the filing of foreign patent applications corresponding to our U.S. patent 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 patent applications have claims directed to the composition of compounds that are necessary to make our potential products, none of our issued patents have such claims. Specifically, we do not have a patent with claims directed to the composition of mifepristone. Our rights under our issued patents cover only the use of GR-II antagonists, including mifepristone, 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 similar restrictions on CORLUX for the treatment of 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 psychotic depression.



## **Table of Contents**

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

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

As discussed above 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 new drug application, or 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.

## **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 investigational new drug application, or 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,

## **Table of Contents**

which must be approved before beginning clinical trials in humans. Typically, human clinical trials are conducted in three sequential phases that may overlap.

Phase 1. Clinical trials are conducted with a small number of subjects to determine the early safety profile, maximum tolerated dose and pharmacokinetics of the product candidate in human volunteers.

Phase 2. Clinical trials are conducted with groups of patients afflicted with a specific disease to determine preliminary efficacy, optimal dosages and expanded evidence of safety.

Phase 3. Large-scale, multi-center, comparative trials are conducted with patients afflicted with a target disease to establish the overall risk/benefit ratio of the drug and to provide enough data to demonstrate with substantial evidence the efficacy and safety of the product, as required by the FDA.

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

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

If the FDA approves an NDA, the subject drug becomes available for physicians to prescribe in the United States. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-market regulatory standards is not maintained. The drug developer must submit periodic reports to the FDA. Adverse experiences with the product must be reported to the FDA and could result in the imposition of marketing restrictions through labeling changes or product removal. Product approvals may be withdrawn if problems with 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, or 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.



## **Table of Contents**

*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 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.

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

## **Employees**

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

As of December 31, 2007, we had 9 full-time employees, four part-time employees and eight long-term contract staff. Three of our employees and one of our long-term contract staff are M.D.s. We consider our employee relations to be good. None of our employees is covered by a collective bargaining agreement.

## **Available Information**

We are subject to the information requirements of the Securities Exchange Act of 1934 and we therefore file periodic reports, proxy statements and other information with the Securities and Exchange Commission, or 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 at Room 1580, 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the SEC's Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site that contains reports, proxy statements and other information regarding issuers like us that file electronically with the SEC. The address of the SEC's Internet site is [www.sec.gov](http://www.sec.gov). For more information about us, please visit our website at [www.corcept.com](http://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](http://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.

## **Table of Contents**

### **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 will depend heavily on the success of our lead product candidate, CORLUX for the treatment of the psychotic features of psychotic depression, which is still in development. Our first three Phase 3 trials did not meet their primary and key secondary endpoints. If we are unable to commercialize CORLUX for this indication, or experience significant delays in doing so, we may be unable to generate revenues and our stock price may 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 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 the psychotic features of psychotic depression. We have completed three Phase 3 clinical trials evaluating CORLUX for this indication. None of the first three trials met its primary or key secondary endpoints. The FDA generally requires two positive Phase 3 studies prior to the submission of an NDA or one positive Phase 3 study plus sufficient supportive data. Many factors could harm our efforts to develop and commercialize CORLUX, including:

insufficient funding;

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

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

changes or delays in our clinical development program;

rapid technological change making CORLUX obsolete;

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

increases in the costs of our clinical trials;

an inability to obtain, or delay in obtaining, regulatory approval for the commercialization of CORLUX for the treatment of 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.

## **Table of Contents**

**Although our pivotal Phase 3 clinical trial in Cushing's Syndrome only requires 50 patients, both site selection and enrollment could be a relatively slow process. Delays in site selection and / or patient enrollment could extend the time and cost for completion or inhibit our ability to complete the trial at all.**

Cushing's Syndrome is a rare disorder. An estimated 10 to 15 of every one million people are affected each year.

The majority of the sites that treat patients with Cushing's Syndrome are at academic institutions or large clinics in or affiliated with private hospitals. Academic institutions often take a prolonged period of time to complete the administrative activities required before a clinical trial can be initiated at that site. Because the disease is seen so infrequently, the process of identifying and screening the patients for participation in our study may be lengthy.

Any delays in the process of identifying and screening either the clinical sites or the patients for enrollment in the study could delay the completion of the study, increase the cost or even inhibit our ability to complete the trial at all.

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

To gain regulatory approval from the FDA to market CORLUX, our Phase 3 clinical trials must demonstrate the safety and efficacy of CORLUX for the particular indication. Our first three Phase 3 studies evaluating CORLUX for the treatment of the psychotic features of psychotic depression did not meet their primary or key secondary endpoints. In addition to the need for an additional Phase 3 clinical trial, we are conducting, or plan to conduct, other studies in support of a potential NDA. Clinical development is a long, expensive and uncertain process and is subject to delays, and data obtained from clinical trials and supportive studies are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. While we obtained favorable results in our Phase 2 clinical trials program in psychotic depression, these results were not replicated in a robust enough way in Studies 07, 09 or 06 and are not sufficient to support an application for FDA approval. In addition, we cannot assure you that supportive studies and tests will produce favorable results.

**The development plan for CORLUX is not certain, and will require additional, expensive clinical and preclinical trials. We may not be able to finance the development program.**

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. Because the results of our recently completed Phase 3 trials evaluating CORLUX for treatment of the psychotic features of psychotic depression did not meet their primary endpoints, the FDA will require us to pursue an additional clinical trial to demonstrate the safety and/or efficacy of CORLUX for this indication. The FDA generally requires two positive Phase 3 studies or one positive Phase 3 study with other supportive data to be completed prior to the submission of an NDA. In addition, the FDA may require us to pursue additional supportive studies. Recently, the FDA recommended that we conduct a dose proportionality study and other studies to determine whether there are interactions between CORLUX and some commonly used drugs. We are continuing our dialogue with the FDA to define any additional data needed to complete an NDA.

Further, we may decide, or the FDA or other regulatory authorities may require us, to pursue additional clinical, pre-clinical or manufacturing studies to satisfactorily complete our NDA. For example, the FDA may require us to perform a bioequivalence study comparing our recently reformulated CORLUX clinical trial materials to the materials used in our earlier clinical trials. 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 psychotic depression.

## Table of Contents

If adequate funds are not available for our currently contemplated trials and studies, or for any further ones that we may decide are necessary or desirable, we may be required to delay, reduce the scope of or eliminate some or all of our research or development programs. Even if funds are available, additional equity financing may be dilutive to stockholders; debt financing, if available, may involve restrictive covenants; obtaining funds through collaborations may be on unfavorable terms or may require us to relinquish certain rights to our technologies or product candidates, potentially including our lead product candidate, that we would otherwise seek to develop on our own. Even after we conduct all of the clinical trials and supportive studies that we consider appropriate for an optimal NDA, we may not receive regulatory approval to market CORLUX.

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

negative or inconclusive results;

slow patient enrollment;

patient noncompliance with the protocol;

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

FDA inspections of our clinical operations; and

real or perceived lack of effectiveness or safety of CORLUX.

**We have incurred losses since inception and anticipate that we will incur continued losses for the foreseeable future.**

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 the psychotic features of psychotic depression and for the treatment of Cushing's Syndrome. 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, 2007, we had an accumulated deficit of \$110.0 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 for the foreseeable future. We are unable to predict the extent of any future losses or whether or when we will become profitable.

**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 signed a Letter of Intent with a contract research organization, or CRO, that is conducting our fourth Phase 3 trial evaluating CORLUX for the treatment of the psychotic features of psychotic depression and anticipate signing an agreement with them to monitor clinical site performance and to perform investigator supervision, data collection and analysis for this trial. We may not be able to successfully complete those



## **Table of Contents**

negotiations or to maintain these relationships with this or other CROs or with the clinical investigators and the clinical sites through the completion of all trial activities without 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 investigative research sites. The conduct, timing and cost of these trials will be subject to the same kinds of risks as discussed above.

**In Study 14, our fourth clinical trial evaluating CORLUX for the psychotic features of psychotic depression, we have engaged MedAvante to provide centralized psychiatric ratings services. 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, reliability and quality of the psychiatric assessments.**

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

**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, 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.

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**Table of Contents**

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

the FDA may not find that the candidate is safe;

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

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

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

If we receive regulatory approval for our product candidates, including CORLUX, we will also be subject to ongoing FDA obligations and continued regulatory oversight and review, such as continued safety reporting requirements; and we may also be subject to additional FDA post-marketing obligations. If we are not able to maintain regulatory compliance, we may not be permitted to market our product candidates.

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

**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. Outside the United States, we can commercialize a product only if we receive a marketing authorization and, in some cases, pricing approval, from the appropriate regulatory authorities. This foreign regulatory approval process includes all of the risks associated with the FDA approval process, and, in some cases, additional risks. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. We have not taken any actions to obtain foreign approvals. We may not develop our product candidates in the clinic in order to obtain foreign regulatory approvals on a timely basis, if at all.

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

**The 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



## **Table of Contents**

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 the psychotic features of psychotic depression, endogenous Cushing's Syndrome or the mitigation of weight gain induced by the administration of atypical antipsychotic medications, CORLUX may never be accepted as a treatment for the approved indications.**

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

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

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

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

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

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

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

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

the extent and success of our sales and marketing efforts;

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

negative publicity concerning CORLUX, RU-486 or mifepristone.

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

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

The active ingredient in CORLUX, mifepristone, or RU-486, is used to terminate pregnancy. As a result, mifepristone has been and continues to be the subject of considerable ethical and political debate in the United States and elsewhere. Public perception of mifepristone may limit our ability to engage alternative manufacturers and may limit the commercial acceptance of CORLUX by patients and physicians. Even though we intend to create measures to minimize the likelihood of the prescribing of CORLUX to a pregnant woman, physicians may decline to prescribe

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CORLUX to a woman simply to avoid altogether any risk of unintentionally terminating a pregnancy. We intend to create measures for controlling the distribution of CORLUX to reduce the potential for diversion. However, controlled distribution may negatively impact sales of CORLUX.

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**Table of Contents**

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

We currently have no experience in, and we do not own facilities for, nor do we plan to develop facilities for, manufacturing any products. We have agreements with two manufacturers of the active pharmaceutical ingredient, or API, of mifepristone and an agreement with a tablet manufacturer for development quantities of CORLUX. The tablet manufacturer is a single source supplier to us. Our current arrangements with these manufacturers are terminable by either party at any time. Although we anticipate engaging our current tablet supplier to produce commercial quantities of CORLUX, we cannot guarantee that we will enter into an agreement with them on terms acceptable to us. If we are unable, for whatever reason, to obtain the active pharmaceutical ingredient or CORLUX tablets from our contract manufacturers, we may not be able to manufacture our required quantities of CORLUX in a timely manner, 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, or cGMP, regulations and guidelines. Our suppliers and manufacturers may encounter difficulties in achieving quality control and quality assurance and may experience shortages of qualified personnel. Their failure to follow cGMP or other regulatory requirements and to document their compliance with cGMP may lead to significant delays in the availability of products for commercial use or clinical study or the termination or hold on a clinical study, or may delay or prevent filing or approval of marketing applications for CORLUX.

Failure of our third party suppliers and manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could harm our business. If the operations of any current or future supplier or manufacturer were to become unavailable for any reason, commercialization of CORLUX could be delayed and our revenue from product sales could be reduced.

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

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

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

regulatory authorities may withdraw their approvals;

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

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

## Table of Contents

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 could have to engage in costly litigation or obtain a license and we may be unable to commercialize our product candidates.**

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

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

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

Our patent applications and patents licensed or issued to us may be challenged by third parties and our patent applications may not result in issued patents. For example, in 2004, Akzo Nobel filed an observation challenging the claims of our exclusively licensed European patent application with claims directed to psychotic depression. In 2005, we filed a rebuttal to the EPO that responded to the points raised by Akzo Nobel. In February 2006, the EPO allowed our patent application and in July 2006, this patent was issued. In April 2007 the Company received notification that there will be no opposition proceedings in Europe in regards to this patent.

Our presently pending and future patent applications may not issue as patents, and any patent issued to us may be challenged, invalidated, held unenforceable or circumvented. For example, the arguments presented by Akzo Nobel could be raised in the United States either before the U.S. Patent and Trademark Office or in a court of law. Furthermore, the claims in patents which have been issued to us, or which may be issued to us in the future, may not be sufficiently broad to prevent third parties from producing competing products. In addition, the laws of various foreign countries in which we compete may not protect our intellectual property to the same extent as do the laws of the United States. If we fail to obtain adequate patent protection for our proprietary technology, our competitors may produce competing products based on our technology, which would impair our ability to compete.

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

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## **Table of Contents**

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 psychotic depression rather than CORLUX.**

We have an exclusive license from Stanford University to a patent covering the use of GR-II antagonists, including mifepristone, targeted 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. All of our issued patents and all but three of our 11 U.S. patent applications relate to use patents. Because none of our issued patents covers the composition of mifepristone or any other compound, we cannot prevent others from commercializing mifepristone or any other GR-II antagonist in indications not covered by our 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.

