

CORCEPT THERAPEUTICS INC  
Form 10-Q  
November 14, 2007  
Table of Contents

---

**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

---

**FORM 10-Q**

---

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

For the quarterly period ended September 30, 2007

or

.. **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 000-50679

**CORCEPT THERAPEUTICS INCORPORATED**

(Exact Name of Corporation as Specified in Its Charter)

Delaware  
(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

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

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

Large Accelerated Filer

Accelerated Filer

Non-accelerated filer

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

On November 6, 2007 there were 39,548,489 shares of common stock outstanding at a par value \$.001 per share.

---

**Table of Contents**

**TABLE OF CONTENTS**

	<b>Page</b>
PART I FINANCIAL INFORMATION	
ITEM 1. FINANCIAL STATEMENTS	
<u>Condensed Balance Sheets</u>	3
<u>Condensed Statements Of Operations</u>	4
<u>Condensed Statements Of Cash Flows</u>	5
<u>Notes To Condensed Financial Statements</u>	6
<u>ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	12
<u>ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	21
<u>ITEM 4. CONTROLS AND PROCEDURES</u>	21
PART II OTHER INFORMATION	
<u>ITEM 1. LEGAL PROCEEDINGS</u>	22
<u>ITEM 1A. RISK FACTORS</u>	22
<u>ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u>	35
<u>ITEM 3. DEFAULTS UPON SENIOR SECURITIES</u>	36
<u>ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS</u>	36
<u>ITEM 5. OTHER INFORMATION</u>	36
<u>ITEM 6. EXHIBITS</u>	37
<u>SIGNATURES</u>	38
EXHIBIT INDEX	

**Table of Contents****CORCEPT THERAPEUTICS INCORPORATED****(A DEVELOPMENT STAGE COMPANY)****CONDENSED BALANCE SHEETS**

(In thousands)

	September 30, 2007 (Unaudited)	December 31, 2006 (See Note 1)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 18,565	\$ 8,906
Short-term investments	2,017	550
Prepaid expenses and other current assets	430	343
Total current assets	21,012	9,799
Property and equipment, net of accumulated depreciation	28	38
Other assets	64	65
Total assets	\$ 21,104	\$ 9,902
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,666	\$ 916
Accrued clinical expenses	612	2,224
Accrued compensation	121	138
Obligations under capital lease, short-term	14	13
Other accrued liabilities	250	222
Total current liabilities	2,663	3,513
Obligations under capital lease, long-term	19	29
Total liabilities	2,682	3,542
Commitments		
Stockholders' equity:		
Preferred stock		
Common stock	40	26
Additional paid-in capital	124,332	105,125
Notes receivable from stockholders	(111)	(125)
Deferred compensation	(22)	(228)
Deficit accumulated during the development stage	(105,818)	(98,438)
Accumulated other comprehensive income	1	
Total stockholders' equity	18,422	6,360
Total liabilities and stockholders' equity	\$ 21,104	\$ 9,902

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		Nine Months Ended		Period from
	September 30,		September 30,		inception
	2007	2006	2007	2006	(May 13, 1998)
					to September 30,
	2007	2006	2007	2006	2007
Collaboration revenue	\$	\$	\$ 482	\$ 221	\$ 776
Operating expenses:					
Research and development*	2,426	5,147	5,188	17,912	82,985
General and administrative*	1,192	1,402	3,120	3,900	27,393
Total operating expenses	3,618	6,549	8,308	21,812	110,378
Loss from operations	(3,618)	(6,549)	(7,826)	(21,591)	(109,602)
Interest and other income, net	191	154	453	609	4,047
Other expense	(1)	(8)	(7)	(14)	(263)
Net loss	\$ (3,428)	\$ (6,403)	\$ (7,380)	\$ (20,996)	\$ (105,818)
Basic and diluted net loss per share	\$ (0.09)	\$ (0.28)	\$ (0.23)	\$ (0.93)	
Shares used in computing basic and diluted net loss per share	36,608	22,719	32,466	22,691	
*Includes non-cash stock-based compensation consisting of the following:					
Research and development	\$ 64	\$ 103	\$ 149	\$ 455	\$ 4,680
General and administrative	299	274	411	803	6,215
Total non-cash stock-based compensation	\$ 363	\$ 377	\$ 560	\$ 1,258	\$ 10,895

See accompanying notes.

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

(Unaudited)

(In thousands)

	Nine Months Ended September 30,		Period from inception (May 13, 1998) to September 30, 2007
	2007	2006	
<b>Operating activities</b>			
Net loss	\$ (7,380)	\$ (20,996)	\$ (105,818)
Adjustments to reconcile net loss to net cash used in operations:			
Depreciation and amortization of property and equipment	10	10	85
Expense related to stock options, net of reversals	561	1,227	10,541
Expense related to stock issued for services or in conjunction with license agreement		12	75
Expense related to stock issued below fair value		23	522
Interest accrued on convertible promissory note			104
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(87)	(75)	(430)
Other assets	1	(10)	(64)
Accounts payable	750	2,069	1,666
Accrued clinical	(1,612)	20	612
Other liabilities	11	25	371
<b>Net cash used in operating activities</b>	<b>(7,746)</b>	<b>(17,695)</b>	<b>(92,336)</b>
<b>Investing activities</b>			
Purchases of property and equipment			(54)
Purchases of short-term and long-term investments	(2,016)	(1,311)	(110,362)
Maturities of short-term investments	550	18,476	108,346
<b>Net cash provided by (used in) investing activities</b>	<b>(1,466)</b>	<b>17,165</b>	<b>(2,070)</b>
<b>Financing activities</b>			
Proceeds from issuance of common stock, net of cash paid for issuance costs	18,866	19	70,903
Proceeds from issuance of convertible preferred stock, net of cash paid for issuance costs			40,378
Proceeds from issuance of convertible notes			1,543
Proceeds from repayment of stockholder notes	14		173
Principal payments of obligations under capital leases	(9)	(9)	(26)
<b>Net cash provided by financing activities</b>	<b>18,871</b>	<b>10</b>	<b>112,971</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>9,659</b>	<b>(520)</b>	<b>18,565</b>
Cash and cash equivalents, at beginning of period	8,906	3,816	
<b>Cash and cash equivalents, at end of period</b>	<b>\$ 18,565</b>	<b>\$ 3,296</b>	<b>\$ 18,565</b>

