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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

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

For the fiscal year ended December 31, 2004

or

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

For the transition period from to

Commission File Number: 000-50679

CORCEPT THERAPEUTICS INCORPORATED

(Exact Name of Corporation as Specified in Its Charter)

Delaware	**77-0487658**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

275 Middlefield Road, Suite A
Menlo Park, CA 94025

(Address of principal executive offices, including zip code)

(650) 327-3270
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:
None

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $0.001 par value

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 an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

On March 23, 2005 there were 22,693,813 shares of common stock outstanding at a par value $.001 per share.

The aggregate market value of voting and non-voting common equity held by non-affiliates of the Registrant was approximately $68,000,000 as of June 30, 2004 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. The number of shares outstanding of the Registrant's Common Stock on June 30, 2004 was 22,686,636 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for its 2005 Annual Meeting of Stockholders (the "Proxy Statement"), to be filed with the Securities and Exchange Commission, are incorporated by reference into Part III of this Form 10-K.

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Form 10-K
For the year ended December 31, 2004

PART I

Item 1. *BUSINESS*

Overview

We are a pharmaceutical company engaged in the development of drugs for the treatment of severe psychiatric and neurological 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 neurological disorders and aberrant cortisol.

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 have initiated two Phase III clinical trials for CORLUX for the treatment of the psychotic features of psychotic major depression, or PMD. Both of these trials are covered by Special Protocol Assessments, or SPAs, from the FDA. Additionally, in the second quarter of 2005 we intend to initiate a third Phase III clinical trial in Europe. We have also initiated a clinical study to evaluate the safety and efficacy of CORLUX in improving cognition in patients with mild to moderate Alzheimer's disease.

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 manic depressive illness. The disorder 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 early dementia, such as early dementia associated with Alzheimer's disease, mild cognitive impairment, psychosis associated with cocaine addiction, and weight gain following treatment with antipsychotic medication. We have also filed patent applications for additional diseases that may benefit from treatment with a drug that blocks the GR-II receptor.

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 neurological 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 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 in the bloodstream to the brain, where it directly influences neurological 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 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 a congressionally mandated study, the National Co-Morbidity Survey published in 2003, indicate that each year approximately 7% of adults in the United States, or about 14 million people, experience a major depressive episode. Of these people, many published studies show that approximately 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.

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, 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 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 have completed the following four clinical trials with CORLUX for the treatment of psychotic features of PMD:

- Our first trial was an open-label dose finding study in which we concluded that patients receiving daily doses of 600 mg or 1200 mg of CORLUX were more likely than patients receiving 50 mg of CORLUX to experience a clinically meaningful reduction in the psychotic symptoms of PMD.
- Our second and third trials, which we call the 02 study and 03 study, tested a regimen of 600 mg of CORLUX dosed for 7 days. These were double-blind, placebo-controlled safety and efficacy studies in which a total of 429 patients were enrolled. The 02 study confirmed that CORLUX was well tolerated and that there were no discernable problems with drug interactions between CORLUX and commonly prescribed antipsychotic and antidepressant medications. The 03 study demonstrated with statistical significance (p value = 0.01) 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. 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 the 02 study 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. All p values for the 03 study 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 the 02 and 03 studies, and our analysis indicates that patients tolerated their retreatment well.

We have initiated two Phase III clinical trials in the United States in September and October 2004 and intend to initiate an additional Phase III trial in Europe in the second quarter of 2005 to evaluate further the safety and efficacy of CORLUX. We expect that the initial results of the studies in the United States will be reported in the first half of 2006 and that the initial results of the European study will be reported by the end of 2006. The design of these studies is similar to that of the 03 study.

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

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

Results were similar in the 600 mg and 1200 mg dose groups, but there was an apparent dose-response relationship when the results of the 50 mg group were compared to the two higher dose groups. Sixty-eight 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, 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 the 02 study 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 the 02 study, patients received their usual treatment plus CORLUX or placebo. In the 03 study, 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.

02 Study. The results of the 02 study 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 the 02 study were receiving in addition to CORLUX was four. Although patients in the usual treatment plus CORLUX group more frequently achieved the study's primary endpoint, a rapid and sustained reduction in psychotic symptoms as measured by a 30% decline in the BPRS at day 7 sustained to day 28, than did patients in the usual treatment plus placebo group, the difference between the groups was not statistically significant. The study did demonstrate with statistical significance (p value = 0.02) that the usual treatment plus placebo group required ECT or more antipsychotic medication between day 7 and day 28 and was less likely to be discharged from the hospital during the week of dosing (p value = 0.05) relative to the usual treatment plus CORLUX group. Post-hoc analysis of the 02 study 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).

03 Study. The results of the 03 study 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. The 03 study 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. The 03 study 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.

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 12 on the BPRS PSS), the 03 study 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 02 study analysis. In the 03 study, as in the 02 study, only a small number of patients became asymptomatic at the end of one week and, in the 03 study, there was no statistically significant difference between the CORLUX and placebo groups.

Of the approximately 480 patients who have been enrolled in our completed studies, over 240 individuals have been treated with CORLUX. The drug seemed to be well tolerated by these patients, with a low incidence of adverse events. In the 02 and 03 studies, 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 the 02 study, 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 the 03 study, 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 the 02 and 03 studies. Twenty-eight patients completed the study. Our analysis indicates that patients tolerated their retreatment well.

Phase III Clinical Trials. We have initiated two randomized, double-blind, placebo-controlled Phase III clinical trials in the United States and plan to initiate a third Phase III trial in Europe to further assess the safety and efficacy of CORLUX for the treatment of the psychotic features of PMD.

Our two U.S.-based Phase III trials are covered by Special Protocol Assessments, or SPAs, from the FDA. The SPA is a process that provides for an official FDA evaluation of Phase III 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 these trials in the United States is 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 at least mild psychotic symptoms (BPRS PSS 12) to enter the studies and will be hospitalized if clinically necessary. BPRS PSS assessments will also be made at Days 14, 28 and 42. The primary endpoint for the European trial is 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 the European trial is the same as that primary endpoint for the two U.S. trials.

The first of these trials, Corcept 07, which began in September 2004, will enroll as many as 280 patients at up to 20 sites in the United States with a randomized one-to-one distribution into either a treatment or a placebo arm. Patients in the treatment arm will receive 600 mg of CORLUX once daily for a period of seven days. Patients may not take any antidepressant and antipsychotic medication for at least one week before beginning the seven day treatment period. After the seven days of CORLUX treatment, all patients will receive antidepressant therapy through Day 56. Treatment with antipsychotic medications or electroconvulsive therapy will not be allowed at any time during the study. We expect to report the initial results of this trial in the first half of 2006.

The second clinical trial, Corcept 06, which began in October 2004, will enroll approximately 440 patients at up to 30 sites in the United States. These patients will be 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 may not take any antidepressant and antipsychotic medication for at least one week before the seven day treatment period and will receive antidepressant therapy starting on Day 1 through Day 56. As with Corcept 07, treatment with antipsychotic medications or electroconvulsive therapy will not be allowed at any time during this study. We expect to report the initial results of this trial in the first half of 2006.

The third trial, Corcept 09, which is expected to begin in the second quarter of 2005, will enroll as many as 280 patients at up to 20 sites in Europe with a randomized one-to-one distribution into either a treatment or a placebo arm. Patients in the treatment arm will receive 600 mg of CORLUX once daily for a period of seven days. Patients may not take any antidepressant and antipsychotic medication for at least one week before beginning the seven day treatment period and will receive antidepressant therapy starting on Day 1 through Day 56. Treatment with antipsychotic medications or electroconvul-

sive therapy will not be allowed at any time during the study. We expect to report the initial results of this trial by the end of 2006.

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 NDA.

Additional Trials and Studies. In support of our 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 are conducting a standard 12-month toxicology study and two carcinogenicity studies 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 with Scirex Corporation (Scirex), 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 Scirex 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. These organizations are working with us to conduct our Phase III clinical trials of CORLUX.

Overview of Alzheimer's Disease

In addition to our development program for CORLUX for the psychotic features of PMD, we have initiated a clinical study to evaluate the safety and efficacy of CORLUX in patients with mild to moderate Alzheimer's disease because we believe that CORLUX may improve cognition in these patients.

No current treatment can change the ultimate course of Alzheimer's disease, a disease that affects more than 3.5 million people in the United States. For some people in the early and middle stages of the disease, medications that inhibit acetylcholinesterase, an enzyme that breaks down a particular neurotransmitter, may help slow the decline in cognition for a limited time. In clinical trials with acetylcholinesterase inhibitors, the reduction in the rate of decline as measured by standard scales was modest, with many patients showing no improvement at all.

In addition to the acetylcholinesterase inhibitors, the compound memantine has also been approved for the treatment of Alzheimer's disease. Memantine studies have shown small but statistically significant benefits in patients with more severe or advanced Alzheimer's disease.

Also, a variety of medications are used to help control behavioral symptoms associated with Alzheimer's disease, such as agitation. Antipsychotics are frequently used for treating agitation. Anticonvulsants or mood stabilizers are often prescribed for hostility or aggression and anxiolytics are prescribed for anxiety, restlessness and verbally disruptive behavior.

Current treatments have a modest effect and only slow the decline in cognition for a short period of time. Therefore, there is a need for new therapies that could enhance cognition and improve behavioral problems in Alzheimer's patients.

Published studies have suggested that higher cortisol levels are associated with more rapid decline in Alzheimer's patients. For example, several studies suggest that among individuals with early-stage Alzheimer's disease, higher baseline cortisol was associated with a significantly greater rate of decline in cognitive function based on standardized measurements of cognition. Also, a small clinical study evaluated the use of mifepristone in patients with mild to moderate Alzheimer's disease and indicated that patients treated with mifepristone for six weeks had improved scores on a standard cognition scale, whereas patients taking placebo worsened.

CORLUX Clinical Trial. We are conducting a clinical trial designed to demonstrate the safety of CORLUX and whether or not CORLUX will improve cognition in Alzheimer's patients. The study is a randomized, double-blind, parallel group comparison of the effects of CORLUX and placebo. The trial assesses the effects of CORLUX on cognition and behavior when administered daily over a period of 16 weeks. Because a diagnosis of Alzheimer's disease is required for participation in the trial and acetylcholinesterase inhibitors are currently standard treatment for this condition, patients in the

trial are required to be on a stable regimen of an acetylcholinesterase inhibitor for at least 12 weeks before enrolling in the trial.

The trial's primary efficacy measure will be the ADAS-Cog, which assesses a patient's cognitive capabilities. The ADAS-Cog is a battery of individual tests relating to recall, naming, commands, orientation, word recognition, spoken language and comprehension and word finding, among other cognitive functions. In clinical trials, the ADAS-Cog has been used to measure the cognitive and neuropsychological effects of treatment.

The study is designed to enroll up to 160 patients. During the first quarter of 2005 the independent Data Monitoring Committee, charged with evaluating the ongoing safety of patients participating in the trial, met to review safety data to date. The committee recommended that the trial continue. We hope to report the initial results of this study by the end of 2005.

GR-II Antagonist Platform

We have assembled a patent portfolio covering the treatment of psychiatric and neurological 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:

- early dementia, including early Alzheimer's disease;
- mild cognitive impairment;
- psychosis associated with cocaine addiction; and
- weight gain following treatment with antipsychotic medication.

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

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 use in our growing number of proprietary uses. Our discovery chemistry was conducted on our behalf 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, unlike CORLUX, do not block the progesterone receptor and only block the GR-II 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 a human clinical trial with the selected compound in 2006.

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 sales force of approximately 25 to 35. 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 currently have no commercialization staff. 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 accelerate the development of CORLUX and other products rather than diverting resources to establishing our own manufacturing facilities.

We intend to continue to rely on experienced contract manufacturers to produce our products. We have entered into a manufacturing agreement with a contract manufacturer, ScinoPharm Taiwan, to produce the active pharmaceutical ingredient, or API, for CORLUX. This agreement 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. Although we do not currently have a second supplier of API, we have completed feasibility studies with a second contract manufacturer. We have entered into a supply agreement with a contract manufacturer, PharmaForm, L.L.C., for the production of CORLUX tablets. In the event we are unable, for whatever reason, to obtain mifepristone or CORLUX from our contract manufacturers, we may not be able to identify alternate manufacturers able to meet our needs on commercially reasonable terms and in a timely manner, or at all. To date, our need for CORLUX tablets has been limited to the amounts required to support our clinical trials.

Competition

If approved for commercial use as a treatment for the psychotic features of 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.

While we are unaware of any public disclosures of other ongoing clinical trials, 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 products. 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 products, obtain required regulatory approvals and manufacture and successfully market our products either alone or through outside parties.

Intellectual Property

Patents and other proprietary rights are important to our business. It is our policy to seek patent protection for our inventions, and to rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position.

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

U.S. Patent Number	Subject Matter	Expiration Date
U.S. Pat. No. 6,150,349	Use of GR-II antagonists in the treatment of PMD	October 5, 2018
U.S. Pat. No. 6,369,046	Use of GR-II antagonists in the treatment of early dementia, including early Alzheimer's disease	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

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 these agreements. 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 and for the treatment of weight gain following treatment with antipsychotic medication. 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:

- delirium;
- migraine;
- postpartum psychosis;
- antipsychotic induced weight gain;
- gastrointestinal reflux disease;
- Down's syndrome; and
- post-traumatic stress disorder.

We are also considering, where appropriate, the filing of foreign patent applications corresponding to our U.S. patent applications.

However, we cannot assure you that any of our patent applications will result in the issuance of patents, that any issued patent will include claims of the breadth sought in these applications or that competitors will not successfully challenge or circumvent our patents if they are issued.

Although three of our patent applications have claims directed to the composition of compounds that are necessary to make our potential products, none of our issued patents have such claims. Specifically, we do not have a patent with claims directed to the composition of mifepristone. Our rights under our issued patents cover only the use of GR-II antagonists, including mifepristone, in the treatment of specific diseases.

The patent covering the product mifepristone has expired. The only FDA-approved use of mifepristone is to terminate pregnancy. The FDA has imposed significant restrictions on administering physicians for use of mifepristone to terminate pregnancy and may impose similar restrictions on CORLUX for the treatment of the 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 products while attempting to design around other patents, or determine that we are unable to commercialize our products 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.

A third party 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. The third party 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 another of its employees while the two were employed by the third party. We contended that the invention was actually conceived by Drs. Schatzberg and 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.

Akzo Nobel has filed an observation to the grant of our exclusively licensed European patent application with claims directed to PMD, in which Akzo Nobel challenges the grant of that patent. We have submitted a rebuttal to the European Patent Office that responds to the points raised by Akzo. During prosecution of the U.S. patent for the use of CORLUX to treat the psychotic features of PMD, the U.S. Patent and Trademark Office considered issues similar to those raised by Akzo and the U.S. patent was ultimately granted. We cannot assure you, however, that the European Patent Office will reach the same conclusion. Should Akzo's arguments persuade the European Patent Office that the claims should not issue, we will not have the benefit of patent protection in Europe for CORLUX to treat the psychotic features of PMD. 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 products will require regulatory approval by government agencies prior to commercialization. The process required by the FDA before a new drug may be marketed in the United States generally involves the following: completion of preclinical laboratory and animal testing; submission of an investigational new drug application, or IND, which must become effective before clinical trials may begin; performance of adequate and well controlled human clinical trials to establish the safety and efficacy of the proposed drug or biologic's intended use; and, in the case of a new drug, approval by the FDA of an NDA. The process of complying with these and other federal and state statutes and regulations in order to obtain the necessary approvals and subsequently complying with federal and state statutes and regulations involves significant time and expense.

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

- *Phase I.* Clinical trials are conducted with a small number of subjects to determine the early safety profile, maximum tolerated dose and pharmacokinetics of the product in human volunteers.
- *Phase II.* 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 III.* 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 III 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 agency may request additional information rather than accept an NDA for filing. If the agency accepts an NDA for filing, the FDA 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 IV 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 cGMP regulations. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product or voluntary recall of a product.

With respect to post market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among others, standards and regulations for direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving the Internet. The FDA has very broad enforcement authority under the Federal Food Drug and Cosmetic Act, and failure to abide by these regulations can result in penalties including the issuance of a warning letter directing a company to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions.

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

Approvals outside the United States. We have not started the regulatory approval process in any jurisdiction other than the United States and we are unable to estimate when, if ever, we will commence the regulatory approval process in any foreign jurisdiction. We will have to complete an approval process similar to the U.S. approval process in foreign target markets for our products 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, 2004, we have 11 full-time employees, six part-time employees and three 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.

FACTORS THAT MAY AFFECT FUTURE RESULTS

In addition to other information in this report, the following factors should be considered carefully in evaluating our company. If any of the risks or uncertainties described in this Form 10-K actually occurs, our business, results of operations or financial condition could be materially adversely affected. The risks and uncertainties described in this Form 10-K are not the only ones facing the company. Additional risks and uncertainties of which we are unaware or currently deem immaterial may also become important factors that may harm our business.

Risks Related to Our Business

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 future clinical trials support 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, 2004, we had an accumulated deficit of approximately $53.5 million. We do not know when or if we will generate product revenue. We expect our research and development expenses to increase in connection with the planned clinical trials and other development activities for CORLUX and for other product candidates. We expect to incur significant expenses related to the commercialization of CORLUX. As a result, we expect that our losses will increase for the foreseeable future. We are unable to predict the extent of any future losses or whether or when we will become profitable.

We depend heavily on the success of our lead product, CORLUX, which is still in development. 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 successful development, approval and commercialization of CORLUX. We plan to conduct at least two Phase III clinical trials in the United States for CORLUX for the treatment of the psychotic features of PMD before submitting an application for FDA approval. The first of these trials commenced in September 2004. The second trial began in October 2004. Both of these trials are covered by Special Protocol Assessments from the FDA. Additionally, in the second quarter of 2005, we intend to initiate a third Phase III trial in Europe.

