

CORCEPT THERAPEUTICS INC

Form 10-Q

August 09, 2011

[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

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

For the quarterly period ended June 30, 2011

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)

Edgar Filing: CORCEPT THERAPEUTICS INC - Form 10-Q

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

**77-0487658**  
(I.R.S. Employer Identification No.)

**149 Commonwealth Drive**  
**Menlo Park, CA 94025**

(Address of principal executive offices, including zip code)

**(650) 327-3270**

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one.)

Large Accelerated Filer  Accelerated Filer

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

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

On August 4, 2011 there were 84,203,431 shares of common stock outstanding at a par value of \$0.001 per share.

**Table of Contents**

**TABLE OF CONTENTS**

<b><u>PART I. FINANCIAL INFORMATION</u></b>	4
ITEM 1. <b><u>FINANCIAL STATEMENTS</u></b>	4
<b><u>CONDENSED BALANCE SHEETS</u></b>	4
<b><u>CONDENSED STATEMENTS OF OPERATIONS</u></b>	5
<b><u>CONDENSED STATEMENTS OF CASH FLOWS</u></b>	6
<b><u>NOTES TO CONDENSED FINANCIAL STATEMENTS</u></b>	7
ITEM 2. <b><u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u></b>	11
ITEM 3. <b><u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u></b>	17
ITEM 4. <b><u>CONTROLS AND PROCEDURES</u></b>	17
<b><u>PART II. OTHER INFORMATION</u></b>	19
ITEM 1. <b><u>LEGAL PROCEEDINGS</u></b>	19
ITEM 1A. <b><u>RISK FACTORS</u></b>	19
ITEM 2. <b><u>UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u></b>	37
ITEM 3. <b><u>DEFAULTS UPON SENIOR SECURITIES</u></b>	37
ITEM 4. <b><u>(REMOVED AND RESERVED)</u></b>	37
ITEM 5. <b><u>OTHER INFORMATION</u></b>	37
ITEM 6. <b><u>EXHIBITS</u></b>	38
<b><u>SIGNATURES</u></b>	39

**Table of Contents**

**CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS**

*This Quarterly Report on Form 10-Q 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-Q other than statements of historical fact are forward-looking statements. When used in this report or elsewhere by management from time to time, the words believe, anticipate, intend, plan, estimate, expect, may, will, should, seeks and similar 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 Quarterly Report on Form 10-Q may include, but are not limited to, statements about:*

*the progress and timing of our research, development and clinical programs and the timing of regulatory activities, including the anticipated timing of completion of review by the United States Food and Drug Administration (FDA) of the New Drug Application (NDA) for CORLUX® for the treatment of Cushing's Syndrome, and the results of the review of the NDA by the FDA;*

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

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

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

*uncertainties associated with obtaining and enforcing patents;*

*our estimates for future performance; and*

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

*Forward-looking statements are not guarantees of future performance and involve risks and uncertainties. Actual events or results may differ materially from those discussed in the forward-looking statements as a result of various factors. For a more detailed discussion of such forward-looking statements and the potential risks and uncertainties that may impact upon their accuracy, see Part II, Item 1A, Risk Factors and the Overview and Liquidity and Capital Resources sections of Part I, Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations included in this Quarterly Report on Form 10-Q. These forward-looking statements reflect our view only as of the date of this report. Except as required by law, we undertake no obligations to update any forward-looking statements. Accordingly, you should also carefully consider the factors set forth in other reports or documents that we file from time to time with the Securities and Exchange Commission (SEC).*

**Table of Contents****PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****CORCEPT THERAPEUTICS INCORPORATED****(A DEVELOPMENT STAGE COMPANY)****CONDENSED BALANCE SHEETS**

(In thousands)

	<b>June 30, 2011 (Unaudited)</b>	<b>December 31, 2010 (See Note 1)</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 52,230	\$ 24,578
Prepaid expenses and other current assets	455	418
<b>Total current assets</b>	<b>52,685</b>	<b>24,996</b>
Property and equipment, net of accumulated depreciation	3	4
Other assets	32	104
<b>Total assets</b>	<b>\$ 52,720</b>	<b>\$ 25,104</b>
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 2,291	\$ 817
Accrued clinical expenses	799	815
Accrued compensation	214	1,806
Other accrued liabilities	552	422
<b>Total current liabilities</b>	<b>3,856</b>	<b>3,860</b>
Commitments		
Stockholders equity:		
Preferred stock		
Common stock	84	72
Additional paid-in capital	240,973	197,473
Notes receivable from stockholders	(6)	(97)
Deficit accumulated during the development stage	(192,187)	(176,204)
<b>Total stockholders equity</b>	<b>48,864</b>	<b>21,244</b>
<b>Total liabilities and stockholders equity</b>	<b>\$ 52,720</b>	<b>\$ 25,104</b>

See accompanying notes.



**Table of Contents**

**CORCEPT THERAPEUTICS INCORPORATED**  
**(A DEVELOPMENT STAGE COMPANY)**  
**CONDENSED STATEMENTS OF OPERATIONS**

(Unaudited)

(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30		Period from inception  (May 13, 1998) to June 30, 2011
	2011	2010	2011	2010	2011
Collaboration revenue	\$	\$	\$	\$	\$ 1,014
Operating expenses:					
Research and development*	6,203	4,574	11,127	9,063	144,288
General and administrative*	2,666	1,871	4,840	3,446	54,089
Total operating expenses	8,869	6,445	15,967	12,509	198,377
Loss from operations	(8,869)	(6,445)	(15,967)	(12,509)	(197,363)
Interest and other income, net	(1)	753	1	755	6,824
Other expense	(12)	(3)	(17)	(14)	(1,648)
Net loss and comprehensive loss	\$ (8,882)	\$ (5,695)	\$ (15,983)	\$ (11,768)	\$ (192,187)
Basic and diluted net loss per share	\$ (0.11)	\$ (0.09)	\$ (0.19)	\$ (0.18)	
Weighted average shares outstanding used in computing basic and diluted net loss per share	84,010	66,142	82,396	64,408	
* Includes non-cash stock-based compensation consisting of the following:					
Research and development	\$ 267	\$ 62	\$ 323	\$ 125	\$ 5,818
General and administrative	602	440	1,126	861	12,584
Total non-cash stock-based compensation	\$ 869	\$ 502	\$ 1,449	\$ 986	\$ 18,402

See accompanying notes.

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

(Unaudited)

(In thousands)

	Six Months Ended June 30,		Period from inception (May 13, 1998) to June 30, 2011
	2011	2010	2011
<b>Operating activities</b>			
Net loss	\$ (15,983)	\$ (11,768)	\$ (192,187)
Adjustments to reconcile net loss to net cash used in operations:			
Depreciation and amortization of property and equipment	1	5	117
Expense related to stock options, net of reversals	1,449	986	18,028
Expense related to stock issued for services or in conjunction with license agreement			95
Expense related to stock issued below fair value			522
Interest accrued on convertible promissory note			104
Settlement of liquidated damages in stock			1,281
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(37)	(68)	(455)
Other assets	72	(5)	(32)
Accounts payable	1,474	(97)	2,291
Accrued clinical expenses	(16)	414	799
Other liabilities	(1,462)	129	766
Net cash used in operating activities	(14,502)	(10,404)	(168,671)
<b>Investing activities</b>			
Purchases of property and equipment			(61)
Purchases of investments			(118,320)
Maturities of investments			118,320
Net cash used in investing activities			(61)
<b>Financing activities</b>			
Proceeds from issuance of common stock and warrants, including collection of notes receivable, net of issuance costs	42,154	21,928	179,100
Proceeds from issuance of convertible preferred stock, net of cash paid for issuance costs			40,378
Proceeds from issuance of convertible notes			1,543
Principal payments of obligations under capital leases		(6)	(59)
Net cash provided by financing activities	42,154	21,922	220,962
Net increase in cash and cash equivalents	27,652	11,518	52,230
Cash and cash equivalents, at beginning of period	24,578	23,867	



Edgar Filing: CORCEPT THERAPEUTICS INC - Form 10-Q

Cash and cash equivalents, at end of period	\$ 52,230	\$ 35,385	\$ 52,230
---	-----------	-----------	-----------

See accompanying notes.