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**

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

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

The accompanying unaudited balance sheet as of September 30, 2007, statements of operations for the three-month and nine-month periods ended September 30, 2007 and 2006, and statements of cash flows for the nine-month periods ended September 30, 2007 and 2006 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 nine-month periods ended September 30, 2007 are not necessarily indicative of the results that may be expected for the year ending December 31, 2007 or any other period. These financial statements and notes should be read in conjunction with the financial statements for the year ended December 31, 2006 included in the Company's Annual Report on Form 10-K. The accompanying balance sheet as of December 31, 2006 has been derived from audited financial statements at that date.

**Liquidity**

In the course of its development activities, the Company has sustained operating losses and expects such losses to continue for at least the next several years. The Company plans to continue to finance its operations through the sale of its equity and debt securities. The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The Company's ability to continue as a going concern is dependent upon successful execution of its financing and business strategies.

As reflected in the accompanying financial statements as of September 30, 2007, the Company had cash, cash equivalents and investments of \$20.6 million, working capital of \$18.3 million and an accumulated deficit of \$105.8 million. The Company believes that it has sufficient funds to maintain its current and planned operations through the second quarter of 2008, including the completion of the final reporting activities on its recently completed trials, commencement of the Company's next series of clinical trials, which include the next Phase 3 trial in psychotic depression, a trial in Cushing's Syndrome and a trial to further evaluate the management of weight gain induced by antipsychotic medications, and the continued development of the Company's new chemical entities. The Company will need to raise additional funds in order to sustain its operations at anticipated levels beyond the second quarter of 2008. Although the Company's management recognizes the need to raise funds in the future, there can be no assurance that the Company will be successful in consummating any such transaction, or, if the Company does consummate such a transaction, that the terms and conditions of such financing will not be unfavorable to it. Any failure by the Company to obtain additional funding will have a material adverse effect and will likely result in the Company's inability to continue as a going concern. If the Company is not able to raise additional funds, it will not be able to continue operations beyond the second quarter of 2008.

**Use of Estimates**

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

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

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

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

**Table of Contents**

**CORCEPT THERAPEUTICS INCORPORATED**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO CONDENSED FINANCIAL STATEMENTS, Continued**

**Revenue Recognition**

Collaboration revenue relates to services rendered in connection with an agreement signed in October 2005 with Eli Lilly and Company, or Lilly, in which Lilly has agreed to support the Company's proof-of-concept clinical study evaluating the ability of CORLUX, the Company's lead product candidate, to mitigate weight gain associated with the use of olanzapine, an atypical antipsychotic medication. Under the agreement, Lilly agreed to supply olanzapine and pay for the study. The Company is required to perform development activities as specified in this agreement and is reimbursed based on the costs associated with the conduct of the trial and the preparation and packaging of clinical trial materials. Revenue is recognized as services are rendered in accordance with the agreement. The cost of providing these research services approximates the revenue recognized. In June 2007 the Company announced preliminary top line results in this study, with the final activities to be completed by the fourth quarter of 2007.

**Research and Development**

Research and development expenses consist of costs incurred for Company-sponsored research and development activities. These costs include direct expenses (including nonrefundable payments to third parties) and research-related overhead expenses, as well as the cost of funding clinical trials, pre-clinical studies, manufacturing development and the contract development of second-generation compounds. Such costs 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 also expensed when incurred.

**Income Taxes**

The Company accounts for income taxes under Statement of Financial Accounting Standards No. 109, *Accounting for Income Taxes*, or SFAS 109. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates that will be in effect when the differences are expected to reverse. A valuation allowance is recorded when it is more likely than not that the deferred tax asset will not be recovered.

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

No amounts have been recognized as interest or penalties on income tax related matters.

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

**Recently Issued Accounting Standards**

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

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

In June 2007, the Emerging Issues Task Force of the Financial Accounting Standards Board, or EITF, adopted a draft of Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, or EITF 07-3. EITF 07-3 requires that nonrefundable advance payments for future research and

**Table of Contents**

**CORCEPT THERAPEUTICS INCORPORATED**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO CONDENSED FINANCIAL STATEMENTS, Continued**

development activities should be deferred and recognized as expense as the goods are delivered or the related services are performed, unless the entity does not expect the goods to be delivered or the services to be rendered. EITF 07-3 is effective for the fiscal years beginning after December 31, 2007, including interim periods within those fiscal years. Earlier adoption is not permitted. The Company does not anticipate that there will be a material effect on its financial statements on the implementation of this standard.

**2. Commitments**

On May 31, 2007, the Company signed an agreement for the conduct of research activities on new compounds. On July 17, 2007, the Company initiated an agreement for a human microdosing study of one of the Company's new chemical entities. The total commitment under these two agreements is approximately \$830,000. Approximately \$230,000 of this commitment was expensed during the third quarter of 2007.

Approximately \$365,000 is expected to be incurred during the fourth quarter of 2007 and the remainder will be incurred in 2008. In addition, under this research agreement, the Company may be obligated to make milestone payments upon the occurrence of certain events, including: (i) patent filings in connection with the project; (ii) entries into Phase 1 clinical trials; and (iii) national regulatory approval of each product arising from work performed under the agreement, provided that sales of the product by the Company or any future licensees reach \$5,000,000. No milestone events have occurred related to this agreement through September 30, 2007.

On September 18, 2007, the Company initiated additional work under the agreement for its cardiac study for an additional commitment of approximately \$1.7 million. Approximately \$850,000 of this amount was incurred as of September 30, 2007, with the remainder to be incurred before the end of 2007.

**3. Capital Stock**

On March 30, 2007, the Company sold 9.0 million shares of common stock at a price of \$1.00 per share in a private placement. The net proceeds were approximately \$8.8 million after deducting issuance costs.