While we expect that the initial results of the two U.S.-based trials will be reported before the end of the first half of 2006 and that the initial results of the European trial will be reported before the end of 2006, we cannot assure you that this will occur. Even though we have SPAs covering the U.S.-based trials, we may decide, or the FDA may require us, to pursue additional clinical trials or other additional studies on CORLUX. If we are unable to successfully conclude our clinical development program and obtain regulatory approval for CORLUX for the treatment of the psychotic features of PMD, we may be unable to generate revenue and our stock price may decline.

Many factors could harm our efforts to develop and commercialize CORLUX, including

- negative, inconclusive or otherwise unfavorable results from our pre-clinical or clinical development programs;
- changes or delays in our clinical development program;
- rapid technological change making CORLUX obsolete;
- 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 trials of CORLUX for the treatment of the psychotic features of PMD do not demonstrate safety and efficacy, or if the clinical trials are delayed or terminated, our business will be harmed.

To gain regulatory approval from the FDA to market CORLUX, our recently initiated pivotal clinical trials must demonstrate the safety and efficacy of CORLUX for the treatment of the psychotic features of PMD. Clinical development is a long, expensive and uncertain process and is subject to delays. 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 have obtained favorable results in some of our clinical trials, these results have not been sufficient to support an application for FDA approval. The pivotal clinical trials we are currently conducting may not demonstrate that CORLUX is safe or effective.

In addition, data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. To obtain marketing approval, we may decide, or the FDA or other regulatory authorities may require us, to pursue additional clinical, pre-clinical or manufacturing studies. These studies could significantly delay the approval and commercialization of CORLUX and would require us to commit significant additional financial resources. Even after we conduct these additional clinical trials, we may not receive regulatory approval to market CORLUX.

Many other factors could delay or result in termination of our clinical trials, including:

- negative or inconclusive results;
- slow patient enrollment or 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.

In addition to our clinical trials, we plan to conduct carcinogenicity studies and toxicology tests in support of our planned NDA to market CORLUX for the treatment of the psychotic features of PMD. We cannot assure you that these studies and tests will produce results that support our planned NDA, and these studies and tests may delay commercialization of CORLUX.

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 these clinical investigators and clinical sites fail to enroll a sufficient number of patients in our clinical trials, we will be unable to complete these trials, which could prevent us from obtaining regulatory approvals for CORLUX.

We have contracted with Scirex Corporation (Scirex), 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 our Phase III clinical trials. In addition, we have identified approximately 70 clinical sites for our Phase III clinical trials and are in the process of qualifying those sites and negotiating contracts with them to conduct clinical testing. We may not be able to maintain these relationships with Scirex, PPD or i3 or to establish relationships with qualified clinical sites without undue delays or excessive expenditures. Any delay in contracting with qualified clinical sites to conduct our clinical testing may delay the completion of our Phase III clinical trials or the commercialization of CORLUX.

Our agreements with clinical investigators and clinical sites for clinical testing and with Scirex, PPD and i3 for trial management services place substantial responsibilities on these parties, which could result in delays in, or termination of, our Phase III 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, our Phase III clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for, or successfully commercialize, CORLUX.

If we are unable to obtain or maintain regulatory approval, we will be limited in our ability to commercialize our products, 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.

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 products.

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 products abroad.

We intend to commercialize our products 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 products 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 products 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 products in fast track development may qualify for expedited FDA review under the policies and procedures offered by the FDA, but the fast track designation does not assure any such qualification. Although we have obtained a fast track designation from the FDA for CORLUX for the treatment of the psychotic features of 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 currently 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. In addition, 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 have no manufacturing capabilities and we currently depend on third parties who are single source suppliers to manufacture CORLUX. 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, manufacturing any products. We have a contract with ScinoPharm Taiwan, Ltd., a manufacturer of the active pharmaceutical ingredient, or API, of mifepristone and a contract with PharmaForm, L.L.C., a tablet manufacturer for CORLUX. PharmaForm is a single source supplier to us for tablet manufacture. Our agreement with PharmaForm is terminable by either party at any time. ScinoPharm is a single source supplier, as well. Although we have identified a potential second API manufacturer, we cannot guarantee that we will enter into an agreement with them to manufacture API on terms acceptable to us. Our agreement with ScinoPharm is terminable by either party at any time. 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 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 products, 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 requires 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 products are on the market, we may be required to perform lengthy additional clinical trials, change the labeling of our products or withdraw our 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 products are on the market:

- regulatory authorities may withdraw their approvals;
- we may be required to reformulate our products, conduct additional clinical trials, make changes in labeling of our products or implement changes to or obtain re-approvals of our manufacturing facilities;
- we may experience a significant drop in the sales of the affected products;
- our reputation in the marketplace may suffer; and
- we may become the target of lawsuits, including class action lawsuits.

Any of these events could harm or prevent sales of the affected products or could increase the costs and expenses of commercializing and marketing these products.

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 products.

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 two 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 ten 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.

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, a third party 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. The third party 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 another of its employees while the two were employed by the third party. We contended that the invention was actually conceived by Drs. Schatzberg and 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.

In addition, Akzo Nobel has filed an observation in our exclusively licensed European patent application with claims directed to PMD, in which Akzo Nobel challenges the claims of that patent application. We have submitted a rebuttal to the European Patent Office that responds to the points raised by Akzo. During prosecution of the U.S. patent for the use of CORLUX to treat the psychotic features of PMD, the U.S. Patent and Trademark Office considered issues similar to those raised by Akzo and the U.S. patent was ultimately granted. We cannot assure you, however, that the European Patent Office will reach the same conclusion. Should Akzo's arguments persuade the European Patent Office that the claims should not issue, we will not have the benefit of patent protection in Europe for CORLUX to treat the psychotic features of PMD.

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

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

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

In addition to patents, we rely on a combination of confidentiality, nondisclosure and other contractual provisions, laws protecting trade secrets and security measures to protect our trade secrets and proprietary information. Nevertheless, these measures may not adequately protect our trade secrets or other proprietary information. If they do not adequately protect our rights, third parties could use our proprietary information, which could diminish our ability to compete in the market. In addition, employees, consultants and others who participate in the development of our products 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 13 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 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, early dementia, mild cognitive impairment, psychosis associated with cocaine addiction and weight gain following treatment with antipsychotic medication, in addition to ten U.S. method of use patent applications covering GR-II antagonists for the treatment of a number of other neurological and psychiatric disorders and three U.S. composition of matter patent applications covering specific GR-II antagonists.

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

We may elect to enter into collaboration arrangements with respect to one or more of our product candidates. If we do enter into such an arrangement, we would be dependent on a collaborative partner for the success of the product candidates developed under the arrangement. Any future collaborative partner may fail to successfully develop or commercialize a product candidate under a collaborative arrangement.

We only have experience with CORLUX and we may determine that CORLUX is not desirable for uses other than for the treatment of the psychotic features of PMD. In that event, we would have to identify and may need to secure rights to a different GR-II antagonist. Our ongoing discovery research program may fail to generate commercially viable product candidates in spite of the resources we are dedicating 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. 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.

If we need additional capital sooner than anticipated, it could reduce our ability to compete.

We anticipate that our existing capital resources will be sufficient to enable us to complete the clinical development of CORLUX, for the treatment of the psychotic features of PMD. However, our expectations are based on our currently planned clinical development program for PMD and our current operating plan, which may change as a result of many factors, including:

- the costs and timing of our clinical trials;
- changes in the exchange rate between the Euro and the U.S. Dollar;
- the results of our research efforts and clinical trials;
- the timing of the approval by the FDA, if any, to market CORLUX for the treatment of the psychotic features of PMD;
- developments or disputes concerning patents or proprietary rights, including announcements of claims of infringement, interference or litigation against us or our licensors;
- actual or anticipated fluctuations in our operating results;
- changes in our growth rates;
- the timing of commercialization of CORLUX and future product candidates; and
- changes in the reimbursement policies of third-party insurance companies or government agencies.

Consequently, we may need additional funding sooner than anticipated. We currently have no credit facility or committed sources of capital. Our inability to raise capital would harm our business and product development efforts.

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

We 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 products are not effective, whether by participants in our clinical trials or by patients using our products. A product liability claim may damage our reputation by raising questions about our products' 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 products for which we obtain marketing approval. However, this insurance may be prohibitively expensive or may not fully cover our potential liabilities. Our inability to obtain adequate insurance coverage at an acceptable cost could prevent or inhibit the commercialization of our products. 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 products, our liability could exceed our total assets.

We have no sales and marketing staff 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 and marketing staff. 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. 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 will need to increase the size of our organization, and we may experience difficulties in managing growth.

As we expand our research and development efforts and develop a sales and marketing organization, we expect to experience growth, which may strain our operations, product development and other managerial and operating resources. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. To date, we have relied on a small management team, including a number of part-time contributors. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

- manage our research and development efforts effectively;
- manage our clinical trials effectively;
- integrate additional management, administrative and sales and marketing personnel;
- expand the size and composition of our management team;
- develop our administrative, accounting and management information systems and controls; and
- hire and train additional qualified personnel.

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

If we are unable to obtain acceptable prices or adequate reimbursement for our products 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 medications in both domestic and international markets is dependent on whether third-party coverage and reimbursement is available for the ordering of our medications by the medical profession for use by their patients. 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 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 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 products or the exclusion of our 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. While we are unaware of any other ongoing clinical trials for new medicines for the treatment of PMD, other companies may also be developing new medicinal 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.

Rapid technological change could make our products obsolete.

Pharmaceutical technologies have undergone rapid and significant change and we expect that they will continue to do so. 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 products obsolete or uneconomical.

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 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 products. Our insurance may not be adequate to cover, and our insurance policies may exclude coverage for, our losses resulting from disasters or other business interruptions.

Risks Related to Our Stock

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

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. Since initial trading of our stock began on April 14, 2004 through March 23, 2005 our average daily trading volume has been approximately 58,000 shares and our price has ranged from $12.65 to $4.35. 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:

- actual or anticipated timing and results of our clinical trials;
- actual or anticipated regulatory approvals of our products or of competing products;
- changes in laws or regulations applicable to our products 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;
- 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; 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.

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, recently-adopted 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 will lead to a number of fundamental changes in how analysts are reviewed and compensated. In particular, many investment banking firms will be required to contract with independent financial analysts for their stock research. It may be difficult for companies such as ours with smaller market capitalizations to attract independent financial analysts that will cover our common stock. This could have a negative effect on our market price.

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

Sales of a substantial number of shares of our common stock in the public market could harm the market price of our common stock. As additional shares of our common stock become available for resale in the public market, the supply of our common stock will increase, which could decrease the price. Following the expiration in October 2004 of lock-up arrangements between our stockholders and the underwriters associated with our initial public offering and subject to applicable volume and other resale restrictions, substantially all of the shares of our common stock are eligible for sale.

Our officers, directors and principal stockholders control approximately 81% of our common stock after our initial public offering in April 2004 and will be able to significantly influence corporate actions.

As of March 23, 2005, our officers, directors and principal stockholders control approximately 81% 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 less than a year, 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. This requirement may first apply to our annual report on Form 10-K for our fiscal year ending December 31, 2005. 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 guidance from relevant accounting authorities, including the SEC. For example, to date, we have not been required to record stock-based compensation charges if an employee's stock option exercise price equals or exceeds the fair value of our common stock at the date of grant. However, in December 2004, the Financial Accounting Standards Board adopted Financial Accounting Standard 123(R), "Share Based Payment." This statement, which we plan to adopt in the third quarter of 2005, requires the recording of expense for the fair value of stock options granted. As a result, our operating expenses could increase. We rely heavily on stock options to compensate existing employees and attract new employees. Because we will be required to expense stock options on a fair-value basis, we may then 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 2. *Properties*

We have a month-to-month lease covering approximately 3,200 square feet of office space in Menlo Park, California for our corporate facilities. In December 2004 we received notice of termination of this lease effective June 30, 2005. We believe that alternative space will be available at or before June 30, 2005 on commercially reasonable terms.

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 2004.

PART II

ITEM 5. *MARKET FOR REGISTRANT'S COMMON STOCK AND RELATED STOCKHOLDER MATTERS*

Market Information

Our common stock is traded on The Nasdaq Stock Market under the symbol "CORT". The following table sets forth for high and low intra-day sale prices per share of our common stock on The Nasdaq Stock Market for the quarterly periods from our initial public offering in April 2004 through December 31, 2004. These prices represent quotations among dealers without adjustments for retail mark-ups, markdowns or commissions, and may not represent prices of actual transactions.

2004	High	Low
Second Quarter	$ 12.65	$ 7.15
Third Quarter	$ 8.98	$ 4.90
Fourth Quarter	$ 7.89	$ 4.35

Stockholders of Record and Dividends

As of March 23, 2005, we had 22,693,813 shares of common stock outstanding held by approximately 96 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.

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 (the "Registration Statement") (Reg. No. 333-112676) that was declared effective by the SEC on April 14, 2004. The offering commenced 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, 2004, approximately $8.6 million of the net proceeds was used for research and development activities and approximately $2.3 million was used for general and administrative activities. The remaining proceeds from the offering have been placed in temporary investments of marketable securities for future use as needed.

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, 2002, 2003, and 2004 and for the period from inception (May 13, 1998) to December 31, 2004 and the balance sheet data as of December 31, 2003 and 2004 are derived from our audited financial statements included in this Form 10-K. The statements of operations data for the years ended December 31, 2000 and 2001, and the balance sheet data as of December 31, 2000, 2001 and 2002 have been derived from our audited financial statements, which are not included in this Form 10-K. The selected financial data set forth below should be read in conjunction with our financial statements, the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Form 10-K.

	Year Ended December 31,					Period from Inception (May 13, 1998) to December 31, 2004
	2000	2001	2002	2003	2004	
	(In thousands, except for per share data)					
Statement of Operations Data:						
Operating expenses:						
Research and development*	$ 1,319	$ 5,390	$ 13,264	$ 8,223	$ 11,551	$ 39,888
General and administrative*	577	2,616	5,531	1,746	4,494	15,148
Total operating expenses	1,896	8,006	18,795	9,969	16,045	55,036
Loss from operations	(1,896)	(8,006)	(18,795)	(9,969)	(16,045)	(55,036)
Non-operating income, net	50	552	291	156	511	1,564
Net loss	$ (1,846)	$ (7,454)	$ (18,504)	$ (9,813)	$ (15,534)	$ (53,472)
Net loss per share:						
Basic and diluted	$ (0.50)	$ (1.39)	$ (2.75)	$ (1.22)	$ (0.84)	
Weighted average shares — basic and diluted	3,708	5,376	6,720	8,069	18,440	
* Includes non-cash stock-based compensation of the following:						
Research and development	$ 90	$ 1,214	$ 1,957	$ 551	$ 202	$ 4,022
General and administrative	—	680	2,145	(308)	1,475	3,992
Total non-cash stock-based compensation	$ 90	$ 1,894	$ 4,102	$ 243	$ 1,677	$ 8,014

	As of December 31,				
	2000	2001	2002	2003	2004
	(In thousands)				
Balance Sheet Data:					
Cash, cash equivalents and investments	$ 1,000	$ 22,980	$ 21,543	$ 11,577	$ 46,887
Working capital	(227)	22,224	20,222	10,729	36,415
Total assets	1,046	24,259	21,795	11,781	47,771
Long-term liabilities	—	463	503	524	—
Convertible preferred stock	1,803	29,914	41,716	41,716	—
Total stockholders' equity (net capital deficiency)	(2,000)	(7,539)	(21,941)	(31,473)	45,948

See our financial statements and related notes for a description of the calculation of the net loss per common share and the weighted-average number of shares used in computing the per share data. Certain amounts in periods prior to 2004 have been reclassified to conform to the current year presentation.

ITEM 7. *MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS*

Forward-Looking Information

This Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the "Factors that May Affect Future Results" section of Part I of this Form 10-K. This 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 statements about:

- *the progress of our research, development and clinical programs and timing of the introduction of CORLUX and future product candidates;*
- *estimates of the dates by which we expect to report results of our clinical trials;*
- *our ability to market, commercialize and achieve market acceptance for CORLUX or other future product candidates;*
- *uncertainties associated with obtaining and enforcing patents;*
- *our estimates for future performance; and*
- *our estimates regarding our capital requirements and our needs for additional financing.*

Forward-looking statements are not guarantees of future performance and involve risks and uncertainties. Actual events or results may differ materially from those discussed in the forward-looking statements as a result of various factors. For a more detailed discussion of such forward-looking statements and the potential risks and uncertainties that may impact upon their accuracy, see the "Factors that May Affect Future Results" and "Overview" 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 human medicines for the treatment of severe psychiatric and neurological diseases. Since our inception in May 1998, our activities have primarily been associated with the development of 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 FDA has granted "fast track" status to the CORLUX development program for the treatment of the psychotic features of PMD. We have completed the analysis of our first two large, double-blind trials, and, in September and October 2004, we initiated two Phase III clinical trials in the United States to support a planned New Drug Application, or NDA. Both of these trials are covered by Special Protocol Assessments, or SPAs, from the FDA. Additionally, we plan to initiate a third Phase III clinical trial in Europe in the second quarter of 2005. We also initiated a clinical study in 2003 to explore the tolerability and efficacy of our medicine in improving cognition in patients with mild to moderate Alzheimer's disease.

Specifically, 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. The loan we received from one research institution was converted into common stock on June 30, 2004.

We are in the development stage and have incurred significant losses since our inception because we have not generated any revenue, and do not expect to generate any revenue for the foreseeable future. As of December 31, 2004 we had an accumulated deficit of approximately $53.5 million. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for CORLUX, discovery research, non-clinical activities such as toxicology and carcinogenicity studies, manufacturing process development and regulatory activities, as well as general and administrative expenses. We expect to continue to incur net losses over the next several years as we complete our CORLUX clinical trials, 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.

RESULTS OF OPERATIONS

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, enrollment and monitoring expenses, regulatory costs and the costs of manufacturing development.

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.

Years Ended December 31, 2004 and 2003

Research and development expenses. Research and development expenses increased 41% to $11.6 million for the year ended December 31, 2004, from $8.2 million for the year ended December 31, 2003.

