

CORCEPT THERAPEUTICS INC

Form 10-K

April 02, 2007

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, 2006

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**

*(State or other jurisdiction of incorporation or organization)*

**149 Commonwealth Drive**

**Menlo Park, CA 94025**

*(Address of principal executive offices, including zip code)*

**77-0487658**

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

---

**(650) 327-3270**

*(Registrant's telephone number, including area code)*

---

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

<b>Title of Each Class:</b>	<b>Name of Each Exchange on which Registered:</b>
Common Stock, \$0.001 par value	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

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 \$38,000,000 as of June 30, 2006 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 30, 2007 there were 34,731,766 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, 2006**

	<b>Page</b>
<b><u>PART I</u></b>	
ITEM 1. <u>Business</u>	1
ITEM 1A. <u>Risk Factors</u>	18
ITEM 1B. <u>Unresolved Staff Comments</u>	34
ITEM 2. <u>Properties</u>	34
ITEM 3. <u>Legal Proceedings</u>	34
ITEM 4. <u>Submission of Matters to a Vote of Security Holders</u>	34
<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>	35
ITEM 6. <u>Selected Financial Data</u>	38
ITEM 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	39
ITEM 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	48
ITEM 8. <u>Financial Statements and Supplementary Data</u>	49
ITEM 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	49
ITEM 9A. <u>Controls and Procedures</u>	49
ITEM 9B. <u>Other Information</u>	49
<b><u>PART III</u></b>	
ITEM 10. <u>Directors and Executive Officers and Corporate Governance</u>	50
ITEM 11. <u>Executive Compensation</u>	54
ITEM 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	64
ITEM 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	65
ITEM 14. <u>Principal Accounting Fees and Services</u>	66
<b><u>PART IV</u></b>	
ITEM 15. <u>Exhibits, Financial Statement Schedules</u>	67

**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.*

*Our current capital is not sufficient to fund operations beyond early 2008. We need additional capital in order to continue operations and capital may not be available to us at all or on favorable terms.*

*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**

Corcept 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.

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

Our lead product candidate, 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. We have been granted fast track status by the United States Food and Drug Administration, or FDA, and, in the last two and one half years ran three double-blind studies to test the efficacy of CORLUX for the treatment of the psychotic features of psychotic major depression, or PMD. These three clinical trials have been completed. The primary endpoint was not met in any of these trials but the results were sufficiently instructive to enable the company to design a Phase 3 trial that we believe will demonstrate the efficacy of CORLUX in this indication. We expect to initiate this trial later in 2007.

## **Table of Contents**

In the first quarter of 2006, we initiated a proof-of-concept clinical study evaluating the ability of CORLUX to mitigate weight gain associated with the use of Zyprexa® (olanzapine), a commercially successful antipsychotic medication.

PMD is a serious psychiatric disorder that affects approximately three million people annually in the United States. It is more prevalent than either schizophrenia or bipolar I disorder. PMD is characterized by severe depression accompanied by psychosis (delusions and/or hallucinations). People with PMD are approximately 70 times more likely to commit suicide in their lifetime than the general population and often require lengthy and expensive hospital stays.

There is no FDA-approved treatment for PMD. However, there are two treatment approaches for PMD currently used by psychiatrists: electroconvulsive therapy, or ECT, commonly referred to as electroshock therapy, and combination drug therapy. ECT involves passing an electrical current through the brain until the patient has a seizure. Combination drug therapy involves the simultaneous use of antidepressant and antipsychotic medications. Both ECT and combination drug therapy almost always have slow onsets of action and debilitating side effects.

We have an exclusive license to the patent for the use of GR-II antagonists to treat the psychotic features of PMD. 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. These include patents for the use of GR-II antagonists for the treatment of weight gain following treatment with antipsychotic medication, early dementia, such as early dementia associated with Alzheimer's disease, mild cognitive impairment, stress disorders and psychosis associated with cocaine addiction. We have also filed patent applications for additional diseases that may benefit from treatment with a drug that blocks the GR-II receptor.

Once we obtain FDA approval, we initially intend to market and sell CORLUX for PMD 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 PMD 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.

### **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 PMD patients 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 PMD patients 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

## **Table of Contents**

with antidepressant medications, could be useful in treating PMD. 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 PMD. 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 PMD.

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 disease states, particularly PMD. 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 PMD patients because it allowed for a specific target for a potential medication. CORLUX, also known as mifepristone or RU-486, works by 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 Major Depression**

PMD 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.

PMD 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 PMD. Most PMD patients 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.

## **Table of Contents**

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

reluctance on the part of patients with PMD 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 PMD.

### **Current Treatments for PMD**

There are two treatment approaches for PMD currently used by psychiatrists: ECT and combination drug therapy. Neither of these treatments has been approved by the FDA for PMD 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 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 PMD 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 PMD, as such a medication would substantially reduce the length of suffering associated with the illness. We believe that people suffering from PMD would prefer a treatment that did not involve the risks of anesthesia and stigma associated with ECT or the adverse side effects and 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 PMD patients would choose that alternative.

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

CORLUX is an oral medication that we are developing to treat the psychotic features of PMD. CORLUX is a GR-II antagonist that appears to mitigate the effects of the elevated and abnormal release patterns of cortisol in PMD patients. We intend CORLUX to be a once-daily treatment given to PMD patients 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 PMD 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



## **Table of Contents**

because we believe that CORLUX will enable PMD patients to improve their quality of life more quickly and with fewer side effects than with ECT or combination drug therapy.

### **CORLUX for PMD 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 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:** This is an instrument designed to measure the severity of a number of depressive symptoms such as insomnia, depressed mood, concentration, ability 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 (Corcept 07) and October 2004 (Corcept 06) and an additional Phase 3 trial in Europe in the second quarter of 2005 (Corcept 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 PMD:

In 2001, we completed our first trial, a dose finding clinical trial evaluating the efficacy, tolerability and dose response of CORLUX for the treatment of the psychotic features of PMD. 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. 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 PMD. 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.



**Table of Contents**

*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	600 mg Dose	1200 mg Dose	600 mg and 1200 mg Dose Groups Combined
	Group	Group	Group	Group
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 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 PMD are contained in the BPRS positive symptom subscale. Every PMD patient 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 positive symptom subscale 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 PMD. 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 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

---

**Table of Contents**

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 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 PMD. Two of these trials (Study 06 and Study 07) were conducted primarily in the United States. The third trial

## **Table of Contents**

(Study 09) was conducted in Europe. The design of all three trials was based on the design of Study 03, described above.

Study 06 and Study 07 were covered by Special Protocol Assessments, or SPAs, from the FDA. The SPA is a process that provides for an official FDA evaluation of Phase 3 clinical study protocols. The SPA provides trial sponsors with binding written agreement that the design and analysis of the studies are adequate to support a license application submission if the study is performed according to the SPA and the results are successful. The SPA agreement may only be changed by the sponsor company or the FDA by a written agreement, or if the FDA becomes aware of a substantial scientific issue essential to product efficacy or safety.

The primary endpoint for each of 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. Both of these endpoints are known as categorical improvements. 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 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 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 PMD. We do not expect to be able to use Study 07 as one of the two positive efficacy trials required by the FDA for a fileable New Drug Application, or NDA.

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.

---

**Table of Contents**

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. We do not know, however, whether the populations represented by the group of 215 or the group of 42 more accurately demonstrate the activity of CORLUX. We continue to analyze the data from this trial to determine reasons for this site by treatment effect.

An important teaching from Study 07 derives from a post hoc 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. A post hoc analysis examines the data for relationships not designated before the study began. Patients with CORLUX plasma levels higher than 1650 nanograms per milliliter had statistically significantly greater response rates observed than did patients who received placebo. The response rate on the primary endpoint in patients with plasma concentrations of CORLUX of less than 1650 nanograms per milliliter did not statistically separate from the response rates observed in 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 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% 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

## **Table of Contents**

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.

*Upcoming Phase 3 trial.* We believe that the confirmation of a drug concentration threshold for efficacy, as well as other observations from Study 06 and the company's two other recently completed Phase 3 clinical trials, will serve as a strong basis for the company's next Phase 3 study which is planned to commence later in 2007. The protocol for this trial will incorporate the learnings from the three completed trials that address the sensitivity of the model and decrease the random variability observed in the results of the psychometric instruments used to measure efficacy. We intend to meet with the FDA to discuss and seek input concerning the design of this trial. In this trial we expect to use 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 threshold concentration. In Study 06, 80% of the patients achieved a drug plasma level sufficient for a strong clinical response at that dose. 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. We believe that this change in dose as well as other modifications to the protocol should allow us to definitively demonstrate the efficacy of CORLUX in the treatment of the psychotic symptoms of PMD.

Given the serious nature of PMD, 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 PMD. In addition, the FDA has indicated that CORLUX will receive a priority review if no other treatment is approved for PMD 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.* We have clinical development agreements covering the conduct of our Phase 3 clinical trials of CORLUX with Premier Research (formerly Scirex Corporation) (Premier), PPD Development, LP (PPD), and i3 Research, an Ingenix Company (i3), under which these organizations, at our request, oversee clinical trials at various institutions to test the safety and efficacy of CORLUX for the psychotic features of PMD. The Premier and PPD agreements may be terminated by us at any time upon thirty days' written notice. The i3 agreement may be terminated by us at any time upon 45 days' written notice.

## Table of Contents

### **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 PMD, we own or have exclusively licensed issued patents for the use of GR-II antagonists to treat:

weight gain following treatment with antipsychotic medication;

early dementia, including early Alzheimer's disease;

mild cognitive impairment;

the prevention and treatment of stress disorders; and

psychosis associated with cocaine addiction.

We believe that cortisol plays a role in a variety of other diseases. We have ten 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.*

*Alzheimer's disease.* We announced in September 2005 that we closed enrollment in a clinical proof-of-concept study evaluating the safety and efficacy of 4 months of CORLUX treatment to improve cognition in patients with mild to moderate Alzheimer's disease. Patients in this trial were dosed with an acetylcholinesterase inhibitor, medications that are routinely prescribed for patients with Alzheimer's disease, and CORLUX or placebo. The study protocol prohibited the concomitant use of Namenda (memantine), a recently approved treatment for Alzheimer's disease which was commercialized after the trial was initiated. Because a large number of Alzheimer's disease patients are now treated with the combination of Namenda and an acetylcholinesterase inhibitor, enrollment in our study slowed significantly. The study had enrolled 80 patients when enrollment was closed. It was originally designed to enroll 160 patients. The study was not powered to show statistically significant results with only 80 patients. Analysis of the data demonstrated that no discernable change in cognition occurred in the CORLUX treated patients. Review of the safety data from the trial revealed no serious safety findings. A post-hoc analysis identified weight reduction in obese patients as a possible effect of CORLUX treatment.

*Mitigation of antipsychotic medication induced weight gain.* In October 2005, we announced that we signed an agreement with Eli Lilly and Company (Lilly) in which Lilly agreed to support our proof-of-concept clinical study evaluating the ability of CORLUX to mitigate weight gain associated with the use of Zyprexa, one of six commercially available medications of the class of drugs known as atypical antipsychotics. The labels of all of the drugs in this class contain a warning for hyperglycemia and diabetes mellitus, both associated with weight gain. This study is being conducted in healthy male volunteers of normal weight.

Under the agreement, Lilly will supply Zyprexa and pay for the study. Data resulting from the study will be shared with Lilly. Neither we nor Lilly intend to pursue commercially the use of CORLUX and olanzapine in combination for the treatment of antipsychotic medication-induced weight gain. The purpose of this study is to explore the mechanism of action of GR-II antagonists for mitigating weight gain associated with atypical antipsychotic medications. Although initially placed in a small clinical research organization in the U.S., we stopped the study there, made minor modifications to the protocol and initiated the study at a site in Bangalore, India, in part to enhance the availability of male subjects of normal weight and have made minor changes in the protocol. We began screening patients in March 2007 and expect to report the results of this study at the end of the second quarter of 2007.

In May 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.





## **Table of Contents**

### **Discovery Research**

In early 2002, 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 series of GR-II antagonists that, like CORLUX, block the GR-II receptor but, unlike CORLUX, do not block the progesterone receptor. These compounds bind to the GR-II receptor with a potency similar to that of CORLUX. We have concluded the contract with the U.K.-based contract research organization and are currently evaluating which compound or compounds we intend to move toward an Investigational New Drug application (IND). We hope to initiate human clinical trials under an exploratory IND with the selected compound or compounds late in 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 PMD in the United States is highly concentrated and accessible. We anticipate that this will include hiring a small, experienced field 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 a majority of ECT procedures. Subsequently, we also intend to expand our commercialization efforts to address the larger set of PMD patients 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 PMD beyond patients currently treated by ECT and combination drug therapy. A large portion of the people who suffer from PMD remain unrecognized and undertreated. We intend to develop medical educational programs to alert the medical community about early diagnosis of PMD 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 Synthèse 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.

## **Table of Contents**

### **Competition**

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

ECT has been shown to be the most effective treatment for PMD, despite the risks of anesthesia and the adverse effects and 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 will be companies that market antipsychotic drugs that are used off-label as part of combination drug therapy for PMD. To reduce the psychotic features of PMD, 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 thioridazine, Schering Corporation's Trilafon and Eli Lilly's Zyprexa.

We are aware of one clinical trial, conducted by the pharmaceutical division of Akzo Nobel, for a new chemical entity for the treatment of PMD. 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 PMD, 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. We are not aware of any public disclosures by any company, other than Akzo Nobel, regarding the development of new medicinal products to treat PMD. However, other companies may be developing new drug products to treat PMD 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.

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 PMD	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, including early Alzheimer's disease	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 our CORLUX license or other 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 PMD or develop mifepristone as a treatment for early dementia, including early Alzheimer's disease.

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 and for the treatment of delirium. In addition, we have three U.S. composition of matter patent applications covering specific GR-II antagonists and nine U.S. method of use patent applications covering certain GR-II antagonists for increasing the therapeutic response to ECT, preventing neurological damage in premature infants and for the treatment of:

migraine;

postpartum psychosis;

antidepressant induced weight gain;

catatonia;

psychosis associated with interferon-alpha therapy;

gastroesophageal reflux disease; and

Down's syndrome.

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.

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

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 administering physicians for use of mifepristone to terminate pregnancy and may impose similar restrictions on CORLUX for the treatment of the

## **Table of Contents**

psychotic features of PMD. 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, (3) the different patient populations, administering physicians and treatment settings between the use of mifepristone to terminate pregnancy and to treat PMD and (4) the likely denial of reimbursement for off-label uses of mifepristone to provide us an exclusive market position for the term of our use patent for the treatment of the psychotic features of PMD.

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 PMD. 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 PMD. 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 PMD and for the treatment of early dementia, we are required to pay Stanford \$50,000 annually as a nonrefundable royalty payment. This payment is creditable against future royalties. We are also obligated to pay Stanford a \$50,000 milestone upon the filing of the NDA for CORLUX for the treatment of PMD 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

## **Table of Contents**

of a new drug, approval by the FDA of an NDA. The process of complying with these and other federal and state statutes and regulations in order to obtain the necessary approvals and subsequently complying with federal and state statutes and regulations involves significant time and expense.

Preclinical studies are generally conducted in laboratory animals to evaluate the potential safety and the efficacy of a product. Drug developers submit the results of preclinical studies to the FDA as a part of an IND, which must be approved before beginning clinical trials in humans. Typically, human clinical trials are conducted in three sequential phases that may overlap.

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

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

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

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

After Phase 3 trials are completed, drug developers submit the results of preclinical studies, clinical trials, formulation studies and data supporting manufacturing to the FDA in the form of a new drug application 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

## **Table of Contents**

requirement that future advertising and promotional materials be pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions.

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

*Approvals outside the United States.* We have not started the regulatory approval process in any jurisdiction other than the United States and we are unable to estimate when, if ever, we will commence the regulatory approval process in any foreign jurisdiction. We 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 PMD. 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.

## **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, 2006, we had 11 full-time employees, three part-time employees and six long-term contract staff. Three of our full-time 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.



## **Table of Contents**

### **ITEM 1A RISK FACTORS**

*An investment in our common stock involves significant risks. In addition to other information in this report, 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 actually occur, our business, prospects, financial condition and results of operations 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. Additional risks and uncertainties of which we are unaware or that we currently deem immaterial may also become important factors that affect us. Except as required by law, we undertake no obligations to update any risk factors.*

#### **Risks Related to Our Business**

**Our current capital is not sufficient to fund operations beyond early 2008. We need additional capital in order to continue operations and capital may not be available to us at all or on favorable terms.**

We expect that our existing cash resources will not be sufficient to fund our operations beyond early 2008. Our cash and marketable securities have enabled us to complete the third of our three Phase 3 clinical studies evaluating our lead product candidate, CORLUX, for treating the psychotic features of PMD. However, we do not have sufficient funds to maintain our current infrastructure beyond the completion and reporting of results of the proof-of-concept weight-gain mitigation study and to prepare for our next Phase 3 trial. We will require substantial additional funding in the form of public or private equity offerings, debt financings, strategic partnerships and/or licensing arrangements in order to continue our operations.

Additional financing may not be available on acceptable terms or at all. We believe that our ability to secure substantial additional funding will depend largely on investors' acceptance of our business plan going forward, which includes the completion of a fourth Phase 3 clinical trial in PMD, opportunities that may be created by the results of the proof-of-concept mitigation of atypical antipsychotic induced weight gain trial and the development of our new chemical entities.

If we are unable to raise additional funds, we may, among other things, be required to delay, reduce the scope of or eliminate one or more of our research or development programs or to obtain funds through collaborations with others that are on unfavorable terms or that may require us to relinquish certain rights to our technologies or products, including potentially our lead product candidate, that we would otherwise seek to develop on our own; or we may be required to discontinue operations.

Even if we are successful in raising funds in the near term, we will need to raise substantial additional funds to complete the development of and the potential commercialization of CORLUX for PMD and for other development programs. We may choose to raise additional capital at any time based on market conditions or strategic considerations even if we believe we have raised sufficient funds for our current or future operating plans. Additional financing may be dilutive to stockholders, may involve the relinquishment of valuable rights, and may involve restrictive covenants.

**We will depend heavily on the success of our lead product candidate, CORLUX for the treatment of the psychotic features of PMD, 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, 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. We currently do not have any commercial products and we anticipate that for the foreseeable future our ability to generate revenues and achieve profitability will be solely dependent on the

## Table of Contents

successful development, approval and commercialization of CORLUX. We have completed three Phase 3 clinical trials evaluating CORLUX for the treatment of the psychotic features of PMD. None of the first three trials met its primary or key secondary endpoints. The FDA generally requires at least two positive Phase 3 studies prior to the submission of an NDA. 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 PMD;

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 that could limit the market acceptance of CORLUX.

**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 PMD does not demonstrate safety and efficacy, our business will be harmed.**

To gain regulatory approval from the FDA to market CORLUX for the treatment of the psychotic features of PMD, our Phase 3 clinical trials must demonstrate the safety and efficacy of CORLUX for this treatment. Our first three Phase 3 studies did not meet their primary or key secondary endpoints. In addition to the need for additional Phase 3 clinical trials, 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. Favorable results of preclinical studies and initial clinical trials of CORLUX are not necessarily indicative of the results we will obtain in later clinical trials. While we obtained favorable results in our Phase 2 clinical trials program, 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 may require additional, expensive clinical and preclinical trials. We may not be able to finance the development program.**

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

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 did not meet their primary endpoints, the FDA will require us to pursue additional clinical trials to demonstrate the safety and/or efficacy of CORLUX. The FDA generally requires at least two positive Phase 3 studies 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

## Table of Contents

complete an NDA. Although our cash and marketable securities have enabled us to complete our ongoing Phase 3 trials, we will need to raise additional funds for our research and development and general and administrative activities in 2007 and subsequent years. We believe that our ability to secure substantial additional funding in the near term will depend largely on investors' acceptance of our business plan going forward, which includes a Phase 3 clinical trial in PMD and the development of our new chemical entities. We cannot be certain that additional funding will be available on acceptable terms or at all. Our inability to raise capital will result in a delay of the performance of these activities and harm our business and product development efforts. Without additional funding we will not be able to continue the company's operations beyond early 2008.