On August 16, 2007, the Company signed an agreement for the private placement of a total of approximately 4.8 million shares of its common stock at a price of \$2.10 per share. Approximately 3.6 million shares were sold on August 17, 2007 with the remaining 1.2 million shares sold on September 24, 2007. The aggregate net proceeds of this financing were approximately \$10.0 million after deducting issuance costs.

**4. Stock Option Plans**

*Stock Option Plans*

Under the 2004 Equity Incentive Plan (the "2004 Plan") options, stock purchase and stock appreciation rights and restricted stock awards can be issued to employees, officers, directors and consultants of the Company. The 2004 Plan provides that the exercise price for incentive stock options will be no less than 100% of the fair value of the Company's common stock, as of the date of grant. Generally, options granted under the 2004 Plan have a ten year contractual life and vest over either a four or five year period. The vesting period is approximately equivalent to the requisite service period. Upon exercise, new shares are issued. Prior to our initial public offering in 2004, options were granted to employees, directors and non-employees under the 2000 Stock Option Plan (the "2000 Plan"). Although options are no longer granted under the 2000 Plan, there are still options outstanding under that plan.

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

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

During the second quarter of 2007 the Board of Directors granted stock options for a total of 2.3 million shares to employees and officers of the Company at an average exercise price of \$1.50 per share. The exercise price of each option grant is based on the closing price of the Company's stock on the Nasdaq Stock Market as of the date of grant. These options vest monthly over a four-year period.

Also, during the nine months ended September 30, 2007, options for a total of approximately 395,000 shares were cancelled or forfeited as the result of employee terminations and the Company recorded a reversal of approximately \$395,000 of stock-compensation expense related to an employee resignation. This reversal represents the excess of expense related to options granted to this individual that has been recorded under the graded vesting method as compared with the expense

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

associated with stock options that actually vested prior to the termination of employment. During the three- and nine-month periods ended September 30, 2006, the Company had recorded a reversal of approximately \$35,000 of stock-compensation expense related to options that did not vest because of an employee termination.

There were stock options exercised for 26,250 shares during the nine months ended September 30, 2007.

*Stock-based compensation for employee options.*

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

*Pro-forma net loss information required under SFAS 123 for options accounted for under the intrinsic value method*

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

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

	Three Months Ended		Nine Months Ended	
(in Thousands, except per share data)	September 30, 2007	September 30, 2006	September 30, 2007	September 30, 2006
Net loss as reported	\$ (3,428)	\$ (6,403)	\$ (7,380)	\$ (20,996)
Adjustments to net loss related to stock awards to employees and directors accounted for under the intrinsic value method:				
Add back amortization of deferred compensation	12	81	86	310
Deduct stock-based compensation expense determined under SFAS 123	(17)	(110)	(113)	(411)

Edgar Filing: CORCEPT THERAPEUTICS INC - Form 10-Q

Pro forma net loss	\$ (3,433)	\$ (6,432)	\$ (7,407)	\$ (21,097)
Net loss per share				
As reported basic and diluted	\$ (0.09)	\$ (0.28)	\$ (0.23)	\$ (0.93)
Pro forma basic and diluted	\$ (0.09)	\$ (0.28)	\$ (0.23)	\$ (0.93)

The pro forma adjustments reflected in the table above relate only to those options granted to employees and directors prior to the IPO because as discussed above, these options continue to be accounted for using the intrinsic value method. This pro forma adjustment is not required after December 31, 2005 for options granted after the IPO as the expense related to these options has been recorded based on fair value at the date of grant since the adoption of SFAS 123R.



Table of Contents**CORCEPT THERAPEUTICS INCORPORATED**

(A DEVELOPMENT STAGE COMPANY)

**NOTES TO CONDENSED FINANCIAL STATEMENTS, Continued***Assumptions used in determining fair value for options granted to employees*

The following table summarizes the weighted-average assumptions and resultant fair value for options granted to employees and directors during the nine months ended September 30, 2007 and 2006.

	Nine Months Ended September 30, 2007	Nine Months Ended September 30, 2006
Weighted average assumptions for stock options granted:		
Risk-free rates	4.69%	4.98%
Expected term	6.0 years	6.0 years
Expected volatility of stock price	87.1%	78.6%
Dividend rate	0%	0%
Weighted average fair value of grants issued	\$ 1.13	\$ 3.09

The expected term is based on the simple method prescribed by the SEC in Staff Accounting Bulletin 107, and considers the weighted average of the vesting period and contractual life of the options. There has been no adjustment made to the expected term to adjust for employees expected exercise and expected post-vesting termination behavior because the Company has a limited employee base and does not have sufficient historical information to determine such an adjustment.

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

*Non-employees*

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

**5. Comprehensive Loss**

Comprehensive loss is comprised of net loss and the change in unrealized gains and losses on available-for-sale securities. The following table presents the components of comprehensive loss for the periods presented. All figures are in thousands.

	Three Months Ended		Nine Months Ended	
	September 30, 2007	September 30, 2006	September 30, 2007	September 30, 2006
	<i>(in thousands)</i>			
Net loss as reported	\$ (3,428)	\$ (6,403)	\$ (7,380)	\$ (20,996)
Change in unrealized loss	1	37	1	100

Comprehensive net loss	\$ (3,427)	\$ (6,366)	\$ (7,379)	\$ (20,896)
------------------------	------------	------------	------------	-------------

**6. Net Loss Per Share**

Basic and diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding during the period less outstanding shares subject to repurchase. Outstanding shares subject to repurchase are not included in the computation of basic net loss per share until the Company's time-based repurchase rights have lapsed.