The year over year increase in our research and development activities included a net increase of $770,000 in the costs of clinical trials, an increase of $910,000 in expenses for pre-clinical studies, an increase of $750,000 for the production and testing of clinical supplies, an increase of approximately $510,000 in the discovery research program, and an increase of $250,000 in support costs, such as consultants, product liability insurance, travel and facilities, as compared with 2003. The increase in clinical trial costs reflects a net increase in clinical trial expenses for PMD of approximately $980,000 as the expenses associated with the commencement of various clinical trials, including the Phase III trials discussed above and other PMD-related trials more than offset the reduction in costs due to the completion of a double-blind PMD clinical trial in late 2003 and a decrease of approximately $210,000 in the costs of the Alzheimer's disease trial.

Salaries and benefits for research and development increased by approximately $500,000 for the year ended December 31, 2004, as compared to the year ended December 31, 2003 due to the hiring of additional staff in these areas. These increases were offset by a decrease of approximately $370,000 in stock compensation expense. The decrease in stock compensation expense includes an expense reversal of approximately $230,000 recorded in the third quarter of 2004, upon the change in status of a research employee to a consultant and a reduction of approximately $140,000 in the amortization of non-cash stock-based deferred compensation due to the decelerating scale of expense recognition under the graded-vesting method.

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

Project	Year Ended December 31, 2003	2004
	(In thousands)	
CORLUX for the treatment of the psychotic features of PMD	$ 4,775	$ 8,107
CORLUX for the treatment of mild to moderate Alzheimer's disease	838	641
Discovery research	2,059	2,600
Total research and development expense (excluding non-cash stock-based compensation)	$ 7,672	$ 11,348

We expect that research and development expenditures will increase during 2005 and subsequent years due to the continuation and expansion of clinical trials and other development activities of CORLUX for PMD and Alzheimer's disease,

the initiation of trials of CORLUX for other indications and additional study expenditures for new GR-II antagonists and other pharmaceutical candidates.

Many factors can affect the cost and timing of our clinical trials including the strength of results, the pace of patient enrollment, the medication's side effect profile and the availability of clinical supplies. In addition, the development of all of our products 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 products.

General and administrative expenses. General and administrative expenses increased 157% to $4.5 million for the year ended December 31, 2004, from $1.7 million for the year ended December 31, 2003.

This increase was attributable, in part, to an increase in non-cash stock-based compensation of $1.8 million. In addition, there were increases in staffing costs of $300,000, insurance costs of $220,000 and patent, legal and professional fees of $500,000, due to increased intellectual property activities and increased costs related to being a public company. The increase in stock-based compensation between years is largely due to an expense reversal during 2003 of $1.4 million of stock-based compensation expense that we recorded upon the termination of an employee and the reduction in service of a director, which represents 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 options.

We expect that general and administrative expenses will increase during 2005 and subsequent years as we increase payroll, increase our commercialization efforts and expand our operational infrastructure. An increase in general and administrative expenses is also expected due to the increased costs of our public company reporting and governance activities.

Under our present accounting policies using the intrinsic method of accounting for employee stock options granted at a price equal to the market value on the date of grant, we would expect non-cash stock-based compensation costs to decrease due to the decelerating scale of amortization of our existing deferred compensation under the graded-vesting method. However, as discussed below under the caption "Critical Accounting Estimates", we plan to adopt Statement of Financial Accounting Standard 123R, "Share-Based Payment", or SFAS 123R, in the third quarter of 2005 and are in the process of assessing the impact that this statement may have on our future financial condition and results of operations. The adoption of the new standard would apply to the non-cash stock-based compensation included in research and development expenses, as well as general and administrative expenses.

Interest and other income, net. Interest and other income, net, increased 203% to approximately $580,000 for the year ended December 31, 2004, from approximately $190,000 for the year ended December 31, 2003. The increase was principally attributable to higher average cash, cash equivalents, and investment balances during 2004, due to the investment of the net proceeds from the initial public offering in April 2004.

Non-operating expense. Non-operating expense increased 101% to approximately $68,000 in the year ended December 31, 2004, from approximately $34,000 for the year ended December 31, 2003. State tax expense, which is based in part on the amount of assets on the balance sheet, increased by approximately $40,000 due to the increase in assets generated by the initial public offering. This was offset by a $10,000 decrease in interest expense on our convertible note payable to the Institute for the Study of Aging, which was converted into common stock on June 30, 2004.

Years Ended December 31, 2003 and 2002

Research and development expenses. Research and development expenses decreased 38% to $8.2 million for the year ended December 31, 2003, from $13.3 million for the year ended December 31, 2002.

This decrease of $5.0 million was primarily attributable to decreases in preclinical and clinical trial expenses of $4.3 million due to the completion of one double-blind PMD clinical trial at the end of 2002, partially offset by the costs of the early-stage Alzheimer's disease trial commenced in 2003. The decrease was also attributable to a decrease in non-cash stock-based compensation of $1.4 million due to the graded-vesting method used to determine non-cash employee stock-based compensation, which results in greater expense in earlier years. We also experienced decreased costs of $1.3 million related to clinical supplies, as no purchases of clinical supplies were required in 2003, and to certain manufacturing capacity development projects that were completed in 2002. Those decreases were partially offset by an increase in GR-II antagonists drug discovery research activities in 2003 resulting in additional research and development expenses of $1.9 million.

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

Project	Year Ended December 31, 2002	2003
	(In thousands)	
CORLUX for the treatment of the psychotic features of PMD	$ 11,188	$ 4,775
CORLUX for the treatment of early-stage Alzheimer's disease	12	838
Drug discovery research	108	2,059
Total research and development expense (excluding non-cash stock-based compensation)	$ 11,308	$ 7,672

General and administrative expenses. General and administrative expenses decreased 68% to $1.7 million for the year ended December 31, 2003, from $5.5 million for the year ended December 31, 2002.

This decrease of $3.8 million was primarily attributable to a decrease in non-cash stock-based compensation of $2.5 million. Included in the total decrease is the reversal of $1.4 million expense to reverse stock-based compensation expense as a result of using the graded vesting method for unvested options forfeited by terminated employees and by a director due to a reduction in service. In addition, there was a reduction of $1.2 million in professional service fees, $1.0 million of which related to the expenses of a proposed public offering withdrawn in October 2002.

Interest and other income, net. Interest and other income, net, decreased 42% to $190,000 for the year ended December 31, 2003 from $330,000 for the year ended December 31, 2002. The decrease was principally attributable to lower average cash, cash equivalents, and short-term investments balances during the year ended December 31, 2003 as compared to the year ended December 31, 2002.

Non-operating expense. Non-operating expense decreased 11% to approximately $34,000 in the year ended December 31, 2003, from approximately $38,000 for the year ended December 31, 2002. The decrease in non-operating expense is due to a decrease in state tax expense, which is based in part on the amount of assets on the balance sheet. Interest expense, which represented interest on our convertible note payable to the Institute for the Study of Aging, was $21,000 in each of the years ended December 31, 2003 and 2002.

Liquidity and Capital Resources

We have incurred annual operating losses since inception, and at December 31, 2004, we had a deficit accumulated during the development stage of $53.5 million. Since our inception, we have relied primarily on the proceeds from public and private sales of our equity securities to fund our operations.

At December 31, 2004, we had cash, cash equivalents and investments balances of $46.9 million, compared to $11.6 million at December 31, 2003 and cash and cash equivalents of $21.5 million at December 31, 2002. Net cash used in operating activities for the years ended December 31, 2004, 2003 and 2002, was $13.7 million, $10.0 million and $13.2 million, respectively. The use of cash in each period was primarily a result of net losses associated with our research and development activities and amounts incurred to develop our administrative infrastructure. The increase in cash used in operating activities during 2004 was due to the expansion of our development program in PMD, as well as our general and administrative infrastructure. We expect cash used in operating activities to continue to increase during 2005 and later years due to the continuation and expansion of our development program for PMD, research activities and general and administrative expenses.

We believe that our current cash and investment balances and interest thereon, will be sufficient to enable us to complete the clinical development, as currently planned, of CORLUX, for the treatment of the psychotic features of PMD, and to satisfy our other anticipated cash needs for operating expenses at least through 2006. However, we cannot be certain that additional funding will not be required or desirable during this period and, if so, 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 products, including potentially our lead product, that we would otherwise seek to develop on our own.

Contractual Obligations and Commercial Commitments

Our contractual payment obligations that are fixed and determinable as of December 31, 2004 were as follows:

Payments Due by Period	2005	2006	2007	2008	2009	Beyond 2009
			(In thousands)			
Research and development studies(1)(2)	$ 10,700	$ 5,500	$ —	$ —	$ —	$ —
Drug discovery(3)	508	—	—	—	—	—
Operating lease(4)	155	—	—	—	—	—
Minimum royalty payments(5)	50	50	50	50	50	50 per year
Total	$ 11,413	$ 5,550	$ 50	$ 50	$ 50	$ 50 per year

(1) During 2004, 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 thirty 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.

(2) As of December 31, 2004, we had signed a letter of intent for the preliminary work on a European clinical trial for a commitment of approximately 310,000 Euros, which we expect will be paid in early 2005.

(3) During 2004, we gave notice of our intent to terminate our agreement with a third party for drug discovery research to be effective March 31, 2005. Under the agreement, we may be obligated to make milestone payments upon the occurrence of certain events, including: (i) patent filings in connection with the project; (ii) entries into Phase I clinical trials; and (iii) national regulatory approval of each product arising from work performed under the agreement, provided that sales of the product by us or any future licensees reach $5,000,000.

(4) Our operating lease commitment relates to the lease of our office facility. In December 2004, we received notice that the lease will be terminated in June 2005. However, we have the option of vacating earlier.

(5) Under our cancelable license agreements 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. In early 2005, we cancelled our rights to the Blood-Brain Permeability license; thus the $10,000 annual fee for that agreement has not been included in the table above.

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

Net Operating Loss Carryforwards

At December 31, 2004 we had approximately $20.4 million of federal net operating loss carryforwards and approximately $270,000 in federal research and development tax credit carryforwards, as well as approximately $19.2 million of California net operating loss carryforwards and approximately $370,000 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 Estimates

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States. 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.

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

Deferred stock-based compensation related to option grants to employees and directors represents the difference between the exercise price of an option and the deemed fair value of our common stock on the date of the grant. Given the absence of an active market for our common stock prior to the time of our initial public offering in April 2004, management was required to estimate the fair value of our common stock based on a variety of company and industry-specific factors for the purpose of measuring the cost of the transaction and properly reflecting it in our financial statements. Since our initial public offering, all stock option grants have been at the closing price for the stock on the Nasdaq Stock Market as of the date of grant. Deferred compensation is included as a reduction of stockholders' equity and is being amortized to expense over the vesting period of the underlying options, generally five years. Our policy is to use the graded-vesting method for recognizing compensation costs for fixed employee awards. We amortize the deferred stock-based compensation of employee options on the graded-vesting method over the vesting periods of the applicable stock options. The graded-vesting method provides for vesting of portions of the overall awards at interim dates and results in greater 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 required to be reversed upon such termination.

We recognized non-cash stock-based compensation expense related to option grants to employees and directors of approximately $1.5 million, $86,000 and $4.0 million for the years ended December 31, 2004, 2003 and 2002, respectively. In 2003, we recorded an expense reversal of $1.4 million, which represents 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 options by employees and a director who terminated or reduced their level of service to the company during 2003. In 2004, we recorded a similar expense reversal of approximately $10,000 related to employees who terminated during 2004. In addition, during 2004, we recorded an expense reversal of approximately $230,000, upon the change in status of a research employee to a consultant, 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 individual's service as an employee. Certain of the options previously granted to this individual will continue to vest as the individual provides consulting services to the Company, and therefore, we also recognized $154,000 of deferred compensation attributable to the fair value as of the date of change in status of the remaining option rights to be vested as a consultant. This amount, subject to the periodic adjustments in fair value of unvested options, is being amortized to expense over the remaining vesting period, which is approximately 2 years, using the straight-line method.

As of December 31, 2004, we had remaining employee deferred stock-based compensation of approximately $1.6 million, of which approximately $900,000 would be amortized to expense in 2005 under our present accounting methods.

In December 2004, the FASB adopted Statement of Financial Accounting Standard 123R, "Share-Based Payment", or SFAS 123R. The newly adopted statement addresses the accounting for transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise's equity instruments or that may be settled by the issuance of such equity instruments. SFAS 123R eliminates the ability to account for share-based compensation transactions using APB 25, and generally would require, instead, that such transactions be accounted for using a fair-value based method. In accordance with SFAS 123R, companies will be required to recognize an expense for compensation cost related to share-based payment arrangements including stock options and employee stock purchase plans, effective for interim or annual periods beginning after June 15, 2005. Retroactive application of the requirements of SFAS 123 to the beginning of the fiscal year that includes the effective date is permitted, but not required.

We plan to adopt SFAS 123R in the third quarter of 2005 and are in the process of assessing the impact that this statement may have on our future financial condition and results of operations. As a part of that assessment, we plan to review the option pricing model that we use to determine fair value and all assumptions that are used as inputs, including the expected volatility of the price of our stock, projected employee turnover and the expected term of options from the date of grant to the expected date of exercise. To date, in preparing the disclosures required under Statement of Financial Standard 123, or SFAS 123, that are contained in the footnotes to our financial statements included in Item 8 of this Form 10-K, we used the full 10 year contractual life of the options as the expected term. Because our stock was not publicly traded until our initial public offering in April 2004, the stock volatility factor used to date for the SFAS 123 footnote disclosures has been 70%, which we believe is a reasonable representation of the stock volatility for newly-public companies in our industry and stage of development. As we prepare to adopt SFAS 123R, we will review these factors and may determine that a change in these assumptions would be appropriate.

Deferred stock-based compensation related to option grants to non-employees represents the fair value of the options on the grant date, using the Black-Sholes 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. Deferred compensation related to non-employee options is amortized to expense on the straight-line basis as the options vest. The remaining balance of deferred compensation related to unvested non-employee options is remeasured on a quarterly basis based on the then current stock price as reflected on the Nasdaq Stock Market. We recognized stock-based compensation expense related to option grants to non-employees of approximately $180,000, $90,000 and $60,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

Research and Development Costs. We recorded accruals for estimated costs of research, pre-clinical and clinical studies, and manufacturing development of approximately $700,000 and $334,000 as of December 31, 2004 and 2003, respectively. The related 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. 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.

Recently Issued Accounting Standards

See discussion above under the caption “Critical Accounting Estimates — Stock-based compensation” regarding the adoption of SFAS 123R in December 2004.

ITEM 7A — *QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK*

Quantitative and Qualitative Disclosures About 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, 2004, 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 market 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 adverse impact on the total value of our portfolio as of December 31, 2004.

As of December 31, 2004, we had engaged a contract research organization to begin the preparatory work for the initiation of one of our planned clinical trials in Europe and were in discussions with them regarding proposals for a second European clinical trial. These two trials are expected to be conducted over the course of the next two years. The costs of these trials will be denominated in Euros, which the vendor will convert into U.S. dollars for invoicing as costs are incurred on a monthly basis. Thus, we may bear some currency rate exposure for the costs of these trials. As of December 31, 2004, we had signed a letter of intent for the preliminary work on one of the trials for a total commitment of approximately 310,000 Euros, which we expect will be paid in early 2005. The contract for the conduct of the full scope of this trial, which is expected to

commence during the second quarter of 2005, was executed in February 2005. The total expense for this trial, including the amount under the letter of intent, is expected to approximate 4.3 million Euros over the course of the trial. A 1% increase or decrease in the currency rate of exchange between the US Dollar and Euros would have an impact of approximately $60,000 on the cost of this trial. The agreement for the second European trial has not been finalized at the time of submission of this Form 10-K. The timing of payments for these trials will depend upon various factors including the pace of site selection, patient enrollment, and other trial activities. Both of the European trials discussed here are expected to be conducted under our master agreement with i3 that 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*

Evaluation of disclosure controls and procedures. Based on their evaluation as of December 31, 2004, our chief executive officer and chief financial officer have concluded that 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) were sufficiently effective 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.

Changes in internal controls. There were no changes in our internal controls over financial reporting during the quarter ended December 31, 2004 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the effectiveness of controls. Our management, including our chief executive officer and chief financial officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. In addition, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our chief executive officer and chief financial officer have concluded, based on their evaluation, that our disclosure controls and procedures were sufficiently effective as of December 31, 2004 to provide reasonable assurance that the objectives of our disclosure control system were met.

ITEM 9B. *OTHER INFORMATION*

In December 2004, James N. Wilson, our Chairman, adopted a plan for sales of our common stock in accordance with Rule 10b5-1 under the Securities and Exchange Act of 1934. Under this plan, shares will be sold from time to time over a 12-month period, beginning in March 2005.

In November 2004, we signed a master services agreement with i3 Research, an Ingenix Company, under which this organization will assist in the oversight of clinical trials at various institutions. This agreement may be terminated by us at any time upon 45 days' written notice. In February 2005, we signed an amendment to that contract for the conduct of a clinical trial to be conducted in Europe, which is expected to commence during the second quarter of 2005. The total expense for this trial, to be conducted over the next two years, is expected to be 4.3 million Euros. The costs of this trial will be denominated in Euros. The timing of payments for this trial will depend upon various factors including the pace of site selection, patient enrollment and other trial activities.

PART III

Certain information required by Part III is incorporated by reference from the Company's definitive Proxy Statement to be filed with the Securities and Exchange Commission in connection with the solicitation of proxies for the Company's 2005 Annual Meeting of Stockholders (the "Proxy Statement") not later than 120 days after the end of the fiscal year covered by this Form 10-K.

Item 10. *Directors and Executive Officers of the Registrant*

The information required by this Item with respect to executive officers is set forth below and the information with respect to directors, code of ethics, audit committee and audit committee financial experts of the company is incorporated by reference to the information set forth under the caption "Election of Directors" in the Company's Proxy Statement for its 2005 Annual Meeting of Stockholders.