---

**Table of Contents**

**CORCEPT THERAPEUTICS INCORPORATED**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

**1. Summary of Significant Accounting Policies**

**Description of Business and Basis of Presentation**

Concept Therapeutics Incorporated was incorporated in the state of Delaware on May 13, 1998, and its facilities are located in Menlo Park, California. Concept is a pharmaceutical company engaged in the discovery, development and commercialization of drugs for the treatment of severe metabolic and psychiatric disorders. Our most advanced program is for the use of CORLUX, our lead product, for the treatment of the signs and symptoms of endogenous Cushing's Syndrome, for which we submitted a New Drug Application (NDA) to the United States Food and Drug Administration (FDA) in April 2011. In June 2001, we received notification from the FDA that this application had been accepted for filing and that the Prescription Drug User Fee Act (PDUFA) goal date for completion of its review is February 17, 2012. We also have a clinical program for the use of CORLUX for the treatment of psychotic depression, where we are currently conducting a Phase 3 study. In addition, we have discovered three series of novel selective glucocorticoid receptor II (GR-II) antagonists and have moved CORT 108297, a compound from one of these series, into clinical development. Unless otherwise stated, all references in these financial statements to we, us, our, Concept, the Company, our company and similar designations refer to Concept Therapeutics Incorporated.

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

The accompanying unaudited balance sheet as of June 30, 2011, statements of operations for the three- and six-month periods ended June 30, 2011 and 2010, and statements of cash flows for the six-month periods ended June 30, 2011 and 2010 have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three- and six-month periods ended June 30, 2011 are not necessarily indicative of the results that may be expected for the year ending December 31, 2011 or any other period. These financial statements and notes should be read in conjunction with the financial statements for the year ended December 31, 2010 included in our Annual Report on Form 10-K. The accompanying balance sheet as of December 31, 2010 has been derived from audited financial statements at that date.

**Management Plans Regarding Liquidity**

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

As reflected in the accompanying financial statements as of June 30, 2011, we had cash and cash equivalents of \$52.2 million, working capital of \$48.8 million and an accumulated deficit of \$192.2 million. We believe that we have sufficient funds to maintain our operations through the end of 2012.

**Use of Estimates**

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

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

period of the change.

## **Table of Contents**

### **CORCEPT THERAPEUTICS INCORPORATED**

#### **(A DEVELOPMENT STAGE COMPANY)**

#### **Cash and Cash Equivalents**

We invest our excess cash in bank deposits, money market accounts, corporate debt securities, and obligations of the U.S. government and U.S. government sponsored entities. We consider all highly liquid investments purchased with maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents are carried at fair value, which approximates cost and, as of June 30, 2011 and December 31, 2010, consist of money market funds maintained at major U.S. financial institutions, which are classified as cash and cash equivalents.

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

Our concentration of credit risk relates to our cash and cash equivalents. We are exposed to credit risk in the event of default by the financial institutions holding these funds to the extent of the amount recorded on the balance sheet. This risk is mitigated by investing in securities with high credit ratings from the major rating services and by limiting the amount of investment in any one issuer. As of June 30, 2011 and December 31, 2010, we had no investments in mortgage-backed securities or auction rate securities. For the six-month periods ended June 30, 2011 and 2010, we experienced no loss or lack of access to cash and cash equivalents in our operating or investment accounts.

We also have a concentration of risk in regard to the manufacture of our product. As of June 30, 2011, we had one pre-existing supplier for our tablet manufacture and had negotiated a contract with a potential back-up tablet manufacturer with whom we have not yet completed process transfer or test manufacture. If we are not able to qualify our second tablet manufacturer or if our pre-existing supplier is unable to prepare the CORLUX tablets in the quantities and time frame required, we may not be able to manufacture our product in a timely manner.

#### **Fair Value Measurements**

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

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

#### **Revenue Recognition**

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

#### **Research and Development**

Research and development expenses consist of costs incurred for research and development activities that we sponsor. These costs include direct expenses (including nonrefundable payments to third parties) and research and development-related overhead expenses, as well as the cost of funding clinical trials, pre-clinical studies, manufacturing development, preparations for the submission of our NDA and the efforts to prosecute and defend that submission and the development of second-generation compounds, and are expensed as incurred. Costs to acquire technologies and materials that are utilized in research and development and that have no alternative future use are expensed when incurred.



**Table of Contents****CORCEPT THERAPEUTICS INCORPORATED****(A DEVELOPMENT STAGE COMPANY)****NOTES TO CONDENSED FINANCIAL STATEMENTS, continued****Segment Reporting**

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

**Stock-Based Compensation***Stock-based compensation for employee and director options*

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

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

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

**2. Fair Value**

As of June 30, 2011 and December 31, 2010, our financial assets were invested in a money market fund, which can be converted to cash at par on demand. These funds, which totaled approximately \$51.6 million and \$23.9 million as of June 30, 2011 and December 31, 2010, respectively, were measured at fair value, which approximates cost, as of the respective dates and were classified as Level 1 assets in the fair value hierarchy for financial assets.

There were no realized gains or losses on investments during the three- and six-month periods ended June 30, 2011 and 2010. The cost of securities sold is determined based upon specific identification.

**3. Other Accrued Liabilities**

The following table presents the components of other accrued liabilities as of the dates presented. All amounts are in thousands.

	<b>June 30, 2011</b>	<b>December 31, 2010</b>
Professional fees	\$ 263	\$ 224
Manufacturing costs	199	59
Other	90	139
Total	\$ 552	\$ 422

**4. Commitments**

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

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

During 2011, we initiated purchase orders with Produits Chimiques Auxiliaires et de Synthese SA (PCAS) for the acquisition of mifepristone, the active pharmaceutical ingredient (API) in CORLUX, for delivery late in 2011 for aggregate commitments of approximately \$2.0 million.

**5. Capital Stock**

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

**6. Stock Option Plans**

We have two stock option plans – the 2000 Stock Option Plan (the 2000 Plan) and the 2004 Equity Incentive Plan (the 2004 Plan). All option grants under the 2000 Plan are fully vested, with grants covering approximately 317,000 shares remaining outstanding as of June 30, 2011, with contractual lives expiring in 2011 through 2014. Vested shares under this plan that are not exercised within the remaining contractual life will expire on that date and not be added to the pool of shares available for future grant.

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

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

During the six-month period ended June 30, 2011, we issued an aggregate of approximately 189,000 shares of our common stock upon the exercise of stock options. Upon exercise of stock options, new shares were issued.

**7. Net Loss Per Share**

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

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

	June 30,	
	2011	2010
Warrants outstanding	9,200	9,200
Stock options outstanding	9,874	7,517



Total	19,074	16,717
-------	--------	--------

**Table of Contents****ITEM 2.**

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

**Overview**

We are a pharmaceutical company engaged in the discovery, development and commercialization of drugs for the treatment of severe metabolic and psychiatric disorders. Our focus is on those disorders that are associated with a steroid hormone called cortisol. Elevated levels and abnormal release patterns of cortisol have been implicated in a broad range of human disorders. Since our inception in May 1998, we have been developing our lead product, CORLUX, a potent glucocorticoid receptor II (GR-II) antagonist, that blocks the activity of cortisol. We have also discovered three series of novel selective GR-II antagonists and have moved CORT 108297, a compound from one of these series, into clinical development. Unless otherwise stated, all references in this document to we, us, our, Corcept, the Company, our company and similar designations refer to Corcept Therapeutics Incorporated.

*Cushing's Syndrome.* Cushing's Syndrome is a disorder caused by prolonged exposure of the body's tissues to high levels of the hormone cortisol. Sometimes called hypercortisolism, it is relatively uncommon and most often affects adults aged 20 to 50. An estimated 10 to 15 of every one million people are newly diagnosed with this syndrome each year, resulting in approximately 3,000 new patients and an estimated prevalence of 20,000 patients with Cushing's Syndrome in the United States. We submitted a New Drug Application (NDA) to the United States Food and Drug Administration (FDA) in April 2011 for the use of CORLUX for the treatment of the signs and symptoms of endogenous Cushing's Syndrome. In June 2011, we received notification from the FDA that this application had been accepted for filing and that the Prescription Drug User Fee Act (PDUFA) goal date for completion of its review is February 17, 2012. Our submission included a proposal for our Risk Evaluation and Mitigation Strategies (REMS). We are developing plans and engaging third-party vendors to support a commercial launch of CORLUX in the United States, if it is approved by the FDA.

The Investigational New Drug application (IND) for the evaluation of CORLUX for the treatment of the signs and symptoms of Cushing's Syndrome was opened in September 2007. During the IND process, the FDA indicated that a single 50-patient open-label study may provide a reasonable basis for the submission of an NDA for this indication. We completed enrollment in this Phase 3 study in June 2010. This open-label Phase 3 study evaluated the response of two patient groups to CORLUX treatment: one included patients who were glucose intolerant, regardless of blood pressure level, and one included patients who had been diagnosed with hypertension but had normal glucose tolerance. The patients in both of these groups were being treated for their symptoms before study entry; CORLUX was added to their existing medications. In December 2010 we announced that both groups in this study achieved their primary endpoints. In January 2011 we announced positive results for the key secondary endpoint of global clinical improvement. All of the patients in the study were included in one group for this endpoint.