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. 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 PMD.

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 or to obtain funds through collaborations with others that are on unfavorable terms or that 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 if funds are available, additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants. 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 PMD. 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, 2006, we had an accumulated deficit of approximately \$98.4 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.



## **Table of Contents**

**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 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 contracted with Premier Research (formerly Scirex Corporation), PPD Development, LP, (PPD), and i3 Research, an Ingenix Company (i3), to monitor clinical site performance and to perform investigator supervision, data collection and analysis in Study 06. We may not be able to maintain these relationships with Premier Research, PPD or i3 or with the clinical sites without excessive expenditures. Our agreements with clinical investigators and clinical sites for clinical testing and with Premier Research, PPD and i3 for trial management services 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 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 clinical research organizations and investigative research sites. The conduct, timing and cost of these trials will be subject to the same kinds of risks as discussed above.

**The contracts for our European trial activities are denominated in Euros and we bear the currency rate exposure for the cost of these trials.**

We have engaged a contract research organization to assist in the conduct of our clinical trial activity in Europe. The costs of these trials are denominated in Euros, which the vendor converts into U.S. dollars for invoicing as costs are incurred on a monthly basis. Thus, we bear some currency rate exposure for the costs of these activities. European trial activity is expected to be conducted through the second quarter of 2007. The timing of payments will depend upon various factors including the timing of final reporting of trial results and the final payments of pass-through costs, such as grants to investigators and laboratory services. All European trial activities are being conducted under a master agreement that provides for termination by us with forty-five days notice.

**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.

---

## **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.

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 PMD 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 Investigational New Drug Application, or 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

## **Table of Contents**

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 PMD, we may not experience a faster development process, review or approval compared to applications considered for approval under conventional FDA procedures. In addition, the FDA may withdraw our fast track designation at any time. If we lose our fast track designation, the approval process may be delayed. In addition, our fast track designation does not guarantee that we will qualify for or be able to take advantage of the expedited review procedures and does not increase the likelihood that CORLUX will receive regulatory approval for the treatment of the psychotic features of PMD.

**Even if we receive approval for the marketing and sale of CORLUX for the treatment of the psychotic features of PMD, it may never be accepted as a treatment for PMD.**

Many factors may affect the market acceptance and commercial success of CORLUX for the treatment of the psychotic features of PMD. Although there is no FDA-approved treatment for PMD, there are two treatment approaches currently used by psychiatrists: electroconvulsive therapy, or ECT, and combination medicinal therapy. Even if the FDA approves CORLUX for the treatment of the psychotic features of PMD, 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 will be essential for market acceptance of CORLUX.

Other factors that may affect the market acceptance and commercial success of CORLUX for the treatment of the psychotic features of PMD 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 insurance or other third-party reimbursement, in particular 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 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.

---

## **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;

our reputation in the marketplace may suffer; and

we may become the target of lawsuits, including class action lawsuits.

## **Table of Contents**

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 PMD 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 four 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 nine 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 PMD, 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 PMD and Alzheimer's disease and our business would be materially harmed.

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 PMD. In 2005, we filed a rebuttal to 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.

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

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

---

**Table of Contents**

**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 PMD 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 PMD 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 PMD. 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 12 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. 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 PMD patients 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 PMD that works through a mechanism which does not involve the GR-II receptor, physicians could prescribe that treatment instead of CORLUX.

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 PMD.

**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 have only recently begun to expand our research and development efforts toward identifying and developing product candidates in addition to CORLUX for the treatment of the psychotic features of PMD. We own or have exclusively licensed issued U.S. patents covering the use of GR-II antagonists to treat PMD, weight gain following treatment with antipsychotic medication, early dementia, mild cognitive impairment, psychosis associated with cocaine addiction, and stress disorders, in addition to ten 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

## **Table of Contents**

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 PMD. In that event, we would have to identify and may need to secure rights to a different GR-II antagonist. For example, we do not intend to develop CORLUX for mitigation of the weight gain associated with the use of olanzapine, even though we have initiated 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 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 announced in 2004 that we had successfully discovered three series of compounds that are specific GR-II antagonists but, unlike CORLUX, do not 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 PMD.

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

We may be subject to product liability or other claims based on allegations that the use of our products has resulted in adverse effects or that our product candidates are not effective, whether by participants in our clinical trials for CORLUX or other product candidates, or by patients using our future products. A product liability claim may damage our reputation by raising questions about our product candidates' safety or efficacy and could limit our ability to sell a product by preventing or interfering with product commercialization. In some cases, less common adverse effects of a pharmaceutical product are not known until long after the FDA approves the product for marketing. The active ingredient in CORLUX is used to terminate pregnancy. Therefore, necessary and strict precautions must be taken by clinicians using the medicine in our clinical trials and, if approved by the FDA, physicians prescribing the medicine to women with childbearing potential, to insure that the medicine is not administered to pregnant women. The failure to observe these precautions could result in significant product claims.

We have only limited product liability insurance coverage, with limits 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

## **Table of Contents**

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.

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

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

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

If resources are made available to continue operations beyond early 2008, we plan to use those resources to expand our research and development efforts and develop a sales and marketing organization when appropriate. In that event, 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, 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 CORLUX is approved and we are unable to obtain acceptable prices or adequate reimbursement for it from third-party payors, we will be unable to generate significant revenues.**

There is significant uncertainty related to the availability of 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. Medicare, 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



---

**Table of Contents**

government and 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 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 PMD.**

If approved for commercial use, CORLUX as a treatment for PMD 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 PMD. The antipsychotics are prescribed for off-label use by physicians to treat the psychotic features of PMD, 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 thioridazine, 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 pharmaceutical division of Akzo Nobel, for a new chemical entity for the treatment of PMD. 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 PMD, 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 PMD. 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 PMD, or any future use, we may be unable to generate the revenues necessary to support our business.

## **Table of Contents**

### **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.

### **If we lose our key personnel or are unable to attract and retain additional skilled personnel, we may be unable to pursue our product development and commercialization efforts.**

We depend substantially on the principal members of our management and scientific staff, including Joseph K. Belanoff, M.D., our Chief Executive Officer, and Robert L. Roe, M.D., our President. We do not have agreements with any of our executive officers that provide for their continued employment with us or employment insurance covering any of our key personnel. Any officer or employee can terminate his or her relationship with us at any time and work for one of our competitors. The loss of these key individuals could result in competitive harm because we could experience delays in our product research, development and commercialization efforts without their expertise.

Our ability to operate successfully and manage our potential future growth depends significantly upon retaining key research, technical, sales, marketing, managerial and financial personnel, and attracting and retaining additional highly qualified personnel in these areas. We face intense competition for such personnel from numerous companies, as well as universities and nonprofit research organizations in the highly competitive northern California business area. Although we believe that we have been successful in attracting and retaining qualified personnel to date, we may not be able to attract and retain sufficient qualified personnel in the future. The inability to attract and retain these personnel could result in delays in the research, development and commercialization of our potential products.

### **If we acquire other GR-II antagonists or other technologies or potential products, we will incur a variety of costs and may never realize the anticipated benefits of the acquisition.**

If appropriate opportunities become available, we may attempt to acquire other GR-II antagonists, particularly GR-II antagonists that do not terminate pregnancy. We may also be able to acquire other technologies or potential products that are complementary to our operating plan. We currently have no commitments, agreements or plans for any acquisitions. The process of acquiring rights to another GR-II antagonist or any other potential product or technology may result in unforeseen difficulties and expenditures and may absorb significant management attention that would otherwise be available for ongoing development of our business. In addition, we may fail to realize the anticipated benefits of any acquired potential product or technology. Future acquisitions could dilute our stockholders' ownership interest in us and could cause us to incur debt, expose us to future liabilities and result in amortization or other expenses related to goodwill and other intangible assets.

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

Because our executive offices are located in the San Francisco Bay Area and some of our current manufacturers are located in earthquake-prone areas, our business is vulnerable to damage from various types of disasters or other similarly disruptive events, including earthquake, fire, flood, power loss and communications failures. In addition, political considerations relating to mifepristone may put us and our manufacturers at increased risk for terrorist attacks, protests or other disruptive events. If any disaster or other similar event were to occur, we may not be able to operate our business and our manufacturers may not be able to produce our product candidates. Our insurance may not be adequate to cover, and our insurance policies may exclude coverage for, our losses resulting from disasters or other business interruptions.

**Table of Contents**

**Risks Related to Our Stock**

**The market price of our common stock may be highly volatile.**

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 30, 2007 our average daily trading volume has been approximately 143,000 shares and the intra-day sales prices per share of our common stock ranged from \$0.68 to \$6.15. 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;

changes in financial estimates or recommendations by securities analysts;

conditions or trends in the biotechnology and pharmaceutical industries;

changes in the market valuations of similar companies;

announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;

additions or departures of key personnel;

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

disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;

developments concerning our collaborations;

trading volume of our common stock;

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.

## **Table of Contents**

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

Our common stock is listed on the Nasdaq Global Market. In order to maintain that listing, we must satisfy minimum financial and other requirements. On November 16, 2006 we received notice from the Nasdaq Global Market that we were not in compliance with two listing requirements.

First, the Nasdaq Stock Market staff notified us that the closing bid price of our common stock had not met the \$1.00 per share minimum requirement for 30 consecutive business days. The closing price of our common stock on the Nasdaq Global Market had been less than \$1.00 for a period of at least 30 business days starting September 29, 2006. On January 11, 2007 the Nasdaq Stock Market staff informed us that we were no longer out of compliance with the minimum closing bid price requirement and that the staff considered the matter closed. Since regaining compliance, the closing bid price of our common stock has remained above \$1.00 in compliance with the minimum bid price requirement.

Second, the Nasdaq Stock Market staff notified us that we were not in compliance with the requirement that stockholders' equity for companies listed on the Nasdaq Global Market should be no less than \$10,000,000. Our third quarter report showed that our stockholders' equity on September 30, 2006 was \$6,978,000. On December 4, 2006, we submitted a plan to regain compliance with the minimum equity requirement which was rejected by the Nasdaq Stock Market staff on December 20, 2006. We appealed the staff's determination of non-compliance on December 27, 2006 and were granted a hearing before the Nasdaq Listings Qualifications Panel on February 15, 2007. We had submitted a revised Plan of Compliance with the minimum stockholders' equity requirement prior to the hearing and discussed this revised plan at the hearing.

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

**A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.**

Sales of a substantial number of shares of our common stock in the public market could harm the market price of our common stock. As additional shares of our common stock become available for resale in the public

## **Table of Contents**

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.

### **Our officers, directors and principal stockholders control a majority of our common stock and will be able to significantly influence corporate actions.**

As of March 30, 2007, our officers, directors and principal stockholders control a majority 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 concentration of ownership may have the effect of delaying or preventing a change in control and might adversely affect the market price of our common stock. In addition, 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.

### **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 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 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. In addition, the independent registered public accounting firm auditing the company's financial statements must attest to and report on management's assessment of the effectiveness of the company's internal controls over financial reporting, as well as the effectiveness of the company's internal controls over financial reporting. This requirement will first apply to our annual report on Form 10-K for our fiscal year ending December 31, 2007. Uncertainty exists regarding our ability to comply with these requirements by applicable deadlines. If we are unable to complete the required assessment as to the adequacy of our internal control reporting 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 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

## **Table of Contents**

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. If we did not reduce our reliance on stock options, our reported losses would increase. Although we believe that our accounting practices are consistent with current accounting pronouncements, changes to or interpretations of accounting methods or policies in the future may require us to reclassify, restate or otherwise change or revise our financial statements.

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

Provisions in our charter and bylaws may delay or prevent an acquisition of us or a change in our management. Some of these provisions divide our board into three classes with only a portion of our directors subject to election at each annual meeting, allow us to issue preferred stock without any vote or further action by the stockholders, require advance notification of stockholder proposals and nominations of candidates for election as directors and prohibit stockholders from acting by written consent. In addition, a supermajority vote of stockholders is required to amend our bylaws. Our bylaws provide that special meetings of the stockholders may be called only by our Chairman, President or the board of directors and that the authorized number of directors may be changed only by resolution of the board of directors. These provisions may prevent or delay a change in our board of directors or our management, which is appointed by our board of directors. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law. Section 203 may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us. These provisions in our charter, bylaws and 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**

Not applicable.

### **ITEM 2. PROPERTIES**

We lease approximately 7,700 square feet of office space in Menlo Park, California for our corporate facilities. The lease has an initial term of 30 months with a commencement date of July 1, 2005 and, provides us with an option to extend for an additional year. 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 2006.

**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 Global 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 Global 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>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

	<b>High</b>	<b>Low</b>
<b>2005</b>		
First Quarter	\$ 6.29	\$ 4.25
Second Quarter	\$ 6.58	\$ 3.41
Third Quarter	\$ 7.00	\$ 4.84
Fourth Quarter	\$ 5.30	\$ 3.63

**Stockholders of Record and Dividends**

As of March 30, 2007, we had 34,731,766 shares of common stock outstanding held by 94 stockholders of record. We have not paid cash dividends on our common stock since our inception and we do not anticipate paying any in the foreseeable future.

**Use of Proceeds from Sale of Registered Securities**

On April 19, 2004, we completed an initial public offering of 4,500,000 shares of our common stock. The shares of common stock sold in the offering were registered under the Securities Act of 1933, as amended, on a Registration Statement on Form S-1 (Reg. No. 333-112676) that was declared effective by the Securities and Exchange Commission on April 14, 2004. After deducting the underwriting discounts and commissions and the estimated offering expenses, we received net proceeds from the offering of approximately \$49.0 million. Between the effective date of the Registration Statement and December 31, 2006, approximately \$39.6 million of the net proceeds was used for research and development activities and approximately \$9.4 million was used for general and administrative activities. The remaining proceeds from the offering have been invested in marketable securities for future use as needed.

**Sale of Unregistered Securities**

On December 15, 2006, the Company sold 3,000,000 shares of Common Stock of Corcept, par value \$0.001, at a price of \$1.00 per share, for aggregate proceeds of \$3,000,000. The investor group was comprised of Paperboy Ventures LLC and Sutter Hill Ventures, both venture capital firms that are currently significant shareholders of the Company, and members of the Company's board of directors, Joseph C. Cook, Jr., David L. Mahoney and James N. Wilson. 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.



## **Table of Contents**

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 December 2006 and March 2007 financings are 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 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 a registration statement with the Securities and Exchange Commission for purposes of registering the resale of certain of the common stock issued in these transactions within two business days following the filing of this Annual Report on Form 10-K.

## **Market Performance Graph**

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 32-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, 2004, 2005, and 2006 and for the period from inception (May 13, 1998) to December 31, 2006 and the balance sheet data as of December 31, 2005 and 2006 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, 2002 and 2003, and the balance sheet data as of December 31, 2002, 2003 and 2004 have been derived from our audited financial statements, which are not included in this Form 10-K. The selected financial data set forth below should be read in conjunction with our financial statements, the related notes and Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Form 10-K.

	Year Ended December 31,					Period from inception
	2006	2005	2004	2003	2002	(May 13, 1998) to December 31, 2006
<i>(In thousands, except per share data)</i>						
<b>Statement of Operations Data:</b>						
Collaboration Revenue	\$ 294	\$	\$	\$	\$	\$ 294
Operating expenses:						
Research and development*	20,834	17,074	11,551	8,223	13,264	77,797
General and administrative*	5,042	4,084	4,494	1,746	5,531	24,273
Total operating expenses	25,876	21,158	16,045	9,969	18,795	102,070
Loss from operations	(25,582)	(21,158)	(16,045)	(9,969)	(18,795)	(101,776)
Non-operating income, net	709	1,065	510	157	291	3,338
Net loss	\$ (24,873)	\$ (20,093)	\$ (15,535)	\$ (9,812)	\$ (18,504)	\$ (98,438)
Net loss per share:						
Basic and diluted	\$ (1.09)	\$ (0.89)	\$ (0.84)	\$ (1.22)	\$ (2.75)	
Weighted average shares basic and diluted	22,841	22,608	18,440	8,069	6,720	
* Includes non-cash stock-based compensation (recovery) of the following:						
Research and development	\$ 535	\$ (26)	\$ 202	\$ 551	\$ 1,957	\$ 4,531
General and administrative	1,013	799	1,475	(308)	2,145	5,804
Total non-cash stock-based compensation	\$ 1,548	\$ 773	\$ 1,677	\$ 243	\$ 4,102	\$ 10,335

**As of December 31,**  
**2006      2005      2004      2003      2002**  
*(In thousands)*

Edgar Filing: CORCEPT THERAPEUTICS INC - Form 10-K

**Balance Sheet Data:**

Cash, cash equivalents and investments	\$ 9,456	\$ 29,619	\$ 46,887	\$ 11,577	\$ 21,543
Working capital	6,286	25,984	36,415	10,729	20,222
Total assets	9,902	30,156	47,772	11,781	21,795
Long-term liabilities	29	42		524	503
Convertible preferred stock				41,716	41,716
Total stockholders' equity (net capital deficiency)	6,360	26,593	45,948	(31,473)	(21,940)

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.

---

**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 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.*

*Our current capital is not sufficient to fund operations beyond early 2008. We need additional capital in order to continue operations and capital may not be available to us at all or on favorable terms.*

*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, targeted for the treatment of the psychotic features of psychotic major depression, or PMD, under an exclusive patent license from Stanford University. 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 PMD. 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 PMD.

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. 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



## Table of Contents

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. 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.

We believe that the confirmation of a drug concentration threshold for efficacy, as well as other observations from Study 06 and the company's other two recently completed Phase 3 clinical trials, will serve as a strong basis for our next Phase 3 study, which is planned to commence later in 2007. The protocol for this trial will incorporate the learnings from the three completed trials that address the sensitivity of the model and decrease the random variability observed in the results of the psychometric instruments used to measure efficacy. We intend to meet with the FDA to discuss and seek input concerning the design of this trial. In this trial we expect to use 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 threshold concentration. In Study 06, 80% of the patients achieved a drug plasma level sufficient for a strong clinical response at that dose. 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. We believe that this change in dose as well as other modifications to the protocol should allow us to definitively demonstrate the efficacy of CORLUX in the treatment of the psychotic symptoms of PMD.

In addition, we initiated two additional Phase 3 clinical trials to evaluate the safety and tolerability of retreatment with CORLUX. The first, Study 10, commenced in the United States in December 2004. The second, Study 13, commenced in Europe in August 2005. We terminated the patient activity related to these clinical trials in the fourth quarter of 2006.

In October 2005, we announced that we had signed an agreement with Eli Lilly and Company, or Lilly, in which Lilly agreed to support our proof-of-concept clinical 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. We have relocated this study to a new site in India and have made minor changes in the protocol. We began screening patients in March 2007 and to report the results of this study at the end of the second quarter of 2007.

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 because we had not generated any revenue through 2005, and do not expect to generate significant revenue for the foreseeable future. As of December 31, 2006, we had an accumulated deficit of approximately \$98.4 million. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for CORLUX, discovery research, non-clinical activities such as toxicology and carcinogenicity studies, manufacturing process development and regulatory activities, as well as general and administrative

## **Table of Contents**

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, expand development of GR-II antagonists for new indications, 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.

Our common stock is listed on the Nasdaq Global Market. In order to maintain that listing, we must satisfy minimum financial and other requirements. On November 16, 2006 we received notice from the Nasdaq Stock Market staff that we were not in compliance with two listing requirements.

First, the Nasdaq Stock Market staff notified us that the closing bid price of our common stock had not met the \$1.00 per share minimum requirement for 30 consecutive business days. The closing price of our common stock on the Global Market had been less than \$1.00 for a period of at least 30 business days starting September 29, 2006. On January 11, 2007, Nasdaq Stock Market staff informed us that we were no longer out of compliance with the minimum closing bid price requirement and that Nasdaq considered the matter closed. Since regaining compliance, the closing bid price of our common stock has remained above \$1.00 in compliance with the minimum bid price requirement.