The section entitled "Compliance Under Section 16(a) of the Securities Exchange Act of 1934" appearing in the Proxy Statement for the Company's 2005 Annual Meeting of Stockholders sets forth the information concerning compliance by officers, directors and 10% shareholders of the company with Section 16 of the Exchange Act of 1934 and is incorporated herein by reference.

Executive Officers

The following table sets forth, as of December 31, 2004, information about our executive officers:

Name	Age	Position
Joseph K. Belanoff, M.D.	47	Chief Executive Officer and Director
Robert L. Roe, M.D.	64	President and Secretary
Fred Kurland	54	Chief Financial Officer

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 Allergenics, Inc. From 1996 to 1999, he was Executive Vice President, Chief Operating Officer and a director of Cytel Corporation. From 1995 to 1996, he was Executive Vice President, Chief Operating Officer and a director of Chugai Biopharmaceuticals, Inc. From 1992 to 1995, Dr. Roe served as President of the Development Research Division and Senior Vice President of Syntex Corporation. Dr. Roe received his B.A. from Stanford University and his M.D. from the University of California, San Francisco.

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.

Item 11. *Executive Compensation*

The information required by this section is incorporated by reference from the information in the section entitled "Executive Compensation and Other Matters" in the Proxy Statement.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management***

The information required by this section is incorporated by reference from the information in the section entitled "Security Ownership of Certain Beneficial Owners and Management" in the Proxy Statement.

Item 13. ***Certain Relationships and Related Transactions***

The information required by this section is incorporated by reference from the information in the section entitled "Certain Relationships and Related Transactions" in the Proxy Statement.

Item 14. ***Principal Accountant Fees and Services***

The information required by this section is incorporated by reference from the information in the section entitled "Ratification of Appointment of Independent Registered Public Accounting Firm" in the Proxy Statement.

Item 15 ***Exhibits, Financial Statement Schedules and Reports on Form 8-K***

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

(1) Financial Statements:

(2) Financial Statement Schedules:

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

(3) Exhibits:

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

(A) EXHIBITS

Exhibit Number	Description of Document
3.1(1)	Amended and Restated Certificate of Incorporation
3.2(1)	Amended and Restated Bylaws
4.1(1)	Specimen Common Stock Certificate
4.2(1)	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(1)	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*(1)	2000 Stock Option Plan
10.2*(1)	Employment offer letter to Robert L. Roe, M.D., dated October 18, 2001
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

Exhibit Number	Description of Document
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	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
14.1(1)	Code of Ethics
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (See page 41)
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

* Management compensatory plan

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

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 29 day of March, 2005.

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:

Signature	Title	Date
/s/ JOSEPH K. BELANOFF **Joseph K. Belanoff, M.D.**	Chief Executive Officer and Director (Principal Executive Officer)	March 29, 2005
/s/ FRED KURLAND **Fred Kurland**	Chief Financial Officer (Principal Financial and Accounting Officer)	March 29, 2005
/s/ JAMES N. WILSON **James N. Wilson**	Director and Chairman of the Board of Directors	March 29, 2005
/s/ G. LEONARD BAKER, JR. **G. Leonard Baker, Jr.**	Director	March 29, 2005
/s/ JOSEPH C. COOK, JR. **Joseph C. Cook, Jr.**	Director	March 29, 2005
/s/ JAMES A. HARPER **James A. Harper**	Director	March 29, 2005
/s/ DAVID L. MAHONEY **David L. Mahoney**	Director	March 29, 2005
/s/ ALIX MARDUEL **Alix Marduel, M. D.**	Director	March 29, 2005
/s/ ALAN F. SCHATZBERG **Alan F. Schatzberg, M.D.**	Director	March 29, 2005
/s/ DAVID B. SINGER **David B. Singer**	Director	March 29, 2005

CORCEPT THERAPEUTICS INCORPORATED
(A DEVELOPMENT STAGE COMPANY)

INDEX TO FINANCIAL STATEMENTS

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, 2003 and 2004, 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, 2004, and for the period from inception (May 13, 1998) to December 31, 2004. 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, 2003 and 2004 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2004 and for the period from inception (May 13, 1998) to December 31, 2004, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Palo Alto, California
March 25, 2005

CORCEPT THERAPEUTICS INCORPORATED
(A DEVELOPMENT STAGE COMPANY)

BALANCE SHEETS

	December 31, 2003	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 10,073,103	$ 5,930,117
Short-term investments	1,504,180	31,471,016
Prepaid expenses and other current assets	165,341	838,114
Total current assets	11,742,624	38,239,247
Long-term investments	—	9,485,523
Property and equipment, net of accumulated depreciation	531	—
Other assets	37,805	46,858
Total assets	$ 11,780,960	$ 47,771,628
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 321,806	$ 549,516
Accrued clinical expenses	334,362	655,488
Other accrued liabilities	357,818	619,037
Total current liabilities	1,013,986	1,824,041
Convertible note payable	523,689	—
Total liabilities	1,537,675	1,824,041
Commitments		
Convertible preferred stock, $0.001 par value, issuable in series; 10,000,000 shares authorized; 6,768,558 shares issued and outstanding at December 31, 2003; no shares outstanding at December 31, 2004	41,715,974	
Stockholders' equity (net capital deficiency):		
Preferred stock, $0.001 par value, undesignated; 10,000,000 shares authorized and no shares outstanding at December 31, 2004		—
Common stock, $0.001 par value; at December 31, 2003, 30,000,000 shares authorized and 9,334,982 shares issued and outstanding; at December 31, 2004, 140,000,000 shares authorized and 22,693,813 shares issued and outstanding	9,335	22,694
Additional paid-in capital	8,981,827	101,360,621
Notes receivable from stockholders	(246,258)	(183,841)
Deferred compensation	(2,279,524)	(1,718,246)
Deficit accumulated during the development stage	(37,937,426)	(53,471,907)
Accumulated other comprehensive loss	(643)	(61,734)
Total stockholders' equity (net capital deficiency)	(31,472,689)	45,947,587
Total liabilities and stockholders' equity	$ 11,780,960	$ 47,771,628

See accompanying notes.

CORCEPT THERAPEUTICS INCORPORATED
(A DEVELOPMENT STAGE COMPANY)

STATEMENTS OF OPERATIONS

	Year Ended December 31,			Period from Inception (May 13, 1998) to December 31,
	2002	2003	2004	2004
Operating expenses:				
Research and development*	$ 13,264,396	$ 8,223,014	$ 11,550,771	$ 39,888,020
General and administrative*	5,530,433	1,746,278	4,494,064	15,147,783
Total operating expenses	18,794,829	9,969,292	16,044,835	55,035,803
Interest and other income, net	328,824	190,765	578,238	1,757,501
Non-operating expense	(37,945)	(33,835)	(67,884)	(193,605)
Net loss	$ (18,503,950)	$ (9,812,362)	$ (15,534,481)	$ (53,471,907)
Basic and diluted net loss per share	$ (2.75)	$ (1.22)	$ (0.84)	
Shares used in computing basic and diluted net loss per share	6,719,787	8,068,560	18,440,390	
*Includes non-cash stock-based compensation of the following:				
Research and development	$ 1,956,874	$ 551,176	$ 202,434	$ 4,021,754
General and administrative	2,144,721	(307,772)	1,474,949	3,992,056
Total non-cash stock-based compensation	$ 4,101,595	$ 243,404	$ 1,677,383	$ 8,013,810

See accompanying notes.

CORCEPT THERAPEUTICS INCORPORATED
(A DEVELOPMENT STAGE COMPANY)

STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)

	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						
Balance at inception (May 13, 1998)	—	$ —	—	$ —	$ —	$ —	$ —	$ —	$ —	$ —
Issuance of common stock to directors for cash in June and July 1998	—	—	7,500,000	7,500	(5,000)	—	—	—	—	2,500
Issuance of common stock to a director for cash in May 1999	—	—	1,770,939	1,771	63,163	—	—	—	—	64,934
Issuance of common stock to Stanford and directors in conjunction with a license agreement in October 1999	—	—	30,000	30	1,070	—	—	—	—	1,100
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 $33,756 in May 1999	607,761	622,626	—	—	—	—	—	—	—	—
Common stock issued to attorneys and consultants in exchange for services in May 1999	—	—	48,750	49	1,739	—	—	—	—	1,788
Issuance of common stock upon option exercise	—	—	60,000	60	(40)	—	—	—	—	20
Repurchase of common stock held by director in March 1999	—	—	(750,000)	(750)	500	—	—	—	—	(250)
Deferred compensation related to options granted to nonemployees	—	—	—	—	64,935	—	(64,935)	—	—	—
Amortization of deferred compensation	—	—	—	—	—	—	7,350	—	—	7,350
Net loss from inception to December 31, 1999	—	—	—	—	—	—	—	(321,110)	—	(321,110)
Balance at December 31, 1999	607,761	622,626	8,659,689	8,660	126,367	—	(57,585)	(321,110)	—	(243,668)

Issuance of Series B convertible preferred stock to institutional and individual investors at $3.00 per share for cash, net of issuance costs of $19,232 in January 2000	399,999	1,180,765	—	—	—	—	—	—	—	—
Deferred compensation related to options granted to an employee and nonemployees	—	—	—	—	248,118	—	(248,118)	—	—	—
Amortization of deferred compensation	—	—	—	—	—	—	90,271	—	—	90,271
Net loss	—	—	—	—	—	—	—	(1,846,166)	—	(1,846,166)
Balance at December 31, 2000 (carried forward)	1,007,760	1,803,391	8,659,689	8,660	374,485	—	(215,432)	(2,167,276)	—	(1,999,563)

CORCEPT THERAPEUTICS INCORPORATED
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STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)(CONTINUED)

	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						
Balance at December 31, 2000 (brought forward)	1,007,760	$ 1,803,391	8,659,689	$ 8,660	$ 374,485	$ —	$ (215,432)	$ (2,167,276)	$ —	$ (1,999,563)
Issuance of Series B convertible preferred stock to consultants in exchange for services in January and April 2001	11,534	204,709	—	—	—	—	—	—	—	—
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	268,077	1,081,155	—	—	—	—	—	—	—	—
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 $95,000 in May and June 2001	3,806,957	26,804,967	—	—	—	—	—	—	—	—
Issuance of Series C convertible preferred stock to consultants in exchange for services in October 2001	1,326	20,049	—	—	—	—	—	—	—	—
Issuance of common stock to a consultant for cash below fair value in April 2001	—	—	50,000	50	49,950		—	—	—	50,000
Issuance of common stock upon option exercises	—	—	767,835	768	438,324	(438,165)	—	—	—	927
Issuance of common stock in conjunction with a license agreement	—	—	1,000	1	15,106	—	—	—	—	15,107

Deferred compensation related to options granted to employees and nonemployees	—	—	—	—	10,225,292	—	(10,225,292)	—	—	—
Amortization of deferred compensation	—	—	—	—	—	—	1,848,807	—	—	1,848,807
Net loss	—	—	—	—	—	—	—	(7,453,838)	—	(7,453,838)
Balance at December 31, 2001 (carried forward)	5,095,654	29,914,271	9,478,524	9,479	11,103,157	(438,165)	(8,591,917)	(9,621,114)	—	(7,538,560)

CORCEPT THERAPEUTICS INCORPORATED
(A DEVELOPMENT STAGE COMPANY)

STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)(CONTINUED)

	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						
Balance at December 31, 2001 (brought forward)	5,095,654	$ 29,914,271	9,478,524	$ 9,479	$ 11,103,157	$ (438,165)	$ (8,591,917)	$ (9,621,114)	$ —	$ (7,538,560)
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 $19,036 in December 2002	1,672,904	11,801,703	—	—	—	—	—	—	—	—
Issuance of common stock upon option exercises	—	—	62,334	62	191	—	—	—	—	253
Amortization of deferred compensation	—	—	—	—	—	—	4,083,707	—	—	4,083,707
Reduction of deferred compensation related to the unamortized portion of deferred stock compensation related to a terminated employee	—	—	—	—	(239,722)	—	239,722	—	—	—
Reversal of previously expensed deferred compensation related to a terminated employee based on the straight line method	—	—	—	—	(50,112)	—	—	—	—	(50,112)
Stock-based compensation related to lapsing repurchase right of stock held by a non-employee					68,000					68,000
Net loss	—	—	—	—	—	—	—	(18,503,950)	—	(18,503,950)
Unrealized loss on short-term investments	—	—	—	—	—	—	—	—	(66)	(66)
Total comprehensive loss										(18,504,016)
Balance at December 31, 2002 (carried forward)	6,768,558	41,715,974	9,540,858	9,541	10,881,514	(438,165)	(4,268,488)	(28,125,064)	(66)	(21,940,728)

CORCEPT THERAPEUTICS INCORPORATED
(A DEVELOPMENT STAGE COMPANY)

STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)(CONTINUED)

	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						
Balance at December 31, 2002 (brought forward)	6,768,558	$41,715,974	9,540,858	$ 9,541	$10,881,514	$ (438,165)	$ (4,268,488)	$ (28,125,064)	$ (66)	$ (21,940,728)
Issuance of common stock upon option exercises	—	—	367	—	274	—	—	—	—	274
Deferred compensation related to options granted to employees and nonemployees	—	—	—	—	1,158,943	—	(1,158,943)	—	—	—
Amortization of deferred compensation	—	—	—	—	—	—	1,559,389	—	—	1,559,389
Reduction of deferred compensation related to the unamortized portion of deferred stock compensation related to terminated employees	—	—	—	—	(1,588,518)	—	1,588,518	—	—	—
Reversal of previously expensed deferred compensation related to terminated employees	—	—	—	—	(1,383,985)	—	—	—	—	(1,383,985)
Repurchase of common stock and reduction of note payable upon termination of employees	—	—	(206,243)	(206)	(154,401)	154,607	—	—	—	—
Repayment of note receivable from stockholder	—	—	—	—	—	37,300	—	—	—	37,300
Stock-based compensation related to lapsing repurchase right of stock held by a non-employee					68,000					68,000
Net loss	—	—	—	—	—	—	—	(9,812,362)	—	(9,812,362)
Unrealized loss on short-term investments	—	—	—	—	—	—	—	—	(577)	(577)
Total comprehensive loss										(9,812,939)
Balance at December 31, 2003 (carried forward)	6,768,558	$41,715,974	9,334,982	$ 9,335	$ 8,981,827	$ (246,258)	$ (2,279,524)	$ (37,937,426)	$ (643)	$ (31,472,689)

CORCEPT THERAPEUTICS INCORPORATED
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STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)(CONTINUED)

	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						
Balance at December 31, 2003 (brought forward)	6,768,558	$ 41,715,974	9,334,982	$ 9,335	$ 8,981,827	$ (246,258)	$ (2,279,524)	$ (37,937,426)	$ (643)	$ (31,472,689)
Sale of Shares in IPO	—	—	4,500,000	4,500	49,020,752	—	—	—	—	49,025,252
Conversion of preferred shares in IPO	(6,768,558)	(41,715,974)	8,807,146	8,807	41,707,170	—	—	—	—	41,715,977
Conversion of note payable	—	—	44,508	45	534,060	—	—	—	—	534,105
Issuance of common stock upon option exercises	—	—	7,177	7	711	—	—	—	—	718
Deferred compensation related to options granted to employees and nonemployees	—	—	—	—	1,446,949	—	(1,446,949)	—	—	—
Amortization of deferred compensation	—	—	—	—	—	—	1,852,839	—	—	1,852,839
Reduction of deferred compensation related to the unamortized portion of deferred stock compensation related to terminated employees and consultants	—	—	—	—	(155,388)	—	155,388	—	—	—
Reversal of previously expensed deferred compensation related to terminated or converted to consultant employees	—	—	—	—	(243,460)	—	—	—	—	(243,460)
Repayment of note receivable from stockholder	—	—	—	—	—	62,417	—	—	—	62,417
Stock-based compensation related to lapsing repurchase right of stock held by a non-employee					68,000					68,000
Net loss	—	—	—	—	—	—	—	(15,534,481)	—	(15,534,481)
Change in unrealized loss on investments	—	—	—	—	—	—	—	—	(61,091)	(61,091)
Total comprehensive loss										(15,595,572)
Balance at December 31, 2004	—	$ —	22,693,813	$22,694	$ 101,360,621	$ (183,841)	$ (1,718,246)	$ (53,471,907)	$ (61,734)	$ 45,947,587

See accompanying notes.