Table of Contents**CORCEPT THERAPEUTICS INCORPORATED**

(A DEVELOPMENT STAGE COMPANY)

**NOTES TO CONDENSED FINANCIAL STATEMENTS, Continued**

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2007	2006	2007	2006
	<i>(In thousands,</i>			
	<i>except per share amounts)</i>			
Net loss (numerator)	\$ (3,428)	\$ (6,403)	\$ (7,380)	\$ (20,996)
Shares used in computing historical basic and diluted net loss per share (denominator)				
Weighted-average common shares outstanding	36,608	22,732	32,466	22,720
Less weighted-average shares subject to repurchase		(13)		(29)
Denominator for basic and diluted net loss per share	36,608	22,719	32,466	22,691
Basic and diluted net loss per share	\$ (0.09)	\$ (0.28)	\$ (0.23)	\$ (0.93)

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.

	September 30,	
	2007	2006
	<i>(in thousands)</i>	
Shares subject to repurchase		5
Stock options outstanding	3,666	1,288
Total	3,666	1,293

**7. Subsequent Events**

On October 23, 2007, the Company signed an agreement for services in connection with the trial to be initiated for CORLUX for the treatment of Cushing's Syndrome. The total commitment under this agreement is approximately \$770,000, which will be expended over approximately a 30-month period. Under the master agreement with this vendor, the agreement may be terminated upon sixty days notice to the vendor. If terminated early, the Company will be responsible for the costs incurred by the vendor through the effective date of the termination.

---

**Table of Contents**

**ITEM 2**

**MANAGEMENT'S DISCUSSION AND ANALYSIS OF**

**FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

**Forward-Looking Information**

*This Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the Risk Factors section of this Form 10-Q. This 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, and similar expressions are forward-looking statements. Such forward-looking statements are based on current expectations, but the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements made in this Form 10-Q include statements about:*

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

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

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

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

*uncertainties associated with obtaining and enforcing patents;*

*our estimates for future performance; and*

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

*We believe that our current capital is sufficient to fund operations only through the second quarter of 2008. We need additional capital in order to continue operations and capital may not be available to us at all or on favorable terms.*

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

**OVERVIEW**

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

*Psychotic Depression*

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

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

We reported the initial results of Study 06, the last of the three Phase 3 trials, in March 2007. These results indicated that this study did not achieve statistical significance with respect to the primary endpoint, 50% improvement in the Brief Psychiatric Rating Scale Positive Symptom Subscale, or BPRS PSS, at Day 7 and at Day 56. However, there was a statistically significant correlation between plasma levels and clinical outcome achieved during treatment. Patients whose plasma levels rose above a predetermined threshold statistically separated from both those patients whose plasma levels were below the threshold and those patients who received placebo. In particular, those patients in Study 06 who achieved a predetermined level of 1661 nanograms of CORLUX per milliliter of plasma separated from the placebo group with

## **Table of Contents**

statistical significance for the primary endpoint. Conversely, at substantially lower plasma levels, there was no distinguishable response rate between patients who received CORLUX and those receiving placebo. This study confirms a similar finding in Study 07 that at higher plasma levels the drug candidate is able to demonstrate desired clinical effects. Further, the incidence of serious adverse events did not differ between placebo and any of the three CORLUX dose groups.

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

We believe that the confirmation of a drug concentration threshold for efficacy, as well as other observations from Study 06 and our other two recently completed Phase 3 clinical trials, will serve as a strong basis for our next Phase 3 study, which is planned to commence enrollment in the first quarter of 2008. The protocol for this trial will incorporate what we have learned from the three completed trials that address the sensitivity of the model and decrease the random variability observed in the results of the psychometric instruments used to measure efficacy. We intend to meet with the FDA to discuss and seek input concerning the design of this trial. In this trial we expect to use a dose level of 1200 mg once per day for seven days because, as expected, at successively higher dosages, more patients achieved the predetermined plasma threshold concentration. In Study 06, 80% of the patients achieved a drug plasma level sufficient for a strong clinical response at that dose. We have seen no difference in the safety data between any of the dose levels used in Study 06 in our initial review of a summary of that data. We believe that this change in dose, as well as other modifications to the protocol, should allow us to demonstrate the efficacy of CORLUX in the treatment of the psychotic symptoms of psychotic depression.

### *Management of Weight Gain induced by Antipsychotics*

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

In this study, 57 lean, healthy men (body mass index of 25 or less) were randomized to receive either olanzapine plus placebo (n=22), olanzapine plus CORLUX (n=24) or CORLUX plus placebo (n=11). This study took place in an institutional setting where daily weights were recorded and a range of metabolic parameters were measured. In the two week study, subjects in the olanzapine alone group gained an average of 2.5 pounds more than subjects in the olanzapine plus CORLUX group and 2.2 pounds more than subjects in the CORLUX alone group, which are highly statistically significant differences ( $p < .001$ ). The difference in weight gain trajectory was apparent in the first days of the study, reaching statistical significance during the first week. A preliminary analysis also indicates that patients who took olanzapine plus placebo had a statistically significant rise in fasting insulin while those who took olanzapine plus CORLUX did not. Additionally, patients who took olanzapine plus placebo had a greater average increase in triglycerides than did patients who took olanzapine plus CORLUX. Further analyses of these variables are ongoing. Although no unexpected study drug related adverse events were seen in any group, a complete review of all safety data has not yet been completed.

The combination of olanzapine and CORLUX is not approved for any indication. The purpose of this study was to explore the hypothesis that GR-II antagonists would mitigate weight gain associated with atypical antipsychotic medications. The group of medications known as atypical antipsychotics, including olanzapine, risperidone, clozapine and quetiapine, are widely used to treat schizophrenia and bipolar disorder. All medications in this group are associated with treatment emergent weight gain of varying degrees and carry a warning label relating to treatment emergent hyperglycemia and diabetes mellitus.

In April 2005, we announced results from two preclinical studies conducted in a rat model of olanzapine induced weight gain. These studies demonstrated that CORLUX reduced both the weight gain associated with ongoing olanzapine use and prevented the weight gain associated with the initiation of treatment with olanzapine.

### *Cushing's Syndrome*

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



---

## **Table of Contents**

Orphan Drug Designation is a special status granted by the FDA to encourage the development of treatments for diseases or conditions that affect fewer than 200,000 patients in the United States. 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.