### **We may be subject to fines, penalties or injunctions if we are determined to be promoting the use of our products for unapproved or off-label uses, resulting in damage to our reputation and business.**

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of a drug for a use that has not been cleared or approved by FDA. Use of a drug outside its approved indications is known as off-label use. Physicians may use our products off-label, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false

## **Table of Contents**

claims for reimbursement. In that event, our reputation could be damaged and adoption of the products would be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of injury to patients, and, in turn, the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention and result in substantial damage awards against us.

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

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

We may not 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 experience with CORLUX and we may determine that CORLUX is not desirable for uses other than for the treatment of the psychotic features of psychotic depression. In that event, we would have to identify and may need to secure rights to a different GR-II antagonist. For example, we may not develop CORLUX for mitigation of the weight gain associated with the use of olanzapine, even though we have reported positive top-line results regarding the proof of concept study described earlier in this Form 10-K. We may pursue other GR-II antagonists for this use. The compounds developed pursuant to our discovery research program may fail to generate commercially viable product candidates in spite of the resources we have dedicated 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 will need additional capital in order to complete the development and commercialization of CORLUX and our other proprietary selective GR-II antagonists. Additional capital may not be available to us at all or on favorable terms.**

We believe that, after completing the financing transactions in March 2008, we have sufficient capital resources to complete the final reporting for our recently completed psychotic depression trials, to conduct our planned clinical trials in Cushing's Syndrome psychotic depression, and the management of weight gain induced by antipsychotic medications, and to continue development work on our proprietary, selective GR-II antagonists.

## Table of Contents

We anticipate that our existing capital resources will be sufficient to fund our current operating plan into early 2010. However, our expectations include an estimate of proceeds from a variable funding source (see risk statement directly below) and are based on our currently planned clinical development and research programs for CORLUX and for certain of our proprietary, selective GR-II antagonists, which may change as a result of many factors, including:

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

the results of our research efforts and clinical trials;

the need to perform additional clinical trials;

the timing of the approval by the FDA, if any, to market CORLUX for the treatment of the psychotic features of PMD;

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

actual or anticipated fluctuations in our operating results;

changes in our growth rates;

changes in our research development plans for our proprietary, selective GR-II antagonist

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

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

We will have to perform additional clinical trials prior to submission of a New Drug Application, or NDA, for CORLUX for the treatment of the psychotic features of psychotic depression and for Cushing's Syndrome. We will need to raise additional funds to complete the development of CORLUX for the treatment of psychotic depression, Cushing's Syndrome and weight gain management associated with antipsychotic medications, to prepare for its commercialization and to continue and expand the development of our proprietary, selective GR-II antagonists.

Consequently, we may need additional funding sooner than anticipated. Our inability to raise capital would harm our business and product development efforts.

In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in dilution to our then-existing stockholders.

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 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.

**The Committed Equity Financing Facility (CEFF) that we entered into with Kingsbridge on March 25, 2008 may not be available to us at certain times, may require us to make additional blackout or other payments to Kingsbridge, and may result in dilution to our stockholders.**

The CEFF entitles us to sell and obligates Kingsbridge to purchase, from time to time over a period of three years, shares of our common stock for cash consideration up to the lesser of \$60.0 million or approximately 9.6 million shares, subject to certain conditions and restrictions. Based on the closing price of our common stock



## Table of Contents

on the Nasdaq Capital Market on March 27, 2008, we would only be able to raise approximately \$27 million in net proceeds under the CEFF.

Kingsbridge will not be obligated to purchase additional shares under the CEFF unless certain conditions are met, which include a minimum price for our common stock; the accuracy of representations and warranties made to Kingsbridge; compliance with laws; the continued effectiveness of the shelf registration statement; and the continued listing of our stock on the Nasdaq Capital Market. 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 shelf 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 shelf registration statement is not effective in circumstances not permitted by our agreement with Kingsbridge, then we must make a payment to Kingsbridge, or issue Kingsbridge additional shares in lieu of the payment, calculated on the basis of the number of shares held by Kingsbridge (exclusive of shares that Kingsbridge may hold pursuant to exercise of the Kingsbridge warrant) and the change in the market price of our common stock during the period in which the use of the shelf registration statement is suspended. If the trading price of our common stock declines during a suspension of the shelf registration statement, the blackout or other payment could be significant.

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

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

The costs required to start or continue many of the programs that our intellectual property allow us to consider for further development are collectively greater than the funds currently available to us. For example, we have successfully discovered three series of compounds that are specific GR-II antagonists but, unlike CORLUX, do not appear to block the progesterone receptor. Further development of these programs and others, such as the use of GR-II antagonists for the mitigation of weight gain associated with olanzapine, may be delayed or cancelled if we determine that such development may jeopardize our ability to complete the clinical development of CORLUX for the treatment of psychotic depression or for Cushing's Syndrome.

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

We may be subject to product liability or other claims based on allegations that the use of our products has resulted in adverse effects or that our product candidates are not effective, whether by participants in our clinical trials for CORLUX or other product candidates, or by patients using our future products. A product liability claim may damage our reputation by raising questions about our product candidates' safety or efficacy and could limit our ability to sell a product by preventing or interfering with product commercialization. In some cases, less common adverse effects of a pharmaceutical product are not known until long after the FDA approves the product for marketing. The active ingredient in CORLUX is used to terminate pregnancy. Therefore, necessary

## **Table of Contents**

and strict precautions must be taken by clinicians using the medicine in our clinical trials and, if approved by the FDA, physicians prescribing the medicine to women with childbearing potential, to insure that the medicine is not administered to pregnant women. The failure to observe these precautions could result in significant product claims.

We have only limited product liability insurance coverage, with limits that we believe to be customary for a development stage company. We intend to expand our product liability insurance coverage to any product candidates for which we obtain marketing approval. However, this insurance may be prohibitively expensive or may not fully cover our potential liabilities. Our inability to obtain adequate insurance coverage at an acceptable cost could prevent or inhibit the commercialization of our product candidates. Defending a lawsuit could be costly and significantly divert management's attention from conducting our business. If a third party successfully sues us for any injury caused by our product candidates, our liability could exceed our total assets.

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

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

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

**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 the psychotic features of psychotic depression or for other indications.**

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

Combination medicinal therapy consists of the use of antipsychotic and antidepressant medicines, not currently approved for the treatment of psychotic depression. The antipsychotics are prescribed for off-label use by physicians to treat the psychotic features of psychotic depression, which is the clinical target of CORLUX. Antipsychotics include Bristol-Myers Squibb's Abilify, Novartis' Clozaril, Pfizer's Geodon and Navane, Ortho-McNeil's Haldol, Janssen Pharmaceutica's Risperdal, AstraZeneca's Seroquel, GlaxoSmithKline's Stelazine and Thorazine, Mylan's Mellaril, Schering Corporation's Trilafon and Eli Lilly's Zyprexa. CORLUX may not compete effectively with these established treatments. We are aware of one clinical trial conducted by the

## **Table of Contents**

pharmaceutical division of Akzo Nobel, for a new chemical entity for the treatment of psychotic depression. This new chemical entity is a GR-II antagonist, the commercial use of which would be covered by our patent. As discussed above, in 2004, Akzo Nobel filed an observation in our exclusively licensed European patent application with claims directed to psychotic depression, in which Akzo Nobel challenged the claims of that patent application. In 2005, we filed a rebuttal to the EPO that responded to the points raised by Akzo Nobel. In February 2006, the EPO allowed our patent application. In July 2006, the patent was issued. We are not aware of any public disclosures by any company, other than Akzo Nobel, regarding the development of new products to treat psychotic depression.

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 began a Phase II clinical trial in Europe and the United States for this indication. If this product is approved for commercialization before CORLUX, our potential future revenue could be reduced by the possibility of off-label use of mifepristone for psychotic depression or for Cushing's Syndrome.

Our present and potential competitors include major pharmaceutical companies, as well as specialized pharmaceutical firms, universities and public and private research institutions. Moreover, we expect competition to intensify as technical advances are made. These competitors, either alone or with collaborative parties, may succeed with the development and commercialization of medicinal products that are superior to and more cost-effective than CORLUX. Many of our competitors and related private and public research and academic institutions have greater experience, more financial resources and larger research and development staffs than we do. In addition, many of these competitors, either alone or together with their collaborative partners, have significantly greater experience than we do in developing human medicines, obtaining regulatory approvals, manufacturing and commercializing products.

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

### **Rapid technological change could make our product candidates obsolete.**

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

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

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

## **Table of Contents**

### **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.

### **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



## **Table of Contents**

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 may 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 25, 2008 our average daily trading volume has been approximately 110,000 shares and the intra-day sales prices per share of our common stock ranged from \$0.70 to \$6.85. As of March 25, 2008, our officers, directors and principal stockholders control approximately 68% of our common stock. The trading price of our common stock is likely 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;

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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;

**Table of Contents**

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 non-affiliates of the company;

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 Stock Market and the market for technology companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Further, there has been particular volatility in the market prices of securities of biotechnology and life sciences companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources.

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

In April 2007, the listing of our common stock was transferred from the Nasdaq Global Market to the Nasdaq Capital Market. In order to maintain that listing, we must maintain minimum stockholders' equity of \$2,500,000 or satisfy minimum financial and other requirements.

If we are unable to meet any of the Nasdaq listing requirements in the future, the Nasdaq Stock 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.





## **Table of Contents**

### **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.

A total of approximately 16.6 million shares of our common stock issued prior to our initial public offering or in connection with private offerings completed during the last two years, the majority of which are held by our officers, directors and principal stockholders, are subject to registration rights pursuant to which we have agreed to file with the Securities and Exchange Commission registration statements covering the resale of these shares. We expect to file these registration statements during 2008, beginning shortly after the filing of this annual report on Form 10-K.

### **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 issued in a private offering in March 2008 and an additional approximately 4.5 million shares underlying warrants issued in connection with the offering provide that if we fail 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 will be required to pay the holders of such shares and warrants liquidated damages equal to up to 10% of the purchase price of these shares and warrants.

See the discussion above under **Risks Related to our Business** **Committed Equity Financing Facility** regarding registration rights under that agreement.

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

### **Our officers, directors and principal stockholders acting as a group, as well as Paperboy Ventures acting alone, will be able to significantly influence corporate actions.**

As of March 25, 2008, our officers, directors and principal stockholders control approximately 68% 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. As of March 25, 2008, Paperboy Ventures LLC owns approximately 23% of our common stock. Allen Andersson, the chairman of Paperboy Ventures LLC, is a member of our board of directors. Paperboy Ventures' ownership interest and board representation may allow it to exert significant control over us and the risks described above regarding our officers, directors and principal stockholders acting as a group are equally applicable to Paperboy Ventures acting alone.

### **We may incur increased costs as a result of recently enacted and proposed changes in laws and regulations.**

Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and regulations of the SEC and the Nasdaq Stock Market, have

## **Table of Contents**

and will continue to result in increased costs to us. The new rules 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 these new rules and regulations or the timing of such costs.

**Because we have been a public company for a relatively short time, we have limited experience complying with public company obligations, including recently enacted changes in securities laws and regulations. Compliance with these requirements will increase our costs and require additional management resources, and we still may fail to comply.**

We are a small company with limited resources. Until April 2004, we operated as a private company, not subject to many of the requirements applicable to public companies.

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 controls over financial reporting in their annual reports on Form 10-K. This requirement first applies to this annual report on this Form 10-K. In addition, the independent registered public accounting firm auditing the company's financial statements must attest to and report on the effectiveness of the company's internal controls over financial reporting, which requirement may first apply to our annual report on Form 10-K for our fiscal year ending December 31, 2008. 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 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 controls over financial reporting as of the required deadline and future year ends, investors could lose confidence in the reliability of our financial reporting.

**Changes in or interpretations of accounting rules and regulations, such as expensing of stock options, could result in unfavorable accounting charges or require us to change our compensation policies.**

Accounting methods and policies for business and marketing practices of pharmaceutical companies, including policies regarding expensing employee stock options, are subject to further review, interpretation and guidance from relevant accounting authorities, including the SEC. For example, in December 2004, the Financial Accounting Standards Board adopted Financial Accounting Standard 123R, Share Based Payment. This statement, which we adopted in the first quarter of 2006, requires the recording of expense for the fair value of stock options granted. As a result, our operating expenses have increased and are likely to continue to increase. We rely heavily on stock options to compensate existing employees and attract new employees. Because we are now required to expense stock options on a fair-value basis, we may choose to reduce our reliance on stock options as a compensation tool. If we reduce our use of stock options, it may be more difficult for us to attract and retain qualified employees. Although we believe that our accounting practices are consistent with current accounting pronouncements, changes to or interpretations of accounting methods or policies in the future may require us to reclassify, restate or otherwise change or revise our financial statements.

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

Provisions in our charter and bylaws may delay or prevent an acquisition of us or a change in our management. Some of these provisions divide our board into three classes with only a portion of our directors subject to election at each annual meeting, allow us to issue preferred stock without any vote or further action by the stockholders, require advance notification of stockholder proposals and nominations of candidates for election as directors and prohibit stockholders from acting by written consent. In addition, a supermajority vote

**Table of Contents**

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.