Second, the Nasdaq Stock Market staff notified us that we were not in compliance with the requirement that stockholders' equity for companies listed on the Nasdaq Global Market should be no less than \$10,000,000. Our third quarter report showed that our stockholders' equity on September 30, 2006 was \$6,978,000. On December 4, 2006, we submitted a plan to regain compliance with the minimum equity requirement which was rejected by the Nasdaq Stock Market staff on December 20, 2006. We appealed the staff's determination of non-compliance on December 27, 2006 and were granted a hearing before the Nasdaq Listings Qualifications Panel on February, 15, 2007. We had submitted a revised Plan of Compliance with the minimum stockholders' equity requirement prior to the hearing and discussed this revised plan at the hearing.

## **Results of Operations**

*Collaboration revenue* Collaboration revenue relates to services rendered in connection with our agreement with Lilly discussed above. Under the agreement, Lilly will supply olanzapine and pay for the budgeted costs of the study. Under the agreement, we are required to perform specified development activities and the fee paid to us by Lilly is based on the costs associated with the conduct of that trial and the preparation and packaging of clinical trial materials. Revenue is recognized as services are rendered in accordance with the agreement. The cost of providing these research services approximates the revenue recognized. If the costs of the study exceed budgeted amounts, Lilly may not pay for the excess. As of December 31, 2006, the costs incurred have not exceeded the budgeted amounts.

During the year ended December 31, 2006, we recognized approximately \$294,000 of revenue under this agreement. No such revenue was recorded during 2005 as the study did not commence until early 2006. Total revenues from this collaboration are expected to be approximately \$775,000 over the course of this study.

*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.



**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 which had increased 48% from \$11.6 million for 2004. The increase in expenses between years reflect clinical trial cost increases of approximately \$4.7 million for 2006 as compared to 2005, which had increased \$7.3 million from 2004 primarily related to clinical trial expenses for PMD. This increase was partially offset by a reduction in 2006 of approximately \$450,000 and a decrease in 2005 of approximately \$1.9 million 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.

In addition, during 2005 as compared to 2004, decreases in production and testing of clinical supplies and manufacturing development of approximately \$370,000 and stock-based compensation of approximately \$228,000 were offset by increases in pre-clinical studies, clinical consulting and infrastructure costs of approximately \$285,000, \$250,000 and \$90,000, respectively.

Research and development expenses discussed above included stock based compensation charges related to option grants to individuals performing these functions of approximately \$575,000, \$224,000 and \$442,000, respectively, for the years ended December 31, 2006, 2005 and 2004. In addition, during the years ended December 31, 2006, 2005 and 2004 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 \$40,000, \$250,000 and \$240,000, 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" 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	2006	Year Ended December 31,	
		2005	2004
		<i>(in thousands)</i>	
CORLUX for the treatment of the psychotic features of PMD	\$ 19,759	\$ 15,391	\$ 8,108
CORLUX for other clinical programs	276	954	641
Drug discovery research	264	755	2,600
Stock-based compensation	535	(26)	202
<b>Total research and development expense</b>	<b>\$ 20,834</b>	<b>\$ 17,074</b>	<b>\$ 11,551</b>

We expect that research and development expenditures will decrease during 2007 because substantially all patient activities related to clinical trials for PMD that we have been conducting were completed during 2006 and remaining reporting activities should be completed by the second quarter of 2007. Research and development expenses in 2007 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 increased 23% to \$5.0 million for the year ended December 31, 2006, from \$4.1 million for the year ended December 31, 2005, which had decreased 9% from \$4.5 million for the year ended December 31, 2004. 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. During 2005 as compared to 2004 decreases in stock based compensation of approximately \$680,000 and legal expenses of \$70,000 were partially offset by increases in professional fees, insurance, market research and staffing of approximately \$120,000, \$80,000, \$55,000 and \$50,000, respectively.

General and administrative expenses included stock-based compensation expense related to option grants to individuals performing these functions of approximately \$1.0 million, \$799,000 and \$1.5 million, respectively, for the years ended December 31, 2006, 2005 and 2004. 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 decrease between 2005 and 2004 was due to the decelerating scale of expense recognition under the graded-vesting method.

The amount of general and administrative expenses in 2007 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, decreased to approximately \$720,000 for the year ended December 31, 2006 from \$1.1 million for the same period in 2005 after having increased from approximately \$578,000 for the year ended December 31, 2004. The change during 2006 as compared to 2005 was principally attributable to decreased earnings due to lower average balance of invested funds that were partially offset by higher yields on the investment portfolios during the 2006 period as compared to the 2005 period. The increase during 2005 as compared to 2004 was principally attributable to higher balance with the investment of funds from the initial public offering of our common stock, or IPO, in April 2004 and to higher yields on the investment portfolios.

*Other expense.* Other expense was \$10,000 for the year ended December 31, 2006, compared to \$52,000 for the same period in 2005 and \$68,000 for 2004. Other expense during 2006 and 2005 included state tax and interest expense on capitalized leases entered into during the second quarter of 2005. The expense in 2004 also included interest expense on our convertible note payable to the Institute for the Study of Aging. The note was converted into common stock in June 2004.

## **Liquidity and Capital Resources**

We have incurred operating losses since inception, and at December 31, 2006, we had a deficit accumulated during the development stage of \$98.4 million. Since our inception, we have relied primarily on the proceeds from public and private sales of our equity securities to fund our operations. In December 2006, we completed a private placement of 3 million shares of common stock at a price of \$1.00 per share. Net proceeds of this financing were approximately \$2.9 million after deducting expenses.

**Table of Contents**

At December 31, 2006, we had cash, cash equivalents and investments balances of \$9.5 million, compared to \$29.6 million at December 31, 2005. Net cash used in operating activities for the years ended December 31, 2006, 2005 and 2004, were \$23.2 million, \$17.2 million and \$13.7 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. On March 30, 2007, we sold 9 million shares of common stock at a price of \$1.00 per share in a private placement. The net proceeds were approximately \$8.8 million after deducting issuance costs.

We have sufficient funds to maintain our current operations through the completion and reporting of results of the proof-of-concept weight-gain mitigation study, expected in June 2007, to prepare for the next Phase 3 trial and to continue development of our new chemical entities. If we are not able to raise additional funds, we will not be able to continue operations beyond early 2008.

We will have to perform additional efficacy trials prior to submission of an NDA for CORLUX for the treatment of the psychotic features of PMD. We will need to raise additional funds to complete the development of CORLUX for the treatment of PMD and other indications, to prepare for its commercialization and to conduct other research activities. The additional funds will be used to fund increases in our research and development and general and administrative activities in 2008 and subsequent years.

We believe that funds should be available for these purposes assuming investors' acceptance of our business plan going forward, which includes a fourth Phase 3 clinical trial in PMD, opportunities that may be created by the results of the proof-of-concept trial evaluating mitigation of atypical antipsychotic induced weight gain and the development of our new chemical entities. 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 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 to obtain funds through collaborations with others that are on unfavorable terms or that 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; or we may be required to discontinue operations.

**Contractual Obligations**

The following table presents our estimates of obligations under contractual agreements as of December 31, 2006:

Payments Due by Period	Less than 1	1-3 Years	3-5 Years	More than
	year			5 Years
	<i>(in thousands)</i>			
Research and development studies <sup>(1) (2) (3) (4)</sup>	\$ 1,550	\$	\$	\$
Operating lease <sup>(5)</sup>	171			
Capital leases <sup>(6)</sup>	13	29		
Minimum royalty payments <sup>(7)</sup>	50	100	100	50 per year
<b>Total</b>	<b>\$ 1,784</b>	<b>\$ 129</b>	<b>\$ 100</b>	<b>\$ 50 per year</b>

(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, 2006.

(2) During 2004, 2005 and 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 PMD. 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, 2006, substantially all patient activities had been completed and remaining reporting activities are expected to be completed by the second quarter of 2007.

(3) Certain of the agreements discussed in footnotes (2) above relate to trials to be conducted in Europe. The contractual agreements for these trials are denominated in Euros, which are converted to U.S. Dollars at the time of invoicing. The remaining obligations under these agreements are subject to fluctuation based on the changes in the currency rates. See discussion under Item 7A - Quantitative and Qualitative Disclosures about Market Risk.

---

## **Table of Contents**

- (4) In November 2006, we signed an agreement with a contract research organization to assist in the conduct of a weight-gain mitigation study to be performed in 2007. The total commitment remaining outstanding as of December 31, 2006 is approximately \$336,000. The costs of this study will be reimbursed to us under a collaboration agreement with Lilly that was signed in October 2005.
- (5) Our operating lease commitment relates to the lease of our office facility.
- (6) During 2005, we entered into capital leases for the acquisition of certain pieces of office furniture and equipment.
- (7) 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 from 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. Under our license agreement with Stanford University related to the patent covering the use of GR-II antagonists to treat the psychosis associated with PMD and early dementia, including early Alzheimer's disease, we are obligated to make milestone payments to Stanford of \$50,000 upon filing of an NDA covering the licensed product and \$200,000 upon FDA approval of the licensed product. The milestone payments payable to Stanford under these licenses are creditable against future royalties. In addition, 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. 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 its development and commercial needs for an initial period of five years. The agreement provides for an automatic extension for one additional year unless either party gives twelve months prior notice that it does not want the extension. There is no guaranteed minimum purchase commitment under this agreement. If PCAS is unable to manufacture the product for a consecutive six-month period, we have the right to terminate the agreement without penalty.

### **Net Operating Loss Carryforwards**

At December 31, 2006 we had approximately \$37.8 million of federal net operating loss carryforwards and approximately \$640,000 in federal research and development tax credit carryforwards, as well as approximately \$37.5 million of California net operating loss carryforwards and approximately \$740,000 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 supplies olanzapine and pays for the budgeted costs of the study. We are required to perform development activities as specified in this agreement and the fee that we are paid for these services is based on the costs associated with the conduct of the trial and the preparation and packaging of clinical trial materials. Revenue is recognized as services are rendered in accordance with the agreement. The cost of providing these research services approximates the revenue recognized. If the costs of the study exceed budgeted amounts, Lilly may not pay for the excess.

---

**Table of Contents**

*Accruals of Research and Development Costs.* We recorded accruals for estimated costs of research, pre-clinical and clinical studies, and manufacturing development of approximately \$2.2 million and \$2.5 million as of December 31, 2006 and 2005, respectively. These costs are a significant component of our research and development expenses. We make significant judgments and estimates in determining the accrual balance in each reporting period. Accrued clinical trial costs are based on estimates of the work completed under the service agreements, milestones achieved, patient enrollment and past experience with similar contracts and service providers. Our estimate of the work completed and associated costs to be accrued includes our assessment of the information received from our third-party contract research organizations and the overall status of our clinical trial activities. In the past, we have not experienced any material deviations between accrued clinical trial expenses and actual clinical trial expenses. However, actual services performed, number of patients enrolled and the rate of patient enrollment may vary from our estimates, resulting in adjustments to clinical trial expense in future periods.

*Stock-based compensation 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, the Company 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* ( APB 25 ), and had adopted the disclosure-only alternative of SFAS No. 123, *Accounting for Stock-Based Compensation* ( SFAS 123 ), as amended by SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure* ( SFAS 148 ). Because we had used the minimum value method for options granted prior to the IPO in 2004 for SFAS 123 pro forma disclosure requirements, 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.

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 Bulletin 107, 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.

**Table of Contents**

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.

*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 SFAS 123 disclosures 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 remeasured quarterly, based on the then current stock price as reflected on the Nasdaq Stock Market.

**Stock-based compensation for options to employees impact of adopting SFAS 123R**

The following table indicates the impact of implementation of SFAS 123R for employee options on our statement of operations.

Operating Expense Category	Research and development	Year Ended December 31, 2006	
		General and administrative	Total
		<i>(amounts in thousands)</i>	
Expense under provisions of APB 25	\$ (2)	\$ 373	\$ 371
Incremental expense	440	632	1,072
Expense under provisions of SFAS 123R	\$ 438	\$ 1,005	\$ 1,443

As of December 31, 2006, the Company had the following amounts of unrecognized compensation expense for employee options outstanding as of that date.

	Amount	Weighted-average period
	<i>(in thousands)</i>	
	<i>(in years)</i>	
Remaining deferred compensation related to options granted prior to the IPO, to be expensed under the provisions of APB 25	\$ 228	2.1
Remaining fair value to be expense		
Options granted after IPO through 2005, using fair value under SFAS 123	648	2.8
Options granted during 2006, using fair value under SFAS 123R	1,520	3.5
Total	\$ 2,396	

**Off-Balance Sheet Arrangements**

We do not have any off-balance sheet financing as of December 31, 2006.

**Recently Issued Accounting Standards**

In June 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48), an interpretation of SFAS No. 109, *Accounting for Income Taxes* (SFAS 109). FIN 48 clarifies the



---

**Table of Contents**

accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS 109 by prescribing a minimum recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition measurement, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. We have adopted FIN 48 as of January 1, 2007, as required. We are currently evaluating the impact of adopting FIN 48 on our financial statements.

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. We do not believe that implementation of SAB 108 will have a material effect on our financial statements.

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. We are currently evaluating the impact of adopting SFAS 157 and SFAS 159 on our financial statements.

**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, 2006, our cash and cash equivalents consisted primarily of money market funds maintained at major U.S. financial institutions, and the short-term and long-term investments consist of corporate debt securities and U.S. government obligations. 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, 2006.

***Currency Risk***

In 2004, we signed a master agreement with a CRO to assist us in the conduct of clinical trials in Europe. The costs of these trials are denominated in Euros, which the vendor converts into U.S. dollars for invoicing as costs are incurred, generally on a monthly basis. Thus, we may bear some currency rate exposure for the costs of these trials. As of December 31, 2005, we had executed amendments to this agreement that included Euro-denominated commitments of approximately 6.0 million Euros. In March 2006, we signed an additional amendment to our agreement with this CRO to add five European sites to our U.S.-based Phase 3 trials. The preparatory work for this effort had begun in late 2005 under a letter of intent with the CRO. The total



## **Table of Contents**

commitment under this amendment is approximately 818,000 Euros, approximately \$975,000 based on the conversion rate at the time of signing, of which approximately \$65,000 (53,000 Euros) had been committed previously under the letter of intent.

These trials were originally expected to be conducted through the third quarter of 2007. In late October 2006, we notified the CRO of our intent to terminate Study 13, the retreatment study. As of December 31, 2006, all three Euro-denominated trials have completed all patient activities and remaining reporting activities should be completed by the second quarter of 2007.

Approximately 270,000 Euros of the contractual commitments had not been expended or accrued as of December 31, 2006, which is equivalent to approximately \$355,000, using the exchange rate as of that date. A 1% increase or decrease in the currency rate of exchange between the U.S. Dollar and the Euro would have an impact of approximately \$4,000 on the unexpended cost of these trials based on the original commitments. The timing of payments for these trials will depend upon various factors including the timing of final reporting of trial results and the final payments of pass-through costs, such as grants to investigators and laboratory services. The master agreement with this CRO provides for termination by us with forty-five days notice.

### **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. CONTROLS AND PROCEDURES**

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

**Evaluation of disclosure controls and procedures.** As of December 31, 2006, our chief executive officer and chief financial 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 financial officer have concluded that our disclosure controls and procedures are effective.

**Changes in internal controls.** There were no changes in our internal controls over financial reporting during the quarter ended December 31, 2006 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

Not applicable

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

In March 2007, James N. Wilson, our Chairman, adopted plans in accordance with Rule 10b5-1 under the Exchange Act for sales of our common stock owned by a family trust and a family partnership. Under these plans, shares will be sold from time to time over 12-month periods, beginning in March 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, 2006, 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>	63	Chairman of the Board of the Company
Joseph K. Belanoff, M.D.	49	Chief Executive Officer of the Company
G. Leonard Baker, Jr. <sup>(2)</sup>	64	Venture Capitalist
Joseph C. Cook, Jr. <sup>(1)</sup>	65	Executive/Investor
James A. Harper <sup>(2)</sup>	59	Retired Pharmaceutical Executive
David L. Mahoney <sup>(1)(2)</sup>	52	Private Equity Investor
Alix Marduel, M.D. <sup>(2)(3)</sup>	49	Venture Capitalist
Alan F. Schatzberg, M.D. <sup>(3)</sup>	62	Chairman, Dept. of Psychiatry and Behavioral Sciences, Stanford University School of Medicine
David B. Singer <sup>(1)</sup>	44	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.

*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 currently serves on the Board of Therma-Wave, Inc., which is a publicly traded company, and 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

**Table of Contents**

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 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., a biotechnology company. 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.

*Alan F. Schatzberg, M.D.* is a co-founder of the Company and has served as a member of the Board of Directors and as Chairman of the Company's Scientific Advisory Board since 1998. Since 1991, Dr. Schatzberg has been a Professor and the Chairman of the Department of Psychiatry and Behavioral Sciences at Stanford University's School of Medicine and is Past President of the American College of Neuropsychopharmacology. Dr. Schatzberg received his B.S. from New York University and his M.D. from New York University School of Medicine.

*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, 2006, information about our executive officers:

<b>Name</b>	<b>Age</b>	<b>Position</b>
Joseph K. Belanoff, M.D.	49	Chief Executive Officer and Director
Robert L. Roe, M.D.	66	President and Secretary
Fred Kurland*	56	Chief Financial Officer

\* Mr. Kurland has resigned his position as our Chief Financial Officer effective as of April 13, 2007.

*Joseph K. Belanoff, M.D.* is a co-founder and has served as a member of our board of directors and as our Chief Executive Officer since 1999. Dr. Belanoff is currently a clinical faculty member and has held various positions in the Department of Psychiatry and Behavioral Sciences at Stanford University since 1992. From 1997 to 2001, he served as the Director of Psychopharmacology at the outpatient division of the Palo Alto Veterans Affairs Hospital. Dr. Belanoff received his B.A. from Amherst College and his M.D. from Columbia University's College of Physicians & Surgeons.

*Robert L. Roe, M.D.* joined us as President in October 2001. Dr. Roe has spent more than 25 years in the pharmaceutical and biotechnology industries. From 1999 to 2001, he served as President and Chief Executive Officer of Allergenic, 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.

*Fred Kurland* joined us as Chief Financial Officer in February 2004. Mr. Kurland served as Vice President and Chief Financial Officer of Genitope Corporation from 2002 until February 2004. From 1998 to 2002 he served as Senior Vice President and Chief Financial Officer of Aviron. Mr. Kurland served as Vice President and Chief Financial Officer of Protein Design Labs, Inc. from 1996 to 1998. From 1995 to 1996, he served as Vice President, Chief Financial Officer and Secretary of Applied Immune Sciences, Inc. From 1991 to 1995, Mr. Kurland served as Vice President and Controller of Syntex Corporation. Mr. Kurland received his B.S. from Lehigh University and his J.D. and M.B.A. degrees from the University of Chicago.

**Board Meetings and Committees**

The Board met eight times during fiscal 2006; four of them telephonically, and took action via unanimous written consent twice. The Audit Committee met six times and the Compensation Committee met two times. The Nominating and Corporate Governance Committee met one time during fiscal 2006. 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 G. Leonard Baker, Jr. and Alix Marduel, M.D. who attended 70% and 73% of such meetings, respectively.

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

*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. The Board has determined that David L. Mahoney qualifies as an Audit Committee financial expert as defined by the rules of the Securities and Exchange Commission (the SEC). 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 the

---

## **Table of Contents**

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 accountants.

*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 James N. Wilson (chairman), Alan F. Schatzberg, M.D., and Alix Marduel, M.D. 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 its Board by writing to them c/o Secretary, Concept 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 has a policy of encouraging all directors to attend the annual stockholder meetings. Two of the Company's directors attended the 2006 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, 2006 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 Concept 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 2006, such SEC filing requirements were satisfied except that Joseph K. Belanoff, M.D. and Robert L. Roe, M.D. each reported two dispositions and David L. Mahoney reported a purchase of Company securities on Form 4s one day after they due. For Dr. Belanoff and Dr. Roe, the first dispositions occurred on February 17, 2006 with the Form 4s being filed on February 22, 2006 and the second dispositions occurred on February 28, 2006 with the Form 4s being filed on March 3, 2006. Mr. Mahoney's purchase occurred on February 17, 2006 with the Form 4 being filed on February 22, 2006.

---

**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 Fred Kurland, our Chief Financial Officer, or 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 executive officers 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 Financial 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 Compensation Committee collectively have developed a clear understanding and knowledge of the compensation structures that are necessary to attract, motivate and retain management talent.