In September 2007, we received notification that the FDA has opened the Investigational New Drug application, or IND, for CORLUX for the treatment of Cushing's Syndrome. In the communication regarding the opening of the IND, the FDA indicated that a single study may provide a reasonable basis for the submission of a New Drug Application, or NDA, for CORLUX for the treatment of Cushing's Syndrome. Receipt of this communication from the FDA allows us to initiate the 50-patient open label study defined by the protocol submitted with the application for the IND. We have begun qualifying potential sites for this study and expect to open the trial for enrollment late in the fourth quarter of 2007.

### *Research and Human Biology*

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

In May 2007 we signed a new agreement to continue our discovery research activities on new compounds for a period of six months.

### *General*

Our activities to date have included:

product development;

designing, funding and overseeing clinical trials;

regulatory affairs; and

intellectual property prosecution and expansion.

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

We are in the development stage and have incurred significant losses since our inception because we had not generated any revenue through September 2007 other than the revenue under the collaboration agreement with Lilly, and do not expect to generate significant revenue for the foreseeable future. As of September 30, 2007, we had an accumulated deficit of \$105.8 million. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for CORLUX, discovery research, non-clinical activities such as toxicology and carcinogenicity studies, manufacturing process development and regulatory activities, as well as general and administrative expenses. We expect to continue to incur net losses over at least the next several years as we continue our CORLUX clinical development program, apply for regulatory approvals, initiate development of newly identified GR-II antagonists for various indications, continue our discovery research program, acquire and develop treatments in other therapeutic areas, establish sales and marketing capabilities and expand our operations.

Our business is subject to significant risks, including the risks inherent in our research and development efforts, the results of our CORLUX clinical trials, uncertainties associated with securing financing, uncertainties associated with obtaining and enforcing patents, our investment in



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

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.

**Table of Contents**

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

**Results of Operations****Three and Nine Month Periods Ended September 30, 2007 and 2006**

*Collaboration revenue* Collaboration revenue relates to services rendered in connection with our agreement with Lilly discussed above. Under the agreement, Lilly agreed to supply olanzapine and pays for the costs of the study. We are required to perform development activities as specified in this agreement and we are reimbursed based on the costs associated with the conduct of the trial and the preparation and packaging of clinical trial materials. Revenue is recognized as the services are rendered in accordance with the agreement. The cost of providing these research services approximates the revenue recognized.

During the first nine months of 2007 and 2006, we recognized approximately \$482,000 and 221,000, respectively, under this agreement. We did not recognize any revenue during the third quarter of 2007 or 2006. There will be no significant revenue under this agreement in the future as the majority of the activities were completed by the end of the second quarter of 2007.

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

Research and development expenses decreased 53% to \$2.4 million for the three-month period ended September 30, 2007, from \$5.1 million for the three-month period ended September 30, 2006. For the nine months ended September 30, 2007, research and development expenses decreased 71% to \$5.2 million from \$17.9 million for the nine months ended September 30, 2006. The decrease in expenses reflects clinical trial cost decreases of approximately \$2.9 million and \$12.3 million, respectively, for the current quarter and year-to-date periods as compared to the same periods of 2006 due to the substantial completion of the Phase 3 clinical trials for psychotic depression in late 2006 and early 2007, which were partially offset by increases in clinical trial costs related to other programs of \$90,000 and \$405,000, respectively. There were also increases in contract research expenses during the three- and nine-month periods of 2007 as compared to 2006 of approximately \$225,000 and \$205,000, respectively, principally due to basic research work in new chemical compounds and increases in manufacturing expenses of approximately \$245,000 and \$105,000, respectively, due to the manufacture of additional materials for upcoming clinical trials. In addition, during the three- and nine-month periods ended September 30, 2007 as compared to the similar periods in 2006, there were decreases in pre-clinical studies of approximately \$265,000 and \$745,000, respectively, and staffing expenses of approximately \$175,000 and \$545,000, respectively, which included decreases in non-cash stock-based compensation of approximately \$40,000 and \$245,000, respectively. The decreases in staffing expenses were partially offset by increases in consulting and professional fees of \$110,000 and 155,000, respectively, for the three- and nine-month periods ended September 30, 2007 as compared to the similar periods in 2006.

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

Project	Three Months Ended		Nine Months Ended	
	September 30, 2007	September 30, 2006	September 30, 2007	September 30, 2006
	<i>(in thousands)</i>			
CORLUX for the treatment of the psychotic features of psychotic depression	\$ 1,918	\$ 4,918	\$ 3,873	\$ 17,000
CORLUX for other clinical programs	137	3	798	205
Drug discovery research	307	123	368	252
Stock-based compensation	64	103	149	455
<b>Total research and development expense</b>	<b>\$ 2,426</b>	<b>\$ 5,147</b>	<b>\$ 5,188</b>	<b>\$ 17,912</b>

We expect that research and development expenditures will increase during the fourth quarter of 2007 as compared to 2006 due to the costs incurred during the preparation for the planned clinical trials and the increased discovery research activity. Research and development expenses

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

during future years will be largely dependent on the availability of additional funds to finance clinical development plans based on our experience from prior trials. See also, the [Liquidity and Capital Resources](#) section in this Form 10-Q.

---

**Table of Contents**

Many factors can affect the cost and timing of our trials including inconclusive results requiring additional clinical trials, slow patient enrollment, adverse side effects in study patients, insufficient supplies for our clinical trials and real or perceived lack of effectiveness or safety of the drug in our trials. In addition, the development of all of our products will be subject to extensive governmental regulation. These factors make it difficult for us to predict the timing and costs of the further development and approval of our products.

*General and administrative expenses.* General and administrative expenses consist primarily of the costs of administrative personnel and related facility costs along with legal, accounting and other professional fees.