**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. The lease had an initial term of 30 months with a commencement date of July 1, 2005. In July 2007, we exercised our option to extend the lease for an additional year, through the end of 2008. 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. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

No matters were submitted to a vote of security holders during the fourth quarter of fiscal 2007.

**Table of Contents****PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND 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.

	<b>High</b>	<b>Low</b>
<b>2007</b>		
First Quarter	\$ 1.39	\$ 0.68
Second Quarter	\$ 2.99	\$ 0.97
Third Quarter	\$ 6.85	\$ 1.90
Fourth Quarter	\$ 5.25	\$ 2.44

	<b>High</b>	<b>Low</b>
<b>2006</b>		
First Quarter	\$ 5.59	\$ 3.45
Second Quarter	\$ 6.15	\$ 4.04
Third Quarter	\$ 4.54	\$ 0.75
Fourth Quarter	\$ 1.70	\$ 0.68

**Stockholders of Record and Dividends**

As of March 31, 2008, we had 48,473,164 shares of common stock outstanding held by 120 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 in the foreseeable future.

**Sale of Unregistered Securities**

On March 30, 2007, the Company sold 9,000,000 shares of Common Stock of Corcept, par value \$0.001, at a price of \$1.00 per share, for aggregate proceeds of \$9,000,000. The investor group included Paperboy Ventures LLC, Sutter Hill Ventures and Alta Partners LLP, all venture capital firms that are currently significant shareholders of the Company, members of the Company's board of directors, Joseph C. Cook, Jr., David L. Mahoney, Alan F. Schatzberg, M.D. and James N. Wilson, and other qualified investors. G. Leonard Baker, Jr., a member of the Company's board of directors, is also managing director of the general partner of Sutter Hill Ventures.

The March 2007 financing was exempt from registration pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(2) the Securities Act of 1933, as amended. The securities sold and issued in connection with the private placement were not initially registered under the Securities Act of 1933, as amended, or any state securities laws and may not be offered or sold in the United States absent registration with the Securities and Exchange Commission or an applicable exemption from the registration requirements. As part of the transaction, the Company agreed to file a registration statement with the Securities and Exchange Commission for purposes of registering the resale of certain of the common stock issued in this transaction.

A resale Form S-1 was filed on April 4, 2007, to register for resale 4,900,000 of the shares sold in the March Financing and 1,992,527 shares sold in a private equity financing in December 2006.

## **Table of Contents**

On August 16, 2007, we agreed to sell an aggregate of 4,790,473 shares of common stock, par value \$0.001, at a price of \$2.10 per share, for aggregate proceeds of approximately \$10.1 million, hereinafter referred to as the August / September Financing. We completed the initial closing of the August / September Financing on August 17, 2007, selling 3,599,997 shares of common stock, par value \$0.001, at the purchase price of \$2.10 per share for gross proceeds of \$7.6 million. The Purchasers in the initial closing included Paperboy Ventures, LLC, Sutter Hill Ventures and Alta Partners, LLP, all venture capital firms that are currently significant shareholders of the Company. The Purchasers also included various entities affiliated with G. Leonard Baker, Jr., Joseph C. Cook, Jr., David L. Mahoney and James N. Wilson, who are members of the Company's board of directors, and other qualified investors. Allen Andersson, a member of the Company's board of directors, is the chairman of Paperboy Ventures. Mr. Baker is a partner and managing director of Sutter Hill Ventures. Alix Marduel, M.D., a member of the Company's board of directors, is a managing director of Alta Partners. On September 24, 2007, after receiving approval at a special meeting of stockholders, we completed the second closing under the agreement selling an additional 1,190,476 shares of common stock, par value \$0.001, at the purchase price of \$2.10 per share to Paperboy Ventures LLC for additional proceeds of \$2.5 million.

This August / September Financing is exempt from registration pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(2) the Securities Act of 1933, as amended, and Regulation D under the Securities Act of 1933, as amended. The securities sold and issued in connection with the private placement have not been registered under the Securities Act of 1933, as amended, or any state securities laws and may not be offered or sold in the United States absent registration with the Securities and Exchange Commission or an applicable exemption from the registration requirements.

As part of the transaction, we agreed to file a registration statement with the Securities and Exchange Commission for purposes of registering the resale of the common stock issued in these transactions within forty-five business days following the filing of this Annual Report on Form 10-K. Shares of common stock sold in the private equity transactions in December 2006 and March 2007 that were not registered for resale in the April 2007 Form S-1 will be included for registration for resale in this same registration statement.

On March 14, 2008, we entered into a definitive agreement with certain accredited investors for the private placement of approximately 8.9 million shares of our common stock at a price of \$2.77 per share and warrants to purchase approximately 4.5 million shares of our common stock, at a price of \$0.125 per warrant. The warrants have a seven year term and an exercise price of \$2.77 per share. The closing for the financing occurred on March 25, 2008 and generated approximately \$25 million in net proceeds, after deducting the costs of issuance.

The Purchasers in this transaction were led by Longitude Capital Management Co., LLP. Other investors participating in the offering include Paperboy Ventures LLC, Sutter Hill Ventures and Alta Partners, LLP, venture capital firms that are all significant shareholders in Corcept, as well as various entities and individuals related to these firms. Also investing are trusts and other entities related to members of the Corcept Board of Directors, Joseph C. Cook, Jr., David L. Mahoney, G. Leonard Baker and James N. Wilson, and other accredited investors. Mr. Baker is a partner and managing director of Sutter Hill Ventures. Alix Marduel, M.D., a member of the Company's board of directors, is a managing director of Alta Partners. Allen Anderson, a member of the Company's board of directors, is the chairman of Paperboy Ventures.

The March 2008 Financing is exempt from registration pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(2) the Securities Act of 1933, as amended, and Regulation D under the Securities Act of 1933, as amended. The securities sold and issued in connection with the private placement have not been registered under the Securities Act of 1933, as amended, or any state securities laws and may not be offered or sold in the United States absent registration with the Securities and Exchange Commission or an applicable exemption from the registration requirements. As part of the transaction, the Company agreed to file the initial registration statement with the Securities and Exchange Commission for purposes of registering the resale of the common stock issued in this transaction within 30 days of the closing of this transaction.

## **Table of Contents**

On March 25, 2008, we entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge), a private investment group. Under the terms of the agreement, Kingsbridge has committed to provide up to \$60 million of capital during the next three years through the purchase of newly-issued shares of Corcept's common stock. The maximum number of shares that can be sold by Corcept under this agreement is approximately 9.6 million shares. Under the terms of the agreement, the determination of the exact timing and amount of any CEFF financings will be made solely by Corcept, 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 Corcept's stock during the pricing periods of each sale.

Certain details of the CEFF are as follows:

Under the terms of the agreement, Corcept has access to up to \$60 million from Kingsbridge in exchange for newly-issued shares of Corcept's common stock for a period of up to three years after the Securities and Exchange Commission declares effective the registration statement to be filed by Corcept 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.

Corcept can access capital under the CEFF in tranches of up to 1.25% of Corcept's market capitalization at the time of the initiation of the draw down period, or, at Corcept's option, the lesser of (a) 2.5% of Corcept's 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 the 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 Corcept's 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 Corcept's securities.

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

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

In connection with the CEFF, Corcept 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 a 125% premium over the average of the closing bid prices of Corcept's common stock during the 5 trading days preceding the signing of the agreement. The warrant will become exercisable after the six month anniversary of the date of the agreement. The warrant will remain exercisable, subject to certain exceptions, until five years after the date it becomes exercisable.

The CEFF, and the issuance of the warrant in connection with the CEFF, is exempt from registration pursuant to the exemption for transactions by an issuer not involving a public offering under Section 4(2) of the Securities Act of 1933, as amended, and Regulation D under the Securities Act of 1933, as amended.

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, have not been registered under the Securities Act, or state securities





## **Table of Contents**

laws, and may not be offered or sold in the United States without being registered with the SEC or through an applicable exemption from SEC registration requirements. Corcept has agreed to file a registration statement with the SEC covering the resale of the shares issuable under the CEFF and the shares issuable upon the exercise of the warrant within 60 days of the date of the agreement.

### **Sales and Repurchases of Securities**

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

### **Market Performance Graph**

*The graph and the accompanying text below is not soliciting material, is not deemed filed with the SEC and is not to be incorporated by reference in any filings by us under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, 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 the Company include in a line-graph presentation comparing cumulative stockholder returns on the Company's common stock with the NASDAQ Composite Index (which tracks the aggregate price performance of equity securities of companies traded on NASDAQ) and either a published industry or line-of-business standard index or an index of peer companies selected by the Company. The Company has elected to use the NASDAQ Biotechnology Index (consisting of a group of approximately 130 companies in the biotechnology sector, including the Company) 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 the Company's common stock.

**Table of Contents**

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

COMPARISON OF 44-MONTH CUMULATIVE TOTAL RETURN\* AMONG  
CORCEPT THERAPEUTICS, THE NASDAQ STOCK MARKET (U.S.) INDEX  
AND THE NASDAQ BIOTECHNOLOGY INDEX

\* \$100 invested on 4/14/04 including reinvestment of dividends. Fiscal year ending December 31.

**Table of Contents****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, 2005, 2006, and 2007 and for the period from inception (May 13, 1998) to December 31, 2007 and the balance sheet data as of December 31, 2006 and 2007 are derived from our audited financial statements included in this Annual Report on Form 10-K, or Form 10-K. The statements of operations data for the years ended December 31, 2003 and 2004, and the balance sheet data as of December 31, 2003, 2004 and 2005 have been derived from our audited financial statements, which are not included in this Form 10-K. The selected financial data set forth below should be read in conjunction with our financial statements, the related notes and Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Form 10-K.

	Year Ended December 31,					Period from inception (May 13, 1998) to December 31, 2007
	2007	2006	2005	2004	2003	
<i>(In thousands, except per share data)</i>						
<b>Statement of Operations Data:</b>						
Collaboration Revenue	\$ 482	\$ 294	\$	\$	\$	\$ 776
Operating expenses:						
Research and development*	7,860	20,834	17,074	11,551	8,223	85,657
General and administrative*	4,867	5,042	4,084	4,494	1,746	29,140
Total operating expenses	12,727	25,876	21,158	16,045	9,969	114,797
Loss from operations	(12,245)	(25,582)	(21,158)	(16,045)	(9,969)	(114,021)
Non-operating income, net	672	709	1,065	510	157	4,010
Net loss	\$ (11,573)	\$ (24,873)	\$ (20,093)	\$ (15,535)	\$ (9,812)	\$ (110,011)
Net loss per share:						
Basic and diluted	\$ (0.34)	\$ (1.09)	\$ (0.89)	\$ (0.84)	\$ (1.22)	
Weighted average shares basic and diluted	34,251	22,841	22,608	18,440	8,069	
* Includes non-cash stock-based compensation (recovery) of the following:						
Research and development	\$ 213	\$ 535	\$ (26)	\$ 202	\$ 551	\$ 4,744
General and administrative	846	1,013	799	1,475	(308)	6,650
Total non-cash stock-based compensation	\$ 1,059	\$ 1,548	\$ 773	\$ 1,677	\$ 243	\$ 11,394

	As of December 31,				
	2007	2006	2005	2004	2003
<i>(In thousands)</i>					
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and investments	\$ 17,366	\$ 9,456	\$ 29,619	\$ 46,887	\$ 11,577
Working capital	14,662	6,286	25,984	36,415	10,729

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Total assets	17,744	9,902	30,156	47,772	11,781
Long-term liabilities	16	29	42		524
Convertible preferred stock					41,716
Total stockholders' equity (net capital deficiency)	14,734	6,360	26,593	45,948	(31,473)

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

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**Table of Contents**

**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 Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended 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, expect, and similar expressions are forward-looking statements. Such forward-looking statements are based on current expectations, but the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements may include, but are not limited to, statements about:*

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

*the timing of the market introduction of CORLUX® and future product candidates;*

*estimates of the dates by which we expect to report results of our clinical trials;*

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

*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 Securities and Exchange Commission.*

**Overview**

We are a pharmaceutical company engaged in the development of medications for the treatment of severe psychiatric and metabolic diseases. Since our inception in May 1998, we have been developing our lead product, CORLUX, a glucocorticoid receptor II, or GR-II, antagonist.

*Psychotic Depression*

Our lead program is for the development of CORLUX for the treatment of the psychotic features of psychotic major depression, under an exclusive patent license from Stanford University. Psychotic major depression, or PMD, will hereinafter be referred to as psychotic depression. The United States Food and Drug Administration, or FDA, has granted fast track status to evaluate the safety and efficacy of CORLUX for the treatment of the psychotic features of psychotic depression. Between August 2006 and March 2007 we announced the top line results of our initial three Phase 3 trials in which CORLUX was evaluated for treating the psychotic features of psychotic depression.