Statistically significant improvement in the primary endpoint was achieved for each group with 60% responding in the group of patients with abnormal glucose tolerance with or without a diagnosis of hypertension (the glucose intolerant group) and 38% responding in the group of patients with a diagnosis of hypertension (the hypertensive group). The patients in the study, whether included in the glucose intolerant group or the hypertensive group for the purpose of evaluating the primary endpoints, were evaluated as a single group on the key secondary endpoint of global clinical improvement; 87% of patients showed significant clinical improvement as evaluated by an independent board of three physicians highly experienced in the treatment of Cushing's Syndrome. A review of the safety data indicates that CORLUX had an acceptable risk-benefit profile in this Phase 3 study. Adverse events related to treatment included signs and symptoms of adrenal insufficiency, endometrial thickening and hypokalemia, all of which were consistent with earlier published reports. The majority of the serious adverse events (SAEs) reported in the study were not related to CORLUX treatment, as determined by the clinical investigators. All of the treatment-related SAEs resolved with clinical management. Eighty-eight percent of the patients who completed the Phase 3 study opted to enter our long-term extension study. Eleven of these patients have now been treated with CORLUX for over two years.

Detailed data from the Phase 3 study data were presented as part of a session titled "Will Medical Management Replace Surgery for Cushing's Syndrome?" on June 4, 2011 at the Endocrine Society's 93rd Annual Meeting.

In July 2007, we received Orphan Drug Designation from the FDA for CORLUX for the treatment of endogenous Cushing's Syndrome. Orphan Drug Designation is a special status granted by the FDA to encourage the development of treatments for diseases or conditions that affect fewer than 200,000 patients in the United States. Drugs that receive Orphan Drug Designation obtain seven years of marketing exclusivity from the date of drug approval, as well as tax credits for clinical trial costs, marketing application filing fee waivers and assistance from the FDA in the drug development process.

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

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

---

**Table of Contents**

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

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

In addition, we also are utilizing a third party centralized rating service to independently evaluate the patients for entry into the study as well as to evaluate their level of response throughout their participation in the study. We believe the centralization of this process will improve the consistency of rating across clinical trial sites and reduce the background noise that was experienced in earlier studies and is endemic to psychopharmacologic studies. We believe that this change in dose, as well as the other modifications to the protocol, should allow us to demonstrate the efficacy of CORLUX in the treatment of the psychotic symptoms of psychotic depression. In mid-2009, in order to conserve financial resources, we reduced the number of clinical sites in this study to eight and extended the timeline for its completion.

*Antipsychotic-induced Weight Gain Mitigation.* In 2005, we announced the results of studies in rats that demonstrated that CORLUX both reversed the weight gain associated with the ongoing use of olanzapine and mitigated the weight gain associated with the initiation of treatment with olanzapine (the active ingredient in Zyprexa). The results from this study were published in the journal *Brain Behavioral Research* in early 2006. This study was paid for by Eli Lilly and Company (Eli Lilly).

During 2007 we announced positive results from our clinical proof-of-concept study in lean healthy male volunteers evaluating the ability of CORLUX to mitigate weight gain associated with the use of Zyprexa. The results show a statistically significant reduction in weight gain in those subjects who took Zyprexa plus CORLUX compared to those who took Zyprexa plus placebo. Also, the addition of CORLUX to treatment with Zyprexa had a beneficial impact on secondary metabolic measures such as fasting insulin, triglycerides and abdominal fat, as indicated by waist circumference. Eli Lilly provided Zyprexa and financial support for this study and its results were published in the journal *Advances in Therapy* in 2009. In January 2009, we announced positive results from a similar proof-of-concept study evaluating the ability of CORLUX to mitigate weight gain associated with the use of Johnson & Johnson's Risperdal. This study confirmed and extended the earlier results seen with CORLUX and Zyprexa, demonstrating a statistically significant reduction in weight gain and in the secondary metabolic endpoints of fasting insulin, triglycerides and abdominal fat, as indicated by waist circumference. The results from the study of CORLUX and Risperdal were presented at several scientific conferences, including the American Diabetes Association meeting in June 2009, and were published in the journal *Obesity* in 2010.

The combination of Zyprexa or Risperdal and CORLUX is not approved for any indication. The purpose of these studies was to explore the hypothesis that GR-II antagonists, such as CORLUX and our next generation of selective GR-II antagonists, would mitigate weight gain associated with antipsychotic medications. The group of medications known as second generation antipsychotic medication, including Zyprexa, Risperdal, Clozaril and Seroquel, are widely used to treat schizophrenia and bipolar disorder. All medications in this group are associated with treatment emergent weight gain of varying degrees and carry a warning in their labels relating to treatment emergent hyperglycemia and diabetes mellitus.

*Selective GR-II Receptor Antagonists.* In 2003, we initiated a discovery research program to identify and patent selective GR-II antagonists to develop a pipeline of products for proprietary use. Three distinct series of GR-II antagonists were identified. These compounds, like our lead product CORLUX, potentially block the cortisol receptor (GR-II) but, unlike CORLUX, they do not appear to block the PR (progesterone), ER (estrogen), AR (androgen) or GR-I (mineralocorticoid) receptors. Both the United States Patent & Trademark Office (USPTO) and the European Patent Office (EPO) have issued to us composition of matter patents on all of the three series. A fourth composition of matter patent application is pending.

---

**Table of Contents**

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

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

At the American Diabetes Association conference in June 2009 there was also a presentation of preclinical data from another study of CORT 108297 conducted at Stanford University. This study demonstrated that CORT 108297 suppresses body weight gain and improves insulin sensitivity in healthy mice fed a 60% fat diet and high sucrose liquid.

The manufacturing and preclinical development of CORT 108297 began late in 2008 and resulted in the submission of an IND to the FDA in December 2009 for the prevention of weight gain induced by antipsychotic medication. Phase 1b/2a studies of this drug are in progress.

In addition, we are continuing research and pre-clinical efforts to identify additional selective GR-II antagonists for clinical study.

*General*

Our activities to date have included:

product development, including designing, funding and overseeing clinical trials and conducting non-clinical activities such as toxicological testing;

discovery research;

regulatory affairs;

intellectual property prosecution and expansion; and

preparations for the commercialization of our lead product.

Historically, we have financed our operations and internal growth primarily through private placements of our preferred and common stock and the public sale of common stock rather than through collaborative or partnership agreements. Therefore, we have no research funding or collaborative payments payable to us.

We are in the development stage and have incurred significant losses since our inception. We have not generated any revenue other than the revenue under the agreements with Eli Lilly discussed above, and do not expect to generate significant revenue until CORLUX has been approved by the FDA for marketing in the United States, if at all. As of June 30, 2011, we had an accumulated deficit of \$192.2 million. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for CORLUX and CORT 108297, discovery research, non-clinical activities such as toxicology and carcinogenicity studies, manufacturing process development and regulatory activities, as well as general and administrative expenses, including preparations for the commercial launch of CORLUX for Cushing's Syndrome should we receive regulatory approval. We expect to continue to incur net losses over at least the next few years as we continue our CORLUX and CORT 108297 clinical development programs, apply for regulatory approvals, continue discovery and

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

initiate development of other selective GR-II antagonists for various indications, acquire and /or develop treatments in other therapeutic areas, establish sales and marketing capabilities and expand our operations.

## Table of Contents

Our business is subject to significant risks, including the risks inherent in our research and development efforts, the results of our CORLUX and CORT 108297 clinical trials, uncertainties associated with securing financing, uncertainties associated with obtaining and enforcing patents, our investment in manufacturing set-up, the lengthy and expensive regulatory approval process and competition from other products. Our ability to successfully generate revenues in the foreseeable future is dependent upon our ability, alone or with others, to finance our operations and develop, obtain regulatory approval for, manufacture and market our lead product.

### **Results of Operations**

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

We did not recognize any revenue under the agreements during any period in 2011 or 2010 and none will be recognized in the future as all of the activities relating to these agreements were completed by mid-2009.

*Research and development expenses* Research and development expenses include 1) the personnel costs related to our development activities, including facilities costs and non-cash stock-based compensation, 2) the costs of discovery research, 3) costs associated with IND-enabling activities and pre-clinical studies, 4) costs of clinical trials, including trial preparation, enrollment, site monitoring and data analysis expenses, 5) regulatory costs, 6) the costs of manufacturing development, 7) the costs of manufacture and / or acquisition of clinical trial materials and material used in registration batches included in the NDA submission for CORLUX for the treatment of Cushing's Syndrome and 8) other costs associated with the preparation and prosecution of the NDA.

Research and development expenses increased 36% to \$6.2 million for the three-month period ended June 30, 2011 from \$4.6 million for the comparable period in 2010. For the six-month period ended June 30, 2011, research and development expenses increased 23% to \$11.1 million from \$9.1 million for the six-month period ended June 30, 2010.