CORCEPT THERAPEUTICS INCORPORATED
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STATEMENTS OF CASH FLOWS

	Year Ended December 31,			Period from Inception (May 1, 1998) to December 31,
	2002	2003	2004	2004
Operating activities				
Net loss	$ (18,503,950)	$ (9,812,362)	$ (15,534,481)	$ (53,471,907)
Adjustments to reconcile net loss to net cash used in operations:				
Depreciation	20,138	22,551	531	53,966
Amortization of deferred compensation, net of reversals	4,033,595	175,404	1,609,382	7,757,459
Expense related to stock issued for services	—	—	—	45,696
Expense related to stock issued in conjunction with license agreement	—	—	—	14,570
Expense related to stock issued below fair value	68,000	68,000	68,000	431,487
Interest accrued on convertible promissory notes	20,832	20,832	10,416	103,769
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	468,639	30,089	(672,773)	(838,114)
Other assets	545,709	(4,762)	(9,053)	(46,858)
Accounts payable	(56,236)	(483,168)	227,710	549,516
Accrued liabilities	171,850	(19,470)	582,345	1,281,829
Net cash used in operating activities	(13,231,423)	(10,002,886)	(13,717,923)	(44,118,587)
Investing activities				
Purchases of property and equipment	(7,035)	—	—	(53,966)
Purchases of short-term investments	(3,142,246)	(11,667,577)	(103,898,273)	(118,708,096)
Maturities of short-term investments	—	13,305,000	64,384,823	77,689,823
Net cash provided by (used in) investing activities	(3,149,281)	1,637,423	(39,513,450)	(41,072,239)
Financing activities				
Proceeds from issuance of common stock, net of cash paid for issuance costs	253	274	49,025,970	49,099,878
Proceeds from issuance of convertible note payable	—	—	—	462,929
Proceeds from convertible promissory notes	—	—	—	1,080,000
Proceeds from repayment of stockholder note	—	37,300	62,417	99,717
Payment to repurchase common stock	—	—	—	(250)
Proceeds from issuance of convertible preferred stock, net of cash paid for issuance costs	11,801,703	—	—	40,378,669
Net cash provided by financing activities	11,801,956	37,574	49,088,387	91,120,943
Net (decrease) increase in cash and cash equivalents	(4,578,748)	(8,327,889)	(4,142,986)	5,930,117
Cash and cash equivalents at beginning of period	22,979,740	18,400,992	10,073,103	—
Cash and cash equivalents at end of period	$ 18,400,992	$ 10,073,103	$ 5,930,117	$ 5,930,117
Supplemental disclosure of noncash financing activities:				
Conversion of convertible promissory notes and accrued interest				
— to convertible preferred stock	$ —	$ —	$ —	$ 1,111,155
— to common stock	$ —	$ —	$ 534,105	$ 534,105
Issuance of preferred stock for services	$ —	$ —	$ —	$ 34,533
Supplemental disclosure of cash flow information:				
Interest paid	$ —	$ —	$ —	$ 1,788
Income taxes paid	$ —	$ —	$ —	$ 1,121

See accompanying notes.

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NOTES TO FINANCIAL STATEMENTS

1. 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 biopharmaceutical company engaged in the development of drugs for the treatment of severe psychiatric and neurological 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. No revenues have been generated to date from these activities. Accordingly, the Company is considered to be in the development stage.

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 Company's ability to continue as a going concern is dependent upon successful execution of its financing strategy and, ultimately, upon achieving profitable operations.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States 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.

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 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).

Expense 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 contract research organizations and the overall status of clinical trial activities.

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.

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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 enterprisewide 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, 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 U.S. government obligations. 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 U.S. government obligations.

All short-term and long-term investments, which primarily represent marketable debt securities, have been classified as “available-for-sale.” 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 income. 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.

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:

	Years Ended December 31,		
	2002	2003	2004
	(In thousands, except per share amounts)		
Net loss applicable to common stockholders (numerator)	$ (18,504)	$ (9,812)	$ (15,534)
Shares used in computing historical basic and diluted net loss per share applicable to common stockholders (denominator)			
Weighted-average common shares outstanding	9,529	9,377	18,703
Less weighted-average shares subject to repurchase	(2,809)	(1,308)	(263)
Denominator for basic and diluted net loss per share	6,720	8,069	18,440
Basic and diluted net loss per share applicable to common stockholders	$ (2.75)	$ (1.22)	$ (0.84)

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NOTES TO FINANCIAL STATEMENTS — (Continued)

In connection with the closing of the Company's initial public offering in April 2004 (the "IPO"), 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 all convertible preferred stock (prior to its automatic conversion into shares of common stock as described above), stock options and outstanding shares of common stock subject to repurchase from the calculation of diluted net loss per common share because all such securities are antidilutive for all periods presented. The total number of shares excluded from the calculations of diluted net loss per share was 11,880,748; 10,585,914 and 4,026,218 for the years ended December 31, 2002, 2003 and 2004, respectively.

The basic and diluted net loss per share amounts for periods prior to 2004 have been revised to reflect a change in the calculation of the weighted average number of shares outstanding used to compute net loss per share. Because these revisions relate only to the weighting of the shares used in the net loss per share computations, all of the information in the Company's final prospectus dated April 14, 2004 regarding the actual number of shares outstanding is correct. These changes also had no impact on the Company's previously reported total operating expenses, net loss, cash flows or balance sheets for any period.

Revised figures for shares used as the denominator in computing basic and diluted net loss per share are 6,719,787 and 8,068,560 for the years ended December 31, 2002 and 2003, respectively, compared to 7,392,016 and 8,650,471, respectively, as originally reported.

Revised basic and diluted net loss per share amounts are $2.75 and $1.22 for the years ended December 31, 2002 and 2003, respectively, compared to $2.50 and $1.13, respectively, as originally reported.

As discussed above, the Company has changed the calculation of the weighted average number of shares outstanding used to compute net loss per share prior to this current period. The revised figures for the total number of shares excluded from the calculations of historical diluted net loss per share are 11,880,748 and 10,585,914 for the years ended December 31, 2002 and 2003, respectively, compared to 10,188,519 and 9,661,881, respectively, as originally reported.

Stock-Based Compensation

Stock-based compensation arises from the granting of stock options to employees, directors and non-employees. The Company accounts for stock-based compensation using the intrinsic value method prescribed in Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB 25"), and has 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"). Options granted to nonemployees 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.

Under the intrinsic value method, deferred stock-based compensation related to option grants to employees and directors represents the difference between the exercise price of an option and the deemed fair value of our common stock on the date of the grant. Given the absence of an active market for the Company's common stock prior to the initial public offering 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 initial public offering, all stock option grants have been at the closing price for the stock on the Nasdaq Stock Market as of the date of grant. Deferred compensation is included as a reduction of stockholders' equity and is being amortized to expense over the vesting period of the underlying options, generally five years. The Company's policy is to use the graded-vesting method for recognizing compensation costs for fixed employee awards. The Company amortizes the deferred stock-based compensation of employee options on the graded-vesting method over the vesting periods of the applicable stock options. The graded-vesting method provides for vesting of portions of the overall awards at interim dates and

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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 upon such termination.

Deferred stock-based compensation related to option grants to non-employees represents the fair value of the options on the grant date, using the Black-Sholes 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, the Company uses the remaining contractual term as the life of the option. Deferred compensation related to non-employee options is amortized to expense on the straight-line basis as the options vest. The remaining balance of deferred compensation related to unvested non-employee options is remeasured on a quarterly basis based on the then current stock price as reflected on the Nasdaq Stock Market.

The information set forth below regarding pro forma net loss prepared in accordance with SFAS 123 has been determined as if the Company had accounted for employee stock options under the fair value method proscribed by SFAS 123. The resulting effect on net loss pursuant to SFAS 123 is not likely to be representative of the effects in future years, due to inclusion in subsequent years of additional grants and year of vesting.

The Company estimates the fair value of these options at the date of grant in accordance with SFAS 123, which allows non-public companies to use the minimum value option pricing model and requires the use of a model such as the Black-Scholes 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-Scholes option pricing model for determining the fair value of options granted on or after that date. The Company used the following weighted-average assumptions for grants in 2002, 2003 and 2004, respectively: risk-free interest rate of 5.5%, 4% and 4%; expected life of the options of 10 years, expected volatility of stock price of 70% and a dividend yield of zero. The weighted-average grant date fair value of stock options granted in 2002, 2003 and 2004 was $2.31, $7.39 and $6.73, respectively. The Company's assumptions used in prior periods are materially consistent with those used in the periods presented.

As required under SFAS 123 as amended by SFAS 148, the following pro forma net loss presentation reflects the amortization of the fair value of the stock option grants as expense. For purposes of this disclosure, the fair value of the stock options is amortized to expense over the options' vesting periods using the graded-vesting method.

	December 31,			Period from Inception (May 13, 1998) to December 31,
	2002	2003	2004	2004
Net loss — as reported	$ (18,503,950)	$ (9,812,362)	$ (15,534,481)	$ (53,471,907)
Add back: Amortization of deferred compensation related to employees	4,020,679	1,470,384	1,740,113	8,771,798
Deduct: Stock-based employee compensation expense determined under SFAS 123	(4,376,579)	(1,770,770)	(3,006,960)	(10,159,606)
Pro forma net loss	$ (18,859,850)	$ (10,112,748)	$ (16,801,328)	$ (54,859,715)
As reported net loss per share — basic and diluted	$ (2.75)	$ (1.22)	$ (0.84)	
Pro forma net loss per share — basic and diluted	$ (2.81)	$ (1.25)	$ (0.91)	

As discussed above under Net Loss Per Share, basic and diluted net loss per share amounts prior to the current period have been revised to reflect a change in the calculation of the weighted average number of shares outstanding used to compute net loss per share. Revised pro forma net loss per share amounts reflecting the stock-based employee compensation expense determined under SFAS 123 are $2.81 and $1.25 for the years ended December 31, 2002 and 2003, respectively, compared to $2.55 and $1.17, respectively, as originally reported.

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Recently Issued Accounting Standards

In December 2004, the FASB adopted Statement of Financial Accounting Standard 123R, "Share-Based Payment ("SFAS 123R.") The newly adopted statement addresses the accounting for transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise's equity instruments or that may be settled by the issuance of such equity instruments. SFAS 123R eliminates the ability to account for share-based compensation transactions using APB 25, and generally would require, instead, that such transactions be accounted for using a fair-value based method. In accordance with SFAS 123R, companies will be required to recognize an expense for compensation cost related to share-based payment arrangements including stock options and employee stock purchase plans, effective for interim or annual periods beginning after June 15, 2005. Retroactive application of the requirements of SFAS 123 to the beginning of the fiscal year that includes the effective date is permitted, but not required.

The Company plans to adopt SFAS 123R in the third quarter of 2005 and is in the process of assessing the impact that this statement may have on our future financial condition and results of operations. As a part of that assessment, the Company plans to review the option pricing model that it uses to determine fair value and the assumptions that are used as inputs, including the expected volatility of the price of our stock, projected employee turnover and the expected term of options from the date of grant to the expected date of exercise. To date, in preparing the disclosures presented above in accordance with SFAS 123, the Company has used the full 10 year contractual life of the options as the expected term. Because the Company's stock was not publicly traded until the initial public offering in April 2004, the stock volatility factor used to date for the SFAS 123 footnote disclosures has been 70%, which the Company believes is a reasonable representation of the stock volatility for newly-public companies in its industry and stage of development. As the Company prepares to adopt SFAS 123R management will be reviewing all assumptions used in the fair value calculation and may determine that changes in these assumption are appropriate.

In March 2004, the EITF reached a consensus on EITF 03-01, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments.* EITF 03-01 provides guidance regarding disclosures about unrealized losses on available-for-sale debt and equity securities accounted for under SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities.* In September 2004, the EITF delayed the effective date for the measurement and recognition guidance; however the disclosure requirements remain effective for annual periods ending after June 15, 2004 (see Note 3). We have complied with the disclosure requirements of EITF 03-01 in preparing our 2004 financial statements and we will evaluate the impact of the measurement and recognition provisions of EITF 03-01 once final guidance is issued.

Reclassification

Certain data for the years ended December 31, 2002 and 2003 and for the period from inception (May 13, 1998) to December 31, 2004 have been reclassified to conform to the current period presentation.

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

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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 and the $50,000 annual nonrefundable royalty payments and value of the common stock issued to Stanford as research and development costs.

In March 2001, the Company entered into another agreement with Stanford in which Stanford granted the Company an exclusive license agreement for invention and patents related to "Glucocorticoid Blocking Agents for Increasing Blood-Brain Permeability" owned by Stanford. 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 $20,000, immediately issue 1,000 shares of the Company's common stock and make annual payments of $10,000. In February 2005, the Company terminated its rights to this patent application. The final payment under this agreement was made in 2004 and charged to research and development expense. There are no further obligations to Stanford in regard to this agreement.

Manufacturing Agreement

In June 2000, the Company entered into a Memorandum of Understanding with a pharmaceutical manufacturer, ScinoPharm Taiwan, in which the manufacturer agreed to produce 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 amounts of approximately $410,000 and $340,000 in 2002 and 2004, respectively. No such costs were incurred in 2003. Further, the Company has committed to purchase $1,000,000 of CORLUX per year from the manufacturer following the receipt of marketing approval and initiation of sales of CORLUX.

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 in exchange for conducting 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 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 neurological 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 the years ended December 31, 2003 and 2004, the Company recorded approximately $1.9 million and $2.1million, respectively, as research and development expense related to this contract.

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 will be concluded. 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

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Phase I 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 completion of the agreement.

Development Agreements

During 2004, the Company executed a number of agreements to conduct clinical trials and pre-clinical studies for further development of our lead product, CORLUX, targeted for the treatment of the psychotic features of psychotic major depression, or PMD. During the quarter ended September 30, 2004, the Company executed amendments to clinical development agreements with two of its contract research organizations to assist us in the oversight of clinical trial activities at various institutions and signed an agreement for a 2-year mouse carcinogenicity study. In March 2004, the Company signed an agreement for a 2-year rat carcinogenicity study. The total commitment under these agreements is approximately $21 million. The agreements provide for termination by us upon thirty days' written notice or less. During 2004 the Company expensed $4.2 million under these agreements as research and development expense with the remainder of costs expected to be incurred during 2005 and 2006.

In early 2005, the Company signed agreements for the conduct of additional trials. See discussion in Note 12 — Subsequent Events.

3. Financial Instruments

The following is a summary of cash, cash equivalents, short-term and long-term investments as of December 31, 2003 and 2004:

December 31, 2004	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Fair Value
Cash	$ 258,832	$ —	$ —	$ 258,832
Money market funds	4,424,160	—	—	4,424,160
Commercial paper	3,856,118	—	(1,958)	3,854,160
Corporate debt securities	30,826,687	1,581	(51,813)	30,776,455
United States government obligations	7,582,593	4	(9,548)	7,573,049
	$ 46,948,390	$ 1,585	$ (63,319)	$ 46,886,656
Reported as:				
Cash and cash equivalents	$ 5,930,202	$ —	$ (85)	$ 5,930,117
Short-term investments	31,518,763	151	(47,898)	31,471,016
Long-term investments	9,499,425	1,434	(15,336)	9,485,523
	$ 46,948,390	$ 1,585	$ (63,319)	$ 46,886,656

December 31, 2003	Amortized Cost	Unrealized (Loss)	Fair Value
Cash	$ 160,442	$ —	$ 160,442
Money market funds	9,912,661	—	9,912,661
Corporate debt securities	1,003,328	(553)	1,002,775
United States government obligations	501,495	(90)	501,405
	$ 11,577,926	$ (643)	$ 11,577,283
Reported as:			
Cash and cash equivalents	$ 10,073,103	$ —	$ 10,073,103
Short-term investments	1,504,823	(643)	1,504,180
	$ 11,577,926	$ (643)	$ 11,577,283

All short-term and long-term investments at December 31, 2004 have remaining maturities of less than two years, with an average maturity of less than one year.

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NOTES TO FINANCIAL STATEMENTS — (Continued)

4. Property and Equipment

Property and equipment consists of the following:

	December 31, 2003	December 31, 2004
Computer equipment	$ 46,931	$ 46,931
Software	7,035	7,035
Less: accumulated depreciation	(53,435)	(53,996)
	$ 531	$ —

Depreciation expense amounted to $20,138, $22,551 and $531 in 2002, 2003 and 2004, respectively, and $53,996 for the period from inception (May 13, 1998) to December 31, 2004. As of December 31, 2004, the Company had not entered into any capital leases.

5. Accrued Liabilities

At December 31, 2003 and 2004 other accrued liabilities consisted of the following:

	December 31, 2003	December 31, 2004
Accrued compensation	$ 253,285	$ 343,128
Accrued legal fees	71,767	70,333
Other	32,766	205,576
	$ 357,818	$ 619,037

6. Convertible Promissory Notes

In December 2000, the Company entered into convertible promissory notes with several investors for a total of $900,000, including $50,000 with a founder (who is also an officer). The notes accrued interest at 8% per year and were to mature on December 31, 2001, if not earlier converted into Series BB convertible preferred stock. In January 2001, the Company issued an additional $150,000 convertible note payable to a founder (who is also an officer). In May 2001, the Company converted the notes and accrued interest of $31,211 into 268,077 shares of Series BB convertible preferred stock at $4.033 per share.

7. Related Party Transactions

The Company leases its facilities under an operating lease arrangement with a stockholder that is also an affiliate of a person who served as a member of the Company's board of directors until January 2004. Under this arrangement, the Company leases approximately 3,200 square feet for general corporate purposes in Menlo Park, California. The lease arrangement is currently month-to-month, with a minimum of 180 days notice required by either party to terminate the lease. In December 2004, the stockholder gave the Company notice that the lease will be terminated in June 2005. However, the Company has the option of leaving earlier. The cost of this lease is approximately $22,000 per month and is allocated to the functional groups based on the number of employees occupying the space. Rent expense amounted to approximately $199,000, $205,000, $239,000 and $800,000 for the years ended December 31, 2002, 2003 and 2004, and the period from inception (May 13, 1998) to December 31, 2004, respectively.

This stockholder also provides legal services to the Company. Legal expenses incurred with this stockholder were approximately $814,000, $100,000, $153,000 and $1.6 million for the years ended December 31, 2002, 2003 and 2004, and the period from inception (May 13, 1998) to December 31, 2004, respectively, and were recorded as general and administrative expense in each period. In addition, we paid this shareholder approximately $503,000 during 2004 that was accounted for as a cost of equity financing.

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NOTES TO FINANCIAL STATEMENTS — (Continued)

8. Convertible Preferred Stock and Stockholders' Equity

Convertible Preferred Stock

As of December 31, 2003, the Company was authorized to issue up to 10,000,000 shares of convertible preferred stock, issuable in series, with the rights and preferences of each designated series to be determined by the Company's board of directors. The Company had designated convertible preferred stock consisting of Series A, B, BB, and C convertible preferred stock, collectively referred to as "preferred stock."

Preferred stock at December 31, 2003 is summarized below:

	Designated Shares	Shares Issued and Outstanding	Per Share Liquidation Preference	Aggregate Liquidation Preference
Series A convertible preferred stock	610,000	607,761	$ 1.08	$ 656,382
Series B convertible preferred stock	415,000	411,533	$ 3.00	1,234,599
Series BB convertible preferred stock	268,077	268,077	$ 4.033	1,081,155
Series C convertible preferred stock	5,506,557	5,481,187	$ 7.066	38,730,067
Balance at December 31, 2003	6,799,634	6,768,558		$ 41,702,203

Series A, B, BB, and C convertible preferred stockholders are entitled to receive non-cumulative dividends at the annual rate of $0.0648, $0.18, $0.24198, and $0.42396 per share, respectively, when and if declared by the board of directors and payable in preference to common stock dividends.