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**Table of Contents**

We reported the initial results of Study 06, the last of the three Phase 3 trials, in March 2007. These results indicated that this study did not achieve statistical significance with respect to the primary endpoint, 50% improvement in the Brief Psychiatric Rating Scale Positive Symptom Subscale, or BPRS PSS, at Day 7 and at Day 56. However, there was a statistically significant correlation between plasma levels and clinical outcome achieved during treatment. 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. In particular, those patients in Study 06 who achieved a predetermined level of 1661 nanograms of CORLUX per milliliter of plasma separated from the placebo group with statistical significance for the primary endpoint. Conversely, at substantially lower plasma levels, there was no distinguishable response rate between patients who received CORLUX and those receiving placebo. This study confirms a similar finding in Study 07 that at higher plasma levels the drug candidate is able to demonstrate desired clinical effects. Further, the incidence of serious adverse events did not differ between placebo and any of the three CORLUX dose groups.

Data aggregated from our major efficacy studies of similar design, Study 03, Study 06, Study 07 and Study 09, (724 observed cases) indicate that the patients who received CORLUX separated from the placebo group with statistical significance for the endpoint, 50% improvement in the BPRS PSS at Day 7 and at Day 56. In addition, using the same endpoint, patients who achieved a drug level in their plasma that was greater than the 1661 nanograms per milliliter threshold mentioned above, statistically separated from both those patients whose plasma levels were below this threshold and those patients who received placebo.

We believe that the confirmation of a correlation between drug concentration and clinical response, as well as other observations from Study 06 and our other two completed Phase 3 clinical trials, serves as a strong basis for our current Phase 3 study, which commenced enrollment in March of 2008. The protocol for this trial incorporates what we have learned from the three completed trials addressing the established relationship between increased drug plasma levels and clinical response and attempt to decrease the random variability observed in the results of the psychometric instruments used to measure efficacy. In this trial we are using a dose level of 1200 mg once per day for seven days because, as expected, at successively higher dosages, more patients achieved the predetermined plasma concentration that correlates with response. In Study 06, 80% of the patients who took 1200 mg of Corlux achieved a drug plasma level sufficient for a strong clinical response. We have seen no difference in the safety data between any of the dose levels used in Study 06 in our initial review of a summary of that data. We believe that this change in dose, as well as other modifications to the protocol, should allow us to demonstrate the efficacy of CORLUX in the treatment of the psychotic symptoms of psychotic depression.

*Management of Weight Gain induced by Antipsychotics*

During 2007 we announced the top-line results of our proof-of-concept study evaluating the ability of CORLUX to mitigate weight gain associated with the use of olanzapine. This study in healthy male volunteers was initiated during the first quarter of 2006. The top line results indicated a statistically significant reduction in weight gain in those subjects who took olanzapine plus CORLUX compared to those who took olanzapine alone. Eli Lilly and Company, or Lilly, provided olanzapine and financial support for this study.

The combination of olanzapine and CORLUX is not approved for any indication. The purpose of this study was to explore the hypothesis that GR-II antagonists would mitigate weight gain associated with atypical antipsychotic medications. The group of medications known as atypical antipsychotics, including olanzapine, risperidone, clozapine and 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 label relating to treatment emergent hyperglycemia and diabetes mellitus.

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 reduced both the weight gain associated with ongoing olanzapine use and prevented the weight gain associated with the initiation of treatment with olanzapine.

## **Table of Contents**

### *Cushing's Syndrome*

In July 2007, we received Orphan Drug Designation from the FDA for CORLUX for the treatment of 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 rare and most commonly affects adults aged 20 to 50. An estimated 10 to 15 of every one million people are affected each year.

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.

The Investigational New Drug application (IND) for the evaluation of CORLUX for the treatment of Cushing's Syndrome was opened in September 2007. The FDA has indicated that a single study may provide a reasonable basis for the submission of a New Drug Application (NDA) for this indication. This trial is now open for enrollment.

### *Research and Human Biology*

In July 2007, we executed an agreement with Xceleron Limited to conduct a human microdosing study of one of Corcept's new chemical entities, a selective GR-II antagonist, utilizing Xceleron's Accelerator Mass Spectrometry, or AMS, technology. In early 2003, we initiated a discovery research program to identify and patent selective GR-II antagonists to develop a pipeline of products for proprietary use. Three distinct series of GR-II antagonists were identified. These compounds appear to be as potent as our lead product CORLUX in blocking cortisol but, unlike CORLUX, they do not appear to block the progesterone or other steroid receptors. We are evaluating one of the compounds, which develops particularly high plasma and brain concentrations in an animal model, in a human microdosing study using Xceleron's AMS technology.

During 2007 and early 2008 we signed agreements with our contract research scientists to continue our discovery research activities on new compounds for through June 2008.

### *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 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 revenue under the agreement with Lilly discussed above.

We are in the development stage and have incurred significant losses since our inception. We have not generated any revenue through December 2007 other than the revenue under the collaboration agreement with Lilly, and do not expect to generate significant revenue for the foreseeable future. As of December 31, 2007, we had an accumulated deficit of \$110.0 million. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for CORLUX, discovery research,





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## **Table of Contents**

non-clinical activities such as toxicology and carcinogenicity studies, manufacturing process development and regulatory activities, as well as general and administrative expenses. We expect to continue to incur net losses over at least the next several years as we continue our CORLUX clinical development program, apply for regulatory approvals, initiate development of newly identified GR-II antagonists for various indications, continue our discovery research program, acquire and develop treatments in other therapeutic areas, establish sales and marketing capabilities and expand our operations.

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

In April 2007, Nasdaq granted our request to transfer the listing of our common stock from the Nasdaq Global Market to the Nasdaq Capital Market. Since transferring to the Nasdaq Capital Market, we have been in compliance with all listing requirements.

### **Results of Operations**

*Collaboration revenue* Collaboration revenue relates to services rendered in connection with our agreement with Lilly discussed above under the caption Overview-Management of Weight Gain induced by Antipsychotics. Under the agreement, Lilly agreed to supply olanzapine and pay for the costs of the study. We were required to perform development activities as specified in this agreement 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 agreement.

During the years ended December 31, 2007 and 2006, we recognized approximately \$482,000 and \$294,000, respectively, under this agreement. There will be no significant revenue under this agreement in the future as the majority of the activities were completed during 2007.

*Research and development expenses.* Research and development expenses include the personnel costs related to our development activities, including non-cash stock-based compensation, as well as the costs of discovery research, pre-clinical studies, clinical trial preparations, enrolment and monitoring expenses, regulatory costs and the costs of manufacturing development.

Research and development expenses decreased 62% to \$7.9 million for the year ended December 31, 2007, from \$20.8 million for the year ended December 31, 2006. The decrease in expenses reflects clinical trial cost decreases of approximately \$13.7 million due to the substantial completion of our earlier Phase 3 clinical trials for psychotic depression in late 2006 and early 2007, which were partially offset by approximately \$145,000 in costs associated with the preparations for our upcoming psychotic depression trial and increases in clinical trial costs related to other programs of approximately \$510,000. During the year ended December 31, 2007 as compared to 2006, there were also increases in contract research expenses of approximately \$725,000 due to basic research work in new chemical compounds and the initiation of the micro-dosing study on a selected compound, increases in analytical testing of approximately \$75,000 and increases in manufacturing expenses of approximately \$360,000 due to the manufacture of additional materials for upcoming clinical trials and manufacturing process development. In addition, during the year ended December 31, 2007 as compared to 2006, there were decreases in pre-clinical studies of approximately \$995,000 and staffing expenses of approximately \$480,000, which included decreases in non-cash stock-based compensation of approximately \$275,000. The decreases in staffing expenses were offset by increases in consulting and professional fees of \$435,000 for 2007 as compared to 2006.

**Table of Contents**

Research and development expenses increased 22% to \$20.8 million for the year ended December 31, 2006 from \$17.1 million for 2005. The increase in expenses between years reflect clinical trial cost increases of approximately \$4.7 million for 2006 as compared to 2005 primarily related to clinical trial expenses for our first three Phase 3 psychotic depression studies. This increase was partially offset by a reduction in 2006 of approximately \$450,000 in expenses for our discovery research program due to the successful conclusion of a program focusing on the discovery of new chemical entities that will be available for future development.

During 2006 as compared to 2005, the costs of our clinical program also reflected a decrease of approximately \$695,000 from the conclusion of our study in mild to moderate Alzheimer's disease in 2005 and an increase of approximately \$275,000 related to the commencement of the olanzapine induced weight gain mitigation clinical trial in collaboration with Lilly. In addition, during 2006, as compared to 2005 there were decreases in pre-clinical studies and manufacturing development of approximately \$365,000 and \$205,000, respectively, decreases in travel, consulting and other expenses of \$435,000 and increases in staffing expenses of approximately \$545,000. The increases in staffing expenses were primarily due to higher non-cash stock-based compensation expense.

Research and development expenses discussed above included stock based compensation charges related to option grants to individuals performing these functions of approximately \$240,000, \$575,000 and \$224,000, respectively, for the years ended December 31, 2007, 2006 and 2005. The increase in expense between 2006 and 2005 was due principally to the implementation of SFAS 123R in January 2006. The decrease between 2007 and 2006 was due principally to the cancellation of unvested options due to the resignation of an employee early in 2007, which was partially offset by increases in expense related to options granted during 2007. In addition, during the years ended December 31, 2007, 2006 and 2005 upon the termination of employees or the change in status of employees who worked in a development function to consultants, we recorded reversals of approximately \$25,000, \$40,000 and \$250,000, respectively, of previously reported stock-based compensation expense, which represents the difference between the expense recorded and the expense that would have been recorded based upon the rights to options that vested during the service of these individuals as employees. See the discussion below under the caption "Stock-based compensation for options to employees" regarding the impact of adopting SFAS 123R regarding the impact of adoption in January 2006.

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

Project	Year Ended December 31,		
	2007	2006	2005
	<i>(in thousands)</i>		
CORLUX for the treatment of the psychotic features of psychotic depression	\$ 5,645	\$ 19,759	\$ 15,391
CORLUX for other clinical programs	1,085	276	954
Drug discovery research	917	264	755
Stock-based compensation	213	535	(26)
<b>Total research and development expense</b>	<b>\$ 7,860</b>	<b>\$ 20,834</b>	<b>\$ 17,074</b>

We expect that research and development expenditures will increase during 2008 as compared to 2007 due to the commencement of our Phase 3 studies in Cushing's Syndrome and psychotic depression, the clinical trials to further evaluate the management of weight gain induced by antipsychotic medications, and to continue development of our proprietary selective GR-II antagonists. Research and development expenses in 2009 and future years will be largely dependent on the availability of additional funds to finance clinical development plans based on our experience from prior trials. See also, the "Liquidity and Capital Resources" section in this Form 10-K.

## Table of Contents

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. 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.

General and administrative expenses decreased 3% to approximately \$4.9 million for the year ended December 31, 2007, from \$5.0 million for the year ended December 31, 2006. The decrease in costs between years was comprised of decreases in legal and professional fees of approximately \$100,000 due primarily to lower costs related to patents. Staffing costs also decreased by approximately \$30,000 in 2007 as compared to 2006. The changes in staffing costs included a decrease in non-cash stock-based compensation of approximately \$160,000, which was offset by increases in salaries and wages of \$125,000.

The decreases in stock-based compensation expense during 2007 included a reversal of approximately \$395,000 of stock-compensation expense during the second quarter of 2007 in connection with the resignation of an officer, which represents the excess of expense under the graded vesting method as compared with the expense associated with stock options that actually vested prior to this termination. There were net increases of approximately \$195,000 between 2007 and 2006 in stock-based compensation charges related to stock options granted to officers and employees during 2007, which were partially offset by declining expense of earlier options due to the decelerating scale of expense under the graded vesting method and options cancelled due to the termination.

General and administrative expenses increased 23% to \$5.0 million for the year ended December 31, 2006, from \$4.1 million for the year ended December 31, 2005. The increase in 2006 as compared to 2005 was primarily due to increases in professional fees of approximately \$560,000 and increases in staffing costs of approximately \$455,000. The increases in staffing expenses were primarily due to higher non-cash stock-based compensation expense.

General and administrative expenses included stock-based compensation expense related to option grants to individuals performing these functions of approximately \$1.2 million, \$1.0 million and \$800,000, respectively, for the years ended December 31, 2007, 2006 and 2005. See discussion below under the caption "Stock-based compensation for options to employees" impact of adopting SFAS 123R regarding the impact of adoption in January 2006.

The amount of general and administrative expenses in 2008 and future years will be largely dependent on our assessment of the staff necessary to support our continued clinical development activities and the availability of additional funds. See also, the "Liquidity and Capital Resources" section in this Form 10-K.

*Interest and other income, net.* Interest and other income, net of investment management fees, was approximately \$690,000 for the year ended December 31, 2007 as compared to \$720,000 for the same period in 2006 and \$1.1 million in 2005. The decreases in each successive period were principally attributable to decreased interest on investments due to lower average balance of invested funds that were partially offset by higher yields on the investment portfolios.

*Other expense.* Other expense was approximately \$15,000 for the year ended December 31, 2007 as compared to \$10,000 for the same period in 2006 and \$50,000 in 2005. Other expense includes interest expense on capitalized leases entered into during the second quarter of 2005 and state tax on capital which is based on our capital and asset positions as of each year-end.