During the second quarter and first half of 2011 as compared to the corresponding periods in 2010, there were increases of approximately \$1.0 million and \$1.8 million, respectively, in consultancy and staffing costs due to the additional resources necessary for the preparation, submission and prosecution of the NDA, and to assist in the management of other research and development activities. Approximately \$200,000 of the increase during both the three- and six-month periods is related to non-cash stock-based compensation costs.

CORLUX manufacturing costs increased approximately \$945,000 and \$1.4 million, respectively, during the second quarter and first half of 2011 as compared to the corresponding periods in 2010, due to the acquisition of active pharmaceutical ingredient for CORLUX and the initiation of manufacturing development work at a potential back-up site for the manufacture of CORLUX. There were also increases during the second quarter and first half of 2011 as compared to the corresponding periods in 2010, of approximately \$280,000 and \$350,000, respectively in research and manufacturing related to our proprietary, selective new GR-II antagonists. In addition, there were increases of approximately \$170,000 and \$300,000, respectively, during the second quarter and first half of 2011 as compared to the corresponding periods in 2010, related to increased attendance at and financial support for medical conferences and seminars in support of our Cushing's Syndrome program.

There were net decreases in clinical trial costs of approximately \$825,000 and \$1.7 million, respectively, during the second quarter and first half of 2011, as compared to the corresponding periods of 2010. Clinical trial cost decreases during the three- and six-month periods ended June 30, 2011, as compared to the same periods in 2010, included decreases of approximately \$1.1 million and \$1.9 million, respectively related to drug-drug interaction and other NDA-supportive studies with CORLUX and approximately \$120,000 and \$245,000, respectively, related to the clinical trials with CORLUX for the treatment of Cushing's Syndrome. During the second quarter and first half of 2011 as compared to the corresponding period in 2010, there were net increases of approximately \$355,000 and \$485,000, respectively, related to clinical studies with CORT 108297 as we moved into Phase 1b/2a studies after completion of the Phase 1a study with this product.

During the second quarter and first half of 2011 as compared to the corresponding period in 2010, there were also decreases of approximately \$60,000 and \$190,000, respectively, related to the IND-enabling work on CORT 108297 as that product was moved into the clinic during 2010.

**Table of Contents**

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

Project	Three-Months Ended June 30,		Six-Months Ended June 30,	
	2011 (in thousands)	2010 (in thousands)	2011 (in thousands)	2010 (in thousands)
<b>CORLUX</b>				
Cushing's Syndrome	\$ 3,291	\$ 1,170	\$ 5,565	\$ 2,344
Psychotic Depression	596	565	977	1,268
Selective GR-II antagonists	1,743	1,213	2,868	2,287
Unallocated activities, including NDA supportive studies and manufacturing, regulatory and pre-clinical activities	306	1,564	1,394	3,039
Stock-based compensation	267	62	323	125
<b>Total research and development expense</b>	<b>\$ 6,203</b>	<b>\$ 4,574</b>	<b>\$ 11,127</b>	<b>\$ 9,063</b>

We expect that research and development expenditures will increase during the remainder of 2011 as compared to 2010 due to the prosecution of our NDA filing for CORLUX for the treatment of Cushing's Syndrome, increased manufacturing activities for pre-validation and validation batches of CORLUX, continuation of our long-term extension study in Cushing's Syndrome, continuation of our Phase 3 study of CORLUX for the treatment of psychotic depression and the continued development of CORT 108297 and our other proprietary selective GR-II antagonists, which costs will be only partially offset by decreases in the costs related to the completion of our Phase 3 study in Cushing's Syndrome. Research and development expenses in 2012 and future years will be largely dependent on the availability of additional funds to finance clinical development plans. See also, [Liquidity and Capital Resources](#).

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

*General and administrative expenses* General and administrative expenses consist primarily of the costs of administrative personnel and related facility costs along with legal, accounting and other professional fees and the costs of executing on our commercial plans related to CORLUX, including conducting market research and engaging third-party vendors to support distribution and other logistical needs, if CORLUX is approved by the FDA.

For the three-month period ended June 30, 2011, general and administrative expenses increased 42% to \$2.7 million from \$1.9 million for the comparable period in 2010. For the six-month period ended June 30, 2011, general and administrative expenses increased 40% to \$4.8 million from \$3.4 million for the six-month period ended June 30, 2010. During the second quarter and first half of 2011 as compared to the corresponding periods in 2010, staffing and consultancy costs increased approximately \$730,000 and \$1.2 million, respectively, due primarily to additional resources necessary to engage in preparations for the potential commercialization of CORLUX for Cushing's Syndrome, approximately \$160,000 and \$265,000 of which represented increases for the respective comparable periods in noncash stock-based compensation costs related to stock options granted to employees, directors and consultants. There was also an increase in legal costs related to patents, commercialization planning and other corporate matters of approximately \$130,000 and \$230,000, respectively, during the second quarter and first half of 2011 as compared to the corresponding periods of 2010.

We expect that general and administrative expenses will increase during the remainder of 2011 as compared to 2010 in regard to activities directly associated with preparations for potential product commercialization and the need to increase our administrative infrastructure to support these activities. The amount of general and administrative expenses in 2012 and future years will be largely dependent on our assessment of the staff necessary to support expected product commercialization and our continued clinical development activities and the availability of additional funds. See also, [Liquidity and Capital Resources](#).

*Interest and other income, net* Interest and other income, net of investment management fees, was approximately (\$1,000) and \$1,000, respectively, for the three- and six month periods ended June 30, 2011, as compared to \$753,000 and \$755,000 for the respective comparable periods of 2010. During the quarter ended June 30, 2010, we had received a favorable settlement for \$750,000 in connection with a lawsuit



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

brought on our behalf against an individual for defamation and harassment.

*Other expense* Other expense for the three- and six-month periods ended June 30, 2011 was approximately \$12,000 and \$17,000, respectively, as compared to \$3,000 and \$14,000, respectively, for the corresponding periods in 2010.

---

## **Table of Contents**

### **Liquidity and Capital Resources**

We have incurred operating losses since inception, and at June 30, 2011, we had a deficit accumulated during the development stage of \$192.2 million. Since our inception, we have relied primarily on the proceeds from public and private sales of our equity securities to fund our operations.

At June 30, 2011, we had cash and cash equivalents of \$52.2 million, compared to \$24.6 million at December 31, 2010. Net cash used in operating activities for the six-month periods ended June 30, 2011 and 2010 was \$14.5 million and \$10.4 million, respectively. The use of cash in each period was primarily a result of our research and development activities, including efforts toward the submission of the NDA for CORLUX for the treatment of Cushing's Syndrome, and amounts incurred to develop our administrative infrastructure, including the increased infrastructure that will be necessary to support the commercialization of CORLUX, if approved by the FDA.

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

We expect cash used in operating activities to increase during the remainder of 2011 as compared to spending levels in 2010 due to the prosecution of our NDA for CORLUX for the treatment of Cushing's Syndrome, increased manufacturing activities for pre-validation and validation batches of CORLUX, pre-commercialization activities, continuation of the long-term extension study of CORLUX for Cushing's Syndrome and the continued development of our selective GR-II antagonists. We expect our funding requirements for operating activities may increase during later years as costs associated with the continuation and expansion of our development programs for Cushing's Syndrome, psychotic depression and our selective GR-II antagonists, research activities, commercialization activities and general and administrative expenses may be only partially offset by revenues from sales of CORLUX if approval for marketing is received from the FDA.

We believe that we have sufficient capital resources to maintain our operations through the end of 2012, including the planned continuation of our long-term extension study of CORLUX for the treatment of Cushing's Syndrome, prosecution of our NDA submission and commercialization activities for CORLUX for this indication, the continuation of enrollment in our Phase 3 psychotic depression trial, the completion of our current Phase 1b/2a multi-dose safety and proof of concept clinical studies for CORT 108297, one of our proprietary, selective GR-II antagonists, and research and pre-clinical activities related to additional selective GR-II antagonists.

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

We cannot be certain that additional funding will be available on acceptable terms or at all. Further, any additional equity financing may be dilutive to stockholders, and any debt financing, if available, may involve restrictive covenants. If we obtain funds through collaborations with others, these arrangements may be on unfavorable terms or may require us to relinquish certain rights to our technologies or product candidates, including potentially our lead product candidate that we would otherwise seek to develop on our own. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or we may be required to discontinue operations.