## **Table of Contents**

### ***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:

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.

Other benefits: employee benefit plans in which executives and all employees participate.

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 his 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.

Within its performance-based compensation program, the Company aims to compensate the NEOs in a manner that is tax effective for the Company. Section 162(m) of the Internal Revenue Code generally disallows an income tax deduction to publicly-held corporations for compensation in excess of \$1,000,000 paid for any fiscal year to the corporation's Chief Executive Officer or to any of its four most highly compensated officers. However, the statute exempts qualifying performance-based compensation from the deduction limit if certain requirements are met. The policy of the Compensation Committee has been to attempt to structure the compensation of our NEOs to avoid the loss of the deductibility of any compensation, even though Section 162(m) does not preclude the payment of compensation in excess of \$1,000,000. Certain option grants made under our equity plans were 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.

### ***Compensation Benchmarking***

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 of, consultants to, board and compensation committee members of, or venture capitalists with investments in similar biotechnology and specialty pharmaceutical industry companies.

### ***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



---

**Table of Contents**

negotiations with each NEO when such individual first joined the Company as an employee. Base salaries have not changed in 2006 as compared to 2005 other than for annual cost of living adjustments of approximately 3-4% 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 the commencement of certain clinical trials. No performance-based cash or equity bonuses were awarded in 2006. For the next fiscal year, the Compensation Committee believes that performance-based compensation should continue to 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.

*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 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.

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 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 March 2006, Dr. Roe and Mr. Kurland were granted stock options

## **Table of Contents**

for 50,000 and 25,000 shares of common stock, 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 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.

## **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 Arrangements**

The Company has entered into an offer letter agreement with Robert L. Roe, M.D., the Company's President, dated October 18, 2001 (the Roe Offer Letter). Pursuant to the Roe Offer Letter, if the Company terminates Dr. Roe's employment for any reason other than for cause, Dr. Roe will receive a lump sum severance payment equal to 12 months of his base salary in effect at the time of his termination. This severance arrangement was designed to attract Dr. Roe to the position of President and retain him in that position as the Company competes for talented executives in the marketplace where such protections are commonly offered. The severance arrangement provides benefits to ease Dr. Roe's transition due to an unexpected employment termination by the Company due to changes in the Company's employment needs.

## **Change of Control Arrangements**

The Company's 2000 Stock Option Plan and 2004 Equity Incentive Plan provide that upon a change of control, the successor entity to the Company or a parent or subsidiary of the successor entity may assume or substitute a stock option or other award granted under such plan. Under the stock option agreements entered into pursuant to the 2000 Stock Option Plan, in the event of a change of control, 20% of the total shares subject to such options shall become immediately vested; thereafter, such options shall continue vesting according to the original vesting schedule. If the stock options or other award granted are not assumed or substituted, such options or other awards will become fully vested and exercisable for all of the shares subject to such option or award immediately prior to the effective date of the transaction. The Compensation Committee believes that such single trigger change of control policy is consistent with the objectives of providing the highest possible return to stockholders by allowing management to be able to effectively participate equally with stockholders in evaluating alternatives to the NEO in the event of a change of control transaction, without compelling the executive officer to remain employed under new ownership and with a continuing illiquid stake in the Company.

Further, the 2004 Equity Incentive Plan provides that in the event of an involuntary termination of services for any reason other than death, disability or cause, within 12 months following a change of control, any awards that were assumed or substituted in a change of control shall accelerate fully so that such awards are immediately exercisable upon termination.

## **Table of Contents**

Under the Roe Offer Letter, in the event of a change of control, the vesting of any stock option then held by Dr. Roe will be immediately accelerated by an additional 20% of the shares subject to such stock options. The change of control arrangement for Dr. Roe was designed to retain him and provide continuity of management in the event of an actual or threatened change of control. Such arrangements encourage executives, such as Dr. Roe, to remain focused on the Company's business in the event of rumored or actual fundamental corporate changes.

### **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) and the Company's other executive officer for fiscal year 2006 whose salary and bonus for the fiscal year 2006 exceeded \$100,000. Collectively, together with the CEO and CFO, these are the named executive officers.

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

The following table provides compensation information for the year ended December 31, 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	2006	\$ 395,200							\$ 395,200
Robert L. Roe, M.D., President	2006	\$ 364,208			\$ 181,500				\$ 545,708
Fred Kurland, Chief Financial Officer	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 this Annual Report on Form 10-K for the relevant assumptions used to determine the valuation of our option awards.

**Grants of Plan-Based Awards**

The following table summarizes the grants of stock and option awards we made to the named executive officers in 2006.

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 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.											
Robert L. Roe, M.D.	03/02/06								50,000 <sup>(2)</sup>	\$ 4.95	181,500
Fred Kurland	03/02/06								25,000 <sup>(2)</sup>	\$ 4.95	90,750

(1) Refer to Notes 1 Accounting Policies and Estimates Stock-Based Compensation included in the Part II Item 8 Financial Statements in this 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, 2006.

Name	Number of Securities Underlying Unexercised Options Exercisable (#)	Option Awards				Stock Awards			
		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 Unearned Shares, Units or Other Rights That Have Not Vest (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (\$)
Joseph K. Belanoff, M.D.									
Robert L. Roe, M.D.	10,000 <sup>(1)</sup>			\$ 0.10	10/1/2010				
	61,750 <sup>(1)</sup>	38,250		\$ 7.00	11/23/2013				
	36,700 <sup>(1)</sup>	63,300		\$ 4.82	2/10/2015				
		50,000 <sup>(2)</sup>		\$ 4.95	3/2/2016				
Fred Kurland	113,480 <sup>(1)</sup>	86,520		\$ 7.00	2/6/2014				
	18,350 <sup>(1)</sup>	31,650		\$ 4.82	2/10/2015				
		25,000 <sup>(2)</sup>		\$ 4.95	3/2/2016				

(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.

**Option Exercises and Stock Vested**

None of our named executive officers exercised stock options during 2006. 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 Agreement**

The Company has entered into an offer letter agreement with Robert L. Roe, M.D., the Company's President, dated October 18, 2001 (the "Roe Offer Letter"). Pursuant to the Roe Offer Letter, if the Company terminates Dr. Roe's employment for any reason other than for cause (as defined

Edgar Filing: CORCEPT THERAPEUTICS INC - Form 10-K

in the Roe Offer Letter), Dr. Roe will receive a lump sum severance payment equal to 12 months of his base salary in effect at the time of his termination.



**Table of Contents****Change of Control Arrangements**

The Company's 2000 Stock Option Plan (the "2000 Plan") and 2004 Equity Incentive Plan (the "2004 Plan") provide that upon a change of control, the successor entity to the Company or a parent or subsidiary of the successor entity may assume or substitute a stock option or other award granted under such plan. Under the stock option agreements entered into pursuant to the 2000 Stock Option Plan, in the event of a change of control, 20% of the total shares subject to such options shall become immediately vested; thereafter, such options shall continue vesting according to the original vesting schedule. If the stock options or other award granted are not assumed or substituted, such options or other awards will become fully vested and exercisable for all of the shares subject to such option or award immediately prior to the effective date of the transaction.

Further, the 2004 Plan provides that in the event of an involuntary termination of services for any reason other than death, disability or cause, within 12 months following a change of control, any awards that were assumed or substituted in a change of control shall accelerate fully so that such awards are immediately exercisable upon termination.

Under the Roe Offer Letter, in the event of a change of control (as defined in the Roe Offer Letter), the vesting of any stock option then held by Dr. Roe will be immediately accelerated by an additional 20% of the shares subject to such stock options.

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, 2006, and estimates the value to the named executive officer as a result of each triggering event.

Name	Benefit	Termination Without Cause	Change of Control Under the Roe Offer Letter	Change of Control Under the 2000 Plan or 2004 Plan	Involuntary Termination Other Than for Death, Disability or Cause Within 12 Months of Change of Control
Joseph K. Belanoff, M.D.					
Robert L. Roe, M.D.	Base Salary	\$ 364,208			
	Accelerated Vesting of Stock Options		(3)	(1)(3)	(2)(3)
Fred Kurland	Accelerated Vesting of Stock Options			(1)(3)	(2)(3)

(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 assumed or substituted by the successor entity to the Company or a parent or subsidiary of the successor entity.

(3) For all unvested options held by named executive officers as of December 31, 2006, there is no value to the change of control acceleration features under the 2000 Plan, the 2004 Plan or the Roe Offer Letter because the exercise price of the options exceeded the closing stock price for the Company's common stock on the Nasdaq Global Stock Market as of that date.

**Table of Contents****Equity Compensation Plan Information**

The following table provides information as of December 31, 2006 with respect to the shares of the Company's common stock that may be issued under all of the Company's existing equity compensation plans, including the 2004 Equity Incentive Plan and the 2000 Stock Option Plan.

Plan Category	(a) Number of Securities to Be Issued upon Exercise of Outstanding Options	(b) Weighted Average Exercise Price of Outstanding Options	(c) Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column(a))
Equity compensation plans approved by stockholders	1,809,686	\$ 5.80	2,679,996 <sup>(1)</sup>
Equity compensation plans not approved by stockholders			
<b>Total</b>	<b>1,809,686</b>	<b>\$ 5.80</b>	<b>2,679,996</b>

(1) Includes a total of 2,679,996 shares of common stock remaining available for future issuance under the Company's 2004 Equity Incentive Plan as of December 31, 2006. The 2004 Equity Incentive Plan contains an evergreen provision that automatically increases on the first business day of each fiscal year beginning January 1, the lesser of an additional (i) 1,000,000 shares of the Company's common stock, (ii) 2% of the outstanding shares of capital stock on such date, or (iii) an amount determined by the Board. None of the Company's other plans has an evergreen provision.

**DIRECTOR COMPENSATION**

The following table provides compensation information for the one year period ended December 31, 2006, for each member of our Board of Directors.

Name	Fees Earned or Paid in		Non-Equity Incentive Plan		Change in Pension		Total
	Cash	Stock Awards	Option Awards	Compensation	Value and Nonqualified Deferred Compensation	All Other Compensation	
	(\$)	(\$)	(\$) <sup>(4)(5)</sup>	(\$)	Earnings (\$)	(\$)	(\$)
James N. Wilson <sup>(2)</sup>	\$						
Joseph K. Belanoff, M.D. <sup>(3)</sup>							
G. Leonard Baker, Jr.	\$ 15,000						\$ 15,000
Joseph C. Cook, Jr. <sup>(1)</sup>	\$ 25,000						\$ 25,000
James A. Harper <sup>(1)</sup>	\$ 15,000						\$ 15,000
David L. Mahoney <sup>(1)</sup>	\$ 25,000		\$ 36,300				\$ 61,300
Alix Marduel, M.D.	\$ 15,000						\$ 15,000
Alan F. Schatzberg, M.D.	\$ 15,000						\$ 15,000
David B. Singer	\$ 25,000						\$ 25,000

(1) The following are the aggregate number of shares represented by option awards outstanding that have been granted to each of our non-employee directors as of December 31, 2006, the last day of the 2006 fiscal year: Mr. Cook: 75,000; Mr. Harper: 60,000; Mr. Mahoney: 70,000.

(2) Mr. Wilson is an employee director. He receives no additional compensation in his capacity as a director.

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

- (3) Dr. Belanoff is a full time employee and a named executive officer of the company and is compensated in that capacity. He receives no additional compensation in his capacity as a director.
- (4) Refer to Notes 1 Accounting Policies and Estimates Stock-Based Compensation included in Part II Item 8 Financial Statements in this Annual Report on Form 10-K for the relevant assumptions used to determine the valuation of our option awards.
- (5) The option was granted under the Company's 2004 Equity Incentive Plan and 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.

---

## **Table of Contents**

Non-employee directors receive a director fee from the Company for their services as members of the Board in the amount of \$15,000 per year. Directors receive an initial stock option grant of 60,000 shares of the Company's common stock in connection with their initial election to the Board. Such options will vest with respect to 25% of the shares on the first anniversary of the date of the grant and, thereafter, at the rate of 2.0834% per month, until fully vested. Members of the Audit Committee receive an additional \$10,000 per year. In addition, during 2006, the chairman of the Audit Committee received an additional stock option grant of 10,000 shares of the Company's common stock. Directors are reimbursed for certain expenses in connection with attending Board and committee meetings.

Pursuant to the Company's non-employee director compensation policy, on March 2, 2006, the Company granted David L. Mahoney, the chair of the Audit Committee, an option to purchase 10,000 shares of common stock at an exercise price of \$4.95 per share. This option vests with respect to 25% of the shares on the first anniversary of the date of the grant and, thereafter, at the rate of 2.0834% per month, until fully vested.

### **Compensation Committee Interlocks and Insider Participation**

No interlocking relationship exists, or in the past fiscal year has existed, between any member of the Company's Compensation Committee and any member of any other company's board of directors or compensation committee.

### **Compensation Committee Report**

The Compensation Committee of the Board of Directors (the Compensation Committee) has furnished this report on executive compensation. None of the members of the Compensation Committee is currently an officer or employee of the Company and all are non-employee directors for purposes of Rule 16b-3 under the Securities Exchange Act of 1934 and outside directors for purposes of Section 162(m) of the Internal Revenue Code. The Compensation Committee is responsible for designing, recommending to the Board of Directors for approval and evaluating the compensation plans, policies and programs of the Company and reviewing and approving the compensation of the Chief Executive Officer and other officers and directors.

This report, filed in accordance with Item 407(e)(5) of Regulation S-K, should be read in conjunction with the other information relating to executive compensation which is contained elsewhere in this Annual Report on Form 10-K and is not repeated here.

In this context, the Compensation Committee hereby reports as follows:

1. The Compensation Committee has reviewed and discussed the Compensation Discussion and Analysis section contained herein with management.
2. Based on the review and discussions referred to in paragraph (1) above, the Compensation Committee recommended to our board of directors, and our Board of Directors has approved, that the Compensation Discussion and Analysis be included in this Annual Report on Form 10-K for filing with the SEC.

### **COMPENSATION COMMITTEE**

G. LEONARD BAKER, JR., CHAIRMAN

JAMES A. HARPER

DAVID L. MAHONEY

ALIX MARDUEL, M.D.

**Table of Contents****ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The following table sets forth information regarding ownership of the Company's common stock as of March 31, 2007 or earlier date for information based on filings with the SEC by (a) each person known to the Company to own more than 5% of the outstanding shares of its common stock, (b) each director of the Company, (c) the Company's Chief Executive Officer and each other executive officer named in the compensation tables appearing earlier in this Form 10-K and (d) all directors and executive officers as a group. The information in this table is based solely on statements in filings with the SEC or other information the Company believes to be reliable. Percentage of ownership is based on 34,731,766 shares of common stock outstanding as of March 31, 2007. Beneficial ownership is determined in accordance with the rules of the SEC, and includes voting and investment power with respect to the shares. Shares of common stock subject to outstanding options and warrants exercisable within 60 days of March 31, 2007 are deemed outstanding for computing the percentage of ownership of the person holding such options or warrants, but are not deemed outstanding for computing the percentage of any other person.

Name of Beneficial Owner <sup>(1)</sup>	Number of Shares Beneficially Owned <sup>(2)</sup>	Percentage of Shares Beneficially Owned
<b>5% Stockholders</b>		
Paperboy Ventures LLC	6,642,527	19.1%
Sutter Hill Ventures <sup>(3)</sup>	5,691,106	16.4%
Entities affiliated with Alta Partners, LLP <sup>(4)</sup>	3,198,274	9.2%
Maverick Capital, Ltd. <sup>(5)</sup>	2,122,841	6.1%
<b>Directors and Named Executive Officers</b>		
G. Leonard Baker, Jr. <sup>(6)</sup>	4,144,112	11.9%
Alix Marduel <sup>(5)</sup>	3,198,274	9.2%
Joseph K. Belanoff <sup>(7)</sup>	2,764,195	8.0%
Alan Schatzberg <sup>(8)</sup>	2,738,749	7.9%
James N. Wilson <sup>(9)</sup>	2,654,154	7.6%
Joseph C. Cook, Jr. <sup>(10)</sup>	967,525	2.8%
David B. Singer <sup>(11)</sup>	778,667	2.2%
David L. Mahoney <sup>(12)</sup>	507,660	1.5%
Robert L. Roe <sup>(13)</sup>	288,623	*
Fred Kurland <sup>(14)</sup>	167,496	*
James A. Harper <sup>(15)</sup>	98,438	*
All directors and executive officers as a group (11 persons) <sup>(16)</sup>	18,307,893	52.1%

\* Less than 1% of Corcept's outstanding common stock.

- (1) Unless otherwise indicated, the address of each of the named individuals is c/o Corcept Therapeutics, 149 Commonwealth Drive, Menlo Park, California 94025.
- (2) Beneficial ownership of shares is determined in accordance with the rules of the SEC and generally includes any shares over which a person exercises sole or shared voting or investment power, or of which a person has the right to acquire ownership within 60 days after March 31, 2006. Except as otherwise noted, each person or entity has sole voting and investment power with respect to the shares shown.
- (3) Consists of: (a) 3,381,387 shares held by Sutter Hill Ventures, A California Limited Partnership (Sutter Hill Ventures), (b) 29,273 shares held by Sutter Hill Entrepreneurs Fund (AI), L.P. (SHAI), (c) 74,113 shares held by Sutter Hill Entrepreneurs Fund (QP), L.P. (SHQP), (d) 1,546,994 shares held by individuals affiliated with Sutter Hill Ventures and entities affiliated with such individuals, (e) 205,439 shares of Common Stock owned by G. Leonard Baker, Jr., one of our directors, (f) 102,195 shares held by Mr. Baker, Trustee of The Baker Revocable Trust and (g) 351,705 shares held by Saunders Holdings, L.P. of which Mr. Baker is a General Partner. Mr. Baker has shared voting and dispositive power with respect to the shares held by The Baker Revocable Trust and Saunders Holdings, L.P. Mr. Baker, Sutter Hill Ventures, SHAI and SHQP do not have any voting or dispositive power with respect to the shares held by individuals affiliated with Sutter Hill Ventures and entities affiliated with such individuals referenced under part (d) of this note. Mr. Baker shares voting and dispositive power with respect to the shares held by Sutter Hill Ventures, SHAI and SHQP with the following natural persons: David L. Anderson, William H. Younger, Jr., Tench Cox, Gregory P. Sands, James C. Gaither, James N. White, Jeffrey W. Bird and David E. Sweet. As a result of the shared voting and dispositive powers referenced herein, Messrs. Baker, David L. Anderson, William H. Younger, Jr., Tench Cox, Gregory P. Sands, James C. Gaither, James N. White, Jeffrey W. Bird and David E. Sweet may each be deemed to beneficially own the shares held by Sutter Hill Ventures, SHAI and SHQP.