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**Table of Contents**

**Liquidity and Capital Resources**

We have incurred operating losses since inception, and at December 31, 2007, we had a deficit accumulated during the development stage of \$110.0 million. Since our inception, we have relied primarily on the proceeds from public and private sales of our equity securities to fund our operations. On March 30, 2007, we sold 9 million shares of common stock at a price of \$1.00 per share in a private placement, which generated net proceeds of approximately \$8.8 million after deducting issuance costs. During the third quarter of 2007, we sold approximately 4.8 million shares of common stock at a price of \$2.10 per share in a private placement, which generated net proceeds of approximately \$10.0 million after deducting issuance costs.

At December 31, 2007, we had cash, cash equivalents and investments balances of \$17.4 million, compared to \$9.5 million at December 31, 2006. Net cash used in operating activities for the years ended December 31, 2007, 2006 and 2005, were \$11.0 million, \$23.2 million and \$17.2 million, respectively. The use of cash in each period was primarily a result of net losses associated with our research and development activities and amounts incurred to develop our administrative infrastructure. We expect cash used in operating activities to increase during 2008 and later years due to the continuation and expansion of our development programs for psychotic depression, Cushing's Syndrome and the management of weight gain induced by atypical antipsychotic medications, research activities, commercialization activities and general and administrative expenses.

On March 25, 2008, we sold approximately 8.9 million shares of our common stock at a price of \$2.77 per share and warrants to purchase approximately 4.5 million shares of its common stock, at a price of \$0.125 per warrant in a private placement. The warrants have a seven year term and an exercise price of \$2.77 per share. The March 2008 Financing generated approximately \$25 million in net proceeds, after deducting the costs of issuance.

On March 25, 2008, we entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge), a private investment group. Under the terms of the agreement, 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 Securities and Exchange Commission declares effective the registration statement to be filed by Corcept 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 can be sold by Corcept under this agreement is approximately 9.6 million shares. Under the terms of the agreement, the determination of the exact timing and amount of any CEFF financings will be made solely by Corcept, subject to certain conditions. Based on the closing stock price of the Company's common stock on March 27, 2008, the maximum amount of net proceeds that could be raised under the CEFF is approximately \$27 million. The actual amount of net proceeds 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 Corcept's stock during the pricing periods of each sale.

We believe that, with the completion of these March 2008 financing transactions, we will have sufficient capital resources to complete the final reporting for our recently completed psychotic depression trials, to conduct clinical trials in Cushing's Syndrome, psychotic depression, and the management of weight gain induced by antipsychotic medications, and to continue development work on our proprietary, selective GR-II antagonists. Our projections include an estimate of proceeds from a variable funding source based on the calculations as of March 27, 2008 discussed in the preceding paragraph. (See Part I, Item 1A, Risk Factors for a discussion of risks related to the Committed Equity Financing Facility.)

We will have to perform additional clinical trials prior to submission of an NDA for CORLUX for the treatment of the psychotic features of psychotic depression and for Cushing's Syndrome. We will need to raise additional funds to complete the development of CORLUX for the treatment of psychotic depression, to initiate its clinical development for other indications, to prepare for its commercialization and to conduct other research activities.

**Table of Contents**

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 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.

**Contractual Obligations and Commercial Commitments**

The following table presents our estimates of obligations under contractual agreements as of December 31, 2007:

Payments Due by Period	Less than	1-3	3-5	More than
	1 year	Years	Years	5 Years
	<i>(in thousands)</i>			
Research and development studies <sup>(1) through (6)</sup>	\$ 2,380	\$ 754	\$	\$
Purchase commitments <sup>(7)</sup>	537			
Operating lease <sup>(8)</sup>	241			
Capital leases <sup>(9)</sup>	13	16		
Minimum royalty payments <sup>(10)</sup>	50	100	100	50 per year
Total	\$ 3,221	\$ 870	\$ 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, 2007.
- (2) During 2004 through 2006, we executed a number of agreements to conduct clinical trials and pre-clinical studies for further development of our lead product, CORLUX, targeted for the treatment of the psychotic features of psychotic depression. The agreements provide for termination by us upon forty-five days written notice or less. The exact amounts and timing of these obligations are dependent on the pace of activities of the various trials and studies. As of December 31, 2007, substantially all patient activities had been completed and remaining reporting activities are expected to be completed in early 2008, at a cost of approximately \$330,000.
- (3) During 2007, the Company signed agreements for services in connection with the trial to be initiated for CORLUX for the treatment of Cushing's Syndrome. The total commitment under agreements signed during 2007 is approximately \$1.6 million. Approximately \$140,000 was expensed under these agreements during 2007, with the remainder to be expensed over the remainder of the trial. Under the master agreement with these vendors, the agreements may be terminated upon sixty days notice to the vendors. If terminated early, the Company would be responsible for the costs incurred by the vendor through the effective date of the termination plus cancellation charges as stipulated in the various agreements.
- (4) During 2007 and early 2008, the Company signed agreements for research services on new compounds. The total commitment under these research agreements is approximately \$1.0 million of which \$425,000 was expensed in 2007; the remainder will be incurred in 2008.
- (5) During 2007, we initiated an agreement for a human microdosing study of one of the Company's new chemical entities. The total commitment under this agreement is approximately \$540,000. Approximately \$210,000 of this commitment was expensed during 2007. The remainder will be incurred in 2008.
- (6) In November 2007, the Company signed a Letter of Intent (LOI) with a contract research organization to assist in preparations for the upcoming Phase 3 clinical trial in psychotic depression. The total commitment under this LOI was approximately \$635,000. Approximately \$90,000 of this commitment was expensed in 2007, with the remainder to be paid in 2008.
- (7) In November 2007, we initiated purchase orders for the acquisition of active pharmaceutical ingredient to be delivered in 2008.
- (8) Our operating lease commitment relates to the lease of our office facility. The operating lease, originally signed in 2005 was effective for a 30 month term, from July 2005 through December 2007 at a monthly rental of approximately \$14,000, plus operating expenses. In July 2007, we extended the lease through December 2008 at a monthly rental of approximately \$20,000, plus operating expenses.
- (9) During 2005, we entered into capital leases for the acquisition of certain pieces of office furniture and equipment.
- (10) Under our cancelable 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, the timing of which is contingent on future events.

<sup>(a)</sup> 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

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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.

## **Table of Contents**

- (b) Under the agreement with our contract research company we may be obligated to make milestone payments upon the occurrence of certain events, including: (i) patent filings in connection with the project; (ii) entries into Phase 1 clinical trials; and (iii) national regulatory approval of each product arising from work performed under the agreement, provided that sales of the product by the Company or any future licensees reach \$5,000,000. These obligations remain in force after the conclusion of work under the agreement. There are no royalty obligations associated with this contract.
- (c) Our agreement with ScinoPharm Taiwan that provides for the manufacture and supply of the active pharmaceutical ingredient for CORLUX includes a minimum purchase commitment of \$1,000,000 per year following the commercial launch of CORLUX. This agreement may be terminated by us at any time without penalty.
- (d) On November 8, 2006, we signed an agreement with Produits Chimiques Auxiliaires et de Synthèse SA ( PCAS ) for the manufacture of mifepristone, the active pharmaceutical ingredient in CORLUX, for our development and commercial needs for an initial period of five years. The agreement provides for an automatic extension for one additional year unless either party gives twelve month s prior notice that it does not want the extension. There is no guaranteed minimum purchase commitment under this agreement. If PCAS is unable to manufacture the product for a consecutive six-month period, we have the right to terminate the agreement without penalty.

In March 2008, we signed an agreement with MedAvante, Inc., to provide centralized psychiatric rating services of patients to be screened and enrolled in our fourth Phase 3 clinical trial evaluating CORLUX for the treatment of the psychotic features of psychotic depression. The total commitment under this agreement is approximately \$4.1 million. Approximately \$1.7 million of this cost will be incurred during 2008, with the remainder occurring over the course of the trial. This agreement may be terminated by Corcept with 30 days notice to MedAvante.

## **Net Operating Loss Carryforwards**

At December 31, 2007 we had approximately \$48.4 million of federal net operating loss carryforwards and approximately \$630,000 in federal research and development tax credit carryforwards, as well as approximately \$48.1 million of California net operating loss carryforwards and approximately \$725,000 in California research and development tax credit carryforwards, available to offset any future taxable income we may generate. The federal and California net operating loss and tax credit carryforwards will expire beginning in 2019 and 2009, respectively. Our deferred tax assets have been offset by a full valuation allowance as the realization of such assets is uncertain. The Internal Revenue Code of 1986, as amended, places certain limitations on the annual amount of net operating loss and tax credit carryforwards that can be utilized in any particular year if certain changes in our ownership occur.

## **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.

*Revenue recognition Collaboration revenue.* Collaboration revenue relates to services rendered in connection with our agreement signed in October 2005 with Lilly under which Lilly agreed to supply olanzapine and pay for the study. We were required to perform development activities as specified in this agreement 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 agreement. The cost of providing these research services approximates the revenue recognized.

*Accruals of Research and Development Costs.* We recorded accruals for estimated costs of research, pre-clinical and clinical studies, and manufacturing development of approximately \$880,000 and \$2.2 million as of December 31, 2007 and 2006, 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



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**Table of Contents**

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

*Employees and directors*

We adopted Statement of Financial Accounting Standard 123 (Revised 2004), *Share-Based Payment*, or SFAS 123R, as of January 1, 2006 under the modified prospective method, in which compensation cost is recognized beginning with the effective date (a) based on the requirements of Statement 123R for all share-based payment arrangements with employees granted or modified after the effective date and (b) based on the requirements of Statement 123 for all awards granted to employees and directors prior to the effective date of Statement 123R that remain non-vested on the effective date. Prior to the adoption of SFAS 123R, we had accounted for stock-based compensation for options granted to employees and directors using the intrinsic value method prescribed in Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, or APB 25, and had adopted the disclosure-only alternative of SFAS No. 123, *Accounting for Stock-Based Compensation*, or SFAS 123, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*, or SFAS 148. Because we had used the minimum value method for SFAS 123 pro forma disclosure requirements for options granted prior to the IPO in 2004, we continue to account for the portion of these pre-IPO grants that were non-vested as of January 1, 2006 under the provisions of APB 25 and related Interpretations, with pro forma disclosures under SFAS 123.

Under APB 25, we recorded deferred stock-based compensation related to option grants to employees and directors that represents the difference, if any, between the exercise price of an option and the fair value of our common stock on the date of the grant. Given the absence of an active market for our common stock prior to the time of our IPO in April 2004, management was required to estimate the fair value of our common stock based on a variety of company and industry-specific factors for the purpose of measuring the cost of the transaction and properly reflecting it in our financial statements. Since our IPO, all stock options have been granted at exercise prices that represent the closing price for the stock on the Nasdaq Stock Market as of the date of grant. Deferred compensation is included as a reduction of stockholders' equity and is being amortized to expense over the vesting period of the underlying options, generally five years. Our policy has been to use the graded-vesting method for recognizing compensation costs for fixed employee awards for all awards granted through December 31, 2005. We amortize the deferred stock-based compensation of employee options using the graded-vesting attribution method over the vesting periods of the applicable stock options. The graded-vesting method provides for vesting of portions of the overall awards at interim dates and results in greater expense in earlier years than the straight-line method. Upon termination of employment, the difference between the expense recorded under the graded-vesting method and the expense that would have been recorded based upon the vesting of the related option is required to be reversed.

Following is a brief synopsis of the implications of adoption of this statement on 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:

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.

The expected term used in determining the fair value for options is based on the simple method prescribed by the Securities and Exchange Commission, or SEC, in Staff Accounting Bulletins 107 and

**Table of Contents**

110, 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 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.

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

The following table indicates the impact on our statement of operations for the year ended December 31, 2006, as a result of implementing SFAS 123R.

Operating Expense Category	Year Ended December 31, 2006		Total
	Research and development	General and administrative	
	<i>(amounts in thousands)</i>		
Expense under provisions of APB 25	\$ (2)	\$ 373	\$ 371
Incremental expense	440	632	1,072
Expense under provisions of SFAS123R	\$ 438	\$ 1,005	\$ 1,443

As of December 31, 2007, the Company had the following amounts of unrecognized compensation expense for employee options outstanding as of that date.

	Amount <i>(in thousands)</i>	Weighted- average period <i>(in years)</i>
Remaining deferred compensation related to options granted prior to the IPO, to be expensed under the provisions of APB 25	\$ 13	0.9
Remaining fair value to be expensed		
Options granted after IPO through 2005, using fair value under SFAS 123	186	1.9
Options granted after January 1, 2006, using fair value under SFAS 123R	3,453	3.1
<b>Total</b>	<b>\$ 3,652</b>	

*Non-employees*

Stock-based compensation related to option grants to non-employees is charged to expense on a straight line basis over the vesting period of the options, based on the fair value of the options, which approximates the period over which the related services are rendered, using the Black-Scholes option pricing model. The assumptions used in these calculations are similar to those used for the determination of fair value under SFAS 123 and 123R 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 Stock Market.



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## **Table of Contents**

*Income Taxes.* The Company accounts for income taxes under Statement of Financial Accounting Standards No. 109, *Accounting for Income Taxes*, or SFAS 109. Under this method, 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 recovered.