In March 2008, we entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge. Under the terms of the agreement, Kingsbridge committed to provide up to \$60 million of capital in exchange for newly-issued shares of our common stock for a period of up to three years after the SEC declares effective the registration statements filed by us covering the resale of the shares of common stock issuable in connection with the CEFF and the shares of common stock underlying the warrant issued to Kingsbridge. In June 2008, the SEC declared effective our registration statement with the SEC covering the resale of approximately 3.6 million of the shares issuable under the CEFF and the shares issuable upon the exercise of the warrant issued to Kingsbridge. This registration statement covers approximately 37% of the 9.6 million shares of our common stock issuable pursuant to the CEFF and all of the 330,000 shares of our common stock issuable upon exercise of the warrant issued to Kingsbridge. As of the filing of this report, approximately 2.6 million shares remain available for sale under the initial registration statement. We intend to file an additional registration statement covering the resale of the remaining 6.0 million shares of our common stock issuable pursuant to the CEFF approximately 60 days after Kingsbridge and its affiliates have resold substantially all of the securities registered for sale under this initial registration statement.

---

## **Table of Contents**

Under the terms of the agreement, the determination of the exact timing and amount of any CEFF financings will be made solely by us, subject to certain conditions. The agreement currently requires a minimum stock price of \$1.50 per share to allow us to issue shares to Kingsbridge under the CEFF. Through June 30, 2011, we have raised a total of approximately \$2.6 million from the sales of stock under the CEFF. Based on the volume weighted average price on the NASDAQ Capital Market for our common stock for the period from March 25, 2008, the date of the signing of the Kingsbridge CEFF, through August 4, 2011, the maximum amount of additional funds that could be raised under the CEFF is approximately \$28 million. The actual amount of funds that can be raised under this agreement will be dependent on the number of shares actually sold under the agreement and the market value of our stock during the pricing periods of each sale.

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

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

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

During 2011, we initiated purchase orders with PCAS for the acquisition of mifepristone, the active pharmaceutical ingredient in CORLUX, to be delivered late in 2011 for aggregate commitments of approximately \$2.0 million.

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

None.

### **Critical Accounting Policies and Estimates**

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Our critical accounting policies and estimates are discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010. During the six months ended June 30, 2011, we have not made any significant changes to our critical accounting policies and estimates.

## **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

### **Market Risk**

The primary objective of our investment activities is to preserve principal. As of June 30, 2011, our cash and cash equivalents consisted primarily of a money market fund maintained at a major U.S. financial institution. To minimize our exposure to interest rate risk, we have limited the maturities of our investments to less than two years with an average maturity not to exceed one year. Due to the short-term nature of these instruments, a 1% increase or decrease in market interest rates would not have a material impact on the total value of our portfolio as of June 30, 2011.

## **ITEM 4. CONTROLS AND PROCEDURES**

***Evaluation of disclosure controls and procedures.*** Our management, under the supervision and with the participation of our Chief Executive Officer (our principal executive officer) and Vice President and Controller (our principal financial officer), conducted an evaluation of our disclosure controls and procedures, as defined under Rules 13a-15(e) and 15d-15(e) of the Exchange Act as of June 30, 2011. Based on that evaluation, our Chief Executive Officer and Vice President and Controller have concluded that our disclosure controls and procedures were effective in reaching a reasonable level of assurance that the information required to be disclosed by us in this Quarterly Report on Form 10-Q was (1) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and Form 10-Q and (2) accumulated and communicated to our management, including our Chief Executive Officer and Vice President and Controller, as appropriate to allow timely decisions regarding required disclosure. Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that

the objectives of our disclosure control system are met.

**Table of Contents**

*Changes in internal control over financial reporting.* There were no changes in our internal control over financial reporting during the quarter ended June 30, 2011, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

---

**Table of Contents**

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

We are not currently involved in any material legal proceedings.

**ITEM 1A. RISK FACTORS**

*An investment in our common stock involves significant risks. You should carefully consider the risks described below and the other information in this Quarterly Report on Form 10-Q, including our financial statements and related notes, before you decide to invest in our common stock. If any of the following risks or uncertainties actually occurs, our business, results of operations or financial condition could be materially harmed, the trading price of our common stock could decline and you could lose all or part of your investment. The risks and uncertainties described below are those that we currently believe may materially affect us; however, they may not be the only ones that we face. Additional risks and uncertainties of which we are unaware or currently deem immaterial may also become important factors that may harm our business. Except as required by law, we undertake no obligations to update any risk factors.*

**Risks Related to Our Business**

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

We have invested a significant portion of our time and financial resources since our inception in the development of CORLUX for the treatment of Cushing's Syndrome and the psychotic features of psychotic depression. We currently do not have any commercial products and we anticipate that for the foreseeable future our ability to generate meaningful revenues and achieve profitability will be solely dependent on the successful development, approval and commercialization of CORLUX for the treatment of Cushing's Syndrome or for the psychotic features of psychotic depression. Our NDA for CORLUX for the treatment of Cushing's Syndrome was accepted for filing by the FDA and is now under review by that agency. We are continuing to treat patients in the long-term extension study for that indication. We are also conducting a Phase 3 clinical trial in psychotic depression. We have previously completed three Phase 3 clinical trials evaluating CORLUX for psychotic depression, all of which failed to achieve statistically significant results with regard to the primary or key secondary endpoints. Many factors could harm our efforts to develop and commercialize CORLUX, including:

a delay in the FDA's completion of its review of our NDA for the treatment of Cushing's Syndrome, a requirement by the FDA for additional analyses or studies or an unfavorable determination on approvability by the FDA;

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

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

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

insufficient funding;

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

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

changes or delays in our clinical development program;

rapid technological change making CORLUX obsolete;

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

increases in the costs of our clinical trials.

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

To gain regulatory approval from the FDA to market CORLUX, our Phase 3 clinical trials must demonstrate the safety and efficacy of CORLUX for the particular indication. During review of the IND for the study of CORLUX for the treatment

**Table of Contents**

of Cushing's Syndrome, the FDA indicated that a single 50-patient open-label study of CORLUX for the treatment of Cushing's Syndrome may provide a reasonable basis for the submission of an NDA for this indication. However, the FDA may determine that the results of our Phase 3 trial in Cushing's Syndrome, while meeting its primary and key secondary endpoints, do not sufficiently demonstrate efficacy and/or safety. The ongoing Phase 3 clinical trial of CORLUX for the treatment of the psychotic features of psychotic depression, may not demonstrate efficacy or safety results sufficient for approval, and we may need to conduct other studies in support of a potential NDA in that indication. Clinical development is a long, expensive and uncertain process and is subject to delays, and data obtained from clinical trials and supportive studies are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval.

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

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

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

Regulatory approval of an NDA or NDA supplement is never guaranteed. Despite the time, resources and effort expended, failure can occur at any stage. The FDA has substantial discretion in the approval process for human medicines. The FDA can deny, delay or limit approval of a product candidate for many reasons including, but not limited to:

the FDA may not find that the candidate is safe;

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

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

the FDA may not find that our REMS program is adequate to address the risks associated with our product candidate.

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

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

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



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

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

## **Table of Contents**

of drug approval, as well as tax credits for clinical trial costs, marketing application filing fee waivers and assistance from the FDA in the drug development process. Although we have received Orphan Drug Designation from the FDA, we cannot be assured that we will recognize the potential benefits of this designation.

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

If another drug with the same active ingredient is approved for this indication before CORLUX, we will not garner the seven years of marketing exclusivity from the date of drug approval in the U.S. and other benefits that we anticipate. If CORLUX is the first drug approved by the FDA for this indication, any delay in our commercialization of the product, may have a negative impact on the revenue that we might be able to realize from the exclusivity provided during those seven years.

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

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

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

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

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

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

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

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

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

the extent and success of our efforts to manufacture, commercialize, market, distribute and sell CORLUX;

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

negative publicity concerning CORLUX, RU-486 or mifepristone.

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

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

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

The active ingredient in CORLUX, mifepristone (RU-486) is used to terminate pregnancy. As a result, mifepristone has been and continues to be the subject of considerable ethical and political debate in the United States and elsewhere. Public perception of mifepristone may limit our ability to engage alternative manufacturers and may limit the commercial acceptance of CORLUX by patients and physicians. Even though we intend to create measures to minimize the likelihood of the prescribing of CORLUX to a pregnant woman, physicians may choose not to prescribe CORLUX to a woman simply to avoid altogether any risk of unintentionally terminating a pregnancy. We intend to create measures for controlling the distribution of CORLUX to reduce the potential for diversion. Controlled distribution may negatively impact sales of CORLUX.

## **Table of Contents**

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

We currently have no experience in, and we do not own facilities for, nor do we plan to develop facilities for, manufacturing any products. We have an agreement with one manufacturer of the active pharmaceutical ingredient (API) of mifepristone which we included in our NDA submission. We have a memorandum of understanding with a second API manufacturer. However, there are no activities currently being conducted at this site to develop or qualify the manufacturing processes or facilities and we did not request approval of material produced by this second manufacturer when we submitted our NDA for Cushing's Syndrome.