**Table of Contents**

- (4) Includes 3,078,789 shares held of record by Alta BioPharma Partners II, LP and 119,485 shares held of record by Alta Embarcadero BioPharma Partners II, LLC. Dr. Marduel is a managing director of Alta BioPharma Management II, LLC (which is a general partner of Alta BioPharma Partners II, LP) and a manager of Alta Embarcadero BioPharma Partners II, LLC. Dr. Marduel disclaims beneficial ownership of all such shares held by all of the foregoing funds, except to the extent of her proportionate pecuniary interests therein. Alta Parents II, Inc. provides investment advisory services to several venture capital funds including Alta BioPharma Partners II, LP and Alta Embarcadero BioPharma Partners II, LLC. The managing directors of Alta BioPharma Partners II, LP and the managers of Alta Embarcadero BioPharma Partners II, LLC exercise sole voting and investment power with respect to shares owned by such funds. Certain principals of Alta Partners II, Inc. are managing directors of Alto BioPharma Management II, LLC (which is the general partner of Alta BioPharma Partners II, LP), and managers of Alta Embarcadero BioPharma Partners II, LLC. As managing directors and managers of such entities, they may be deemed to share voting and investment powers for the shares held by the funds. The principals of Alta Partners II, Inc. disclaim beneficial ownership of all such shares held by the foregoing funds, except to the extent of their proportionate pecuniary interests therein. The address of Alta Partners II, Inc. is One Embarcadero Center, Suite 3700, San Francisco, California 94111.
- (5) Includes 194,999 shares held of record by Maverick Fund II, Ltd., 607,398 shares held of record by Maverick Fund USA, Ltd., and 1,320,444 shares held of record by Maverick Fund, L.D.C. Maverick Capital, Ltd. is an investment adviser registered under Section 203 of the Investment Advisers Act of 1940 and, as such, has beneficial ownership of the shares held by Maverick Fund USA, Ltd., Maverick Fund II, Ltd. and Maverick Fund, L.D.C. through the investment discretion it exercises over these accounts. Maverick Capital Management, LLC is the General Partner of Maverick Capital, Ltd. Lee S. Ainslie III is a manager of Maverick Capital Management, LLC, and is granted sole investment discretion pursuant to Maverick Capital Management, LLC's Regulations. The address of Maverick Capital, Ltd. is 300 Crescent Court, 18th Floor, Dallas, TX 75201.
- (6) Includes all shares referenced in footnote (3) other than the 1,546,994 shares held by individuals affiliated with Sutter Hill Ventures and entities affiliated with such individuals referenced under part (d) of footnote (3).
- (7) Includes 300,000 shares held as custodian for Edward G. Belanoff and 300,000 shares held as custodian for Julia E. Belanoff under the California Uniform Transfers to Minors Act over which Dr. Belanoff has voting control.
- (8) Includes 300,000 shares held of record by Lindsey D. Schatzberg over which Dr. Schatzberg has voting control.
- (9) Includes 1,988,094 shares held of record by the James N. Wilson and Pamela D. Wilson Trust and 666,060 shares held of record by the James and Pamela Wilson Family Partners, over all of which Mr. Wilson has voting control pursuant to voting agreements. Mr. Wilson disclaims beneficial ownership of such shares, except to the extent of his pecuniary interests in the entities holding such shares.
- (10) Includes 400,000 shares held of record by Farview Management, Co. L.P., a Texas limited partnership, and 67,525 shares issuable pursuant to options exercisable within 60 days of March 31, 2007.
- (11) Includes 43,500 shares held of record by the Singer-Kapp Family Trust FBO Kapp S. Singer and 3,500 shares held of record by the Singer Kapp Family 2000 Trust FBO Elliot Byrd Singer. Mr. Singer is a Principal with Maverick Capital Limited. The address of David Singer is 101 California Street #4015, San Francisco, CA 94111.
- (12) Includes 400,000 shares held of record by the David L. Mahoney and Winnifred C. Ellis 1998 Family Trust and 36,960 shares issuable pursuant to options exercisable within 60 days of March 31, 2007.
- (13) Includes 139,733 shares issuable pursuant to options exercisable within 60 days of March 31, 2007.
- (14) Includes 159,996 shares issuable pursuant to options exercisable within 60 days of March 31, 2007.
- (15) Includes 31,038 shares issuable pursuant to options exercisable within 60 days of March 31, 2007.
- (16) Total number of shares includes common stock held by entities affiliated with directors and executive officers. See footnotes 1 through 15 above.

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

On December 15, 2006, we sold an aggregate of 3,000,000 shares of our common stock, par value \$0.001, at a price of \$1.00 per share to certain investors pursuant to a Common Stock Purchase Agreement dated November 14, 2006 (the December 2006 Financing). The aggregate consideration received by the Company was \$3,000,000. The investors included the Paperboy Ventures, LLC and Sutter Hill Ventures, both venture capital firms that are currently significant shareholders of the Company. Paperboy Ventures, LLC purchased 1,892,527 shares and Sutter Hill Ventures purchased 379,000 shares in the December 2006 Financing. The investors also included G. Leonard Baker, Jr., Joseph C. Cook, Jr., David L. Mahoney and James N. Wilson, who are members of our board of directors. Mr. Baker purchased 12,621 shares, Mr. Cook and related entities purchased 300,000 shares, Mr. Mahoney purchased 200,000 shares and Mr. Wilson purchased 100,000 shares in the December 2006 Financing.

---

**Table of Contents**

On March 30, 2007, we sold an aggregate of 9,000,000 shares of our common stock, par value \$0.001, at a price of \$1.00 per share to certain investors pursuant to a Common Stock Purchase Agreement dated that same date (the "March 2007 Financing"). The aggregate consideration received by the Company was \$9,000,000. The investors included Paperboy Ventures, LLC, Sutter Hill Ventures and Alta Partners, LLP, all venture capital firms that are currently significant shareholders of the Company. Paperboy Ventures, LLC purchased 4,250,000 shares, Sutter Hill Ventures purchased 1,340,000 shares and Alta Partners, LLP purchased 1,500,000 shares. The investors also included G. Leonard Baker, Jr., Joseph C. Cook, Jr., James A. Harper, David L. Mahoney, Alan F. Schatzberg, M.D. and James N. Wilson, who are members of our board of directors. Mr. Baker, a partner at Sutter Hill Ventures, purchased 154,306 shares (as part of the Sutter Hill Ventures purchase noted above), Mr. Cook and related entities purchased 600,000 shares, Mr. Harper purchased 50,000 shares, Mr. Mahoney purchased 200,000 shares, Dr. Schatzberg purchased 50,000 shares and Mr. Wilson and related entities purchased 360,000 shares in the March 2007 Financing. This financing also included the purchase of 650,000 shares by other qualified investors.

Pursuant to a consulting agreement with the Company, Dr. Schatzberg received compensation of \$33,750 for his services as Chair of the Company's Scientific Advisory Board in 2006. The Company terminated this agreement with Dr. Schatzberg in October 2006.

The Company has entered into an agreement with Robert L. Roe, M.D., the Company's President, dated October 18, 2001. Pursuant to such letter agreement, Dr. Roe received an option to purchase 250,000 shares of the Company's common stock with an exercise price of \$0.75 per share and a \$187,250 loan, subject to interest rate of 6.5% and evidenced by a full-recourse promissory note to the Company to finance the exercise of the option. Shares purchased by Dr. Roe pursuant to the option are subject to a right of repurchase in favor of the Company, which lapsed over five years, ending in October 2006. Through December 2006, Dr. Roe had repaid \$99,705 of the principal of the loan plus accrued interest, leaving a total remaining balance of \$87,545 plus accrued interest in the amount of \$28,269 for a total combined balance of \$115,814. If the Company terminates Dr. Roe's employment for any reason other than for cause, Dr. Roe will receive a lump sum severance payment equal to his annual salary in effect at the time of his termination. Dr. Roe received a base salary of \$364,208 from the Company in 2006.

The Company has entered into indemnification agreements with its directors and executive officers. Such agreements require the Company, among other things, to indemnify its officers and directors, other than for liabilities arising from willful misconduct of a culpable nature, and to advance their expenses incurred as a result of any proceedings against them as to which they could be indemnified.

The Board has determined that the following directors are independent under current NASDAQ rules:

G. Leonard Baker, Jr.

Joseph C. Cook, Jr.

James A. Harper

David L. Mahoney

Alix Marduel, M.D.

Alan F. Schatzberg, M.D.

David B. Singer

See "Director Compensation" for a discussion of the Company's director compensation policy.

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

*Audit Fees*

Fees for audit services totaled approximately \$217,000 in 2006 and \$177,000 in 2005, including fees for professional services provided in connection with the annual audit of the Company's financial statements and review of the Company's quarterly financial statement and audit services provided in connection with other statutory or regulatory filings.





**Table of Contents**

*Audit- Related Fees, Tax Fees, and All Other Fees*

There were no fees paid to our principal accounting firm during 2006 or 2005 for any of these services.

*Pre-approval of audit-related and non-audit services*

The Audit Committee has delegated to the Chair of the Audit Committee the authority to pre-approve audit-related and non-audit services not prohibited by law to be performed by the Company's independent registered public accounting firm and associated fees, provided that the Chair shall report any decision to pre-approve such audit-related or non-audit services and fees to the full Audit Committee at its next regular meeting.

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

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

(1) Financial Statements:

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
Audited Financial Statements	
<u>Balance Sheets</u>	F-3
<u>Statements of Operations</u>	F-4
<u>Statement of Convertible Preferred Stock and Stockholders' Equity (Net Capital Deficiency)</u>	F-5
<u>Statements of Cash Flows</u>	F-9
<u>Notes to Financial Statements</u>	F-10

(2) Financial Statement Schedules:

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

(3) Exhibits:

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

(A) EXHIBITS

<b>Exhibit Number</b>	<b>Description of Document</b>
3.1 <sup>(1)</sup>	Amended and Restated Certificate of Incorporation
3.2 <sup>(1)</sup>	Amended and Restated Bylaws
4.1 <sup>(1)</sup>	Specimen Common Stock Certificate

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

4.2 <sup>(1)</sup>	Amended and Restated Information and Registration Rights Agreement by and among Corcept Therapeutics Incorporated and certain holders of preferred stock, dated as of May 8, 2001
4.3 <sup>(1)</sup>	Amendment No. 1 to Amended and Restated Information and Registration Rights Agreement by and among Corcept Therapeutics Incorporated and certain holders of preferred stock, dated as of March 16, 2004
10.1* <sup>(1)</sup>	2000 Stock Option Plan
10.2* <sup>(1)</sup>	Employment offer letter to Robert L. Roe, M.D., dated October 18, 2001

**Table of Contents**

<b>Exhibit Number</b>	<b>Description of Document</b>
10.3*(1)	Employment offer letter to Fred Kurland, dated February 3, 2004
10.4*(1)	Promissory Note and Pledge Agreement by and between Corcept Therapeutics Incorporated and Robert L. Roe, M.D., dated as of October 22, 2001
10.5(1)	Form of Indemnification Agreement
10.6#(1)	License Agreement by and between The Board of Trustees of the Leland Stanford Junior University and Corcept Therapeutics Incorporated, dated as of July 1, 1999
10.7(1)	Research Agreement/cGMP Manufacturing, by and between Corcept Therapeutics Incorporated and KP Pharmaceutical Technology, Inc., dated as of February 12, 2002
10.8(1)	Master Clinical Development Agreement by and between Corcept Therapeutics Incorporated and Scirex Corporation, dated as of July 12, 2001
10.9#(1)	Memorandum of Understanding, Supply and Services Agreement, by and between Corcept Therapeutics Incorporated and ScinoPharm Taiwan, dated as of June 12, 2000
10.10(1)*	Consulting, Confidential Information and Inventions Agreement by and between Corcept Therapeutics Incorporated and Alan Schatzberg M.D., dated as of May 31, 1999
10.11(1)*	2004 Equity Incentive Plan
10.12(1)	Master Services Agreement by and between Corcept Therapeutics Incorporated and PPD Development, LP, dated as of January 17, 2003
10.13(2)	Master Services Agreement by and between Corcept Therapeutics Incorporated and i3 Research, a division of Ingenix Pharmaceuticals Services (UK) Limited, dated as of November 2, 2004
10.14(3)	Office Lease Agreement by and between Corcept Therapeutics Inc., and Exponent Realty, LLC, dated May 23, 2005
10.15##	Manufacturing Agreement with Produits Chimiques Auxiliaries et de Synthèse SA, dated November 8, 2006
10.16(4)	Common Stock Purchase Agreement by and among Corcept Therapeutics Incorporated and each of the Purchasers listed on Exhibit A thereto, dated November 14, 2006.
14.1(1)	Code of Ethics
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (See page 69)
31.1	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Joseph K. Belanoff, M.D.
31.2	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Fred Kurland.
32.1	Certification pursuant to 18 U.S.C. Section 1350 of Joseph K. Belanoff, M.D.
32.2	Certification pursuant to 18 U.S.C. Section 1350 of Fred Kurland.

# Confidential treatment granted

## Confidential treatment requested

\* Management compensatory plan

(1) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (Registration No. 333-112676) initially filed by the registrant with the SEC on February 10, 2004.

(2) Incorporated by reference to the Registrant's Annual Report on Form 10-K filed by the registrant with the SEC on March 29, 2005.

(3) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed by the registrant with the SEC on August 11, 2005.

(4) Incorporated by reference to the registrant's Current Report on Form 8-K filed by the registrant with the SEC on November 14, 2006.

**Table of Contents****SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the issuer, a corporation organized and existing under the laws of the State of Delaware, has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized, in the City of Menlo Park, State of California, on the 2<sup>nd</sup> day of April, 2007.

**CORCEPT THERAPEUTICS INCORPORATED**

By: */s/* JOSEPH K. BELANOFF  
**Joseph K. Belanoff, M.D.,**

**Chief Executive Officer**

**POWER OF ATTORNEY**

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

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

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<i>/s/</i> JOSEPH K. BELANOFF <b>Joseph K. Belanoff, M.D.</b>	Chief Executive Officer and Director (Principal Executive Officer)	April 2, 2007
<i>/s/</i> FRED KURLAND <b>Fred Kurland</b>	Chief Financial Officer (Principal Financial and Accounting Officer)	April 2, 2007
<i>/s/</i> JAMES N. WILSON <b>James N. Wilson</b>	Director and Chairman of the Board of Directors	April 2, 2007
<i>/s/</i> G. LEONARD BAKER, JR. <b>G. Leonard Baker, Jr.</b>	Director	April 2, 2007
<i>/s/</i> JOSEPH C. COOK, JR. <b>Joseph C. Cook, Jr.</b>	Director	April 2, 2007
<i>/s/</i> JAMES A. HARPER <b>James A. Harper</b>	Director	April 2, 2007
<i>/s/</i> DAVID L. MAHONEY <b>David L. Mahoney</b>	Director	April 2, 2007

Edgar Filing: CORCEPT THERAPEUTICS INC - Form 10-K

<i>/s/</i> ALIX MARDUEL	Director	April 2, 2007
<b>Alix Marduel, M. D.</b>		
<i>/s/</i> ALAN F. SCHATZBERG	Director	April 2, 2007
<b>Alan F. Schatzberg, M.D.</b>		
<i>/s/</i> DAVID B. SINGER	Director	April 2, 2007
<b>David B. Singer</b>		

**Table of Contents**

**CORCEPT THERAPEUTICS INCORPORATED**

**(A DEVELOPMENT STAGE COMPANY)**

**INDEX TO FINANCIAL STATEMENTS**

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
Audited Financial Statements	
<u>Balance Sheets</u>	F-3
<u>Statements of Operations</u>	F-4
<u>Statement of Convertible Preferred Stock and Stockholders' Equity (Net Capital Deficiency)</u>	F-5
<u>Statements of Cash Flows</u>	F-9
<u>Notes to Financial Statements</u>	F-10

F-1

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders

Corcept Therapeutics Incorporated

We have audited the accompanying balance sheets of Corcept Therapeutics Incorporated (a development stage company) as of December 31, 2006 and 2005, and the related statements of operations, convertible preferred stock and stockholders' equity (net capital deficiency), and cash flows for each of the three years in the period ended December 31, 2006, and for the period from inception (May 13, 1998) to December 31, 2006. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States.) Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Corcept Therapeutics Incorporated (a development stage company) at December 31, 2006 and 2005 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2006 and for the period from inception (May 13, 1998) to December 31, 2006, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 1 to the financial statements, in 2006 Corcept Therapeutics Incorporated changed its method of accounting for stock-based compensation in accordance with guidance provided in Statement of Financial Accounting Standards No. 123(R), "Share-Based Payment".

/s/ Ernst & Young LLP

Palo Alto, California

March 30, 2007

**Table of Contents****CORCEPT THERAPEUTICS INCORPORATED****(A DEVELOPMENT STAGE COMPANY)****BALANCE SHEETS****(in thousands, except per share amounts)**

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 8,906	\$ 3,816
Short-term investments	550	25,264
Prepaid expenses and other current assets	343	425
Total current assets	9,799	29,505
Long-term investments		539
Property and equipment, net of accumulated depreciation	38	52
Other assets	65	60
Total assets	\$ 9,902	\$ 30,156
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 916	\$ 549
Accrued clinical expenses	2,224	2,521
Accrued compensation	138	144
Obligations under capital lease, short-term	13	12
Other liabilities	222	295
Total current liabilities	3,513	3,521
Obligations under capital lease, long-term	29	42
Total liabilities	3,542	3,563
Commitments		
Stockholders' equity:		
Preferred stock, \$0.001 par value, 10,000 shares authorized and no shares outstanding at December 31, 2006 or 2005		
Common stock, \$0.001 par value; 140,000 shares authorized and 25,732 and 22,704 shares issued and outstanding at December 31, 2006 and 2005, respectively	26	23
Additional paid-in capital	105,125	101,014
Notes receivable from stockholders	(125)	(168)
Deferred compensation	(228)	(603)
Deficit accumulated during the development stage	(98,438)	(73,565)
Accumulated other comprehensive loss		(108)
Total stockholders' equity	6,360	26,593
Total liabilities and stockholders' equity	\$ 9,902	\$ 30,156

See accompanying notes.





Table of Contents**CORCEPT THERAPEUTICS INCORPORATED****(A DEVELOPMENT STAGE COMPANY)****STATEMENTS OF OPERATIONS****(in thousands, except per share amounts)**

	Year ended December 31,			Period from inception (May 13, 1998) to December 31,
	2006	2005	2004	2006
Collaboration Revenue	\$ 294	\$	\$	\$ 294
Operating expenses:				
Research and development*	20,834	17,074	11,551	77,797
General and administrative*	5,042	4,084	4,494	24,273
Total operating expenses	25,876	21,158	16,045	102,070
Loss from operations	(25,582)	(21,158)	(16,045)	(101,776)
Interest and other income, net	719	1,117	578	3,594
Other expense	(10)	(52)	(68)	(256)
Net loss	\$ (24,873)	\$ (20,093)	\$ (15,535)	\$ (98,438)
Basic and diluted net loss per share	\$ (1.09)	\$ (0.89)	\$ (0.84)	
Shares used in computing basic and diluted net loss per share	22,841	22,608	18,440	
* Includes non-cash stock-based compensation (recovery) of the following:				
Research and development	\$ 535	\$ (26)	\$ 202	\$ 4,531
General and administrative	1,013	799	1,475	5,804
Total non-cash stock-based compensation	\$ 1,548	\$ 773	\$ 1,677	\$ 10,335

See accompanying notes.