On January 1, 2007, the Company adopted Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, or FIN 48, an interpretation of SFAS 109. As a result of the implementation of FIN 48, the Company did not recognize any adjustment to the liability for uncertain tax positions or to its deferred tax assets for unrecognized tax benefits, all of which are currently offset by a full valuation allowance. Therefore, there was no adjustment to the beginning balance of retained earnings in 2007.

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.

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.

*Accounting Changes.* In September 2006, the SEC issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*, or SAB 108. SAB 108 addresses quantifying the financial statement effects of misstatements: specifically, how the effects of prior year uncorrected misstatements must be considered in quantifying misstatements in the current year financial statements. SAB 108 is effective for fiscal years ending after November 15, 2006. We have adopted SAB 108 as of January 1, 2007, as required. There was no material impact on our financial statements from the adoption of SAB 108.

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

We do not have any off-balance sheet arrangements as of December 31, 2007, with the exception of the operating lease for our office space. The operating lease, originally signed in 2005 was effective for a 30 month term, from July 2005 through December 2007 at a monthly rental of approximately \$14,000, plus operating expenses. In July 2007, we extended the lease through December 2008 at a monthly rental of approximately \$20,000, plus operating expenses.

### **Recently Issued Accounting Standards**

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements*, or SFAS 157. SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Financing Liabilities including an amendment of SFAS Statement No. 115*, or SFAS 159. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS 157 and SFAS 159 are both effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The Company is currently evaluating the impact of adopting SFAS 157 and SFAS 159 on its financial statements.

In March 2007, the Emerging Issues Task Force of the Financial Accounting Standards Board, or EITF, released a draft of Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be*

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**Table of Contents**

*Used in Future Research and Development Activities*, or EITF 07-3. The initial draft of this Issue was affirmed at EITF meetings in June 2007. EITF 07-3 requires that nonrefundable advance payments for future research and development activities should be deferred and recognized as expense as the goods are delivered or the related services are performed, unless the entity does not expect the goods to be delivered or the services to be rendered. EITF 07-3 is effective for the fiscal years beginning after December 31, 2007, including interim periods within those fiscal years. Earlier adoption is not permitted. The Company does not anticipate that there will be a material effect on its financial statements on the adoption of this standard.

In December 2007, the Financial Accounting Standards Board, or FASB, ratified EITF No. 07-1, *Accounting for Collaborative Arrangements*, or EITF 07-1. EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 also establishes the appropriate income statement presentation and classification for joint operating activities and payments between participants, as well as the sufficiency of the disclosures related to these arrangements. EITF 07-1 is effective for fiscal years beginning after December 15, 2008, and would be applied retrospectively as a change in accounting principle for collaborative arrangements existing at the effective date. The Company does not anticipate that there will be a material effect on its financial statements on the adoption of this standard.

**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, 2007, our cash and cash equivalents consisted primarily of money market funds maintained at major U.S. financial institutions and commercial paper with original maturities of less than 90-days and our short-term investments consist of corporate debt securities. As of December 31, 2007, there were no mortgage-backed securities and no auction rate securities in the portfolio. 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, 2007.

**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 AND ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

**ITEM 9A (T). CONTROLS AND PROCEDURES**

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

***Evaluation of disclosure controls and procedures.*** We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and discussed with our management, including our Chief



## **Table of Contents**

Executive 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, 2007, our Chief Executive 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 Securities Exchange Act of 1934, as amended) which were designed to ensure that the information required to be disclosed by us in this Annual Report on Form 10-K was recorded, processed, summarized and reported within the time periods specified in the SEC's rules and Form 10-K. Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met. Based on the evaluation, our Chief Executive Officer and Chief Accounting Officer have concluded that our disclosure controls and procedures are effective.

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

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

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Accounting Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on our evaluation, we concluded that our internal control over financial reporting was effective as of December 31, 2007.

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

(c) **Changes in internal controls.** There were no changes in our internal controls over financial reporting during the quarter ended December 31, 2007 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **ITEM 9B. OTHER INFORMATION**

In November 2007, Dr. Robert L. Roe, our President, adopted a plan in accordance with Rule 10b5-1 under the Exchange Act for sales of our common stock. Under this plan, shares may be sold from time to time over 12-month periods, beginning in December 2007.

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

The following table sets forth, as of December 31, 2007, the name, age and occupation of each member of our Board of Directors:

<b>Name</b>	<b>Age</b>	<b>Occupation</b>
James N. Wilson <sup>(3)</sup>	64	Chairman of the Board of the Company
Allen Andersson	64	Chairman, Paperboy Ventures LLC
Joseph K. Belanoff, M.D.	50	Chief Executive Officer of the Company
G. Leonard Baker, Jr. <sup>(2)</sup>	65	Venture Capitalist
Joseph C. Cook, Jr. <sup>(1)(3)</sup>	66	Executive/Investor
James A. Harper <sup>(2)</sup>	60	Retired Pharmaceutical Executive
David L. Mahoney <sup>(1)(2)</sup>	53	Private Equity Investor
Alix Marduel, M.D. <sup>(2)(3)</sup>	50	Venture Capitalist
David B. Singer <sup>(1)</sup>	45	Private Investment Fund Principal

(1) Member of audit committee

(2) Member of compensation committee

(3) Member of nominating and corporate governance committee

The directors are elected at each annual meeting of stockholders, or special meeting in lieu thereof. The directors serve for a one-year term until the next annual meeting of stockholders and until their successors are elected and qualified.

*James N. Wilson* has served as a director and as Chairman of the Board since 1999. In addition, since 2005, Mr. Wilson has been the Chairman of the Board of NuGEN Technologies, Inc. Since 2002, he has served as a director of Amylin Pharmaceuticals, Inc. From 1996 to 2001, Mr. Wilson was Chairman of the Board of Amira Medical, Inc. From 1991 to 1994, he was Chief Operating Officer of Syntex Corporation. From 1989 to 1990, Mr. Wilson was Chairman and Chief Executive Officer of Neurex Corporation and from 1982 to 1988, Mr. Wilson was Chief Executive Officer of LifeScan, Inc. Mr. Wilson received his B.A. and M.B.A. from the University of Arizona.

*Allen Andersson* is founder and chairman of Paperboy Ventures LLC, a merchant bank commercializing undervalued science since 2003. A software designer and entrepreneur for over twenty years, he was a founder of LightSpeed International, a developer of voice-over-Internet systems in 1995, Expert Image Systems, a developer of medical diagnostic technology in 1986 and Interleaf, an early word processing developer in 1981. Mr. Andersson has held executive positions in Logos Advanced Technologies, Transatlantic Software. He is also President of The Riecken Foundation, which creates public libraries and promotes prosperity and democracy in Central America. Mr. Andersson received his S.B. in mathematics from the Massachusetts Institute of Technology and served in the Peace Corps in Honduras.

*Joseph K. Belanoff, M.D.* is a co-founder of the Company and has served as a member of the Board of Directors and as the Company's 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.

*G. Leonard Baker, Jr.* has served as a member of the Board of Directors since 1999. Since 1973, Mr. Baker has been a Managing Director of the General Partner of Sutter Hill Ventures, a venture capital firm. Mr. Baker



**Table of Contents**

currently serves on the boards of a number of private companies. Mr. Baker received his B.A. from Yale University and his M.B.A. from Stanford University.

*Joseph C. Cook, Jr.* has served as a member of the Board of Directors since 2002. Mr. Cook is Chairman of the Board of Amylin Pharmaceuticals, Inc. Mr. Cook served as Chief Executive Officer of Amylin Pharmaceuticals from 1998 to 2003. Mr. Cook is a founder and currently serves as Chairman of the Board of Microbia, Inc. Mr. Cook is an officer of Mountain Ventures, Inc. and a founder of Clinical Products, Inc. and Mountain Group Capital, LLC. Mr. Cook retired as Group Vice President of Eli Lilly & Company in 1993 after more than 28 years of service. Mr. Cook received his B.S. from the University of Tennessee.

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

*David L. Mahoney* has served as a member of the Board of Directors since July 2004. From 1999 to 2001, Mr. Mahoney served as co-CEO of McKesson HBOC, Inc., a healthcare supply management and information technology company and as CEO of iMcKesson LLC, a healthcare management and connectivity company. He joined McKesson Corporation in 1990 as Vice President for Strategic Planning. Prior to joining McKesson, Mr. Mahoney was a principal with McKinsey & Company where he worked from 1981 to 1990. He also serves on the Board of Directors of Symantec Corporation, Tercica, Inc., Live Oak School, San Francisco Museum of Modern Art, Mercy Corps and NCPB, Inc., a public television and radio operator. Mr. Mahoney received his B.A. from Princeton University and his M.B.A. from Harvard University.

*Alix Marduel, M.D.* has served as a member of the Board of Directors since May 2001. Since April 1997, Dr. Marduel has been a managing director of Alta Partners, a venture capital firm investing in information technology and life science companies. Prior to joining Alta Partners, she was a partner at Soffinnova, Inc., which she joined in 1990. Dr. Marduel has conducted post-doctoral research in immunology at the University of California at San Francisco and at Stanford University. Prior to moving to the United States in 1986, she was employed by ICI-Pharma, where she organized clinical trials in England and France. She holds a medical doctorate from the University of Paris, and is licensed to practice in Europe and has passed the U.S. equivalency exams.

*David B. Singer* has served as a member of the Board of Directors since 1998. Since December 2004, Mr. Singer has been a Principal at Maverick Capital Ltd., an investment manager to private investment funds. From September 1998 to February 2004, Mr. Singer was Chairman and Chief Executive Officer of GeneSoft Pharmaceuticals, Inc. From 1992 to 1996, he was President and Chief Executive Officer of Affymetrix, Inc. Mr. Singer also serves on the Board of Directors of Affymetrix, Inc. Mr. Singer received his B.A. from Yale University and his M.B.A. from Stanford University.

There are no family relationships among any of the Company's directors or executive officers.

**Table of Contents****Executive Officers**

The following table sets forth, as of December 31, 2007, information about our executive officers:

<b>Name</b>	<b>Age</b>	<b>Position</b>
Joseph K. Belanoff, M.D.	50	Chief Executive Officer and Director
Robert L. Roe, M.D.	67	President and Secretary
Anne M. LeDoux	60	Vice President, Controller and Chief Accounting Officer

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

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

*Anne M. LeDoux* joined the company as Controller in 2004 and was promoted to the position of Vice President, Controller and Chief Accounting Officer in April 2007. Ms. LeDoux has over 15 years of financial and accounting management experience with public pharmaceutical and biotechnology companies. Prior to joining Corcept in 2004, Ms. LeDoux served in various financial positions at Aviron, Roche Biosciences and Syntex Corporation. She was also Vice President and Chief Financial Officer at the Northern California Health Center and Vice President, Finance for the Children's Hospital of San Francisco. Ms. LeDoux is a Certified Public Accountant and has over 13 years of experience in public accounting, primarily at Coopers and Lybrand. Ms. LeDoux received her Bachelor of Arts degree in Business from the University of Massachusetts and a law degree from Western New England College, School of Law.

**Board Meetings and Committees**

The Board met eleven times during fiscal 2007; five of them telephonically, and took action via unanimous written consent once. The Audit Committee met five times and the Compensation Committee met three times. The Nominating and Corporate Governance Committee met twice during fiscal 2007. Each member of the Board attended 75% or more of the total number of Board meetings and meetings of Board committees on which such Board member served, other than David Singer who attended 55% of the Board meetings and 80% of Audit Committee meetings.

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

**Audit Committee.** The Audit Committee currently consists of David L. Mahoney (chairman), Joseph C. Cook, Jr. and David B. Singer. The Board has determined that all members of the Audit Committee are independent directors under the rules of the Nasdaq Stock Market and each of them is able to read and understand fundamental financial statements. In addition, the Board has determined that each member of the Audit Committee also satisfies the independence requirements of Rule 10A-3(b)(1) of the Exchange Act. The Board has determined that David L. Mahoney qualifies as an "Audit Committee financial expert" as defined by Item 407(d)(5) of Regulation S-K of the Securities Act of 1933, as amended and the Securities Exchange Act of 1934, as amended. The purpose of the Audit Committee is to oversee the accounting and financial reporting processes of the Company and audits of its financial statements. The responsibilities of the Audit Committee include appointing and providing the compensation of the independent accountants to conduct the annual audit of

## **Table of Contents**

the Company's accounts, reviewing the scope and results of the independent audits, reviewing and evaluating internal accounting policies, and approving all professional services to be provided to the Company by its independent auditors.

*Compensation Committee.* The Compensation Committee currently consists of G. Leonard Baker, Jr. (chairman), James A. Harper, David L. Mahoney and Alix Marduel, M.D. The Board has determined that all members of the Compensation Committee are independent directors under the rules of the Nasdaq Stock Market. The Compensation Committee administers the Company's benefit plans, reviews and administers all compensation arrangements for executive officers, and establishes and reviews general policies relating to the compensation and benefits of the Company's officers and employees.