We have an agreement with a tablet manufacturer that we included in our NDA submission. This tablet manufacturer is a single source supplier to us. If this single source supplier were to cease manufacturing tablets for us or fail to manufacture tablets on a timely basis, we might be required to qualify an alternate supplier and we would likely experience a lengthy delay in our manufacturing processes. We cannot assure you that our single source supplier will be able or willing to meet our future demands. While we have negotiated a contract with a potential back-up tablet manufacturer, we have not yet completed process transfer or test manufacture and cannot assure you that we will be able to qualify this vendor as an alternate supplier.

Our current arrangements with these manufacturers are terminable by such manufacturers. We anticipate engaging some or all of the suppliers to produce commercial quantities of CORLUX, however we cannot guarantee that we will enter into an agreement with them on terms acceptable to us. If we are unable, for whatever reason, to obtain the active pharmaceutical ingredient or CORLUX tablets from our contract manufacturers, we may not be able to manufacture our required quantities or identify alternate manufacturers of mifepristone or CORLUX tablets in a timely manner or on reasonable terms, if at all.

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

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

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

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

## **Table of Contents**

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

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

regulatory authorities may withdraw their approvals;

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

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

our reputation in the marketplace may suffer; and

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

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

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

During the development of CORLUX, we have been engaged in dialogue with the FDA to determine an acceptable development plan which would enable the FDA to complete its review in a satisfactory manner. We anticipate continued dialogue with the FDA to define any additional data needed to prosecute our NDA for Cushing's Syndrome or to complete an NDA for psychotic depression.

We may decide, or the FDA or other regulatory authorities may require us, to pursue additional clinical, preclinical or manufacturing studies to satisfactorily complete our NDA for either Cushing's Syndrome or psychotic depression. Additional trials or studies will require additional funding which is not assured. Also, it is possible that additional trials or studies that we decide are necessary or desirable will delay or prevent the completion of the development of CORLUX for treating Cushing's Syndrome or the psychotic features of psychotic depression.

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

availability of funding;

negative or inconclusive results;

slow patient enrollment;

patient noncompliance with the protocol;

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

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

real or perceived lack of effectiveness or safety of CORLUX.

Even after we conduct all of the clinical trials and supportive studies that we consider appropriate for an optimal NDA, we may not receive regulatory approval to market CORLUX for either Cushing's Syndrome or psychotic depression.

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

A limited number of our employees have experience in marketing or selling pharmaceutical products. To achieve commercial success for any approved product, we must either develop a sales and marketing force or enter into arrangements with others to market and sell our future products. We currently plan to establish small, specialty sales forces to market and sell CORLUX in the United States for the treatment of Cushing's Syndrome and for the treatment of the psychotic features of psychotic depression, as each indication is approved for marketing by the FDA. However, our sales and marketing efforts may not be successful or cost-effective. If our efforts to develop a sales and marketing force are not successful, cost-effective and timely, we may not achieve profitability.

**We 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.

## **Table of Contents**

Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. To date, we have relied on a small management team, including a number of part-time contributors. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to manage any future growth effectively.

To that end, we must be able to:

manage our research and development efforts effectively;

manage our clinical trials effectively;

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

expand the size and composition of our management team;

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

hire and train additional qualified personnel.

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

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

We depend substantially on the principal members of our management and scientific staff. 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.

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

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





**Table of Contents**

We anticipate that our existing capital resources will be sufficient to fund our current operating plan through the end of 2012. However, our expectations are based on our currently planned clinical development and research programs for CORLUX and for certain of our proprietary, selective GR-II antagonists, including CORT 108297, which may change as a result of many factors, including:

the review and approval of our NDA by the FDA to market CORLUX for the treatment of Cushing's Syndrome;

the timing of commercialization of CORLUX for the treatment of Cushing's Syndrome;

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

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

the results of our research efforts and clinical trials;

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

the need to establish a second source for CORLUX tableting;

the timing of the submission of an NDA to the FDA, the acceptance of the filing and approval of an NDA by the FDA to market CORLUX for the treatment of the psychotic features of psychotic depression;

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

actual or anticipated fluctuations in our operating results;

changes in our growth rates;

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

the timing of commercialization of CORLUX for the treatment of psychotic depression and future product candidates.

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

We cannot be certain that additional funding will be available on acceptable terms or at all. Even though we have raised funds several times over the past twelve months, market and economic conditions may make it difficult for us to raise any or sufficient additional capital. The sales of common stock and warrants during 2010 and in January 2011 have been dilutive to stockholders and any exercise of outstanding warrants and additional equity financing will cause further dilution to stockholders. Debt financing, if available, may involve restrictive covenants. If we

obtain funds through collaborations with others, these arrangements may be on unfavorable terms or may require us to relinquish certain rights to our technologies or product candidates, including our lead product candidate, which we would otherwise seek to develop on our own. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or we may be required to discontinue operations.

**We have incurred losses since inception and anticipate that we will incur continued losses for at least the next few years.**

We are a development stage company with no current source of product revenue. We have a limited history of operations and have focused primarily on clinical trials. We are seeking FDA regulatory clearance to market CORLUX for the treatment of Cushing's Syndrome, and, if the outcome of our clinical trials supports it, we plan to seek FDA regulatory clearance to market CORLUX for the treatment of the psychotic features of psychotic depression. 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 June 30, 2011, we had an accumulated deficit of \$192.2 million. We do not know when or if we will generate product revenue. Subject to our ability to raise additional funds, we expect our research and development expenses to increase in connection with the clinical trials and other development activities for CORLUX and for other product candidates. We expect to incur significant expenses related to the preparation for commercializing CORLUX and for the product's launch, if the FDA approves our NDA. As a result, we expect that our losses will increase at least until CORLUX is launched and commercially available to patients. We are unable to predict the extent of any future losses or whether or when we will become profitable.

---

**Table of Contents**

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

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

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

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

We are entitled in certain circumstances, to deliver a blackout notice to Kingsbridge to suspend the use of the resale registration statement and prohibit Kingsbridge from selling shares thereunder. If we deliver a blackout notice in the 15 trading days following the settlement of a draw down, or if the resale registration statement is not effective in circumstances not permitted by our agreement with Kingsbridge, then we may be required to make a payment to Kingsbridge, or issue Kingsbridge additional shares in lieu of the payment. If the trading price of our common stock declines during a suspension of the resale registration statement, the blackout or other payment could be significant.

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

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

The costs required to start or continue many of the programs that our intellectual property allow us to consider for further development are collectively greater than the funds currently available to us. For example, we have successfully discovered three series of compounds that are specific GR-II antagonists but, unlike CORLUX, do not appear to block the progesterone receptor. Further development of these proprietary compounds, including CORT 108297, or any further development stemming from our method of use patents may be delayed or cancelled if we determine that such development may jeopardize our ability to complete activities necessary for the submission of our NDA for CORLUX for the treatment of Cushing's Syndrome, the support of this NDA through its successful approval, the commercialization of this product for this indication or to complete the clinical development of CORLUX for the treatment of psychotic depression.

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

In the United States and globally, market and economic conditions have been volatile over the past few years, with significantly tighter credit conditions in the markets in which we conduct our operations. The U.S. and global economies have experienced a recession and face continued concerns about the systemic impact of adverse economic conditions, such as



---

## **Table of Contents**

unstable global financial markets, adverse effects on the cost and availability of capital, high corporate, consumer and governmental debt levels and high unemployment. Concern about the stability of the markets generally, and the strength of counterparties specifically, has led and may again lead many lenders and institutional investors to reduce, and in some cases, cease, to provide credit to businesses. Renewed or increased turbulence in the global markets and economies may adversely affect our liquidity and financial condition.

In addition, our access to funds under our CEFF or any credit facility into which we may enter depends on the ability of the counterparties to such facilities to meet their funding commitments to us. We cannot assure you that long-term disruptions in the global economy and the return of tighter credit conditions among, and potential failures of, third party financial institutions as a result of such disruptions will not have an adverse effect on such counterparties.

If we do not have sufficient cash flow to continue operating our business and are unable to borrow funds, access our CEFF or raise equity or debt capital, we may need to find alternative ways to increase our liquidity. Such alternatives may include, without limitation, curtailing clinical or drug development activity, or limiting our commercial efforts, product manufacturing or sales and marketing support, which would have an adverse affect on our business, results of operations, cash flows and financial condition.