**Table of Contents****CORCEPT THERAPEUTICS INCORPORATED****(A DEVELOPMENT STAGE COMPANY)****STATEMENT OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (NET CAPITAL DEFICIENCY)****(in thousands, except per share amounts)**

	Convertible Preferred Stock		Common Stock		Notes Additional Paid-in Capital	Notes Receivable from Stockholders	Deferred Compensation	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Loss	Total Stockholders Equity (Net Capital Deficiency)
	Shares	Amount	Shares	Amount						
Balance at inception (May 13, 1998)		\$		\$	\$	\$	\$	\$	\$	\$
Issuance of common stock to directors for cash in June and July 1998			7,500	8	(5)					3
Issuance of common stock to a director for cash in May 1999			1,771	2	63					65
Issuance of common stock to Stanford and directors in conjunction with a license agreement in October 1999			30		1					1
Issuance of Series A convertible preferred stock to institutional and individual investors at \$1.08 per share for cash and conversion of notes payable, net of issuance costs of \$34 in May 1999	608	623								
Common stock issued to attorneys and consultants in exchange for services in May 1999			49		2					2
Issuance of common stock upon option exercise			60							
Repurchase of common stock held by director in March 1999			(750)	(1)						(1)
Deferred compensation related to options granted to non-employees					65		(65)			
Amortization of deferred compensation							7			7
Net loss from inception to December 31, 1999								(321)		(321)
Balance at December 31, 1999	608	623	8,660	9	126		(58)	(321)		(244)
Issuance of Series B convertible preferred stock to institutional and individual investors at \$3.00 per share for cash, net of issuance costs of \$19 in January 2000	400	1,180								
Deferred compensation related to options granted to an employee and non-employees					248		(248)			
Amortization of deferred compensation							91			91
Net loss								(1,846)		(1,846)
Balance at December 31, 2000	1,008	1,803	8,660	9	374		(215)	(2,167)		(1,999)
Issuance of Series B convertible preferred stock to consultants in exchange for services in January and April 2001	12	205								
Issuance of Series BB convertible preferred stock to institutional and individual investors at \$4.033 per share upon conversion of promissory notes in May 2001	268	1,081								

Edgar Filing: CORCEPT THERAPEUTICS INC - Form 10-K

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

F-5

**Table of Contents****CORCEPT THERAPEUTICS INCORPORATED****(A DEVELOPMENT STAGE COMPANY)****STATEMENT OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (NET CAPITAL DEFICIENCY),  
(Continued)****(in thousands, except per share amounts)**

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Notes Receivable from Stockholder	Deferred Compensation	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Loss	Total Stockholders Equity (Net Capital Deficiency)
	Shares	Amount	Shares	Amount						
Balance at December 31, 2001 (brought forward)	5,096	\$ 29,914	9,479	\$ 9	\$ 11,103	\$ (438)	\$ (8,592)	\$ (9,621)	\$	\$ (7,539)
Issuance of Series C convertible preferred stock to institutional and individual investors at \$7.066 per share for cash, net of issuance costs of approximately \$19 in December 2002	1,673	11,802								
Issuance of common stock upon option exercises			62							
Amortization of deferred compensation							4,085			4,085
Reduction of deferred compensation related to the unamortized portion of deferred stock compensation related to a terminated employee					(239)		239			
Reversal of previously expensed deferred compensation related to a terminated employee based on the straight line method					(50)					(50)
Stock-based compensation related to lapsing repurchase right of stock held by a non-employee					68					68
Net loss								(18,504)		(18,504)
Balance at December 31, 2002	6,769	41,716	9,541	9	10,882	(438)	(4,268)	(28,125)		(21,940)
Deferred compensation related to options granted to employees and non-employees					1,159		(1,159)			1,159
Amortization of deferred compensation							1,559			1,559
Reduction of deferred compensation related to the unamortized portion of deferred stock compensation related to terminated employees					(1,588)		1,588			
Reversal of previously expensed deferred compensation related to terminated employees					(1,384)					(1,384)
Repurchase of common stock and reduction of note payable upon termination of employees			(206)		(155)	155				
Repayment of note receivable from stockholder						37				37
Stock-based compensation related to lapsing repurchase right of stock held by a non-employee					68					68
Net loss								(9,812)		(9,812)
Unrealized loss on short-term investments									(1)	(1)

Edgar Filing: CORCEPT THERAPEUTICS INC - Form 10-K

Total comprehensive loss										(9,813)
--------------------------	--	--	--	--	--	--	--	--	--	---------

Balance at December 31, 2003 (carried forward)	6,769	41,716	9,335	9	8,982	(246)	(2,280)	(37,937)	(1)	(31,473)
--	-------	--------	-------	---	-------	-------	---------	----------	-----	----------

F-6

**Table of Contents****CORCEPT THERAPEUTICS INCORPORATED****(A DEVELOPMENT STAGE COMPANY)****STATEMENT OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (NET CAPITAL DEFICIENCY),  
(Continued)****(in thousands, except per share amounts)**

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Notes Receivable from Stockholder	Deferred Compensation	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Loss	Total Stockholders Equity (Net Capital Deficiency)
	Shares	Amount	Shares	Amount						
Balance at December 31, 2003 (brought forward)	6,769	\$ 41,716	9,335	\$ 9	\$ 8,982	\$ (246)	\$ (2,280)	\$ (37,937)	\$ (1)	\$ (31,473)
Sale of Shares in IPO at \$12.00 per share for cash, net of issuance costs of approximately \$4,974			4,500	5	49,020					49,025
Conversion of preferred shares in IPO	(6,769)	(41,716)	8,807	9	41,707					41,716
Conversion of note payable			45		534					534
Issuance of common stock upon option exercises			7		1					1
Deferred compensation related to options granted to employees and non-employees					1,447		(1,447)			
Amortization of deferred compensation							1,854			1,854
Reduction of deferred compensation related to the unamortized portion of deferred stock compensation related to terminated employees and consultants					(155)		155			
Reversal of previously expensed deferred compensation related to terminated or converted to consultant employees					(243)					(243)
Repayment of note receivable from stockholder						62				62
Stock-based compensation related to lapsing repurchase right of stock held by a non-employee					68					68
Net loss								(15,535)		(15,535)
Change in unrealized loss on investments									(61)	(61)
Total comprehensive loss										(15,596)
Balance at December 31, 2004			22,694	23	101,361	(184)	(1,718)	(53,472)	(62)	45,948
Issuance of common stock upon option exercise for cash in June 2005 at a price of \$0.10 per share			9		1					1
Deferred compensation related to options granted to employees and non-employees					(94)		94			
Amortization of deferred compensation					35		912			947
					(109)		109			

Edgar Filing: CORCEPT THERAPEUTICS INC - Form 10-K

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

F-7



**Table of Contents****CORCEPT THERAPEUTICS INCORPORATED****(A DEVELOPMENT STAGE COMPANY)****STATEMENT OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (NET CAPITAL DEFICIENCY),  
(Continued)****(in thousands, except per share amounts)**

	Convertible Preferred Stock	Common Stock	Additional Paid-in Capital	Notes Receivable from Stockholders	Deferred Compensation	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Loss	Total Stockholders Equity (Net Capital Deficiency)		
	Shares	Amount	Shares	Amount	Capital	Stockholders	Compensation	Stage	Loss	Deficiency)
Balance at December 31, 2005 (brought forward)		\$	22,704	\$ 23	\$ 101,014	\$ (168)	\$ (603)	\$ (73,565)	\$ (108)	\$ 26,593
Sale of common stock in December 2006 at \$1.00 per share for cash, net of issuance costs of approximately \$83			3,000	3	2,914					2,917
Issuance of common stock upon option exercises at various times for cash at a weighted-average exercise price of \$0.73 per share			26		19					19
Issuance of common stock at various times for services in lieu of cash compensation at an average value of \$4.93 per share			2		12					12
Amortization of deferred compensation related to options granted to employees prior to the IPO							375			375
Stock-based compensation under SFAS 123R related to employee options granted after the IPO					1,118					1,118
Stock-based compensation related to options to consultants at various times at prices ranging from \$0.10 to \$10.06					75					75
Reversal of previously expensed compensation related to employees terminated or converted to consultant					(50)					(50)
Repayments of notes receivable from stockholders in October and December of 2006								43		43
Stock-based compensation related to lapsing repurchase right of stock held by a non-employee					23					23
Net loss							(24,873)			(24,873)
Change in unrealized loss on investments									108	108
<b>Total comprehensive loss</b>										<b>(24,765)</b>
Balance at December 31, 2006		\$	25,732	\$ 26	\$ 105,125	\$ (125)	\$ (228)	\$ (98,438)	\$	\$ 6,360

See accompanying notes.

**Table of Contents****CORCEPT THERAPEUTICS INCORPORATED****(A DEVELOPMENT STAGE COMPANY)****STATEMENTS OF CASH FLOWS****(in thousands)**

	Year ended December 31,			Period from
	2006	2005	2004	inception (May 1, 1998) to December 31, 2006
<b>Operating activities</b>				
Net loss	\$ (24,873)	\$ (20,093)	\$ (15,535)	\$ (98,438)
Adjustments to reconcile net loss to net cash used in operations:				
Depreciation and amortization of property and equipment	14	7	1	75
Stock-based compensation, net of recoveries	1,518	697	1,609	9,979
Expense related to stock issued for services	12	2		60
Expense related to stock issued in conjunction with license agreement				15
Expense related to stock issued below fair value	23	68	68	522
Interest accrued on convertible promissory notes			10	104
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	82	413	(672)	(343)
Other assets	(5)	(13)	(9)	(65)
Accounts payable	367	(1)	228	916
Accrued clinical	(297)	1,866	321	2,224
Other liabilities	(79)	(180)	261	360
Net cash used in operating activities	(23,238)	(17,234)	(13,718)	(84,591)
<b>Investing activities</b>				
Purchases of property and equipment				(54)
Purchases of short-term and long-term investments	(1,315)	(25,863)	(66,358)	(108,346)
Maturities of short-term investments	26,676	40,971	26,845	107,797
Net cash provided by (used in) investing activities	25,361	15,108	(39,513)	(603)
<b>Financing activities</b>				
Proceeds from issuance of common stock, net of cash paid for issuance costs	2,936	1	49,026	52,037
Proceeds from issuance of convertible note payable				463
Proceeds from convertible promissory notes				1,080
Proceeds from repayment of stockholder notes	43	16	62	159
Principal payments of obligations under capital leases	(12)	(5)		(17)
Proceeds from issuance of convertible preferred stock, net of cash paid for issuance costs				40,378
Net cash provided by financing activities	2,967	12	49,088	94,100
Net increase (decrease) in cash and cash equivalents	5,090	(2,114)	(4,143)	8,906
Cash and cash equivalents at beginning of period	3,816	5,930	10,073	
Cash and cash equivalents at end of period	\$ 8,906	\$ 3,816	\$ 5,930	\$ 8,906

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

Supplemental disclosure of cash flow information							
Interest paid	\$	4	\$	2	\$	\$	6
Supplemental disclosure of non-cash financing activities							
Conversion of convertible promissory notes and accrued interest							
to convertible preferred stock	\$	\$	\$	\$	1,111		
to common stock	\$	\$	\$	534	\$	534	
Purchase of equipment under capital leases	\$	\$	59	\$	\$	59	

See accompanying notes.

F-9

---

**Table of Contents**

**CORCEPT THERAPEUTICS INCORPORATED**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO FINANCIAL STATEMENTS**

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

**Description of Business**

Corcept Therapeutics Incorporated (the Company or Corcept) was incorporated in the state of Delaware on May 13, 1998, and its facilities are located in Menlo Park, California. Corcept is a pharmaceutical company engaged in the development of drugs for the treatment of severe psychiatric and metabolic diseases.

The Company's primary activities since incorporation have been establishing its offices, recruiting personnel, conducting research and development, performing business and financial planning, raising capital, and overseeing clinical trials. Accordingly, the Company is considered to be in the development stage.

**Management's Plans**

In the course of its development activities, the Company has sustained operating losses and expects such losses to continue for at least the next several years. The Company plans to continue to finance its operations through the sale of its equity and debt securities. The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The Company's ability to continue as a going concern is dependent upon successful execution of its financing strategy. In March 2007 the Company reported that Study 06, the last of three Phase 3 trials evaluating CORLUX<sup>®</sup> for treating the psychotic features of Psychotic Major Depression (PMD), did not achieve statistical significance with respect to its primary endpoint (see Note 12.)

As reflected in the accompanying financial statements as of December 31, 2006, the Company had cash, cash equivalents and investments balances of \$9.5 million, working capital of \$6.3 million and an accumulated deficit of \$98.4 million. On March 30, 2007, the Company completed a private financing transaction that generated net proceeds of approximately \$8.8 million (see Note 12.) With the completion of this financing, the Company has sufficient funds to maintain its current operations through the completion and reporting of results of the proof-of-concept weight-gain mitigation study, expected in June 2007, to prepare for the next Phase 3 trial and to continue development of its new chemical entities.

The Company will need to raise additional funds in order to sustain its operations at anticipated levels beyond early 2008. Although the Company's management recognizes the need to raise funds in the future, there can be no assurance that the Company will be successful in consummating any such transaction, or, if the Company does consummate such a transaction, that the terms and conditions of such financing will not be unfavorable to it. Any failure by the Company to obtain additional funding will have a material effect upon it and will likely result in the Company's inability to continue as a going concern. If the Company is not able to raise additional funds, it will not be able to continue operations beyond early 2008.

**Use of Estimates**

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

Cost accruals for clinical trials are based upon estimates of work completed under service agreements, milestones achieved, patient enrollment and past experience with similar contracts. The Company's estimates of work completed and associated cost accruals include its assessments of information received from third-party

**Table of Contents**

**CORCEPT THERAPEUTICS INCORPORATED**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO FINANCIAL STATEMENTS, Continued**

contract research organizations and the overall status of clinical trial activities. The estimates are updated on a recurring basis as new information becomes available.

Any changes in estimates are recorded in the period of the change.

**Revenue Recognition**

Collaboration revenue relates to services rendered in connection with an agreement signed in October 2005 with Eli Lilly and Company ( Lilly ) in which Lilly agreed to support the Company s proof-of-concept clinical study evaluating the ability of CORLUX, a GR-II antagonist, to mitigate weight gain associated with the use of olanzapine. Under the agreement, Lilly agreed to supply olanzapine and pay for the budgeted costs of the study. Under the agreement, the Company is required to perform specified development activities and the fee paid to us by Lilly is based on the costs associated with the conduct of that trial and the preparation and packaging of clinical trial materials. Revenue is recognized as services are rendered in accordance with the agreement. The cost of providing these research services approximates the revenue recognized. If the costs of the study exceed budgeted amounts, Lilly may not pay for the excess. As of December 31, 2006, the costs have not exceeded the budgeted amounts.

**Research and Development**

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

**Income Taxes**

The Company accounts for income taxes under Statement of Financial Accounting Standards ( SFAS ) No. 109, *Accounting for Income Taxes*. 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.

**Credit Risks and Concentrations**

The Company s concentration of credit risk consists of cash, cash equivalents, and short-term and long-term investments. The Company is exposed to credit risk in the event of default by the financial institutions holding the cash, cash equivalents, and short-term and long-term investments to the extent of the amount recorded on the balance sheets.

The Company also has a concentration of risk in regard to the manufacture of its product. As of December 31, 2006, the Company has a single source supplier for its tablet manufacture. If this supplier is unable to prepare the CORLUX® tablets in the quantities and time frame required, the Company may not be able to manufacture its product in a timely manner.

**Table of Contents**

**CORCEPT THERAPEUTICS INCORPORATED**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO FINANCIAL STATEMENTS, Continued**

**Segment Reporting**

The Company has adopted SFAS No. 131, *Disclosure About Segments of an Enterprise and Related Information*, which requires companies to report selected information about operating segments, as well as enterprise wide disclosures about products, services, geographical areas, and major customers. Operating segments are determined based on the way management organizes its business for making operating decisions and assessing performance. The Company has only one operating segment, which is involved in the development of pharmaceutical products.

**Cash, Cash Equivalents, Short-term and Long-term Investments**

The Company invests its excess cash in bank deposits, money market accounts, corporate debt securities, and obligations of the U.S. government and U.S. government sponsored entities. The Company considers all highly liquid investments purchased with maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents are carried at fair value, which approximates cost, and primarily consist of money market funds maintained at major U.S. financial institutions and obligations of U.S. government sponsored entities.

All short-term and long-term investments, which primarily represent marketable debt securities, have been classified as available-for-sale. Short-term investments includes debt securities with maturities of one year or less from the balance sheet dates. Debt securities with maturities of greater than 12 months from the balance sheet dates are classified as long-term investments. Purchased premiums or discounts on debt securities are amortized to interest income through the stated maturities of the debt securities. The differences between amortized cost and fair values of the debt securities are recorded as a component of accumulated other comprehensive loss. Management determines the appropriate classification of its investments in debt securities at the time of purchase and evaluates such designation as of each balance sheet date. Unrealized gains and losses are included in accumulated other comprehensive loss and reported as a separate component of stockholders' equity. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other expenses. The cost of securities sold is based on the specific identification method. Interest earned on short-term and long-term investments is included in interest income.

**Property and Equipment**

Property and equipment are stated at cost less accumulated depreciation. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets, ranging from three to five years.

During 2005, the Company acquired office equipment and furniture of approximately \$59,000 under leases that are classified as capital leases. Assets acquired under capital leases are amortized over the term of their useful lives or the lease period, whichever is shorter.

**Stock-Based Compensation**

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

The Company adopted Statement of Financial Accounting Standard 123 (Revised 2004), *Share-Based Payment* ( 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

**Table of Contents**

**CORCEPT THERAPEUTICS INCORPORATED**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO FINANCIAL STATEMENTS, Continued**

share-based payments granted or modified after the effective date and (b) based on the requirements of Statement 123 for all awards granted to employees prior to the effective date of Statement 123R that remain unvested on the effective date. See Note 7 for a discussion of the Company's stock option plans and the impact of the Company's results from operations due to the implementation of SFAS 123R. Prior to the adoption of SFAS 123R, the Company 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* ( APB 25 ), and had adopted the disclosure-only alternative of SFAS No. 123, *Accounting for Stock-Based Compensation* ( SFAS 123 ), as amended by SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure* ( SFAS 148 ). Because the Company had used the minimum value method for SFAS 123 pro forma disclosure requirements for options granted prior to the initial public offering of its common stock ( IPO ) in 2004, it continues 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.

*Stock-based compensation for employee options*

From inception in May 1998 through December 31, 2005, the Company accounted for stock-based compensation for options granted to employees and directors using the intrinsic value method prescribed in APB 25 and adopted the disclosure-only alternative of SFAS 123, as amended by SFAS No. 148. As discussed above, the Company adopted SFAS 123R as of January 1, 2006. Following is a brief synopsis of the implications of adoption of this statement on the Company's accounting practices in regard to stock option grants to employees and directors:

Options granted prior to January 1, 2006:

- i For options granted prior to the IPO in 2004, the Company is continuing to account for the portion of these grants that were non-vested as of January 1, 2006 under the provisions of APB 25, with pro forma disclosures under SFAS 123. This treatment is being followed because the Company had used the minimum value method for these options under SFAS 123 pro forma disclosure requirements.
- i For the options granted after the IPO, the Company began, as of January 1, 2006, to record non-cash stock compensation expense in the financial statements in amounts that represent the remaining fair value of the non-vested portion of these grants, utilizing the assumptions and fair value per share information as of the original grant date that the Company has been using for SFAS 123 pro forma disclosure purposes.
- i For all options granted prior to January 1, 2006, the Company is continuing to utilize the graded-vesting attribution method for amortization of the relevant compensation amounts.
- i Since the Company has a limited employee base, it does 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, the Company will record a change in accounting estimate that represents the difference between the expense recorded under the graded-vesting 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.

Edgar Filing: CORCEPT THERAPEUTICS INC - Form 10-K

Options granted or modified on or after January 1, 2006:

- <sup>i</sup> Compensation expense is being recorded in the financial statements based on the fair value on the date of grant, in accordance with the provisions and guidelines of SFAS 123R and all relevant Interpretations and SEC Staff Accounting Bulletins.

F-13



**Table of Contents****CORCEPT THERAPEUTICS INCORPORATED****(A DEVELOPMENT STAGE COMPANY)****NOTES TO FINANCIAL STATEMENTS, Continued**

<sup>i</sup> The grant date fair value for all new grants is being amortized to expense using the straight-line attribution method over the vesting period of the options.

<sup>i</sup> As discussed above, the Company has not determined a 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 amounts of stock compensation expense recorded for the year ended December 31, 2006 and the impact of implementation of SFAS 123R regarding employee options on our statement of operations. Amounts shown are net of recoveries related to the reversal of excess expense recognized over that which was related to options that have vested as of the date of termination or conversion of employee status to consultancy.

Operating Expense Category	Research and development	General and administrative <i>(amounts in thousands)</i>	Total
Expense under provisions of APB 25	\$ (2)	\$ 373	\$ 371
Incremental expense	440	632	1,072
Expense under provisions of SFAS 123R	\$ 438	\$ 1,005	\$ 1,443

The incremental expense of accounting for stock options to employees and directors under the provisions of SFAS 123R represented \$0.05 per share for the year ended December 31, 2006. There were no retroactive or non-recurring charges and there was no impact on our statement of financial condition or cash flows as a result of the implementation.

*Deferred stock-based compensation for employee options*

As discussed above, from its inception in May 1998 through December 31, 2005, the Company accounted for stock-based compensation for options granted to employees and directors using the intrinsic value method prescribed in APB 25. Under the intrinsic value method, deferred stock-based compensation related to option grants to employees and directors represented the difference between the exercise price of an option and the fair value of the Company's common stock on the date of the grant. Given the absence of an active market for the Company's common stock prior to the IPO in April 2004, the Company's management was required to estimate the fair value of its 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 the financial statements. Since the Company's IPO, all stock option grants have been at the closing price for the stock on the Nasdaq Stock Market as of the date of grant and no deferred compensation was recorded related to the options granted after the IPO.