General and administrative expenses decreased 15% to approximately \$1.2 million for the three-month period ended September 30, 2007, from \$1.4 million for the three-month period ended September 30, 2006. For the nine months ended September 30, 2007, general and administrative expenses decreased 20% to \$3.1 million from \$3.9 million for the nine months ended September 30, 2006. During the three- and nine-month periods ended September 30, 2007 legal and professional fees decreased by approximately \$170,000 and \$190,000, respectively, as compared to the similar periods of 2006 due primarily to lower costs related to patents. Staffing costs also decreased by approximately \$50,000 and \$550,000, respectively, for the quarter and nine months ended September 30, 2007 as compared to the similar periods of 2006. The changes in staffing costs included an increase in non-cash stock-based compensation of approximately \$25,000 for the quarter ended September 30, 2007 as compared with 2006 and a decrease of approximately \$392,000 for the nine months ended September 30, 2007 as compared with 2006.

The decreases in stock-based compensation during the nine months ended September 30, 2007 included a reversal of approximately \$395,000 of stock-compensation expense during the second quarter of 2007 in connection with the resignation of an employee, which represents the excess of expense under the graded vesting method as compared with the expense associated with stock options that actually vested prior to this termination. Stock-based compensation expense related to stock options granted to officers and employees during the second quarter of 2007 was partially offset by declining expense of earlier options due to the decelerating scale of expense under the graded vesting method and options cancelled due to an employee termination.

The amount of general and administrative expenses for the remainder of 2007 and future years will be largely dependent on our assessment of the staff necessary to support our continued clinical development activities and the availability of additional funds. See also, the Liquidity and Capital Resources section in this Form 10-Q.

*Interest and other income, net.* Interest and other income, net, increased to approximately \$191,000 for the third quarter of 2007, as compared to approximately \$154,000 in the third quarter of 2006. Interest and other income, net, decreased to approximately \$453,000 for the nine months ended September 30, 2007 as compared to approximately \$609,000 in the same period of 2006. The increase in interest income in the third quarter was attributable to earnings on the proceeds of the equity financing during the third quarter of 2007. The decrease in interest during the nine months ended September 30, 2007 as compared to 2006 was attributable to lower average balance of invested funds which was partially offset by higher yields on the investment portfolios during the 2007 period as compared to the 2006 period.

*Other expense.* Other expense, which represents state tax and interest expense on capitalized leases, was approximately \$1,000 and \$7,000, respectively, for the three- and nine-month periods ended September 30, 2007 as compared to approximately \$8,000 and \$14,000, respectively, for the same periods in 2006.

**Liquidity and Capital Resources**

We have incurred operating losses since inception, and at September 30, 2007, we had a deficit accumulated during the development stage of \$105.8 million. Since our inception, we have relied primarily on the proceeds from public and private sales of our equity securities to fund our operations. On March 30, 2007, we sold 9 million shares of common stock at a price of \$1.00 per share in a private placement, which generated net proceeds of approximately \$8.8 million after deducting issuance costs. During the third quarter of 2007, we sold approximately 4.8 million shares of common stock at a price of \$2.10 per share in a private placement, which generated net proceeds of approximately \$10.0 million after deducting issuance costs.

At September 30, 2007, we had cash, cash equivalents and investments balances of \$20.6 million, compared to \$9.5 million at December 31, 2006. Net cash used in operating activities for the nine-month period ended September 30, 2007 was approximately \$7.7 million as compared to approximately \$17.7 million for the same period in 2006. The use of cash in each period was primarily a result of net losses associated with our research and development activities and amounts incurred to develop our administrative infrastructure. We expect cash used in operating activities to increase for the fourth quarter and later years due to the continuation and expansion of our development programs for psychotic depression, Cushing's Syndrome and the management of weight gain induced by atypical antipsychotic medications, research activities, commercialization activities and general and administrative expenses.



## **Table of Contents**

We believe that we have sufficient funds to maintain our current operations through the completion of the final reporting activities for our recently completed trials, to begin our next series of clinical trials, which include a Phase 3 trial in psychotic depression, a Phase 3 trial in Cushing's Syndrome and a trial to further evaluate the management of weight gain induced by antipsychotic medications, and to continue development of our new chemical entities. If we are not able to raise additional funds, we will not be able to continue operations as currently planned beyond the second quarter of 2008.

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

We plan to raise additional funds assuming investors' acceptance of our business plan going forward, which includes additional Phase 3 clinical trial efforts in psychotic depression, a Phase 3 clinical trial with CORLUX for the treatment of Cushing's Syndrome, development of CORLUX for the management of antipsychotic-induced weight gain and the development of our new chemical entities. We cannot be certain that additional funding will be available on acceptable terms or at all. Further, any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants. If we obtain funds through collaborations with others, these arrangements may be on unfavorable terms or may require us to relinquish certain rights to our technologies or product candidates, including potentially our lead product candidate, that we would otherwise seek to develop on our own. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or we may be required to discontinue operations.

## **Contractual Obligations and Commercial Commitments**

On May 31, 2007, we signed an agreement for the conduct of research activities on new compounds. On July 17, 2007, we initiated an agreement for a human microdosing study of one of the Company's new chemical entities. The total commitment under these two agreements is approximately \$825,000. Approximately \$230,000 of this commitment was expensed during the third quarter of 2007. Approximately \$365,000 is expected to be incurred during the fourth quarter and the remainder will be incurred in 2008. In addition, under this research agreement, the Company may be obligated to make milestone payments upon the occurrence of certain events, including: (i) patent filings in connection with the project; (ii) entries into Phase 1 clinical trials; and (iii) national regulatory approval of each product arising from work performed under the agreement, provided that sales of the product by the Company or any future licensees reach \$5,000,000. No milestone events have occurred related to this agreement through September 30, 2007.

On September 18, 2007, we initiated additional work under the agreement for our cardiac study for an additional commitment of approximately \$1.7 million. Approximately \$850,000 of this amount was incurred by September 30, 2007, with the remainder to be incurred before the end of 2007.

On October 23, 2007, the Company signed an agreement for services in connection with the trial to be initiated for CORLUX for the treatment of Cushing's Syndrome. The total commitment under this agreement is approximately \$770,000, which will be expended over approximately a 30-month period. Under the master agreement with this vendor, the agreement may be terminated upon sixty days notice to the vendor. If terminated early, the Company will be responsible for the costs incurred by the vendor through the effective date of the termination.