*Nominating and Corporate Governance Committee.* The Company's Nominating and Corporate Governance Committee consists of Joseph C. Cook, Jr. (chairman), and Alix Marduel, M.D. and James N. Wilson. Alan F. Schatzberg, M.D. was also a member of the this committee until his term as a director was concluded at the Annual Meeting on June 11, 2007. The Nominating and Governance Committee is responsible for identifying individuals qualified to serve as members of the Board, recommending to the independent members of the Board nominees for election as directors of the Company and providing oversight with respect to corporate governance and ethical conduct. Although Mr. Wilson is an employee of the Company and therefore not an independent director for NASDAQ purposes, the Company's director nomination process meets applicable NASDAQ requirements because the Company's director nominees are selected by the independent members of the Board.

## **Communications with Directors**

Stockholders or other interested parties may communicate with any director or committee of the Board by writing to them c/o Secretary, Corcept Therapeutics, 149 Commonwealth Drive, Menlo Park, California 94025. Comments or questions regarding the Company's accounting, internal controls or auditing matters will be referred to members of the Audit Committee. Comments or questions regarding the nomination of directors and other corporate governance matters will be referred to members of the Nominating and Governance Committee.

The Company encourages its directors to attend the annual stockholder meetings. One of the Company's directors attended the 2007 annual meeting.

## **Code of Ethics**

The Company has adopted a code of ethics that applies to all officers and employees, including its principal executive officer, principal financial officer and controller. This code of ethics has been filed as Exhibit 14.1 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2007 filed with the SEC. The Company will also deliver a copy of its code of ethics to any stockholder, without charge, upon written request to Corcept Therapeutics, 149 Commonwealth Drive, Menlo Park, California 94025, Attention: Secretary, or upon oral request by calling (650) 327-3270.

## **Section 16(A) Beneficial Ownership Reporting Compliance**

Under Section 16(a) of the Exchange Act and SEC rules, the Company's directors, executive officers and beneficial owners of more than 10% of any class of equity security are required to file periodic reports of their ownership, and changes in that ownership, with the SEC. Based solely on its review of copies of these reports and representations of such reporting persons, the Company believes that during fiscal 2007, such SEC filing requirements were satisfied, with the exception that David Singer reported on a Form 5 filed on February 13, 2008, gifts of stock to his children on December 17, 2007 and the grant of a stock option from the Company on December 19, 2007. These transactions should have been reported on Forms 4 within 2 business days after the occurrence.

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**Table of Contents**

**ITEM 11. EXECUTIVE COMPENSATION**

**Compensation Discussion and Analysis**

*Compensation Objectives*

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

In establishing compensation for executive officers, the following are the Compensation Committee's objectives:

Attract and retain individuals of superior managerial talent;

Ensure senior officer compensation is aligned with the Company's corporate strategies, business objectives and the long-term interests of the Company's stockholders;

Increase the incentive to achieve key strategic and financial performance measures by linking incentive award opportunities to the achievement of performance goals in these areas; and

Align officer and shareholder interests, as well as promote retention of key people, by providing a portion of total compensation opportunities for senior management in the form of direct ownership in the Company through stock options.

The Company's overall compensation program is structured to attract, motivate and retain highly qualified executive officers by paying them competitively, consistent with the Company's success and their contribution to that success. The Company believes compensation should be structured to ensure that a portion of compensation opportunity will be directly related to Company stock performance and other factors that directly and indirectly influence stockholder value. Accordingly, the Company sets goals designed to link each NEO's compensation to the Company's performance, such as the attainment of clinical goals and meeting agreed upon financial targets.

The Company provides a base salary to our executive officers. Additionally, consistent with our performance-based philosophy, the Company reserves the largest potential compensation awards for performance- and incentive-based programs for the Company's senior executive management team, comprised of the Chief Executive Officer, President and Chief Accounting Officer. Such programs include stock options grants, designed to provide compensation opportunities if milestones that increase the value of the Company, such as positive results in clinical trials, are attained. Incentive-based programs provide compensation in the form of both cash and equity, to reward for both short-term and long-term performance of the Company. The Compensation Committee allocates total compensation between cash and equity compensation based on the Compensation Committee members' knowledge of compensation practices in the biotechnology and specialty pharmaceutical industries. The balance between equity and cash compensation among members of the senior executive management team, all three of whom are NEOs, is evaluated annually to align the interests of management with stockholders through both short and long term incentives.

The Chairman of the Board and the members of the Compensation Committee are seasoned executives of, consultants to or venture capitalists with investments in the biotechnology and specialty pharmaceutical industry. Collectively they have served as board and compensation committee members of many public and privately held companies including Amylin Pharmaceuticals, Inc., NuGen Technologies, Inc., Neurex Corporation, Praecis Pharmaceuticals, Inc., Tercica, Inc., and Zymogenetics Inc. As a result of this extensive involvement in the compensation of executives in these and other companies, the Chairman of the Board and the members of the

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## **Table of Contents**

Compensation Committee collectively have developed a clear understanding and knowledge of the compensation structures that are necessary to attract, motivate and retain management talent.

### ***Determination of Compensation***

The Compensation Committee is provided with the primary authority to determine and recommend the compensation awards available to the Company's executive officers for approval by the Board of Directors. Based on the Compensation Committee members' collective understanding of compensation practices in similar companies in the biotechnology and specialty pharmaceutical industry, the Company's executive compensation package consists of the following elements, in addition to the employee benefit plans in which all employees may participate:

Base salary: compensation for ongoing performance throughout the year.

Periodic performance-based cash compensation: awards to recognize and reward achievement of performance goals.

Long-term performance-based equity incentive program: equity compensation to provide an incentive to the NEOs to manage the Company from the perspective of an owner with an equity stock in the business.

Severance and change of control benefits: remuneration paid to executives in the event of a change of control of the Company or involuntary employment termination.

To aid the Compensation Committee in making its determination, our Chief Executive Officer provides recommendations annually to the Compensation Committee regarding the compensation of all other executive officers. Each NEO in turn, participates in an annual performance review with our Chief Executive Officer to provide input about their individual contributions to the Company's success for the period being assessed. The overall performance of our senior executive management team is reviewed annually by the Compensation Committee.

The Company sets base salary structures and any grants of stock options based on the Compensation Committee members' collective understanding of compensation practices in the biotechnology and specialty pharmaceutical industry and such members' experiences as seasoned executives, consultants, board and compensation committee members, or investors in similar biotechnology and specialty pharmaceutical industry companies.

### ***Tax Considerations***

A goal of the Compensation Committee is to comply with the requirements of Internal Revenue Code Section 162(m) of the Internal Revenue Code of 1986, as amended (Section 162(m) limits the tax deductibility by the Company of annual compensation in excess of \$1,000,000 paid to our Chief Executive Officer and any of our three other most highly compensated executive officers, other than our Chief Financial Officer. However, performance-based compensation that has been approved by our stockholders is excluded from the \$1,000,000 limit if, among other requirements, the compensation is payable only upon the attainment of pre-established, objective performance goals and the committee of our board of directors that establishes such goals consist only of outside directors. All members of the Compensation Committee qualify as outside directors.

While the tax impact of any compensation arrangement is one factor to be considered, such impact is evaluated in light of the Compensation Committee's overall compensation philosophy and objectives. The Compensation Committee will consider ways to maximize the deductibility of executive compensation, while retaining the discretion it deems necessary to compensate officers in a manner commensurate with performance and the competitive environment for executive talent. From time to time, the Compensation Committee may award compensation to our executive officers which is not fully deductible if it determines that such award is consistent with its philosophy and is in our and our stockholders' best interests.

## **Table of Contents**

Certain option grants made under our equity plans are intended to be structured so that any compensation deemed paid upon the exercise of those options will qualify as performance-based compensation that is not subject to the \$1,000,000 limitation.

### *Elements of Executive Compensation*

#### **Base Compensation**

The Company pays base salaries to provide fixed compensation based on the Compensation Committee's assessment of competitive market practices. Due to the Compensation Committee's collective experience with similar companies in the biotechnology and specialty pharmaceutical industry, the Compensation Committee has intricate knowledge and understanding of what the industry demands in order to motivate and retain our executive officers. The Company provides each NEO with a base salary that was established by extensive negotiations with each NEO when such individual first joined the Company as an employee or was promoted to the position of executive officer. Base salaries have not changed in 2007 as compared to 2006 other than for annual cost of living adjustments of 4% per year that were approved by the Compensation Committee and applied equally to all employees. While base salaries are not considered by the Internal Revenue Service to constitute performance-based compensation, each year the Compensation Committee reviews the CEO's base salary to determine if a change is appropriate based on Company performance, such as the Company's progress on research and development programs. Similarly, the CEO reviews the base salary of the other NEOs and has the ability to propose a change in base salary based on performance to the Compensation Committee. Other than the annual cost of living increases that the Compensation Committee has approved, no formulaic base salary increases are provided to the NEOs.

#### **Performance-Based Compensation**

##### *Performance Goals and Periodic Performance-Based Cash Compensation*

The Company structures its compensation programs to reward executive officers based on the Company's performance. This allows executive officers to receive bonus compensation in the event certain specified corporate performance measures are achieved. To date, the Company has not instituted an annual performance-based cash compensation or annual performance-based equity compensation program because the Compensation Committee believes that the compensation objective to ensure that executive officers' compensation is aligned with the Company's corporate strategies, business objectives and the long-term interests of the Company's stockholders is achieved when milestone successes are met, such as meeting the predetermined endpoints in the Company's clinical trials. The achievement of these milestones does not necessarily correspond with annual performance periods.

Performance-based cash compensation has been awarded in past years primarily to recognize the attainment of certain accomplishments of value enhancing milestones such as successful financing transactions and positive results in clinical trials. The Compensation Committee believes that performance-based compensation should be based on achievement of certain milestone successes, such as the attainment of predetermined end-points in the Company's clinical trials, successful financing transactions and commencement of certain clinical trials. For 2007, the Compensation Committee performed a retrospective assessment of performance during the year and recommended to the Board of Directors the payment of a 25% bonus of actual 2007 salary earned (adjusted for any partial year employees) to each employee of the Company at December 31, 2007, including the officers. This recommendation was approved by the Board of Directors at their meeting in December 2007. This bonus was paid in January 2008.

##### *Long-Term Performance-Based Equity Incentive Program*

The Company's executive officers, along with all of the Company's employees, are eligible to participate in the Company's awarding of stock options under its 2004 Equity Incentive Plan. As discussed above, the

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## **Table of Contents**

Company believes, with its performance-based approach to compensation, that equity ownership in the Company is important to tie the ultimate level of an executive officer's compensation to the performance of the Company's stock and stockholder gains while creating an incentive for sustained growth. The Company has, thus far, only used stock options as the long-term performance-based equity incentive vehicle because the Compensation Committee believes that stock options maximize executive officers' incentive to increase the Company's stock price and maximize stockholder value (i.e. there is no financial gain to an executive officer unless our stock price appreciates.)

Equity compensation in the form of incentive or non-qualified stock options is awarded by the Compensation Committee from time to time. The size and the timing of each grant is based on a number of factors, including the executive officer's salary, such executive officer's contributions to the achievement of the Company's financial and strategic objectives, the value of the stock option at the time of grant, the possible value of the option if the Company achieves its objectives and industry practices and norms from the collective knowledge of the Compensation Committee as seasoned executives of, consultants to, board and compensation members of, and venture capitalists with investments in similar companies in the industry. The relative weight given to each of these factors varies among individuals at the Compensation Committee's discretion. There is no set formula for the granting of stock options to individual executives and employees. Grants also may be made following a significant change in job responsibility or in recognition of a significant achievement. In April 2007, Dr. Belanoff, Dr. Roe and Ms. LeDoux were granted stock options for 1,000,000, 700,000 and 125,000 shares, respectively. The amounts of these stock option grants were awarded in recognition of each individual's outstanding performance and determined by the Compensation Committee through its collective understanding of compensation practices in the biotechnology and specialty pharmaceutical industry.

Stock options granted to NEOs under the various stock plans generally have a four or five-year vesting schedule in order to provide an incentive for continued employment and generally expire ten years from the date of the grant. This provides a reasonable time frame in which to provide the executive officer with the possibility of price appreciation of the Company's shares. The exercise price of options granted under the stock plans is 100% of the fair market value of the underlying stock on the date of grant.

The Company grants all stock option awards based on the fair market value as of the date of grant. The Company does not have a policy of granting stock option awards at other than the fair market value. The exercise price for stock option grants is determined by looking at the fair market value of the last quoted price per share on the Nasdaq Capital Market on the date of grant. The Company does not have a policy and does not intend to have a policy or practice to select option grant dates for executive officers in coordination with the release of material non-public information.

### **Defined Contribution Plans**

The Company has a Section 401(k) Savings/Retirement Plan (the "401(k) Plan") to cover eligible employees of the Company and any designated affiliate. The 401(k) Plan permits eligible employees of the Company to defer up to 100% of their annual compensation, subject to certain limitations imposed by the Internal Revenue Code. The employees' elective deferrals are immediately vested and non-forfeitable upon contribution to the 401(k) Plan. The Company currently makes no matching contributions to the 401(k) Plan. Employees of the Company are eligible to participate in the 401(k) Plan on the first day of the month coinciding with or immediately following the first day of employment.