The Company amortizes the deferred stock-based compensation of employee options to expense using the graded-vesting method over the vesting periods of the applicable stock options, generally five years. The graded-vesting method provides for vesting of portions of the overall awards at interim dates and results in greater vesting 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 reversed. As discussed above, this accounting practice is continuing to be followed in regard to the options granted prior to the IPO.



**Table of Contents****CORCEPT THERAPEUTICS INCORPORATED****(A DEVELOPMENT STAGE COMPANY)****NOTES TO FINANCIAL STATEMENTS, Continued**

*Pro-forma net loss information required under SFAS123 for options accounted for under the intrinsic value method*

The following table presents the pro forma net loss information required under SFAS 123, as amended by SFAS 148, related to stock options granted to employees and directors. In the pro forma calculation, amortization related to options to employees and directors that are accounted for under the intrinsic value method prescribed by APB 25 is added back to income and replaced with the expense that would have been reflected in the statements of operations in the respective periods as if the Company had accounted for these options under the fair value method prescribed by SFAS 123. For purposes of this disclosure, the fair value of the stock options is amortized to expense over the vesting periods of the options using the graded-vesting method. The resulting effects on net loss pursuant to SFAS 123 related to these options are not likely to be representative of the effects in future periods or years, due to the decelerating scale of expense recognition under the graded vesting method or the effect of any terminations.

As noted above, the Company estimated the fair value of these options at the date of grant in accordance with SFAS 123, which allowed non-public companies to use the minimum value option pricing model and required the use of a model such as the Black-Sholes option pricing model for options granted by public companies. The Company has estimated the fair value of options granted prior to February 10, 2004, the date of filing of the Form S-1, using the minimum value option pricing model and has used the Black-Sholes option pricing model for determining the fair value of options granted on or after that date.

	Year Ended December 31,			Period from
	2006	2005	2004	inception (May 13, 1998) to December 31, 2006
Net loss as reported	\$ (24,873)	\$ (20,093)	\$ (15,535)	\$ (98,438)
Adjustments to net loss related to stock awards to employees and directors accounted for under the intrinsic value method:				
Add back: Amortization of deferred compensation	375	841	1,740	9,988
Deduct: Stock-based employee compensation expense determined under SFAS 123	(496)	(2,498)	(3,007)	(13,154)
<b>Pro forma net loss</b>	<b>\$ (24,994)</b>	<b>\$ (21,750)</b>	<b>\$ (16,802)</b>	<b>\$ (101,604)</b>
As reported net loss per share basic and diluted	\$ (1.09)	\$ (0.89)	\$ (0.84)	
Pro forma net loss per share basic and diluted	\$ (1.09)	\$ (0.96)	\$ (0.91)	

The pro forma adjustment reflected in the table above for 2006 relates only to those options granted to employees and directors prior to the IPO because, as discussed above, these options continue to be accounted for using the intrinsic value method. This pro forma adjustment is not required after December 31, 2005, for options granted after the IPO that are now accounted for under SFAS 123R as their expense is recorded based on fair value at the date of grant since the adoption of SFAS 123R. For 2005 and all prior years, the pro forma adjustment relates to all options to employees and directors.

**Table of Contents****CORCEPT THERAPEUTICS INCORPORATED****(A DEVELOPMENT STAGE COMPANY)****NOTES TO FINANCIAL STATEMENTS, Continued***Assumptions used in determining fair value for options granted to employees*

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

	<b>Year Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
<b>Weighted average assumptions for stock options granted:</b>			
Risk-free interest rate	4.98%	4.15%	4.00%
Expected term	6.0 years	8.4 years	10 years
Expected volatility of stock price	78.6%	76.2%	50.3%
Dividend rate	0%	0%	0%
Weighted average fair value of grants issued	\$3.09	\$3.62	\$6.73

The expected term for options granted during 2006 is based on the simple method prescribed by the SEC in Staff Accounting Bulletin 107, and considers the weighted average of the vesting period and contractual life of the options. For options granted during 2005 and 2004 the expected term was based on the 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 the Company has a limited employee base and does not have sufficient historical information to determine such an adjustment.

The expected volatility of the Company's stock used in determining the fair value of option grants is based on a weighted-average combination of the volatility of the Company's own stock price and that of a group of peer companies since the Company does not have sufficient historical data from which to base an appropriate valuation assumption.

*Stock-based compensation expense related to non-employees*

Options granted to non-employees are accounted for in accordance with Emerging Issues Task Force Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring or in Conjunction with Selling, Goods or Services* (EITF 96-18), and are periodically remeasured as they are earned.

**Recently Issued Accounting Standards**

In June 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48), an interpretation of SFAS No. 109, *Accounting for Income Taxes* (SFAS 109). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS 109 by prescribing a minimum recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition measurement, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company is currently evaluating the impact of adopting FIN 48 on our financial statements.

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* (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. The Company has

---

**Table of Contents**

**CORCEPT THERAPEUTICS INCORPORATED**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO FINANCIAL STATEMENTS, Continued**

adopted SAB 108 as of January 1, 2007, as required, and does not believe that implementation of SAB 108 will have a material effect on our financial statements.

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* ( 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 our financial statements.

**2. Significant Agreements**

**Stanford License Agreements**

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

In October 1999, the Company exercised its option to acquire an exclusive license to patents covering the use of glucocorticoid receptors antagonists for the treatment of psychotic major depression, early dementia, and cocaine-induced psychosis, as specified in the license agreement. This license agreement expires upon the expiration of the related patents or upon notification by the Company to Stanford. In exchange for the license, the Company agreed to pay Stanford \$47,000 and immediately issue 30,000 shares of the Company s common stock to Stanford. The Company is further required to pay Stanford \$50,000 per year as a nonrefundable royalty payment. The annual royalty payments are creditable against future royalties. The Company is also obligated to pay a \$50,000 milestone upon filing of the first New Drug Application with the United States Food and Drug Administration ( FDA ) and a \$200,000 milestone upon FDA approval of the related drug. The milestone payments are also creditable against future royalties. The Company has expensed the \$47,000 payment made up front, the \$50,000 annual nonrefundable royalty payments and the value of the common stock issued to Stanford as research and development costs.

**Manufacturing Agreements**

In June 2000, the Company entered into a Memorandum of Understanding with a pharmaceutical manufacturer, ScinoPharm Taiwan, in which the manufacturer agreed to produce the active pharmaceutical ingredient ( API ) in CORLUX for the Company. In exchange, the Company agreed to share initial research and development costs related to the manufacturing process, which consisted of the acquisition of starting materials and equipment, as well as personnel costs, to complete the technology transfer, process development, and scale-up studies. The Company recorded expense for these activities as incurred in the amount of approximately \$340,000 in 2004. No such costs were incurred in either 2005 or 2006. Further, the Company has committed to purchase \$1,000,000 per year of the API in CORLUX from the manufacturer following the receipt of marketing approval and initiation of sales of CORLUX.

---

**Table of Contents**

**CORCEPT THERAPEUTICS INCORPORATED**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO FINANCIAL STATEMENTS, Continued**

On November 8, 2006, the Company signed an agreement with Produits Chimiques Auxiliaires et de Synthese SA ( PCAS ) for the manufacture of the API for its development and commercial needs for an initial period of five years. The agreement provides for an automatic extension for one additional year unless either party gives twelve months' prior notice that it does not want the extension. If PCAS is unable to manufacture the product for a consecutive six-month period, the Company has the right to terminate the agreement. There is no guaranteed minimum purchase commitment under this agreement.

**Institute for the Study of Aging Note Payable**

In January 2001, the Company issued a convertible note payable to the Institute for the Study of Aging whereby the Company received \$462,929 to be used for specified research related to the treatment of Alzheimer's disease. The note bore interest at a rate of 4.5% per year and was payable on demand beginning in January 2008, if not earlier converted. The principal and accrued interest was convertible at the election of the holder following the first to occur of the following events: (1) upon an initial public offering, the note converts into common stock at the offering price; (2) upon a merger or acquisition whereby the holders of the Company's stock do not retain majority voting power, the note converts into preferred stock at the price paid per share in the most recent round of preferred stock financing; or (3) upon approval to market by the FDA of CORLUX for treatment of Alzheimer's disease, the note converts into preferred stock at the price paid per share in the most recent round of preferred stock financing. On June 30, 2004 the principal and accrued interest aggregating \$534,105 were converted into 44,508 shares of the Company's common stock.

**Argenta Discovery Limited**

In January 2003, the Company entered into a contract research agreement with Argenta Discovery Limited ( Argenta ) in which Argenta agreed to conduct research toward identifying a novel small molecule glucocorticoid receptor antagonist for the treatment of psychotic major depression, Alzheimer's disease, and other psychiatric and metabolic disorders. The project was expected to last at least two years, during which time the Company would make payments to Argenta based upon agreed-upon FTE (full-time equivalent) rates. During 2004, the Company gave notice to Argenta of its intent to extend its agreement to March 31, 2005, at which time the work under this agreement was concluded. During the years ended December 31, 2005 and 2004, the Company recorded approximately \$525,000 and \$2.1 million, respectively, as research and development expense related to this contract.

Under the agreement, the Company 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.

**Development Agreements**

During 2004 and 2005, the Company executed a number of agreements to conduct clinical trials and pre-clinical studies for further development of its lead product, CORLUX, targeted for the treatment of the psychotic features of psychotic major depression. These agreements provide for termination by the Company upon forty-five days' written notice or less.

In October 2005, the Company signed an agreement with Eli Lilly and Company ( Lilly ) in which Lilly has agreed to support the Company's proof of concept clinical study evaluating the ability of CORLUX, a GR-II

**Table of Contents**

**CORCEPT THERAPEUTICS INCORPORATED**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO FINANCIAL STATEMENTS, Continued**

antagonist, to mitigate weight gain associated with the use of olanzapine. Under the agreement, Lilly will supply olanzapine and pay for the study. This study will be conducted in healthy male volunteers.

In November 2005, the Company signed an agreement for the performance of testing services in connection with a cardiac study that was performed in 2006. The total commitment under this agreement was originally approximately \$1.8 million. In January 2006, the Company entered into a separate agreement with a CRO to assist in the conduct of this study for an original commitment of approximately \$2.3 million. During 2006, the Company modified the projected enrollment under this study, reducing the expected total cost by approximately \$1.1 million.

In November 2006, the Company signed an agreement with a contract research organization to assist in the conduct of a weight-gain mitigation study to be performed in 2007. The total commitment under this agreement is approximately \$336,000. This agreement provides for termination by the Company with thirty days' notice. The costs of this study will be reimbursed to the Company under a collaboration agreement with Lilly that was signed in October 2005.

In March 2006, the Company signed an amendment to our agreement with the CRO that assists us in the conduct of European clinical trial activities to add five European sites to our U.S.-based Phase 3 trials. The amount of the incremental commitment related to this amendment was approximately \$415,000.

During the course of 2006, the Company modified the projected time table for the completion of enrollment of Study 06, one of its primarily U.S.-based phase 3 trials. The extension in time to complete this trial is expected to increase projected costs by approximately \$1.2 million in excess of the amounts previously reported as commitments for this trial.

As of December 31, 2006, the total amount of commitments under these agreements that had not been expended or accrued as of that date was approximately \$1.7 million. All of these costs are expected to be incurred during 2007.

**Table of Contents****CORCEPT THERAPEUTICS INCORPORATED****(A DEVELOPMENT STAGE COMPANY)****NOTES TO FINANCIAL STATEMENTS, Continued****3. Financial Instruments**

The following is a summary of cash, cash equivalents, short-term and long-term investments as of December 31, 2006 and 2005:

	Cost	Unrealized Gain	Unrealized Loss	Fair Value
		<i>(all amounts in thousands)</i>		
<b>December 31, 2006</b>				
Cash	\$ 80	\$	\$	\$ 80
Money market funds	8,826			8,826
Commercial paper	550			550
	\$ 9,456	\$	\$	\$ 9,456

Reported as:

Cash and cash equivalents	\$ 8,906	\$	\$	\$ 8,906
Short -term investments	550			550
	\$ 9,456	\$	\$	\$ 9,456

	Cost	Unrealized Gain	Unrealized Loss	Fair Value
		<i>(all amounts in thousands)</i>		
<b>December 31, 2005</b>				
Cash	\$ 497	\$	\$	\$ 497
Money market funds	1,672			1,672
Commercial paper	1,647			1,647
Corporate debt securities	11,160		(53)	11,107
Obligations of United States government sponsored entities	14,751		(55)	14,696
	\$ 29,727	\$	(108)	\$ 29,619

Reported as:

Cash and cash equivalents	\$ 3,816	\$	\$	\$ 3,816
Short-term investments	25,372		(108)	25,264
Long-term investments	539			539
	\$ 29,727	\$	(108)	\$ 29,619

All short-term investments at December 31, 2006 have remaining maturities of less than one year.



**4. Property and Equipment**

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

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
	<i>(in thousands)</i>	
Furniture and equipment	\$ 106	\$ 106
Software	7	7
Less: accumulated depreciation and amortization	(75)	(61)
	\$ 38	\$ 52

F-20

**Table of Contents****CORCEPT THERAPEUTICS INCORPORATED****(A DEVELOPMENT STAGE COMPANY)****NOTES TO FINANCIAL STATEMENTS, Continued**

Furniture and equipment recorded under capital leases of approximately \$59,000 was acquired during 2005. Amortization expense related to assets under capital lease was approximately \$14,000 and \$7,000, respectively for the years ended December 31, 2006 and 2005.

Depreciation expense on fixed assets acquired for cash was approximately \$1,000 in 2004 and \$54,000 for the period from inception (May 13, 1998) to December 31, 2004, at which time they were fully depreciated.

**5. Lease Obligations**

In May 2005, the Company entered into a lease agreement for office space at a cost of approximately \$14,250 per month, which is subject to increases each January based on increases in the landlord's operating expenses for the property. The lease has an initial term of 30 months, with a commencement date of July 1, 2005, and provides the Company with an option to extend for an additional year.

During 2005, the Company acquired office equipment and furniture of approximately \$59,000 under leases that are classified as capital leases. The leases are payable over varying terms ranging from 39 to 60 months at regular monthly payments totaling approximately \$1,400. The estimated principal portion of payments under these leases within the next year is classified as short-term, with the remaining balance classified as long-term.

The following table provides a summary of the principal payment obligations under the capital leases and the minimum rental payments under the operating lease as of December 31, 2006.

<b>Year Ending December 31,</b>	<b>Capital</b>	<b>Operating</b>
	<b>Leases</b>	<b>Leases</b>
	<i>(in thousands)</i>	
2006	\$ 13	\$ 171
2007	13	
2008	10	
2009	6	
2010		
Total obligation	42	\$ 171
Less current portion	(13)	
Long-term portion of obligation	\$ 29	

Rent expense amounted to approximately \$171,000, \$225,000, \$239,000 and \$1.2 million for the years ended December 31, 2006, 2005 and 2004, and the period from inception (May 13, 1998) to December 31, 2006, respectively.

**6. Related Party Transactions**

The Company obtained legal services from a stockholder who was also an affiliate of a person who served as a member of the Company's board of directors until January 2004. Legal expenses incurred with this stockholder through that date were approximately \$1.5 million for the period from inception (May 13, 1998) to December 31, 2003.

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

Until June 2005, the Company also leased office space from this stockholder. Rent amounts paid to this stockholder amounted to approximately \$583,000 for the period from inception (May 13, 1998) to December 31, 2003.

F-21

**Table of Contents****CORCEPT THERAPEUTICS INCORPORATED****(A DEVELOPMENT STAGE COMPANY)****NOTES TO FINANCIAL STATEMENTS, Continued****7. Preferred Stock and Stockholders Equity****Preferred Stock**

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

In April 2004, the Convertible Preferred Stock that had been outstanding prior to the IPO was converted into shares of Common Stock, as discussed below. As of December 31, 2005 and 2006, the Company has no outstanding shares of preferred stock.

**Common Stock**

Upon completion of the IPO in April 2004, the Company's authorized capital stock includes 140,000,000 shares of common stock at \$0.001 par value. Holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders of the Company.

In April 2001, the Company issued 50,000 shares of common stock at a price below fair value to a scientific advisor for cash proceeds of \$5,000. The Company has the right to repurchase a portion of the common stock shares upon termination of services at the original exercise price. The Company recorded research and development expense of approximately \$23,000, \$68,000, \$68,000 and \$345,000 during the years ended December 31, 2006, 2005 and 2004 and for the period from inception (May 13, 1998) to December 31, 2006, respectively, for the difference between the fair value and price paid by the advisor related to the portion of the shares for which the Company's right of repurchase lapsed in each period. The Company's right to repurchase these shares expired in April 2006.

On December 31, 2006 the Company sold 3 million shares of common stock at a price of \$1.00 per share in a private placement. The net proceeds were approximately \$2.9 million after deducting issuance costs.

No dividends have been declared or paid by the Company.

Shares of common stock reserved for future issuance as of December 31, 2006 are as follows:

	<i>(in thousands)</i>
Common stock:	
Exercise of outstanding options	1,810
Shares available for grant under stock option plans	2,680
	4,490

See discussion below under, "Stock Option Plans" below regarding automatic annual increase in shares available for grant.

**Stock Option Plans**

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

In October 2000, the Company adopted the 2000 Stock Option Plan (the 2000 Plan ), which provides for the issuance of option grants for up to 1,000,000 shares of the Company s common stock to eligible participants.

F-22

**Table of Contents**

**CORCEPT THERAPEUTICS INCORPORATED**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO FINANCIAL STATEMENTS, Continued**

Under the 2000 Plan, options to purchase common stock may be granted at no less than 100% of fair value on the date of grant for incentive stock options and 85% of fair value on the date of grant for nonqualified options, as determined by the board of directors. Options become exercisable at such times and under such conditions as determined by the board of directors. The 2000 Plan provides for grants of immediately exercisable options; however, the Company has the right to repurchase any common stock upon termination of employment or services at the original exercise price where the right of repurchase has not lapsed. Shares repurchased by the Company prior to March 2004 returned to the option pool. Options generally vest over a four- or five-year period and have a maximum term of ten years. Incentive stock options generally vest at a rate of 20% at the end of the first year of vesting, with the remaining balance vesting ratably on a monthly basis over the remaining four years. In May 2001, the Company increased the number of shares of common stock authorized for issuance under the 2000 Plan by 1,000,000 shares, to a total of 2,000,000 shares.

In March 2004, the Company's board of directors and stockholders approved the 2004 Equity Incentive Plan (the "2004 Plan"), which became effective upon the completion of the IPO. The Company has reserved a total of 3,000,000 shares of its common stock for issuance under the 2004 Equity Incentive Plan. No additional options will be issued under the 2000 Plan. Under the 2004 Plan, options, stock purchase and stock appreciation rights and restricted stock awards can be issued to employees, officers, directors and consultants of the Company. The 2004 Plan provides that the exercise price for incentive stock options will be no less than 100% of the fair value of the Company's common stock, as of the date of grant. Generally, options granted under the 2004 Plan vest over either a four or five year period with 25% or 20%, respectively, of the underlying shares of common stock on the first anniversary of the date of grant and the remainder vesting in subsequent equal monthly installments through the remaining vesting period of the grant. The vesting period of the options is generally equivalent to the requisite service period. Upon exercise, new shares are issued.

The 2004 Plan provides that the share reserve will be cumulatively increased on January 1 of each year, beginning January 1, 2005 and for nine years thereafter, by a number of shares that is equal to the least of (a) 2% of the number of the Company's shares issued and outstanding at the preceding December 31, (b) 1,000,000 shares and (c) a number of shares set by the board. On February 10, 2005, the board approved an increase in the shares available for grant under the 2004 Plan by 453,876 shares, which represents 2% of the common shares outstanding at December 31, 2004. On March 2, 2006, the board of directors approved an increase in the shares available for grant under the 2004 Plan by 454,073 shares, which represents 2% of the common shares outstanding at December 31, 2005. See discussion in Note 12 "Subsequent events" regarding the increase in shares available for grant under the 2004 Plan approved by the board of directors at their meeting on March 1, 2007.