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

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

We have a contract research organization, Octagon Research Solutions, Inc., that managed our data and statistical analysis for our Phase 3 trial of CORLUX for the treatment of Cushing's Syndrome and for the long-term extension study in this indication that was submitted with our NDA. They may be unable to collect, process or analyze the additional data related to the extension study that will be needed for the safety update to be filed with the FDA in a timely manner or they may fail to process the data appropriately, which could delay or prevent us from providing data to the FDA in support of our NDA.

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

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

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

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



---

**Table of Contents**

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

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

During screening for Study 14, we have seen a higher than anticipated incidence of potential patients who do not meet appropriate criteria for entrance into the trial for diagnostic and other clinical reasons. Although we believe that this is the result of improved accuracy in the screening process resulting from the use of the MedAvante centralized rating services as an additional step in the selection of patients appropriate for inclusion in the study, MedAvante's diagnostic screening has resulted in slower patient enrollment and may not actually improve trial performance. In addition, in mid-2009, in order to lower expenses and to conserve financial resources, we scaled back our planned rate of spending on this trial and extended the timeline for its completion. We are currently using a reduced total of eight clinical sites in order to conserve capital. This strategy may result in increased total study costs over the longer term.

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

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

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

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

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

**If CORLUX or future product candidates conflict with the patents of others or if we become involved in other intellectual property disputes, we may have to engage in costly litigation or obtain a license and we may be unable to commercialize our product candidates.**

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

---

**Table of Contents**

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

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

Our patent applications and patents licensed or issued to us may be challenged by third parties and our patent applications may not result in issued patents. For example, in 2004, Akzo Nobel, which was subsequently acquired by Schering Plough which was then subsequently acquired by Merck & Co., filed an observation challenging the claims of our exclusively licensed European patent application with claims directed to psychotic depression. In this instance, the patent later issued and, in 2007, we received notice that there will be no opposition proceedings in Europe in regard to this patent.

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

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

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

In addition to patents, we rely on a combination of confidentiality, nondisclosure and other contractual provisions, laws protecting trade secrets and security measures to protect our trade secrets and proprietary information. Nevertheless, these measures may not adequately protect our trade secrets or other proprietary information. If they do not adequately protect our rights, third parties could use our proprietary information, which could diminish our ability to compete in the market. In addition, employees, consultants and others who participate in the development of our product candidates may breach their agreements with us regarding our trade secrets and other proprietary information, and we may not have adequate remedies for the breach. We also realize that our trade secrets may become known through means not currently foreseen. Notwithstanding our efforts to protect our trade secrets and proprietary information, our competitors may independently develop similar or alternative products that are equal or superior to our product candidates without infringing on any of our proprietary information or trade secrets.



---

**Table of Contents**

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

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

In addition, we cannot be assured that patients will not obtain mifepristone from other sources. As with other pharmaceutical products, patients may be able to purchase mifepristone through the internet or black market. Mifepristone is also sold in the United States by Danco Laboratories for the termination of early pregnancy. While distribution is limited to a single dose provided in the physician's office and covered by other restrictions, we cannot be certain that Cushing's Syndrome patients may not be able to obtain mifepristone from this source.

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

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

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

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

We only have significant clinical experience with CORLUX and we may determine that CORLUX is not desirable for uses other than for the treatment of Cushing's Syndrome or the treatment of the psychotic features of psychotic depression. For example, we do not intend to develop CORLUX for mitigation of the weight gain associated with the use of Zyprexa, Risperdal or other atypical antipsychotics, even though we have reported positive results in the proof of concept studies described in the Overview section of Part I, Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations of this Quarterly Report on Form 10-Q. We are pursuing other GR-II antagonists for this use. The compounds developed pursuant to our early clinical, preclinical and discovery research programs, including CORT 108297, may fail to generate commercially viable product candidates in spite of the resources we may dedicate to the program. Even if product candidates are identified, we may abandon further development efforts before we reach clinical trials or after expending significant expense and time conducting clinical trials due to financial constraints, concerns over safety, efficacy of the product candidates or for other reasons. Moreover, governmental authorities may enact new legislation or regulations that could limit or restrict our development efforts. If we are unable to successfully discover and commercialize new uses for GR-II antagonists, we may be unable to generate sufficient revenue to support our operations.

---

**Table of Contents**

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

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

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

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

There is significant uncertainty related to the availability of third-party insurance coverage and reimbursement for newly approved medications. The commercial success of our potential medications in both domestic and international markets is dependent on whether third-party coverage and reimbursement is available for them. Government payors, including Medicare and Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new medicines, and, as a result, they may not cover or provide adequate payment for our medications. The continuing efforts of government and other third-party payors to contain or reduce the costs of health care and recent healthcare legislation may limit our future revenues. Our near-term dependence on the commercial success of CORLUX makes us particularly susceptible to any such cost containment or reduction efforts. Accordingly, even if CORLUX or future product candidates are approved for commercial sale, unless government and other third-party payors provide adequate coverage and reimbursement for our future products, physicians may not prescribe them. In addition, we may need to obtain approvals from hospital formularies to receive wide-spread third-party coverage and reimbursement for those situations where our products may be needed during in-patient treatment. If we fail to obtain such approvals, this will reduce the level of revenues that we are able to attain.

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

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

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

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

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

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

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

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

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

---

**Table of Contents**

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

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

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

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

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

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

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

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

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

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Moreover, recent health care reform legislation has strengthened these laws. For example, the recently enacted PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes; a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from governmental health care programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

---

## **Table of Contents**

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

As discussed above in the risk related to Orphan Drug Designation, we are aware that Laboratoire HRA Pharma has begun a Phase II clinical trial in Europe and the United States evaluating the use of mifepristone to treat a subtype of Cushing's Syndrome. We are also aware that Novartis is developing a somatostatin analogue and has submitted an NDA to the FDA during the second quarter of 2011 for Cushing's disease, which is a subset of the patients with Cushing's Syndrome. If a product for treatment of Cushing's Syndrome is approved for commercialization before CORLUX, our potential future revenue could be reduced.

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

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

Combination medicinal therapy consists of the use of antipsychotic and antidepressant medicines, not currently approved for the treatment of psychotic depression. The antipsychotics are prescribed for off-label use by physicians to treat the psychotic features of psychotic depression, which is the clinical target of CORLUX. Antipsychotics include Bristol-Myers Squibb's Abilify, Novartis' Clozaril, Pfizer's Geodon and Navane, Ortho-McNeil's Haldol, Janssen Pharmaceutica's Risperdal, AstraZeneca's Seroquel, GlaxoSmithKline's Stelazine and Thorazine, Mylan's Mellaril and Eli Lilly's Zyprexa. CORLUX may not compete effectively with these established treatments. We are aware of one clinical trial conducted by Organon, for a new chemical entity for the treatment of psychotic depression. Organon was the pharmaceutical division of Akzo Nobel, which was purchased by Schering Plough which was then subsequently acquired by Merck & Co. Organon's new chemical entity is a GR-II antagonist; we believe that its commercial use would be covered by our patent. As of the time of filing of this report, we are not aware of any other public disclosures by any company, regarding the development of new products to treat psychotic depression.

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

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

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

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

**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



## **Table of Contents**

difficulties and expenditures and may absorb significant management attention that would otherwise be available for ongoing development of our business. In addition, we may fail to realize the anticipated benefits of any acquired potential product or technology. Future acquisitions could dilute our stockholders' ownership interest in us and could cause us to incur debt, expose us to future liabilities and result in amortization or other expenses related to goodwill and other intangible assets.

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

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

### **Risks Related to Our Stock**

#### **The market price of our common stock has been and is likely to continue to be highly volatile due to the limited number of shares of our common stock held by non-affiliates of the Company or factors influencing the stock market and opportunities for sale at any given time may be limited.**

We cannot assure you that an active trading market for our common stock will exist at any time. Holders of our common stock may not be able to sell shares quickly or at the market price if trading in our common stock is not active. During the 52-week period ended August 4, 2011, our average daily trading volume has been approximately 253,000 shares and the intra-day sales prices per share of our common stock on the NASDAQ Capital Market has ranged from \$2.76 to \$5.07. As of August 4, 2011, our officers, directors and principal stockholders control approximately 40% of our common stock. The trading price of our common stock has been and is likely to continue to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

our cash and short-term investment position;

actual or anticipated timing and results of our clinical trials;

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

changes in laws or regulations applicable to our product candidates or our competitors' products;

changes in the expected or actual timing of our development programs or our competitors' potential development programs;

actual or anticipated variations in quarterly operating results;

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

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

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

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

changes in financial estimates or recommendations by securities analysts;

conditions or trends in the biotechnology and pharmaceutical industries;

changes in the market valuations of similar companies;

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

additions or departures of key personnel;

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

developments concerning collaborations;

trading volume of our common stock;

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

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

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

purchases or sales of our common stock by us, our officers, directors or our stockholders.