### **Severance and Change in Control Arrangements**

On July 24, 2007, the Company entered into Severance and Change in Control Agreements with each of its executive officers: Joseph K. Belanoff, M.D., Chief Executive Officer; Robert L. Roe, M.D., President; and Anne M. LeDoux, Chief Accounting Officer. The terms of the agreements are identical. The agreements provide that, if employment is terminated without cause or for good reason regardless of whether it is in connection with a

## **Table of Contents**

change in control, the executive will be eligible for 12 months of his or her then current base salary and continued health insurance coverage for this same period. In addition, the agreements provide for the full vesting of all outstanding equity awards in the event the executive's employment is terminated without cause or for good reason within 18 months following a change in control. The agreement with Dr. Roe supersedes his prior agreement with the Company. The other officers did not have prior employment or severance agreements.

On July 24, 2007, the Company also entered into a Severance and Change in Control Agreement with James N. Wilson, Chairman of the Board of Directors. The agreement with Mr. Wilson provides that if his employment or service on the Board terminates involuntarily without cause or good reason within eighteen months of a change in control all of his outstanding equity awards shall become fully vested. Mr. Wilson did not have a prior severance agreement.

These severance and change in control arrangements are designed to retain these executives in these key positions as the Company competes for talented executives in the marketplace where such protections are commonly offered. These arrangements provide benefits to encourage the executives to continue to provide necessary or desirable service to the company during a change in control and to ease the transition of the executives due to an unexpected employment termination by the Company due to changes in the Company's employment needs.

### **Other Elements of Compensation and Perquisites**

*Medical Insurance.* The Company, at its sole cost, provides to each employee (including each NEO), and his or her spouse and children such health, dental and optical insurance as the Company may from time to time make available to its other employees of the same level of employment. Such insurance programs are part of an overall broad-based total compensation program designed to facilitate the Company's ability to attract and retain employees as the Company competes for talented individuals in the marketplace where such benefits are commonly offered.

*Life and Disability Insurance.* The Company provides each employee (including each NEO) such disability and/or life insurance as the Company in its sole discretion may from time to time make available to its other employees of the same level of employment. Such insurance programs are part of an overall broad-based total compensation program designed to facilitate the Company's ability to attract and retain employees as the Company competes for talented individuals in the marketplace where such benefits are commonly offered.

### **Policies with Respect to Equity Compensation Awards**

The Company grants all stock option awards based on the fair market value as of the date of grant. The Company does not have a policy of granting stock option awards at other than the fair market value. The exercise price for stock option grants is determined by looking at the fair market value of the last quoted price per share on the Nasdaq Global Market on the date of grant. The Company does not have a policy and does not intend to have a policy or practice to select option grant dates for executive officers in coordination with the release of material non-public information.

The following tables and descriptive materials set forth information concerning compensation earned for services rendered to the Company by its Chief Executive Officer (the CEO), Chief Financial Officer (the CFO), Chief Accounting Officer (the CAO) and the Company's other executive officer for fiscal year 2007 whose salary and bonus for the fiscal year 2007 exceeded \$100,000. The data for the Chief Financial Officer is included for 2006 and through mid-April 2007, at which time Mr. Kurland resigned. Collectively, together with the CEO and CAO, these are the named executive officers for the respective years.



**Table of Contents****Summary Compensation Table**

The following table provides compensation information for the years ended December 31, 2007 and 2006 for each of our named executive officers.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards <sup>(1)</sup> (\$)	Non-Equity Incentive Plan Compensation (\$)	Change in Pension Value and Nonqualified Deferred Compensation Earnings (\$)	All Other Compen- sation (\$)	Total (\$)
Joseph K. Belanoff, M.D., Chief Executive Officer	2007	\$ 411,008	\$ 102,752		\$ 1,130,000				\$ 1,643,760
	2006	\$ 395,200							\$ 395,200
Robert L. Roe, M.D., President	2007	\$ 378,776	\$ 95,294		\$ 791,000			2,400	\$ 1,267,470
	2006	\$ 364,208			\$ 181,500			2,325	\$ 548,033
Anne LeDoux, Vice President and Controller <sup>(2)</sup> (Chief Accounting Officer	2007	\$ 191,777	\$ 47,944		\$ 141,250				\$ 380,971
	2006	(2)	(2)		(2)				(2)
Fred Kurland, Chief Financial Officer <sup>(3)</sup>	2007	\$ 93,408							\$ 93,408
	2006	\$ 257,088			\$ 90,750				\$ 347,838

(1) Refer to Notes 1 Accounting Policies and Estimates Stock-Based Compensation included in Part II Item 8 Financial Statements in the Company's Annual Report on Form 10-K for the relevant assumptions used to determine the valuation of our option awards.

(2) Anne LeDoux promoted to Chief Accounting Officer in April 2007. Compensation earned in 2006 was not in a position as an executive officer.

(3) Fred Kurland resigned from the company effective April 13, 2007.

**Grants of Plan-Based Awards during 2007**

The following table summarizes the grants of stock and option awards we made to the named executive officers in 2007.

Name	Grant Date	Estimated Future Payouts Under Non-Equity Incentive Plan Awards			Estimated Future Payouts Under Equity Incentive Plan Awards			All Other Stock Awards: Number of Shares of Stock or Units (#)	All Other Option Awards: Number of Number of Securities Underlying Options <sup>(1)</sup> (#)	Exercise or Base Price of Option Awards (\$/Sh)	Grant Date Fair Value of Stock and Option Awards (\$)
		Threshold (\$)	Target (\$)	Maximum (#)	Threshold (#)	Target (#)	Maximum (#)				
Joseph K. Belanoff, M.D.	04/16/07								1,000,000 <sup>(2)</sup>	\$ 1.50	\$ 1,130,000
Robert L. Roe, M.D.	04/16/07								700,000 <sup>(2)</sup>	\$ 1.50	\$ 791,000
Anne LeDoux	04/16/07								125,000 <sup>(2)</sup>	\$ 1.50	\$ 141,250

(1) Refer to Notes 1 Accounting Policies and Estimates Stock-Based Compensation included in the Part II Item 8 Financial Statements in the Company's Annual Report on Form 10-K for the relevant assumptions used to determine the valuation of our option awards.

(2) The options were granted under the Company's 2004 Equity Incentive Plan.



**Table of Contents****Outstanding Equity Awards At Fiscal Year-End**

The following table summarizes unexercised options that have not vested and related information for each of our named executive officers as of December 31, 2007.

Name	Option Awards					Stock Awards			Equity Incentive Plan
	Number of Securities Underlying Unexercised Options	Number of Securities Underlying Unexercised Options	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested	Market Value of Shares or Units of Stock That Have Not Vested	Equity Incentive Plan Awards: Number of Shares, Units or Other Rights That Have Not Vested	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested
							(\$)	(\$)	(\$)
Joseph K. Belanoff, M.D.	166,672 <sup>(3)</sup>	833,328		\$ 1.50	4/16/2017				
Robert L. Roe, M.D.	10,000 <sup>(1)</sup>			\$ 0.10	10/1/2010				
	81,790 <sup>(1)</sup>	18,210		\$ 7.00	11/23/2013				
	56,740 <sup>(1)</sup>	43,260		\$ 4.82	2/10/2015				
	21,875 <sup>(2)</sup>	28,125		\$ 4.95	3/2/2016				
	116,670 <sup>(3)</sup>	583,330		\$ 1.50	4/16/2017				
Anne M. LeDoux	12,862 <sup>(1)</sup>	4,648		\$ 12.00	4/16/2014				
	26,953 <sup>(1)</sup>	15,547		\$ 7.73	10/6/2014				
	6,757 <sup>(1)</sup>	8,243		\$ 5.70	9/23/2015				
	20,834 <sup>(3)</sup>	104,166		\$ 1.50	4/16/2017				

(1) The option vests at the rate of 20% at the first anniversary of the grant date and, thereafter, at the rate of 1.67% per month, until fully vested.

(2) The option vests at the rate of 25% at the first anniversary of the grant date and, thereafter, at the rate of 2.0834% per month, until fully vested.

(3) The option vests at the rate of 2.0834% per month until fully vested.

**Option Exercises and Stock Vested**

None of our named executive officers exercised stock options during 2007. To date, no stock awards have been granted to any of our named executive officers.

**Pension Benefits**

None of our named executive officers participate in or have account balances in qualified or non-qualified defined benefit plans sponsored by us.

**Nonqualified Deferred Compensation**

None of our named executives participate in or have account balances in non-qualified defined contribution plans or other deferred compensation plans maintained by us.

**Potential Payments Upon Termination or Change of Control****Severance and Change of Control Agreements**

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On July 24, 2007, the Company entered into Severance and Change in Control Agreements with each of its executive officers: Joseph K. Belanoff, M.D., Chief Executive Officer; Robert L. Roe, M.D., President; and Anne M. LeDoux, Chief Accounting Officer. The terms of the agreements are identical. The agreements provide

**Table of Contents**

that, if employment is terminated without cause or for good reason regardless of whether it is in connection with a change in control, the executive will be eligible for 12 months of his or her then current base salary and continued health insurance coverage for such 12-month period. In addition, the agreements provide for the full vesting of all outstanding equity awards in the event the executive employment is terminated without cause or for good reason within 18 months following a change in control. The agreement with Dr. Roe supersedes his prior agreement with the Company. The other executive officers did not have prior employment or severance agreements.

On July 24, 2007, the Company also entered into a Severance and Change in Control Agreement with James N. Wilson, Chairman of the Board of Directors. The agreement with Mr. Wilson provides that if his employment or service on the Board terminates involuntarily without cause or good reason within eighteen months of a change in control all of his outstanding equity awards shall become fully vested. Mr. Wilson did not have a prior severance agreement.

The following table reflects compensation payable to each named executive officer under a change of control or various employment termination events. The amounts shown below assume that (i) a change of control of the Company or (ii) each named executive officer terminated employment with the Company, was effective as of December 31, 2007, and estimates the value to the named executive officer as a result of each triggering event.

Name	Benefit	Termination Without Cause <sup>(1)</sup>	Involuntary Termination Other Than for Death, Disability or Cause Within 18 Months of Change of Control
Joseph K. Belanoff, M.D.	Base Salary	\$ 411,008	\$ 411,008
	Accelerated Vesting, of Stock Options <sup>(2)(3)</sup>		\$ 1,324,992
	Health Benefit	\$ 10,580	\$ 10,580
Robert L. Roe, M.D.	Base Salary	\$ 378,776	\$ 378,776
	Accelerated Vesting, of Stock Options <sup>(2)(3)</sup>		\$ 927,495
	Health Benefit	\$ 770	\$ 770
Anne M. LeDoux	Base Salary	\$ 200,000	\$ 200,000
	Accelerated Vesting, of Stock Options <sup>(2)(3)</sup>		\$ 165,624
	Health Benefit	\$ 13,503	\$ 13,503

(1) Assumes that the stock options were not assumed or substituted by the successor entity to the Company or a parent or subsidiary of the successor entity.

(2) Assumes that the stock options were not assumed or substituted by the successor entity to the Company or a parent or subsidiary of the successor entity.

(3) For unvested options held by named executive officers as of December 31, 2007, the value ascribed to the change of control acceleration features under the Severance and Change of Control Agreements is calculated as follows:

- a. For options where the exceeded the closing stock price for the Company's common stock on the Nasdaq Stock Market as of that date exceeded the exercise price of the options, the value represents the difference between these factors multiplied by the number of unvested options as of December 31, 2007.
- b. There is no value ascribed to option for which the exercise price of the options exceeded the closing stock price for the Company's common stock on the Nasdaq Stock Market as of December 31, 2007.

**Table of Contents****DIRECTOR COMPENSATION**

The following table provides compensation information for the one year period ended December 31, 2007, for each member of our Board of Directors.

Name	Fees Earned or		Option Awards (\$) <sup>(4)</sup>	Non-Equity Incentive Plan Compensation (\$)	Change in Pension Value and Nonqualified Deferred Compensation	All Other Compensation (\$)	Total (\$)
	Paid in Cash (\$)	Stock Awards (\$)			Earnings (\$)		
James N. Wilson <sup>(2)</sup>	\$						
Allen Andersson	\$ 7,500		\$ 141,400 <sup>(5)</sup>				\$ 148,900
Joseph K. Belanoff, M.D. <sup>(3)</sup>							
G. Leonard Baker, Jr.	\$ 15,000		\$ 57,300 <sup>(6)</sup>				\$ 72,300
Joseph C. Cook, Jr. <sup>(1)</sup>	\$ 25,000		\$ 28,650 <sup>(6)</sup>				\$ 53,650
James A. Harper <sup>(1)</sup>	\$ 15,000		\$ 28,650 <sup>(6)</sup>				\$ 43,650
David L. Mahoney <sup>(1)</sup>	\$ 25,000		\$ 57,300 <sup>(6)</sup>				\$ 82,300
Alix Marduel, M.D.	\$ 15,000		\$ 28,650 <sup>(6)</sup>				\$ 43,650
Alan F. Schatzberg <sup>(7)</sup>	\$ 7,500						\$ 7,500
David							