The holders of each share of preferred stock are entitled to one vote for each share of common stock into which such share is convertible. Each share of preferred stock were convertible into common stock at the option of the holder. In April 2004, the Convertible Preferred Stock that had been outstanding prior to the initial public offering of the Company's Common Stock (the "IPO") was converted into shares of Common Stock, as discussed below. Each share of Series A and B convertible preferred stock was converted into three shares of common stock, and each share of Series BB and C convertible preferred stock was converted into one share of common stock.

Each holder of preferred stock was entitled to receive, prior and in preference to any distribution of the assets or surplus funds of the Company to the holders of common stock, the amount of the liquidation preference of each share plus an amount equal to all declared but unpaid dividends on such shares. If, upon the occurrence of a liquidation event, the assets and funds available to be distributed among preferred stockholders were insufficient to permit payment of the full preferential amount, then the assets and funds of the Company would be distributed ratably based on the total preferential amount due to each preferred stockholder. After full payment has been made to the preferred stockholders, the remaining assets of the Company available for distribution would be distributed ratably among the common stockholders. The definition of a liquidation event includes a change in control. As the liquidation event is outside of the control of the Company, all shares of convertible preferred stock have been presented outside of permanent equity in accordance with EITF Topic D-98, "Classification and Measurement of Redeemable Securities."

No dividends have been declared or paid by the Company.

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 in one or more series and to fix the rights, preferences, privileges and restrictions granted to or imposed upon the preferred stock, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences. The rights of the holders of common stock will be subject to the rights of holders of any preferred stock that may be issued in the future. As of December 31, 2004, the Company has no outstanding shares of preferred stock.

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NOTES TO FINANCIAL STATEMENTS — (Continued)

Common Stock

At December 31, 2003, the Company was authorized to issue 30,000,000 shares of common stock. Upon completion of the initial public offering in April 2004, the Company's authorized capital stock, after giving effect to an amendment and restatement of the Company's certificate of incorporation in connection with the Company's initial public offering, consists of 140,000,000 shares of common stock, $0.001 par value, and 10,000,000 shares of preferred stock, $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 June 1999, the Company issued 1,770,939 shares of common stock at fair value to a director for cash proceeds of $64,934. The Company had the right to repurchase a portion of the common stock shares upon termination of services at the original exercise price, which right lapsed in 2004 with the completion of the service requirement.

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 $68,000 per year in each of the years ended December 31, 2001, 2002, 2003, and $249,000 for the period from inception (May 13, 1998) to December 31, 2004, 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.

On April 19, 2004, the Company sold 4,500,000 shares of common stock in its IPO at a price of $12.00 per share. The net proceeds from the sale of these shares were approximately $49.0 million, after deducting the underwriting discounts and commissions and offering expenses. Upon completion of the Company's IPO, all outstanding shares of convertible preferred stock automatically converted into 8,807,146 shares of common stock in accordance with the conversion ratios stipulated in the respective preferred stock agreements.

On June 30, 2004 the principal and accrued interest of the convertible note payable to the Institute for the Study of Aging aggregate were converted into 44,508 shares of common stock.

At December 31, 2003 and 2004, approximately 684,000 and 127,000 common stock shares issued were subject to repurchase, respectively, with repurchase prices ranging from $0.0001 to $0.75 per share at December 31, 2003 and 2004. The Company's repurchase rights with respect to approximately 120,000 shares automatically lapsed upon completion of the initial public offering of the Company's common stock in April 2004.

Shares of common stock reserved for future issuance as of December 31, 2004 are as follows:

Common stock:	
Exercise of outstanding options	1,140,735
Shares available for grant under stock option plans	2,564,400
	3,705,135

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

Stock Option Plans

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. 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

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NOTES TO FINANCIAL STATEMENTS — (Continued)

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 return 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 initial public offering. 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 with respect to one-fifth of the underlying shares of common stock on the anniversary of the date of grant and in subsequent equal monthly installments through the fifth anniversary of the date of grant.

The following table summarizes all stock plan activity:

	Stock Options			
	Options Available	Options Outstanding	Price Per Share	Weighted-Average Exercise Price
Balance at December 31, 2001	1,278,500	133,665	$ 0.10 - 0.75	$ 0.42
Shares granted	(152,500)	152,500	$ 7.00	$ 7.00
Shares exercised	—	(2,334)	$ 0.10	$ 0.10
Shares forfeited	19,831	(19,831)	$ 0.10 - 0.75	$ 0.26
Balance at December 31, 2002	1,145,831	264,000	$ 0.10 - 7.00	$ 4.24
Shares granted	(207,500)	207,500	$ 7.00	$ 7.00
Shares exercised	—	(367)	$ 0.75	$ 0.75
Shares forfeited	633	(633)	$ 0.75	$ 0.75
Balance at December 31, 2003	938,964	470,500	$ 0.10 - 7.00	$ 5.46
Cancellation of remaining shares authorized under 2000 Plan	(697,152)	—	—	—
Shares authorized under 2004 Plan adoption	3,000,000	—	—	—
Shares granted				
— 2000 Plan	(272,500)	272,500	$ 7.00 - 15.00	$ 9.02
— 2004 Plan	(435,600)	435,600	$ 4.90 - 12.00	$ 6.82
Shares exercised	—	(7,177)	$ 0.10	$ 0.10
Shares cancelled and forfeited	30,688	(30,688)	$ 0.10 - 7.00	$ 6.37
Balance at December 31, 2004	2,564,400	1,140,735	$ 0.10 - 15.00	$ 6.84

In addition, in 2002, the Company issued 60,000 shares of common stock at $0.0003 per share upon exercise of stock options granted outside of the 2000 Plan.

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

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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.

The following is a summary of options outstanding and options exercisable at December 31, 2004.

	Options Outstanding			Options Exercisable	
	Options Outstanding	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Options Exercisable	Weighted Average Exercise Price
$ 0.10 - $ 0.75	100,500	6.34	$ 0.49	72,362	$ 0.45
$ 4.90 - $ 7.73	881,635	9.00	$ 6.58	124,981	$ 7.00
$10.06 - $15.00	158,600	9.34	$ 12.34	—	—
	1,140,735	8.81	$ 6.84	197,343	$ 4.60

Stock-Based Compensation

As discussed in Note 1, the Company applies 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, 2004, 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. Compensation expense of approximately $4.0 million, $86,000, $1.5 million and $7.1million was recognized for employee options using the graded-vesting method during the years ended December 31, 2002, 2003 and 2004, and for the period from inception (May 13, 1998) to December 31, 2004, respectively, net of reversals.

In 2003, the Company reversed $1.6 million from deferred compensation related to outstanding options forfeited by employees and a director who were terminated or reduced their level of service to the Company during 2003, as the terminated employees and director had not vested in the underlying shares. In addition, 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 of $1.4 million was reversed in 2003 upon these events. In 2004, the Company reversed approximately $118,000 from deferred compensation related to employees who terminated during 2004, as the terminated employees had not vested in the underlying shares. 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 of approximately $10,000 was also reversed in 2004 upon the termination of these employees.

In addition, during 2004, we recorded an expense reversal of approximately $230,000, upon the change in status of a research employee to a consultant, 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 individual's service as an employee. Certain of the options previously granted to this individual will continue to vest as the individual provides consulting services to the Company, and therefore, we also recognized $154,000 of deferred compensation attributable to the fair value at the date of conversion of the remaining option rights to be vested as a consultant. This amount, subject to the periodic remeasurement of the fair value of the unvested consultant option rights, is being amortized to expense over the remaining vesting period, which is approximately 2 years, using the straight-line method.

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.

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NOTES TO FINANCIAL STATEMENTS — (Continued)

Stock Options to Consultants

As of December 31, 2003, the Company had granted options to purchase 355,500 shares of common stock to consultants, 300,000 of which were exercised, none of which were subject to repurchase, and 27,843 of which were unvested. These options were granted in exchange for consulting services to be rendered and vest over periods of three to five years.

During 2004, the Company did not grant any new options to consultants, however, options for 7,177 shares were exercised and options for 2,823 shares were cancelled, with respect to the termination of the services of a consultant. During the year, one consultant converted to employment status with options for 2,167 remaining unvested as of the date of conversion. In addition, as discussed above, one employee converted to consultant status. This employee had previously exercised options and owned 23,333 shares as of the date of conversion that were subject to the Company's rights to repurchase.

As of December 31, 2004, options held by consultants to purchase 13,379 shares were unvested and 18,333 shares held by a consultant were subject to the Company's right to repurchase.

For the period from inception (May 13, 1998) to December 31, 2004, the Company recorded approximately $671,000 in deferred compensation for options to consultants, based upon the fair value of the option. The Company recorded charges to operations for stock options granted to consultants using the straight-line vesting method of approximately $63,000, $89,000, $113,000 and $671,000 for the years ended December 31, 2002, 2003 and 2004, and the period from inception (May 13, 1998) to December 31, 2004, respectively.

The unvested shares held by consultants have been and will be revalued using the Company's estimate of fair value at each balance sheet date pursuant to EITF 96-18.

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 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, 2004, the amounts outstanding under these notes included principal in the amount of $246,258 and interest in the amount of $42,058.

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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:

	December 2003	December 31, 2004
Deferred tax assets:		
Federal and state net operating losses	$ 5,405,561	$ 8,067,473
Research credits	288,824	508,531
Other, net	299,079	57,140
Capitalized research and patent costs	6,531,169	9,869,587
Total deferred tax assets	$ 12,524,633	$ 18,502,731
Valuation allowance	(12,524,633)	(18,502,731)
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 $6.0 million and $3.8 million for the years ended December 31, 2004 and December 31, 2004, respectively.

As of December 31, 2004, the Company had net operating loss carryforwards for federal income tax purposes of approximately $20.4 million, which expire in the years 2019 through 2024. The Company also has California net operating loss carryforwards of approximately $19.2 million, which expire in the years 2009 through 2014. The Company also has federal and California research and development tax credits of approximately $270,000 and $370,000. The federal research credits will expire in the years 2019 through 2023 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.

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

	December 2003	December 2004
U.S. federal taxes (benefit) at statutory rate	(3,336,203)	(5,281,724)
State Tax	—	—
Unutilized (utilized) net operating loss	3,248,356	4,679,825
Non-deductible stock based compensation	82,757	570,310
Other	5,090	31,589
Total	0	0

10. Commitments and Contingencies

During 2004, the Company executed a number of agreements to conduct clinical trials and pre-clinical studies for further development of our lead product, CORLUX, targeted for the treatment of the psychotic features of psychotic major depression, or PMD. The agreements provide for termination by us upon thirty days' written notice or less. See the discussion in Note 2 — Significant Agreements — Development Agreements for further discussion regarding these agreements.

In early 2005, the Company signed agreements for the conduct of additional trials. See discussion in Note 12 — Subsequent Events.

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NOTES TO FINANCIAL STATEMENTS — (Continued)

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 products, 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.

11. Quarterly Financial Data (Unaudited)

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

Quarter Ended	March 31	June 30	September 30	December 31
2003(1)				
Net loss	$ (2,812)	$ (2,882)	$ (2,129)	$ (1,990)
Basic and diluted net loss per share	$ (0.37)	$ (0.37)	$ (0.26)	$ (0.23)
2004(1)(2)				
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) See discussion in Note 1 regarding the change in loss per share previously reported for the quarter ended March 31, 2003 and 2004.

(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

In February 2005, the Company signed a contract for the conduct of a clinical trial to be conducted in Europe, which is expected to commence during the second quarter of 2005. The total expense for this trial, to be conducted over the next two years, is expected to be 4.3 million Euros. The costs of this trial will be denominated in Euros. The timing of payments for this trial will depend upon various factors including the pace of site selection, patient enrollment and other trial activities. This trial will be conducted under the master agreement with the vendor that provides for termination by the Company with forty-five days' notice.

In February 2005, the Company cancelled its rights to Blood-Brain Permeability license with Stanford. See discussion under Note 2 — Significant Agreements — Stanford License Agreements.

Exhibit Index

Exhibit Number	Description of Document
3.1(1)	Amended and Restated Certificate of Incorporation
3.2(1)	Amended and Restated Bylaws
4.1(1)	Specimen Common Stock Certificate
4.2(1)	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(1)	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*(1)	2000 Stock Option Plan
10.2*(1)	Employment offer letter to Robert L. Roe, M.D., dated October 18, 2001
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	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
14.1(1)	Code of Ethics
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (See page 41)
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

* Management compensatory plan

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

Exhibit 10.13

MASTER SERVICES AGREEMENT

THIS Master Services Agreement (the "Agreement") is effective as of the 28th day of October, 2004, (the "Effective Date"), by and between i3 Research, a division of Ingenix Pharmaceutical Services (UK) Limited. ("Ingenix"), with offices at Sygnus Court, 22-32 Market Street, Maidenhead, Berkshire, UK SL6 8AD, and Corcept Therapeutics Incorporated ("Sponsor"), with offices at 275 Middlefield Road, Suite A, Menlo Park, CA 94025.

WHEREAS, Sponsor is engaged in research and development of pharmaceutical products; and

WHEREAS, Ingenix is engaged in providing services to pharmaceutical manufacturers in support of their clinical research and product development activities;

WHEREAS, Sponsor wishes to retain Ingenix, from time to time, to assist in certain product development activities relating to certain of Sponsor's clinical studies (each of which shall be referred to as a "Study"); and

WHEREAS, Sponsor agrees to compensate Ingenix for its services.

NOW THEREFORE, in consideration of the premises and the mutual promises and undertakings herein contained, the parties agree as follows:

SECTION 1 — Services — General

1.1 Sponsor hereby retains Ingenix to provide the services (the "Services") that are described in written task orders ("Task Orders", a form of which is attached to this Agreement as Exhibit A) which are executed by the parties from time to time. The parties acknowledge and agree that their respective Affiliates may execute Task Orders under this Agreement. In that event, such Affiliate(s) shall be bound by all terms and conditions of this Agreement and the applicable Task Order, and entitled to all rights and protections afforded Sponsor or Ingenix under this Agreement. While this Agreement creates certain obligations between the parties, it does not create an obligation on the part of Sponsor or any Sponsor Affiliate to engage Ingenix to provide services, or an obligation on the part of Ingenix or any Ingenix Affiliate to provide services; such obligations shall arise only upon the execution of a Letter of Intent (a form of which is attached hereto as Exhibit B), a Task Order, or a written amendment to a Task Order (a "Change Order", a form of which is attached hereto as Exhibit C). The terms of this Agreement shall be made a part of and incorporated by reference into each Task Order and each Task Order is incorporated and made a part of this Agreement. In the event of a conflict between the terms of this Agreement and a Task Order, the terms of this Agreement will govern, unless otherwise agreed in a Task Order.

1.2 "Affiliate" means, when associated with a party to this Agreement, any entity that controls, is controlled by or is under common control with, that party. "Control" means the possession, directly or indirectly, of at least 50% of the share capital or voting rights or of the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of voting securities, by contract or otherwise.

1.3 Each Task Order shall constitute a unique agreement and shall stand alone with respect to any other Task Order entered into under this Agreement. To the extent required under Title 21 CFR Part 312.52 in the United States, and any equivalent laws of other countries, the parties shall document separately in writing the transfer by Sponsor to Ingenix of any of Sponsor's responsibilities. In the absence of such a separate document, the description of Services provided in the relevant Task Order shall be deemed the required written transfer of obligations from Sponsor to i3 Research for that Study. Notwithstanding the foregoing, Sponsor will retain the ultimate authority and control over and

responsibility for each Study. Sponsor shall retain and have responsibility for all Study activities not specifically transferred to Ingenix. The parties acknowledge and agree that Sponsor shall at all times be deemed to be the "sponsor" of each study pursuant to the terms of the U. S. Federal Food, Drug and Cosmetic Act, as from time to time amended, the regulations of the U.S. Food and Drug Administration ("FDA"), as promulgated in the Title 21 of U.S. Code of Federal Regulations, and any equivalent laws of other countries.

1.4 The terms of a Task Order may be amended or modified by mutual written agreement of Ingenix and Sponsor. If Sponsor wishes (i) to change the timelines, deliverables or scope or scale of the Services covered by a Task Order, (ii) to obtain additional services not initially covered by a Task Order, or (iii) to reduce or remove any of the Services covered by a Task Order, Sponsor shall so advise Ingenix. If Ingenix believes a change in the scope or scale of Services is necessary or advisable, Ingenix shall so advise Sponsor. The parties will negotiate diligently and in good faith the proposed revisions to the timelines, deliverables, scope or scale of Services and the professional fees and costs for performing changed or additional services or for reducing or removing Services, and shall execute a Change Order to the applicable Task Order. In the event Ingenix provides additional services or expends resources, at Sponsor's written request and in strict accordance with Sponsor's requirements, in the absence of a Change Order, Sponsor will compensate and/or reimburse Ingenix for all fees and reasonable costs incurred.

1.5 The parties shall perform their obligations under this Agreement and each Task Order in accordance with the terms of this Agreement, the applicable Task Order, applicable provisions of the Study protocol, agreed upon Standard Operating Procedures; the current Guidelines for Good Clinical Practice ("GCP Guidelines"); the Declaration of Helsinki of the 41st World Medical Assembly, South Africa 1996 as amended; and applicable local laws and regulations.