**Table of Contents****CORCEPT THERAPEUTICS INCORPORATED****(A DEVELOPMENT STAGE COMPANY)****NOTES TO FINANCIAL STATEMENTS, Continued***Option activity during 2006*

The following table summarizes all stock plan activity:

	<b>Shares Available</b>	<b>Stock Options Options Outstanding</b>	<b>Weighted- Average Exercise Price</b>
	<i>(in thousands, except per share data)</i>		
Balance at December 31, 2003	939	470	\$ 5.46
Cancellation of remaining shares authorized under 2000 Plan	(666)		
Shares authorized under 2004 Plan adoption	3,000		
Shares granted			
2000 Plan	(273)	273	\$ 9.02
2004 Plan	(436)	436	\$ 6.82
Shares exercised		(7)	\$ 0.10
Shares cancelled and forfeited under 2000 Plan		(31)	\$ 6.37
<b>Balance at December 31, 2004</b>	<b>2,564</b>	<b>1,141</b>	<b>\$ 6.84</b>
Increase in shares authorized under 2004 Plan	454		
Shares granted	(257)	257	\$ 4.71
Shares exercised		(9)	\$ 0.10
Shares issued for services	(1)		\$ 4.87
Shares cancelled and forfeited under 2004 Plan	10	(10)	\$ 5.78
Shares cancelled and forfeited under 2000 Plan		(44)	\$ 9.28
<b>Balance at December 31, 2005</b>	<b>2,770</b>	<b>1,335</b>	<b>\$ 6.41</b>
Increase in shares authorized under 2004 Plan	454		
Shares granted	(637)	637	\$ 4.33
Shares exercised		(26)	\$ 0.73
Shares issued for services	(2)		\$ 4.93
Shares cancelled and forfeited under 2004 Plan	95	(95)	\$ 4.74
Shares cancelled and forfeited under 2000 Plan		(41)	\$ 8.23
<b>Balance at December 31, 2006</b>	<b>2,680</b>	<b>1,810</b>	<b>\$ 5.80</b>

The total intrinsic value of options exercised during the year ended December 31, 2006, 2005 and 2004 were approximately \$360,000, \$14,000 and \$11,000, respectively.

The following table presents the total fair value of options to employees that vested during the years ended December 31, 2006, 2005 and 2004. All amounts are in thousands.

Edgar Filing: CORCEPT THERAPEUTICS INC - Form 10-K

	<b>Year ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
Pre-IPO options, using minimum value method	\$ 1,270	\$ 1,755	\$ 1,358
Options granted after IPO through 2005, using fair value under SFAS 123	829	903	3
Options granted during 2006, using fair values under SFAS 123R	121		
<b>Total</b>	<b>\$ 2,220</b>	<b>\$ 2,658</b>	<b>\$ 1,361</b>

F-24



**Table of Contents****CORCEPT THERAPEUTICS INCORPORATED****(A DEVELOPMENT STAGE COMPANY)****NOTES TO FINANCIAL STATEMENTS, Continued**

As of December 31, 2006, the Company had the following amounts of unrecognized compensation expense for employee options outstanding as of that date.

	<b>Amount</b> <i>(in thousands)</i>	<b>Weighted- average period</b> <i>(in years)</i>
Remaining deferred compensation related to options granted prior to the IPO, to be expensed under the provisions of APB 25	\$ 228	2.1
Remaining fair value to be expensed		
Options granted after IPO through 2005, using fair value under SFAS 123	648	2.8
Options granted during 2006, using fair value under SFAS 123R	1,520	3.5
<b>Total</b>	<b>\$ 2,396</b>	

The following is a summary of options outstanding and options exercisable at December 31, 2006. All options outstanding at December 31, 2006 are either exercisable or expected to become exercisable.

	<b>Options Outstanding</b>				<b>Options Exercisable</b>		
	<b>Number of Shares</b> <i>(in thousands)</i>	<b>Weighted Average Remaining Contractual Life</b> <i>(in years)</i>	<b>Weighted Average Exercise Price</b>	<b>Aggregate Intrinsic Value</b> <i>(in thousands)</i>	<b>Options Exercisable</b> <i>(in thousands)</i>	<b>Weighted Average Exercise Price</b>	<b>Aggregate Intrinsic Value</b> <i>(in thousands)</i>
\$ 0.10 - \$ 0.75	66	4.26	\$ 0.45	\$ 519	66	\$ 0.45	\$ 519
\$ 4.00 - \$ 7.73	1,608	8.12	\$ 5.49	2,151	582	\$ 6.25	1,272
\$ 10.06 - \$ 15.00	136	7.35	\$ 12.07		71	\$ 12.15	
	1,810	7.92	\$ 5.80	\$ 2,670	719	\$ 6.31	\$ 1,791

**Stock-Based Compensation**

As discussed in Note 1, the Company applied APB 25 and related interpretations in accounting for the 2000 Plan and the 2004 Plan for the period from inception (May 13, 1998) to December 31, 2005. During that period, the Company recorded \$10.3 million in deferred compensation for employee stock options to purchase common stock granted at exercise prices deemed to be below the fair value of common stock. The Company amortizes the deferred stock-based compensation of employee options to compensation expense based on the graded-vesting method over the vesting periods of the applicable stock options, generally five years. The graded-vesting method provides for vesting of portions of the overall awards at interim dates and results in greater vesting in earlier years than the straight-line method.

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

As discussed in Note 1, the Company continues to account for stock options granted to employees and directors prior to the IPO using the intrinsic value method with deferred compensation being expensed based on the graded-vesting method. Options granted since the IPO are accounted for in accordance with SFAS 123R with the fair value being expensed either based on the graded-vesting method or on the straight-line method, as discussed in Note 1.

F-25

**Table of Contents**

**CORCEPT THERAPEUTICS INCORPORATED**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO FINANCIAL STATEMENTS, Continued**

Compensation expense of approximately \$1.4 million, \$591,000, \$1.5 million and \$9.1 million was recognized for employee options during the years ended December 31, 2006, 2005 and 2004 and for the period from inception (May 13, 1998) to December 31, 2006, respectively, net of recoveries.

During 2006, the Company recorded recoveries of approximately \$83,000 upon the termination or conversion to consultants of employees representing the difference between the expense recorded and the expense that would have been recorded based upon the vesting of the related options. The recoveries during 2006 were split approximately evenly between employees in development and administrative functions. During 2005 and 2004, upon the termination or change in status of employees who worked in a development function to consultants, the Company recorded reversals of approximately \$250,000 and \$234,000, respectively, of previously reported stock-based compensation expense, which represents the difference between the expense recorded under the graded-vesting method and the expense that would have been recorded based upon the rights to options that vested during the service of these individuals as employees.

In addition, the Company reversed approximately \$110,000 in each of the years ended December 31, 2005 and 2004 from deferred compensation related to outstanding options forfeited by employees who terminated or converted to consultancy status during the year, as the rights to the underlying shares had not fully vested by the date of conversion or termination of service as employees.

Certain of the options previously granted to these individuals will continue to vest as the individuals provide consulting services to the Company. The fair value of options to be vested and earned after the employees' change in status will be charged to expense as such options are earned over the remaining vesting periods using the straight-line method, as discussed below.

See discussion in Note 1 Summary of Significant Accounting Policies, Stock-Based Compensation, for a discussion of the implications of adoption of SFAS 123R effective January 1, 2006 on accounting for stock options to employees.

**Stock Options to Consultants**

As of December 31, 2006, options held by consultants to purchase approximately 60,000 shares were unvested. As of that date, there were no remaining right to repurchase shares held by a consultant.

The Company recorded charges to operations for stock options granted to consultants using the straight-line vesting method of approximately \$83,000, \$107,000, \$113,000 and \$893,000 for the years ended December 31, 2006, 2005, 2004 and the period from inception (May 13, 1998) to December 31, 2006, respectively. The straight-line method is commensurate with the services being provided by such consultants.

**Stockholder Notes Receivable**

In 2001, the Company recorded notes receivable from stockholders in the aggregate amount of \$438,165 in connection with the exercise of 585,000 shares of common stock options issued under the 2000 Plan. The notes are secured by the related shares of common stock and are full recourse notes, with interest compounded annually at the rate of 6.5% per year. The notes mature ten years from the date of issuance.

One of the employees who terminated in 2003 and the director who reduced their level of service to the Company in 2003 originally purchased common stock through the exercise of stock options and the execution of

**Table of Contents****CORCEPT THERAPEUTICS INCORPORATED****(A DEVELOPMENT STAGE COMPANY)****NOTES TO FINANCIAL STATEMENTS, Continued**

stockholder notes receivable as described in the preceding paragraph. The Company repurchased 150,000 unvested shares held by the employee in accordance with the terms of the related share purchase agreement. Upon termination, the outstanding note receivable of \$37,300 related to the vested portion of the stock held by the employee was repaid in full. The Company repurchased 56,243 unvested shares held by the director in accordance with the terms of the related share purchase agreement, and the remaining vested shares held by the director remain subject to the note receivable.

As of December 31, 2006, the amounts outstanding under these notes included principal in the amount of approximately \$125,000 and interest in the amount of approximately \$43,000.

**8. Net Loss Per Share**

The Company follows the provisions of Statement of Financial Accounting Standards No. 128, Earnings Per Share. Basic and diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding during the period less outstanding shares subject to repurchase. Outstanding shares subject to repurchase are not included in the computation of basic net loss per share until the Company's time-based repurchase rights have lapsed.

Basic and diluted net loss per share has been computed as follows:

	<b>Year ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
	<i>(In thousands, except per share amounts)</i>		
Net loss (numerator)	\$ (24,873)	\$ (20,093)	\$ (15,535)
Shares used in computing historical basic and diluted net loss per share (denominator)			
Weighted-average common shares outstanding	2,863	22,699	18,703
Less weighted-average shares subject to repurchase	(22)	(91)	(263)
Denominator for basic and diluted net loss per share	22,841	22,608	18,440
Basic and diluted net loss per share	\$ (1.09)	\$ (0.89)	\$ (0.84)

In connection with the closing of the Company's IPO in April 2004, shares of convertible preferred stock outstanding immediately prior to the closing automatically converted into 8,807,146 shares of common stock. These shares of common stock, together with the 4,500,000 shares of the Company's common stock sold in the IPO, are reflected in the computation of basic and diluted net loss per share on a weighted average basis from the date of the IPO's closing. In June 2004, the note payable to the Institute on Aging was converted into 44,508 shares of common stock.

The Company has excluded the impact of common stock equivalents from the calculation of diluted net loss per common share because all such securities are antidilutive for all periods presented. For the year ended December 31, 2004, the Company excluded approximately 2.6 million shares that represent the impact of all convertible preferred stock from January 1, 2004 through the conversion of these shares into common stock on April 19, 2004, the effective date of the IPO. In addition, for all periods presented, the Company excluded additional shares that might have been issued under stock option grants.



**Table of Contents****CORCEPT THERAPEUTICS INCORPORATED****(A DEVELOPMENT STAGE COMPANY)****NOTES TO FINANCIAL STATEMENTS, Continued**

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

	<b>December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
	<i>(in thousands)</i>		
Shares subject to repurchase		55	127
Stock options outstanding	1,810	1,335	1,141
<b>Total</b>	<b>1,810</b>	<b>1,390</b>	<b>1,268</b>

**9. Income Taxes**

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

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
	<i>(in thousands)</i>	
Deferred tax assets:		
Federal and state net operating losses	\$ 15,033	\$ 11,046
Capitalized research and patent costs	20,063	14,708
Stock-based compensation costs	991	773
Research credits	1,128	792
 Total deferred tax assets	 37,215	 27,319
Valuation allowance	(37,215)	(27,319)
 Net deferred tax assets	 \$	 \$

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by \$9.9 million, \$8.1 million and \$6.3 million for the years ended December 31, 2006, 2005 and 2004, respectively.

As of December 31, 2006, the Company had net operating loss carryforwards for federal income tax purposes of approximately \$37.8 million, which expire in the years 2019 through 2026. The Company also has California net operating loss carryforwards of approximately \$37.5 million, which expire in the years 2009 through 2016. The Company also has federal and California research and development tax credits of approximately \$640,000 and \$740,000, respectively. The federal research credits will expire in the years 2019 through 2026 and the California research credits have no expiration date.

Utilization of the Company's net operating loss may be subject to substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code and similar state provisions. Such an annual limitation could result in the expiration of the net operating loss before utilization.



**Table of Contents****CORCEPT THERAPEUTICS INCORPORATED****(A DEVELOPMENT STAGE COMPANY)****NOTES TO FINANCIAL STATEMENTS, Continued**

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

	<b>Year ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
	<i>(in thousands)</i>		
U.S. federal taxes (benefit) at statutory rate	\$ (8,457)	\$ (6,832)	\$ (5,282)
State Tax			
Unutilized (utilized) net operating loss	8,211	6,649	4,680
Non-deductible stock based compensation	241	175	570
Other	5	8	32
Total	\$	\$	\$

**10. Commitments**

During 2004 through 2006, the Company executed a number of agreements to conduct clinical trials and pre-clinical studies for further development of its lead product, CORLUX, targeted for the treatment of PMD. See the discussion in Note 2 Significant Agreements Development Agreements for further discussion regarding these agreements.

In the ordinary course of its business, the Company makes certain indemnities, commitments and guarantees under which it may be required to make payments in relation to certain transactions. These include indemnities of clinical investigators and contract research organizations involved in the development of the Company's clinical stage product candidates, indemnities of contract manufacturers and indemnities to directors and officers of the Company to the maximum extent permitted under the laws of the State of Delaware. The duration of these indemnities, commitments and guarantees varies, and in certain cases, is indefinite. The majority of these indemnities, commitments and guarantees do not provide for any limitation of the maximum potential future payments the Company could be obligated to make. The Company has not recorded any liability for these indemnities, commitments and guarantees in the accompanying consolidated balance sheets. However, the Company accrues for losses for any known contingent liability, including those that may arise from indemnification provisions, when future payment is probable and in accordance with SFAS No. 5, *Accounting for Contingencies*. No such losses have been recorded to date.



**Table of Contents****CORCEPT THERAPEUTICS INCORPORATED****(A DEVELOPMENT STAGE COMPANY)****NOTES TO FINANCIAL STATEMENTS, Continued****11. Quarterly Financial Data (Unaudited)**

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

<b>Quarter Ended</b>	<b>March 31</b>	<b>June 30</b>	<b>September 30</b>	<b>December 31</b>
<b>2006<sup>(1)</sup></b>				
Net loss	\$ (6,730)	\$ (7,864)	\$ (6,403)	\$ (3,876)
Basic and diluted net loss per share	\$ (0.30)	\$ (0.35)	\$ (0.28)	\$ (0.16)
<b>2005</b>				
Net loss	\$ (5,512)	\$ (4,111)	\$ (5,223)	\$ (5,247)
Basic and diluted net loss per share	\$ (0.24)	\$ (0.18)	\$ (0.23)	\$ (0.23)
<b>2004<sup>(2)</sup></b>				
Net loss	\$ (2,551)	\$ (3,584)	\$ (4,089)	\$ (5,311)
Basic and diluted net loss per share	\$ (0.29)	\$ (0.18)	\$ (0.18)	\$ (0.24)

(1) In December 2006, in connection with a private equity transaction the Company sold 3.0 million shares of common stock,

(2) In April 2004, in connection with the IPO, the Company sold 4.5 million shares of common stock and the Company's convertible preferred stock was converted into 8.9 million shares of common stock.

**12. Subsequent Events**

On March 1, 2007, the board of directors approved an increase in the shares available for grant under the 2004 Equity Incentive Plan by 514,635 shares, which represents 2% of the common shares outstanding at December 31, 2006.

On March 19, 2007, the Company reported the initial results of Study 06, the last of three Phase 3 trials evaluating CORLUX for the treatment of the psychotic features of Psychotic Major Depression. The top line 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 outcomes achieved during treatment that confirmed a similar finding in Study 07, one of the Phase 3 trials for which results were reported in 2006. The confirmation of a drug concentration threshold for efficacy and other observations from Study 06 and the Company's two recently completed Phase 3 clinical trials will serve as a strong basis for the Company's next Phase 3 study which is planned to commence later in 2007.

On March 30, 2007, the Company sold 9 million shares of common stock at a price of \$1.00 per share in a private placement. The net proceeds were approximately \$8.8 million after deducting issuance costs.

**Table of Contents**

**Exhibit Index**

<b>Exhibit Number</b>	<b>Description of Document</b>
3.1 <sup>(1)</sup>	Amended and Restated Certificate of Incorporation
3.2 <sup>(1)</sup>	Amended and Restated Bylaws
4.1 <sup>(1)</sup>	Specimen Common Stock Certificate
4.2 <sup>(1)</sup>	Amended and Restated Information and Registration Rights Agreement by and among Corcept Therapeutics Incorporated and certain holders of preferred stock, dated as of May 8, 2001
4.3 <sup>(1)</sup>	Amendment No. 1 to Amended and Restated Information and Registration Rights Agreement by and among Corcept Therapeutics Incorporated and certain holders of preferred stock, dated as of March 16, 2004
10.1* <sup>(1)</sup>	2000 Stock Option Plan
10.2* <sup>(1)</sup>	Employment offer letter to Robert L. Roe, M.D., dated October 18, 2001
10.3* <sup>(1)</sup>	Employment offer letter to Fred Kurland, dated February 3, 2004
10.4* <sup>(1)</sup>	Promissory Note and Pledge Agreement by and between Corcept Therapeutics Incorporated and Robert L. Roe, M.D., dated as of October 22, 2001
10.5 <sup>(1)</sup>	Form of Indemnification Agreement
10.6# <sup>(1)</sup>	License Agreement by and between The Board of Trustees of the Leland Stanford Junior University and Corcept Therapeutics Incorporated, dated as of July 1, 1999
10.7 <sup>(1)</sup>	Research Agreement/cGMP Manufacturing, by and between Corcept Therapeutics Incorporated and KP Pharmaceutical Technology, Inc., dated as of February 12, 2002
10.8 <sup>(1)</sup>	Master Clinical Development Agreement by and between Corcept Therapeutics Incorporated and Scirex Corporation, dated as of July 12, 2001
10.9# <sup>(1)</sup>	Memorandum of Understanding, Supply and Services Agreement, by and between Corcept Therapeutics Incorporated and ScinoPharm Taiwan, dated as of June 12, 2000
10.10 <sup>(1)*</sup>	Consulting, Confidential Information and Inventions Agreement by and between Corcept Therapeutics Incorporated and Alan Schatzberg M.D., dated as of May 31, 1999
10.11 <sup>(1)*</sup>	2004 Equity Incentive Plan
10.12 <sup>(1)</sup>	Master Services Agreement by and between Corcept Therapeutics Incorporated and PPD Development, LP, dated as of January 17, 2003
10.13 <sup>(2)</sup>	Master Services Agreement by and between Corcept Therapeutics Incorporated and i3 Research, a division of Ingenix Pharmaceuticals Services (UK) Limited, dated as of November 2, 2004
10.14 <sup>(3)</sup>	Office Lease Agreement by and between Corcept Therapeutics, Inc., and Exponent Realty, LLC, dated May 23, 2005
10.15##	Manufacturing Agreement with Produits Chimiques Auxiliaires et de Synthèse SA dated November 8, 2006
10.16 <sup>(4)</sup>	Common Stock Purchase Agreement by and among Corcept Therapeutics Incorporated and each of the Purchasers listed on Exhibit A thereto, dated November 14, 2006.
14.1 <sup>(1)</sup>	Code of Ethics
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (See page 69)

**Table of Contents**

<b>Exhibit Number</b>	<b>Description of Document</b>
31.1	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Joseph K. Belanoff, M.D.
31.2	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Fred Kurland.
32.1	Certification pursuant to 18 U.S.C. Section 1350 of Joseph K. Belanoff, M.D.
32.2	Certification pursuant to 18 U.S.C. Section 1350 of Fred Kurland.

---

# Confidential treatment granted

## Confidential treatment requested

\* Management compensatory plan

- (1) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (Registration No. 333-112676) initially filed by the registrant with the SEC on February 10, 2004.
- (2) Incorporated by reference to the Registrant's Annual Report on Form 10-K filed by the registrant with the SEC on March 29, 2005.
- (3) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed by the registrant with the SEC on August 11, 2005.
- (4) Incorporated by reference to the registrant's Current Report on Form 8-K filed by the registrant with the SEC on November 14, 2006.