---

## **Table of Contents**

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

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

Securities analysts currently covering our common stock may discontinue research coverage. Additional securities analysts may elect not to provide research coverage of our common stock. A lack of research coverage may adversely affect our common stock's market price. The trading market for our common stock may be affected in part by the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts who elects to cover us downgrades our stock, our stock price would likely decline rapidly and significantly. If one or more of these analysts ceases coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline. In addition, rules mandated by the Sarbanes-Oxley Act of 2002, and a global settlement reached in 2003 between the SEC, other regulatory analysts and a number of investment banks have led to a number of fundamental changes in how analysts are reviewed and compensated. In particular, many investment banking firms are required to contract with independent financial analysts for their stock research. It may be difficult for companies such as ours with smaller market capitalizations to attract independent financial analysts that will cover our common stock. This could have a negative effect on our market price.

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

Sales of a substantial number of shares of our common stock in the public market could harm the market price of our common stock. As additional shares of our common stock become available for resale in the public market, the supply of our common stock will increase, which could decrease the price. Substantially all of the shares of our common stock are eligible for sale, subject to applicable volume and other resale restrictions.

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

The registration rights agreement covering the approximately 8.9 million shares of our common stock issued in a private offering in March 2008 and an additional approximately 4.5 million shares of common stock underlying warrants issued in connection with the offering provided that if we failed to file or cause to be declared effective the registration statement covering the resale of these shares prior to specified deadlines, or failed to maintain the effectiveness of such registration statement (subject to limited permissible suspension periods), we would be required to pay the holders of such shares and warrants liquidated damages at the rate of 1% of the purchase price of these shares and warrants per month, up to a total of 10%. The registration statement covering the resale of the shares and shares underlying the warrants sold in this transaction was declared effective by the SEC in November 2008. Since this registration statement was not declared effective within the time frame specified in the registration rights agreement, we became obligated to pay liquidated damages of approximately \$1.3 million in 2008 to the investors in this financing. As noted above, if we fail to maintain the effectiveness of this registration statement, we may be obligated to pay additional liquidated damage amounts in the future.

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

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

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

As of August 4, 2011, our officers, directors and principal stockholders control approximately 40% of our common stock. As a result, these stockholders, acting together, will be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders and may prevent or delay a change in control. This significant concentration of share ownership may adversely affect the trading price of our common stock because investors often perceive disadvantages to owning stock in companies with controlling stockholders.



---

**Table of Contents**

**Changes in laws and regulations may result in increased costs to us, which may harm our financial results.**

New laws and regulations, as well as changes to existing laws and regulations, affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted by the SEC and by The Nasdaq Capital Market, have and will likely continue to result in increased costs to us as we respond to their requirements. We are investing resources to comply with evolving laws and regulations, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities.

In addition, new rules and regulations could make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, or our board committees, or as executive officers. At present, we cannot predict or estimate the amount of the additional costs related to new rules and regulations or the timing of such costs.

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

We are a small company with limited resources.

The federal securities laws and regulations, including the corporate governance and other requirements of the Sarbanes-Oxley Act of 2002, impose complex and continually changing regulatory requirements on our operations and reporting. These requirements impose comprehensive reporting and disclosure requirements, set stricter independence and financial expertise standards for audit committee members, and impose civil and criminal penalties for companies, their chief executive officers, principal financial officers and directors for securities law violations. These requirements have increased and will continue to increase our legal compliance costs, increase the difficulty and expense in obtaining director and officer liability insurance, and make it harder for us to attract and retain qualified members of our Board of Directors and/or qualified executive officers. Such developments could harm our results of operations and divert management's attention from business operations.

In addition, as directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the company's internal control over financial reporting in their annual reports on Form 10-K. This requirement first applied to our annual report on Form 10-K for the year ended December 31, 2007. This same legislation also requires that the independent registered public accounting firm auditing our financial statements must attest to and report on the effectiveness of our internal controls over financial reporting. This requirement first applied to our annual report on Form 10-K for the year ended December 31, 2010. Uncertainty exists regarding our ability to comply with these requirements by applicable deadlines and to maintain compliance in future years. If we are unable to complete the required assessment as to the adequacy of our internal control over financial reporting in future years or if our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal control over financial reporting as of future year ends, investors could lose confidence in the reliability of our financial reporting.

**Changes in or interpretations of accounting rules and regulations could result in unfavorable accounting charges or require us to change our accounting policies or operating practices.**

Accounting methods and policies for business and marketing practices of pharmaceutical companies are subject to continual review, interpretation and guidance from relevant accounting authorities, including the SEC. For example, in December 2004, the Financial Accounting Standards Board adopted a revised standard related to stock-based compensation. This standard, which we adopted in 2006, requires the recording of expense for stock options granted using fair value-based measurements. As a result, our operating expenses have increased and are likely to continue to increase. We rely heavily on stock options to compensate existing employees and attract new employees. Because we are now required to expense stock options using fair value-based measurements, we may choose to reduce our reliance on stock options as a compensation tool. If we reduce our use of stock options, it may be more difficult for us to attract and retain qualified employees. Although we believe that our accounting practices are consistent with current accounting pronouncements, changes to or interpretations of accounting methods or policies in the future may require us to reclassify, restate or otherwise change or revise our financial statements. Any such changes could result in corresponding changes to the amounts of assets, liabilities, revenues, expenses and income. Any such changes could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

## **Table of Contents**

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

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

**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. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

None.

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

### **ITEM 4. (REMOVED AND RESERVED)**

### **ITEM 5. OTHER INFORMATION**

None.

**Table of Contents**

**ITEM 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Description of Document</b>
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the registrant's Registration Statement on Form S-1/A (File No. 333-112676) filed on March 19, 2004).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed on September 27, 2007).
31.1	Rule 13a-14(a)/15d-14(a) Certifications of Joseph K. Belanoff, M.D., Chief Executive Officer of the registrant.
31.2	Rule 13a-14(a)/15d-14(a) Certifications of Anne M. LeDoux, Vice President and Controller of the registrant.
32.1	18 U.S.C. Section 1350 Certifications of Joseph K. Belanoff, M.D., Chief Executive Officer of the registrant.
32.2	18 U.S.C. Section 1350 Certifications of Anne M. LeDoux, Vice President and Controller of the registrant.
101*	The following materials from the registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, formatted in Extensible Business Reporting Language (XBRL): (i) unaudited Condensed Balance Sheets at June 30, 2011 and December 31, 2010, (ii) unaudited Condensed Statements of Operations for the Three and Six Months Ended June 30, 2011 and 2010 and for the period from inception (May 13, 1998) to June 30, 2011, (iii) unaudited Condensed Statements of Cash Flows for the Six Months Ended June 30, 2011 and 2010 and for the period from inception (May 13, 1998) to June 30, 2011, and (iv) Notes to Condensed Financial Statements, tagged as blocks of text

\* Pursuant to Rule 406T of Regulation S-T, these XBRL data files are deemed furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**CORCEPT THERAPEUTICS INCORPORATED**

Date: August 9, 2011

/s/ Joseph K. Belanoff  
**Joseph K. Belanoff, M.D.**

**Chief Executive Officer**

Date: August 9, 2011

/s/ Anne M. LeDoux  
**Anne M. LeDoux**  
**Vice President and Controller**

**(Principal Financial Officer)**

**Table of Contents**

**Exhibit Index**

<b>Exhibit Number</b>	<b>Description of Document</b>
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the registrant's Registration Statement on Form S-1/A (File No. 333-112676) filed on March 19, 2004).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed on September 27, 2007).
31.1	Rule 13a-14(a)/15d-14(a) Certifications of Joseph K. Belanoff, M.D., Chief Executive Officer of the registrant.
31.2	Rule 13a-14(a)/15d-14(a) Certifications of Anne M. LeDoux, Vice President and Controller of the registrant.
32.1	18 U.S.C. Section 1350 Certifications of Joseph K. Belanoff, M.D., Chief Executive Officer of the registrant.
32.2	18 U.S.C. Section 1350 Certifications of Anne M. LeDoux, Vice President and Controller of the registrant.
101*	The following materials from the registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, formatted in Extensible Business Reporting Language (XBRL): (i) unaudited Condensed Balance Sheets at June 30, 2011 and December 31, 2010, (ii) unaudited Condensed Statements of Operations for the Three and Six Months Ended June 30, 2011 and 2010 and for the period from inception (May 13, 1998) to June 30, 2011, (iii) unaudited Condensed Statements of Cash Flows for the Six Months Ended June 30, 2011 and 2010 and for the period from inception (May 13, 1998) to June 30, 2011, and (iv) Notes to Condensed Financial Statements, tagged as blocks of text

\* XBRL Pursuant to Rule 406T of Regulation S-T, these XBRL data files are deemed furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.