1.6 Neither party shall have any obligation of exclusivity of any nature to the other, or any obligation to conduct, sponsor, or to offer to conduct or sponsor, any particular services or study or any number of studies, unless specified in a Task Order. Each party shall be free to provide services to or conduct or sponsor clinical or research studies involving other parties, so long as a party's agreement with any such third party does not prevent it from performing its obligations under this Agreement or a Task Order. Each party understands and agrees that the other party or its Affiliates may be in a business similar to or offer products or services the same as the other party (or one or more of its Affiliates) and may already have developed, be in the process of developing, or plan to develop products, services and information similar to those owned or developed by the other. Nothing contained herein shall be construed to prohibit a party from so doing as long as it does so independently and without using Confidential Information disclosed by the other.

1.7 During the term of this Agreement Ingenix shall maintain all materials and all other data obtained or generated by Ingenix in the course of providing the Services, including all computerized records and files ("Work Product"), in a secure area reasonably protected from fire, theft and destruction. At the expiration or termination of this Agreement and each Task Order Sponsor shall provide Ingenix with written instructions as to the disposition of the Work Product obtained or generated by Ingenix in the course of providing the applicable Services. Such written instructions will provide that Ingenix (a) deliver the Work Product, in the form in which Ingenix currently holds them, to a designated Sponsor location or to such other entity or at such other address as Sponsor may specify, (b) retain the Work Product for the period of time specified in the Task Order, or (c) dispose of the Work Product, except for those portions which Ingenix is required by law or regulation to store or maintain. After termination of this Agreement or the applicable Task Order, storage, destruction, shipping and other services relating to the final record disposition will be billed as Pass — through Expenses (as defined below) to Sponsor. Notwithstanding the foregoing, Ingenix may retain copies of any of the Work Product as are reasonably necessary for regulatory or insurance purposes, subject to its ongoing obligation to maintain the confidentiality of such materials.

SECTION 2 — Institution/Investigator — Services

2.1 The parties acknowledge that Ingenix' Services under a Task Order may include identifying potential medical institutions ("Institutions") or clinical investigators ("Investigators") and/or negotiating, executing and/or administering contracts with them governing their conduct of the Study ("Study Agreements"). If, pursuant to a Task Order, Sponsor delegates to Ingenix the responsibility for negotiating and/or executing Study Agreements, the following provisions will apply:

(a) Sponsor may provide Ingenix with a list of suggested Institutions and/or Investigators to be recruited by Ingenix for a Study. Ingenix shall notify Sponsor in writing as to any listed Institution or Investigator with which Ingenix does not wish to contract.

(b) Selection of all Institutions or Investigators will be subject to approval by Sponsor, in writing, prior to initiation of any Study-related activities involving that Institution/Investigator or the start of any negotiations with such Institution/Investigator.

(c) Each Study Agreement shall be fully consistent with this Agreement and the applicable Task Order. The Study Agreement used with each Institution and Investigator will be in substantially the form attached hereto as Exhibit D, and subject to approval in advance by Sponsor. All changes to such form agreement suggested by an Investigator will require Sponsor's prior review and approval.

(d) Sponsor will provide Ingenix with a current form of Power of Attorney, as required, for each country in which the Study will be conducted.

(e) If an Institution/Investigator requests indemnification from Sponsor, Sponsor will issue a letter of indemnification directly to the Institution/Investigator. Sponsor acknowledges that Ingenix shall have no indemnification obligation to any Institution/Investigator relative to the Study drug or the applicable Study protocol.

(f) Ingenix will administer payments to Institutions/Investigators from funds provided in advance by Sponsor to Ingenix for that purpose. Ingenix will disburse payments to Institutions/Investigators on behalf of Sponsor according to the provisions of the Study Agreement and the applicable Task Order. Ingenix will not be liable for payments not made on a timely basis to any Institution/Investigator as a result of Sponsor's failure to provide, in advance, sufficient funds for such payments. Ingenix will promptly return to Sponsor any funds received from Sponsor for payments to Institutions/Investigators which are remaining as unpaid or unpayable at the expiration or other earlier termination of this Agreement or any Task Order.

2.2 The parties acknowledge and agree that, for the purposes of this Agreement or any Task Order, Institutions/Investigators shall not be considered as employees, agents or subcontractors of Ingenix or of Sponsor and that Investigators will be required to exercise their own independent medical judgement. Ingenix' responsibilities with respect to Institutions/Investigators shall be limited to those specifically set forth in the applicable Task Order.

SECTION 3 — Compensation and Expenses

3.1 As compensation for providing the Services, Sponsor shall pay Ingenix professional fees in the amounts and upon the terms specified in one or more attachments to the applicable Task Order. Each Task Order will include as attachments a study budget containing Ingenix' estimated professional fees and Pass-through Expenses ("the Budget"), a payment schedule (the "Payment Schedule") and a timeline showing performance milestones (the "Timeline"). If the assumptions under which the parties created the Budget, the Payment Schedule or the Timeline prove to be inaccurate, in whole or in part, or if matters reasonably beyond the control of the parties detrimentally affect a Study, then the parties shall review

each of the Budget, the Payment Schedule and the Timeline and incorporate reasonable revisions in a Change Order to the applicable Task Order.

3.2 Sponsor will reimburse Ingenix for reasonable travel and other reasonable out-of-pocket expenses incurred by Ingenix personnel identified in the Budget or at the request of Sponsor ("Pass-through Expenses"), unless Ingenix expressly agrees in advance to waive such reimbursement. Pass-through Expenses shall include the following:

(a) Travel via commercial airlines (using coach class or the equivalent), train or rental car;

(b) Local travel to places other than Ingenix' office by personal car at a rate to be agreed between the parties for each country;

(c) Actual and reasonable lodging and meal expenses;

(d) Actual and reasonable expenses for telephone, mail, express courier, facsimile, storage and photocopying services, and any other communication or technology expenses incurred in the performance of the Services under this Agreement; and

(e) Payments to third party vendors, consultants and independent contractors, including, upon the prior written consent of Sponsor, payments to outside legal counsel relating to review of Study Agreements in countries other than the U.K.

Ingenix shall submit a reasonably detailed invoice with copies of receipts attached of such expenses to Sponsor on a monthly basis.

3.3 Professional fees and estimated Pass-through Expenses, as indicated in the applicable Budget, shall be exclusive of value added tax ("VAT"), except where VAT is irrecoverable by Ingenix.

3.4 All invoices and payments will be stated and made in Euros unless otherwise provided for in the applicable Task Order. If Ingenix performs Services whereby it incurs costs or expenses in a currency different than Euros or another currency specified in a Task Order, Ingenix shall have the option of invoicing Sponsor for such costs and expenses in Euros after applying the applicable exchange spot rate published in the Financial Times on the last business day of the relevant invoice period to the initial currency. Sponsor will pay each invoice, via check or wire transfer of immediately available funds, within 30 days of receipt of the invoice.

3.5 In the event Sponsor disputes one or more items in an invoice, Sponsor will notify Ingenix in writing within fifteen (15) business days of receipt of the invoice and such notice shall contain a reasonably specific description of the item(s) being disputed and the basis therefor. Ingenix will respond to Sponsor within fifteen (15) business days of receipt of the notification. This written communication pattern will continue until Ingenix has provided Sponsor with sufficient justification for the disputed item(s) or until the parties agree to a resolution of the disputed amount. Sponsor shall pay the undisputed portion of the invoice within thirty (30) days of receipt of the invoice and shall use commercially reasonable best efforts to pay the disputed amount within fifteen (15) days of resolution of the dispute. In the event the parties are unable to reach a satisfactory resolution within one hundred eighty (180) days of the original invoice, either party can submit the dispute to binding arbitration in accordance with Section 9.2 of this Agreement.

SECTION 4 — Confidentiality

4.1 Each party acknowledges that in connection with the performance of the Services, it may receive, learn or have access to confidential, trade secret, or proprietary information concerning the other party or third parties to whom the other party has an obligation of confidentiality ("Confidential Information").

4.2 Sponsor's Confidential Information shall include, without limitation, information regarding the Sponsor's business; drug products and proposed drug products; current or proposed studies on Sponsor's products; prior research and results of studies on Sponsor's drug products; and reports and decisions resulting from clinical trials on Sponsor's drug products. Ingenix Confidential Information shall include, without limitation, business information; information regarding Ingenix services and documentation; Ingenix' business methodologies and processes and associated algorithms, tools, programs, software architecture, including but not limited to source codes, and technology.

4.3 Each party agrees that (a) it will use the other party's Confidential Information only as may be necessary in connection with the Services; (b) it will treat such information as confidential and proprietary; (c) without the prior written consent of the other party it will not disclose such information orally or in writing to any third party (except however, to disclose such information to its respective agents or representatives, IRB/Ethics Committee members, or the FDA or other regulatory authorities, all of whom have a need to know such information in connection with the purpose for which it is disclosed to the party); (d) it will take all reasonable precautions to protect the Confidential Information; and (e) it will not otherwise appropriate such information to its own use or to the use of any other person or entity. Without limiting the foregoing, each party agrees to take at least such precautions to protect the other party's Confidential Information as it takes to protect its own Confidential Information. Upon termination of this Agreement, each party will return to the other party or certify as destroyed all tangible items containing any of the other party's Confidential Information that are held by that party or its employees, agents or contractors. However, each party may retain archive copies of information as required by applicable regulatory requirements. Each party agrees to notify the other party if it becomes aware of any unauthorized use or disclosure of the other party's Confidential Information.

4.4 If either party believes it is required by law or by a subpoena or court order to disclose any of the other party's Confidential Information, it shall promptly notify the other party prior to any disclosure and shall make all reasonable efforts to allow the other party an opportunity to seek a protective order or other judicial relief.

4.5 Nothing in this Agreement shall be construed to restrict disclosure or use of information that (a) was in the possession of or rightfully known by the recipient, without an obligation to maintain its confidentiality, prior to receipt from the other party; (b) is or becomes generally known to the public without violation of this Agreement; (c) is obtained by the recipient in good faith from a third party having the right to disclose it without an obligation of confidentiality; (d) is independently developed by the receiving party without reference to the other party's Confidential Information; or (e) is required by law to be disclosed.

4.6 Each party agrees not to disclose or utilize individual patient or medical claim information in any way that would violate any physician-patient confidence or any state or federal laws or regulations.

4.7 Except as required by law neither party shall disclose Sponsor's retention of Ingenix for professional services or the terms of this Agreement or any Task Order, unless each party has agreed in writing that such disclosure may be made.

4.8 The terms of this Section 4, and the parties' obligations hereunder, shall survive termination or expiration of this Agreement and the completion of Ingenix' Services hereunder.

SECTION 5 — Term and Termination

5.1 This Agreement shall commence on the Effective Date and, unless otherwise terminated, shall continue until the later of [three (3)] years from the Effective Date or the completion of Services for all Task Orders entered into within that [three (3)] year period. Each Task Order shall take effect as of an effective date designated in the Task Order and, unless otherwise terminated, shall continue until either the date specified therein as the expiration date or until the Services specified in the Task Order have

been completed. Termination of this Agreement or of any Task Order shall not affect any other Task Order; each Task Order shall continue in full force and effect until its expiration date or completion of the Services, unless specifically earlier terminated in accordance with the terms of this Agreement or the terms of that Task Order.

5.2 In the event that either party commits a breach or defaults in any of the terms or conditions of this Agreement or a Task Order, and that party fails to remedy the default or breach within sixty (60) days after receipt of notice of the default or breach from the other party, the party giving notice may, at its option, immediately terminate this Agreement, or the Task Order, as applicable, at the end of the 60-day notice period.

5.3 Sponsor shall have the right to terminate this Agreement or a Task Order (for other than default or breach by Ingenix) at any time by giving appropriate written notice at least forty-five (45) days prior to the desired termination date.

5.4 Ingenix shall have the right to terminate this Agreement or a Task Order (for other than default or breach by Sponsor) at any time by giving appropriate written notice at least one hundred eighty (180) days prior to the desired termination date.

5.5 Either party shall have the right to terminate this Agreement and/or one or more Task Orders at any time upon receipt of written notice to the other party, if the other party shall be adjudicated insolvent or shall petition for or consent to any relief under any insolvency, re-organization, receivership, liquidation, compromise, or any moratorium statute, whether now or hereafter in effect, or shall make an assignment for the benefit of its creditors, or shall petition for the appointment of a receiver, liquidator, trustee, or custodian for all or a substantial part of its assets, or if a receiver, liquidator, trustee or custodian is appointed for all or a substantial part of its assets and is not discharged within thirty (30) days after the date of such appointment. In the event that any of the above events occur, that party shall immediately notify the other, in writing, of its occurrence.

5.6 Ingenix may, upon fifteen (15) days prior written notice to Sponsor, terminate a Task Order or cease performing its obligations thereunder, without such cessation resulting in an Ingenix breach or default, if Sponsor fails to make payment to Ingenix as required by such Task Order.

5.7 Upon termination of this Agreement or any Task Order the parties will reasonably cooperate with each other to provide for an orderly cessation of Ingenix' Services. Ingenix shall use its commercially reasonable best efforts to minimize costs associated with the cessation of the Services. In the event Sponsor terminates only part of the Services described in a Task Order, the parties will cooperate in good faith to enter into a Change Order amending the terms of that Task Order accordingly. In the event the Agreement or any of the Services is terminated Ingenix will be entitled to receive payment for all work and services performed by it and expenses incurred or irrevocably committed to third parties up to the effective date of termination. In addition, Sponsor shall pay all reasonable fees and expenses incurred by Ingenix that are necessary or reasonably required in connection with the orderly cessation of the Services. If a Study, Task Order, or the Agreement is cancelled or terminated before the Services have been performed completely, Ingenix shall refund to Sponsor any funds advanced to Ingenix for fees and costs not yet incurred or due to the extent that the payments for the liabilities associated with such fees or costs can reasonably be avoided in whole or in part.

5.8 Upon the termination of this Agreement or a Task Order for any reason, and payment by Sponsor of all amounts owed to Ingenix, Ingenix shall arrange for the return to Sponsor of unused supplies of the Study drug and all other materials of Sponsor in Ingenix' possession or control.

SECTION 6 — Delays, Suspension and Correction of Work

6.1 In the event Sponsor provides Ingenix with a written detailed notification of a material error by Ingenix or any employee thereof, in the performance of Ingenix' Services under a Task Order, where Ingenix does not dispute the existence of such material error and such notice is provided in a timely

manner following completion or performance of the Services relating to such material error, Ingenix shall have the option of taking the following steps:

(a) Ingenix can correct the material error free of charge to Sponsor as soon as reasonably possible, or

(b) Ingenix can retain a third party reasonably acceptable to Sponsor to correct the material error for which Ingenix will pay the cost, or

(c) Ingenix can accept reduced payment by an amount to be mutually determined by the parties.

If Ingenix disputes the existence of a material error, the notice from Sponsor is not provided in a timely manner, or the parties cannot agree upon any of the above options, then the provisions of this Agreement relating to dispute resolution shall apply. This section shall not affect Sponsor's right to terminate this Agreement if it considers the material error a breach of this Agreement that is not cured.

6.2 Ingenix will be responsible for and will not seek compensation from Sponsor for additional fees, costs and expenses it incurs due to errors or delays to the extent that such errors or delays are found to be the direct result of Ingenix' failure to perform its required obligations under this Agreement or the relevant Task Order. Sponsor will not hold Ingenix responsible for and will compensate Ingenix appropriately for additional fees, costs and expenses incurred by Ingenix due to errors or delays to the extent that such errors or delays (a) are found to result from (i) the failure of Sponsor to perform its obligations or provide necessary documents, materials, records, direction or cooperation as may be required of it during the course of the performance of this Agreement or a Task Order, or (ii) Sponsor undertaking any action or activity or failing to undertake an action or activity so that Ingenix is or would be prohibited from the due observance or performance of any material covenant, condition or agreement contained in this Agreement or a Task Order, and such action or inaction continues for a period of thirty (30) days after Ingenix gives Sponsor written notice thereof, or (b) are not the direct result of Ingenix' failure to perform.

6.3 In the event the start or progress of a clinical trial that is the subject of a Task Order is delayed for unavoidable or justified reasons, or in the event Sponsor delays, suspends or places a hold on the Study for any reason, Sponsor shall promptly provide Ingenix with written notice of such delay, hold or suspension and Sponsor and Ingenix will, within 30 days of such notice, on appropriate revisions to the applicable Task Order and each party will complete its respective duties and obligations as described in any such resulting Change Order. During the period following Ingenix' receipt of Sponsor's notice of delay, hold or suspension Sponsor will compensate Ingenix for additional professional fees and pass-through expenses incurred by Ingenix as a result of such delay or suspension, as agreed to and set forth in any such resulting Change Order.

6.4 The parties agree that, in the event a delay, hold or suspension exceeds thirty (30) days, and, in the case of a delay, such delay is not caused solely by Ingenix, Ingenix shall have the right, in its sole discretion, to re-deploy its personnel assigned to the Study unless Sponsor and Ingenix agree to appropriate compensation to Ingenix for maintaining the personnel assigned to the Study.

SECTION 7 — Indemnification

7.1 Sponsor agrees to indemnify and hold harmless Ingenix, its affiliates and their respective officers, directors, employees, agents and other representatives against claims, expenses, or losses resulting from Ingenix' provision of the Services, a Study drug, any study conducted pursuant hereto, or this Agreement or any Task Order except to the extent such claims, expenses or losses result from Ingenix' negligence or wilful misconduct.

7.2 Ingenix agrees to indemnify and hold harmless Sponsor, its affiliates and their respective officers, directors, employees, agents and other representatives against claims, expenses or losses resulting from

Ingenix' negligence or wilful misconduct, except to the extent that such claims result from Ingenix' actions taken at the direction of Sponsor.

7.3 Ingenix' indemnification obligation hereunder shall not apply to any claim which is caused in whole or in meaningful part by (i) the negligence, malpractice or intentional misconduct of Sponsor, any clinical investigator or laboratory or their respective personnel, Institutional Review Board/Ethics Committee or its members, any person or entity affiliated with any clinical site, or any independent contractor engaged to provide drug labelling, packaging, storage and shipment services and all such persons and entities shall not be considered affiliates, agents or employees of Ingenix for the purposes of this Agreement; or (ii) the administration of a Study drug or an individual's participation in any study.