---

## **Table of Contents**

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

We believe there have been no significant changes in our critical accounting estimates during the nine months ended September 30, 2007 as compared to what was previously disclosed in our Form 10-K for the year ended December 31, 2006.

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

*Revenue recognition – Collaboration revenue.* Collaboration revenue relates to services rendered in connection with our agreement signed in October 2005 with Lilly under which Lilly agreed to supply olanzapine and pay for the study. We are required to perform development activities as specified in this agreement and are reimbursed based on the costs associated with the conduct of the trial and the preparation and packaging of clinical trial materials. Revenue is recognized as services are rendered in accordance with the agreement. The cost of providing these research services approximates the revenue recognized.

*Accruals of Research and Development Costs.* We recorded accruals for estimated costs of research, pre-clinical and clinical studies, and manufacturing development of approximately \$610,000 and \$2.2 million as of September 30, 2007 and December 31, 2006, respectively. These costs are a significant component of our research and development expenses. We make significant judgments and estimates in determining the accrual balance in each reporting period. Accrued clinical trial costs are based on estimates of the work completed under the service agreements, milestones achieved, patient enrollment and past experience with similar contracts and service providers. Our estimate of the work completed and associated costs to be accrued includes our assessment of the information received from our third-party contract research organizations and the overall status of our clinical trial activities. In the past, we have not experienced any material deviations between accrued clinical trial expenses and actual clinical trial expenses. However, actual services performed, number of patients enrolled and the rate of patient enrollment may vary from our estimates, resulting in adjustments to clinical trial expense in future periods.

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

#### *Employees and directors*

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

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





---

## **Table of Contents**

attribution method over the vesting periods of the applicable stock options. The graded-vesting method provides for vesting of portions of the overall awards at interim dates and results in greater expense in earlier years than the straight-line method. Upon termination of employment, the difference between the expense recorded under the graded-vesting method and the expense that would have been recorded based upon the vesting of the related option is required to be reversed.

Following is a brief synopsis of our accounting practices and the estimates and judgments that are considered in determining fair value under SFAS 123R in regard to stock option grants to employees and directors:

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

The expected term used in determining the fair value for options is based on the simple method prescribed by the SEC in Staff Accounting Bulletin 107, and considers the weighted average of the vesting period and contractual life of the options. There has been no adjustment made to the expected term to adjust for employees' expected exercise and expected post-vesting termination behavior because we have a limited employee base and do not have sufficient historical information to determine such an adjustment.

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

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

### *Non-employees*

Stock-based compensation related to option grants to non-employees is charged to expense on a straight line basis over the vesting period of the options, based on the fair value of the options, which approximates the period over which the related services are rendered, using the Black-Scholes option pricing model. The assumptions used in these calculations are similar to those used for the determination of fair value under SFAS 123 and 123R for options granted to employees, with the exception that, for non-employee options, we are required to use the remaining contractual term as the life of the option and the fair value related to unvested non-employee options is re-measured quarterly, based on the then current stock price as reflected on the Nasdaq Stock Market.

*Income Taxes.* In June 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, or FIN 48, an interpretation of SFAS No. 109, *Accounting for Income Taxes*, or SFAS 109. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS 109 by prescribing a minimum recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition measurement, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. We have adopted FIN 48 as of January 1, 2007, as required. As a result of the implementation of FIN 48, we did not recognize any adjustment to the liability for uncertain tax positions or to our deferred tax assets for unrecognized tax benefits, all of which are currently offset by a full valuation allowance. Therefore, there was no adjustment to the beginning balance of retained earnings in 2007.

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

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

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

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

**Table of Contents**

**Recently Issued Accounting Standards**

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

In March 2007, the Emerging Issues Task Force of the Financial Accounting Standards Board, or EITF, released a draft of Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, or EITF 07-3. The initial draft of this Issue was affirmed at EITF meetings in June 2007. EITF 07-3 requires that nonrefundable advance payments for future research and development activities should be deferred and recognized as expense as the goods are delivered or the related services are performed, unless the entity does not expect the goods to be delivered or the services to be rendered. EITF 07-3 is effective for the fiscal years beginning after December 31, 2007, including interim periods within those fiscal years. Earlier adoption is not permitted. The Company does not anticipate that there will be a material effect on its financial statements on the adoption of this standard.

## **Table of Contents**

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

#### **Market Risk**

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk of loss. As of September 30, 2007, our cash and cash equivalents consisted primarily of cash money market funds maintained at major U.S. financial institutions and short-term investments consisted of commercial paper. To minimize our exposure to interest rate market risk, we limit the maturities of our investments to less than two years with an average maturity not to exceed one year. Due to the short-term nature of these instruments, a 1% increase or decrease in market interest rates would not have a material adverse impact on the total value of our portfolio as of September 30, 2007.

#### **Currency Risk**

In 2004, we signed a master agreement with a contract research organization, or CRO, to assist us in the conduct of clinical trials in Europe. The costs of these trials are denominated in Euros, which the vendor converts into U.S. dollars for invoicing as costs are incurred, generally on a monthly basis. Thus, we may bear some currency rate exposure for the costs of these trials. As of December 31, 2006, we had executed amendments to this agreement that included Euro-denominated commitments of approximately 6.8 million Euros. As of September 30, 2007, all three Euro-denominated trials have completed all patient activities and remaining reporting activities should be completed by the end of 2007. The timing of payments will depend upon the actual completion of these activities. Approximately 140,000 Euros had not been expended or accrued as of September 30, 2007, which is equivalent to approximately \$200,000, using the exchange rate as of that date. A 1% increase or decrease in the currency rate of exchange between the U.S. Dollar and the Euro would have an impact of approximately \$2,000 on the unexpended cost of these trials. The master agreement with this CRO provides for termination by us with forty-five days' notice.

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

***Evaluation of disclosure controls and procedures.*** Based on their evaluation as of September 30, 2007, our chief executive officer and chief accounting officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) were effective to ensure that the information required to be disclosed by us in this Quarterly Report on Form 10-Q was recorded, processed, summarized and reported within the time periods specified in the SEC's rules and Form 10-Q. Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met.