7.4 Each party's obligations under Section 7 of this Agreement are further conditioned upon the indemnified party giving the indemnifying party timely written notice and assistance in the defence of any claim, proceeding or investigation; provided however, that failure of the indemnified party to give such notice shall not limit the indemnified party's right to indemnification except in such case where such failure materially and adversely affects the indemnifying party's ability to defend against such claim, proceeding or investigation.

7.5 Neither party will enter into any settlement agreement that attributes fault or negligence to the other party, requires any payment by the other party, or restricts the future actions or activities of the other party, without the other party's prior written consent.

7.6 Under no circumstances will either party be responsible under this Agreement or a Task Order for any indirect, incidental, special or consequential damages resulting from either party's performance or failure to perform under this Agreement. In addition, in no event shall the collective, aggregate indemnification liability of Ingenix, its Affiliates and their respective directors, officers, employees, agents and representatives under this Agreement exceed the amount of fees actually received by Ingenix from Sponsor for the tasks or services performed from which such liability arose.

7.7 In the event Ingenix incurs costs in excess of $1,000 USD as a result of its becoming involved in or being required to appear or participate with respect to a matter relating to a Sponsor study drug that is the subject of litigation, arbitration or some other dispute resolution mechanism, and where Ingenix' performance of the Services is not at issue, Sponsor shall reimburse Ingenix for such costs. The parties agree to cooperate with each other and to use commercially reasonable best efforts in good faith to minimize Ingenix' in and the costs relating to such disputes.

SECTION 8 — Representations and Warranties

8.1 Each party represents that it is authorized to enter into this Agreement, and any Task Order issued hereunder, and that the terms of this Agreement are not inconsistent with or a violation of any contracted or other legal obligation to which it is subject.

8.2 Each party represents that in performing under this Agreement and each Task Order it shall (a) conduct business in conformance with sound ethical standards of integrity and honesty and in compliance with all applicable laws, regulations and guidelines; (b) conduct business in such a way as to not give the appearance of impropriety, even when the behaviour or activity is in compliance with the law; and (c) not achieve business results by illegal act or unethical conduct.

8.3 Sponsor represents that it has all necessary or appropriate qualifications, authorizations, licenses or permits as the sponsor who is responsible for the marketing of a new drug.

8.4 Ingenix represents and warrants that neither it nor any Ingenix employee who will perform Services has been debarred under Section 306(a) or 306(b) of the U. S. Federal Food, Drug and Cosmetic Act, or any equivalent law of another country, and no debarred person will in the future be employed or utilized to perform any Services. To the best of Ingenix' knowledge, no person performing any Services, including any investigator, has a conviction which could lead to debarment under Section

306(a) or Section 306(b) or any equivalent law of another country. Ingenix agrees to notify Sponsor immediately of any action known to it toward conviction or debarment of any person performing any Services.

SECTION 9 — Dispute Resolution

9.1 Sponsor and Ingenix recognize that a bona fide dispute may arise under this Agreement or a Task Order which may relate to either party's rights and/or obligations hereunder. Sponsor and Ingenix agree that they shall use all commercially reasonable efforts to resolve, in an amicable manner, any dispute that may arise.

9.2 If the parties cannot resolve their dispute within thirty (30) days, Sponsor or Ingenix may at such time initiate arbitration under the Commercial Dispute Resolutions Rules of the American Arbitration Association then in effect.

9.3 Notwithstanding the above, the complaining party reserves the right to seek injunctive or other relief in a court of competent jurisdiction if it believes that immediate relief is necessary to protects its business interests.

SECTION 10 — Force Majeure

Neither Sponsor or Ingenix shall be liable for delays in performing or any failure to perform any of the terms of this Agreement or a Task Order caused by the effects of fire, strike, war (declared or undeclared), insurrection, acts of terror, government restriction or prohibition, force majeure or other causes reasonably beyond its control and without its fault, but the party failing to perform shall use all reasonable endeavour to resume performance of this Agreement as soon as feasible. Any episode of force majeure which continues for 60 days from the date of notification of its existence shall give the non-affected party the right to terminate this agreement upon 30 days additional notice.

SECTION 11 — Patents, Rights in Work Product and Trade Secrets

11.1 Any invention, discovery, or improvement related to Sponsor's products or technology which is conceived or reduced to practice as a direct consequence of Ingenix' performance of the Services hereunder (the "Inventions") shall become Sponsor property and shall be used by Sponsor as Sponsor deems appropriate. Ingenix agrees to execute and have executed assignments of the Inventions to Sponsor, along with other documents that be necessary or helpful to Sponsor in filing patent applications, or which may relate to any litigation or interference and/or controversy in connection therewith. The entire control, prosecution, and conduct of any patent application filed by Sponsor shall be outside the jurisdiction of and without expense to Ingenix and its officers, employees, representatives and agents. Ingenix acknowledges that Sponsor has the exclusive right to file patent applications in connection with the Inventions. Ingenix warrants that neither it, nor its employees, agents and representatives, will prevent Sponsor from filing patent applications for, or from applying the results of the research carried out for Sponsor hereunder.

11.2 All reports, data, technical information, original works of authorship and all other information, furnished by or on behalf of Sponsor, or created for Sponsor as part of the Services rendered hereunder, shall be the sole property of Sponsor.

11.3 Sponsor acknowledges that all computer programs, applications, databases, methods, techniques, processes and other materials and ideas used by Ingenix in performance of the work under this Agreement, and not supplied to Ingenix by Sponsor ("Ingenix Works"), are the exclusive property of Ingenix or its licensors. Sponsor agrees that any improvements, alterations or enhancements to the Ingenix Works during the term of this Agreement or the Study shall be the sole property of Ingenix. In no event shall Ingenix be precluded from use of its general knowledge, skills and experience, and any of its ideas, concepts, know-how and techniques used or developed by it in the course of providing Services under this Agreement.

SECTION 12 — Disclaimer

12.1 Sponsor acknowledges that the results of the Studies for which the Services are to be provided hereunder are inherently uncertain and that, accordingly, there can be no assurance, representation or warranty by Ingenix that the product covered by this Agreement can, either during the term of this Agreement or thereafter, be successfully developed or, if so developed, will receive the required approval by the regulatory authorities.

12.2 Sponsor acknowledges that Ingenix will provide professional services hereunder and not a product. The terms of this Agreement exclude all implied warranties including but not limited to the implied warranties of merchantability and fitness for a particular purpose.

12.3 Sponsor acknowledges that Ingenix will require documents, drug supplies, data, records and cooperation of Sponsor to perform the Services and that Ingenix is not responsible for delays or other consequences arising from Sponsor's failure to provide such documents, drug supplies, data, records or cooperation.

12.4 Sponsor acknowledges that the Services to be provided by Ingenix hereunder are based upon information supplied by both Ingenix and Sponsor, among other elements, and that Ingenix does not guarantee or warrant such Services to any specifications, functions or other standards, except as outlined in this Agreement and/or its Exhibit(s).

12.5 Sponsor acknowledges that the development of the protocol concept and scientific rationale shall be the sole responsibility of Sponsor regardless of Ingenix' involvement or lack thereof.

SECTION 13- Employees

Ingenix' staff are not, nor shall they be deemed to be at any time during the term of this Agreement, the employees of Sponsor. Sponsor agrees that neither it nor its Affiliates shall directly or indirectly solicit for employment, employ or otherwise retain staff of Ingenix during the term of this Agreement nor within the period of twelve (12) months following termination of this Agreement.

SECTION 14 — Communications and Payments

14.1 All communications provided for in this Agreement shall be in English and sent by registered first class mail, postage prepaid, return receipt requested, addressed to the respective parties as follows:

To Sponsor:

Corcept Therapeutics Incorporated
275 Middlefield Road, Suite A
Menlo Park, CA 94025
ATTN: Robert Roe, MD
Tel: (650) 688-8812
Fax: (650) 327-3218

To Ingenix:

Ingenix Pharmaceutical Services (UK) Limited
Sygnus Court
22-32 Market Street
Maidenhead, Berkshire
UK SL6 8AD
ATTN: Nigel Page

With a copy to:

Ingenix Pharmaceutical Services, Inc.
12125 Technology Drive
Eden Prairie, Minnesota 55344
ATTN: General Counsel
Tel: (952) 833-7211
Fax: (952) 833-7201

14.2 All payments to be made to Ingenix by Sponsor shall be in Euros. Payments made via cheque shall be sent to the above UK address. Payments to be made by Sponsor via bank transfer of immediately available funds shall be sent to the following bank account:

NatWest Bank
66 High Street
Maidenhead
Berkshire
UK

Account: 06670571
Sort code: 60-00-04
SWIFT: NWB KGB 2L

SECTION 15 — Miscellaneous

15.1 The parties hereto are independent contractors. Nothing in this Agreement or any Task Order is intended or shall be deemed to constitute a partnership, franchise or joint venture relationship between the parties. Neither party shall incur any debts or make any commitments for the other except to the extent, if at all, specifically provided for in this Agreement, a Task Order or as otherwise authorized in writing

15.2 Neither party shall have the right to assign this Agreement or any of the rights or obligations hereunder without the prior written consent of the other party, except that (a) Ingenix may subcontract with such individuals or entities it deems necessary and appropriate in order to perform the Services, and (b) either party may assign this Agreement to an Affiliate or a successor to that area of its business to which this Agreement is related, upon prior written notice, where such Affiliate or successor has the financial and operational capacity and ability to perform the assigning party's obligations hereunder.

15.3 Ingenix shall maintain complete and accurate records relating to its performance of the Services and pass-through expenses incurred in connection therewith. During the term of this Agreement and for one year thereafter or until a U.S. NDA for a Study relating to a Task Order is filed, whichever is later, Sponsor or Sponsor's designee may, upon reasonable notice and at Sponsor's sole cost and expense, audit Ingenix' records, facilities or procedures related to Ingenix' provision of the Services under this Agreement or a Task Order. Sponsor agrees to hold such records and procedures in confidence. Audits shall be conducted by Sponsor on site at Ingenix, in a manner designed to cause the least interruption to Ingenix' business operations, and shall occur no more than once per year.

15.4 If any provision of this Agreement is found by a court to be voided, invalid or unenforceable, the same shall either be reformed to comply with applicable laws and regulations or stricken if not so conformable, so as not to affect the validity or enforceability of the remaining provisions of this Agreement, except if the principal intent of this Agreement is frustrated by such reformation or deletion in which case this Agreement shall terminate.

15.5 Unless the parties otherwise agree, any document that is provided in connection with this Agreement or a Task Order must be (a) in English, or (b) accompanied by a certified English translation, in which case the English translation shall prevail unless the document is a statutory or other official document.

15.6 The parties hereto acknowledge that each has read this Agreement, understands it and agrees to be bound by its terms. The parties agree that this Agreement, along with each Task Order, is the complete agreement between the parties on the subject matter and supersedes all proposals (oral or written), understandings, representations, conditions, warranties, covenants and other communications between the parties relating to the same subject matter.

15.7 The terms, provisions, representations and warranties contained in this Agreement that, by their sense and context are intended to survive the performance thereof by either party or both parties hereunder, shall so survive the completion of performance, expiration or termination of this Agreement.

15.8 This Agreement shall be interpreted and enforced in accordance with the laws of England and Wales and each party hereby specifically consents to the personal jurisdiction thereof.

15.11 This Agreement may be executed in counterparts, each of which shall be deemed an original but all of which taken together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the following have caused this Master Services Agreement to be executed by their respective duly authorized representatives effective as of the Effective Date.

CORCEPT THERAPEUTICS INCORPORATED		INGENIX PHARMACEUTICAL SERVICES (UK) LIMITED	
By:	/s/ Robert L. Roe	By:	/s/ Alex Kordonsky
Title:	President	Title:	Global Controller / Director of Finance
Date:	02 November 2004	Date:	

LIST OF EXHIBITS:

EXHIBIT A: Form of Task Order

EXHIBIT B: Form of Letter of Intent

EXHIBIT C: Form of Change Order

MASTER SERVICES AGREEMENT: EXHIBIT A

FORM OF TASK ORDER

THIS Task Order is made and entered into to be effective as of the ___ day of ___, ___ by and between Corcept Therapeutics Incorporated. ("Sponsor") and Ingenix Pharmaceutical Services (UK) Limited ("Ingenix").

WHEREAS, Sponsor and Ingenix have entered into that certain Contract Research Organization Master Agreement dated the ___ day of ___, 200___ (hereinafter referred to as the "CRO Master Agreement"); and

WHEREAS, pursuant to the CRO Master Agreement, Ingenix has agreed to perform certain Services in accordance with Task Orders from time to time entered into by the parties, as more fully provided in Section 1 of the CRO Master Agreement, and Sponsor and Ingenix now desire to enter into such a Task Order.

WHEREAS, Ingenix and Sponsor desire that Ingenix provide certain services with respect to a _____ _____ _____ (the "**Study**") for the study of the drug _____ ("**Study Drug**") as set out in the Protocol titled: _____.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, the parties hereby agree as follows:

1. Scope of Services. Ingenix shall perform the services described in the Scope of Services, attached to this Task Order as Attachment A, and any other documents attached to this Task Order ("Services").

2. Compensation. For performance of these Services, Sponsor shall pay to Ingenix the amounts set forth in the Budget set forth in Attachment B to this Task Order, which amounts shall be payable pursuant to the Payment Schedule set forth in Attachment C to this Task Order.

3. Term and Termination. The term of this Task Order shall commence upon the effective date stated above and shall continue until [*state a specific date or completion of Services as described in Attachment B*], provided, however, the provisions of the CRO Master Agreement shall govern its termination prior to completion.

4. Incorporation by Reference; Conflict. The provisions of the CRO Master Agreement are hereby expressly incorporated by reference into and made a part of this Task Order. In the event of a conflict between the terms and conditions of this Task Order and those of the CRO Master Agreement, the terms of this Task Order shall take precedence and control over those of the CRO Master Agreement.

5. Notices. Any Notices given hereunder shall also be sent by fax, with a confirmation copy sent via first class United States mail, as follows, in addition to those noted in the CRO Master Agreement:

{To be specified in each Task Order}

6. Timely Completion. The timeline for this Task Order is attached as Attachment D.

IN WITNESS WHEREOF, the parties have hereunto signed this Task Order effective as of the day and year first written above.

CORCEPT THERAPEUTICS INCORPORATED

By: _____

Its: _____

Date: _____

INGENIX PHARMACEUTICAL
SERVICES (UK) LIMITED

By: _____

Its: _____

Date: _____

LIST OF ATTACHMENTS FOR EACH TASK ORDER:

ATTACHMENT A: SCOPE OF SERVICES
ATTACHMENT B: BUDGET
ATTACHMENT C: PAYMENT SCHEDULE
ATTACHMENT D: TIMELINE

FORM OF CHANGE ORDER

Sponsor:	**Effective Date of CO:**
Sponsor Contact:	**Project Code:**
Sponsor Tel:	**Agreement and all prior COs:**
Project Director:	**PACT No.:**
Project Manager:	**Protocol No.:**
Therapeutic Area:	**Financial Analyst:**
Account Director:	

This Change Order is effective as of the date identified above, by and between Sponsor and i3 Research and shall be incorporated into and become a part of the Agreement. Except as amended hereby, the terms and conditions of the Agreement, including those relating to invoicing and payment, shall remain in full force and effect.

Describe Requested Change In Scope of Services

1.
2.
3.

Fees and/or Expenses associated with Change In Scope

Description of Fees or expense	Agreement Value prior to this Change Order	Revised Agreement Value Including this Change Order	Variance (CO#	Value)
Fixed Costs/Professional Fees				
Estimated Pass-through Expenses				
Other Reimbursable Costs/Expenses				
TOTALS				

The following attachments are included as part of this Change Order

Attachment A — Supporting detail of the fees and expenses associated wit the Change in Scope
Attachment B — Revised Timeline ☐ Yes ☐ No
Attachment C — Revised Payment Schedule ☐ Yes ☐ No
Additional Attachments: [list or state None]

Corcept Therapeutics Incorporated

Signature: _____

Name: _____

Title: _____

Date: _____

i3 Research, a division of Ingenix Pharmaceutical Services (UK) Limited

Signature: _____

Name: _____

Title: _____

Date: _____

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-116127) pertaining to the 2000 Stock Option Plan and the 2004 Equity Incentive Plan of Corcept Therapeutics Incorporated of our report dated March 25, 2005 with respect to the financial statements of Corcept Therapeutics Incorporated included in the Annual Report (Form 10-K) for the year ended December 31, 2004.

/s/ Ernst & Young LLP

Palo Alto, California
March 25, 2005

Exhibit 31.1

CERTIFICATION

I, Joseph K. Belanoff, M.D., certify that:

1. I have reviewed this Annual Report on Form 10-K for the period ended December 31, 2004 of Corcept Therapeutics Incorporated;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) [Paragraph omitted pursuant to SEC Release 33-8238];

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ JOSEPH K. BELANOFF

Joseph K. Belanoff, M.D.
Chief Executive Officer
March 29, 2005

Exhibit 31.2

CERTIFICATION

I, Fred Kurland, certify that:

1. I have reviewed this Annual Report on Form 10-K for the period ended December 31, 2004 of Corcept Therapeutics Incorporated;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) [Paragraph omitted pursuant to SEC Release 33-8238];

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

/s/ Fred Kurland

Fred Kurland
Chief Financial Officer
March 29, 2005

Exhibit 32.1

Corcept Therapeutics Incorporated

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Corcept Therapeutics Incorporated (the "Company") on Form 10-K for the period ended December 31, 2004, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joseph K. Belanoff, M.D., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ JOSEPH K. BELANOFF

Joseph K. Belanoff, M.D.
Chief Executive Officer
March 29, 2005

Exhibit 32.2

Corcept Therapeutics Incorporated

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Corcept Therapeutics Incorporated (the "Company") on Form 10-K for the period ended December 31, 2004, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Fred Kurland, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Fred Kurland

Fred Kurland
Chief Financial Officer
March 29, 2005