***Changes in internal controls.*** There were no changes in our internal controls over financial reporting during the quarter ended September 30, 2007 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. In addition to other information in this report, the following factors should be considered carefully in evaluating our company. If any of the risks or uncertainties described in this Form 10-Q or in our annual report on Form 10-K for the year ended December 31, 2006 actually occurs, our business, results of operations or financial condition could be materially adversely affected. The risks and uncertainties described in this Form 10-Q 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**

**Our current capital is sufficient to fund operations only through the second quarter of 2008. We will need additional capital in order to continue operations and capital may not be available to us at all or on favorable terms.**

We expect that our existing cash resources will be sufficient to fund our operations as currently planned only through the second quarter of 2008. Our cash and marketable securities have enabled us to complete the third of our three Phase 3 clinical studies evaluating our lead product candidate, CORLUX, for treating the psychotic features of psychotic depression. However, we do not have sufficient funds to maintain our current infrastructure beyond the completion of reporting activities on our recently completed trials and the commencement of enrollment in our next series of clinical trials, which include a Phase 3 trial in psychotic depression, our Phase 3 trial in Cushing's Syndrome and a clinical trial to further evaluate the management of weight induced by antipsychotic medications.

We will require substantial additional funding in the form of public or private equity offerings, debt financings, strategic partnerships and/or licensing arrangements in order to continue our operations beyond the second quarter of 2008. Even if available, each source of financing has some risks to our shareholders and to the company. Raising funds through equity financings will be dilutive to our current shareholders. Debt financing arrangements may contain restrictive provisions or covenants. Obtaining funds through collaborations with others may be on unfavorable terms or may require us to relinquish certain rights to our technologies or products, including potentially our lead product candidate, that we would otherwise seek to develop on our own;

Additional financing may not be available on acceptable terms or at all. We believe that our ability to secure substantial additional funding will depend largely on investors' acceptance of our business plan going forward, which includes the completion of a fourth Phase 3 clinical trial in psychotic depression, opportunities that may be created by the recently reported top-line results of the proof-of-concept mitigation of atypical antipsychotic induced weight gain trial, the opening of an Investigational New Drug application (IND) in Cushing's syndrome and the development of our new chemical entities.

If we are unable to raise additional funds, we may, among other things, be required to delay, reduce the scope of or eliminate one or more of our research or development programs or we may be required to discontinue operations.

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

## Table of Contents

**We will depend heavily on the success of our lead product candidate, CORLUX for the treatment of the psychotic features of psychotic depression, which is still in development. Our first three Phase 3 trials did not meet their primary and key secondary endpoints. If we are unable to commercialize CORLUX, or experience significant delays in doing so, we may be unable to generate revenues and our stock price may decline.**

We have invested a significant portion of our time and financial resources since our inception in the development of CORLUX. We currently do not have any commercial products and we anticipate that for the foreseeable future our ability to generate revenues and achieve profitability will be solely dependent on the successful development, approval and commercialization of CORLUX. We have completed three Phase 3 clinical trials evaluating CORLUX for the treatment of the psychotic features of psychotic depression. None of the first three trials met its primary or key secondary endpoints. The FDA generally requires at least two positive Phase 3 studies prior to the submission of an NDA. Many factors could harm our efforts to develop and commercialize CORLUX, including:

insufficient funding;

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

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

changes or delays in our clinical development program;

rapid technological change making CORLUX obsolete;

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

increases in the costs of our clinical trials;

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

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

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

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

To gain regulatory approval from the FDA to market CORLUX for the treatment of the psychotic features of psychotic depression, our Phase 3 clinical trials must demonstrate the safety and efficacy of CORLUX for this treatment. Our first three Phase 3 studies did not meet their primary or key secondary endpoints. In addition to the need for additional Phase 3 clinical trials, we are conducting, or plan to conduct, other studies in support of a potential NDA. Clinical development is a long, expensive and uncertain process and is subject to delays, and data obtained from clinical trials and supportive studies are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Favorable results of preclinical studies and initial clinical trials of CORLUX are not necessarily indicative of the results we will obtain in later clinical trials. While we obtained favorable results in our Phase 2 clinical trials program, these results were not replicated in a robust enough way in

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

Studies 07, 09 or 06 and are not sufficient to support an application for FDA approval. In addition, we cannot assure you that supportive studies and tests will produce favorable results.

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

During the development of CORLUX, we have been engaged in dialogue with the FDA to determine an acceptable development plan which would enable the FDA to complete its review in a satisfactory manner. Because the results of our recently completed Phase 3 trials did not meet their primary endpoints, the FDA will require us to pursue additional clinical trials to demonstrate the safety and/or efficacy of CORLUX. The FDA generally requires at least two positive Phase 3 studies prior to the submission of an NDA. In addition, the FDA may require us to pursue additional supportive studies. Recently, the FDA recommended that we conduct a dose proportionality study and other studies to determine whether there are interactions between CORLUX and some commonly used drugs. We are continuing our dialogue with the FDA to define any additional data needed to complete an NDA.

Although our cash and marketable securities will enable us to complete the final reporting activities for our recently completed Phase 3 trials and to fund the commencement of enrollment in our next series of clinical trials through the second quarter of 2008, we will need to raise additional funds for our research and development and general and administrative activities for the remainder of 2008 and subsequent years. We believe that our ability to secure substantial additional funding in the near term will depend largely on investors' acceptance of our business plan going forward, which includes a Phase 3

---

**Table of Contents**

clinical trial in psychotic depression, a Phase 3 clinical trial for the treatment of Cushing's Syndrome, Phase 2 clinical trials in the prevention and reduction of antipsychotic-induced weight gain and the development of our new chemical entities. We cannot be certain that additional funding will be available on acceptable terms or at all. Our inability to raise capital will result in a delay of the performance of these activities and harm our business and product development efforts. Without additional funding we will not be able to continue the company's operations beyond the second quarter of 2008.

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

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

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

negative or inconclusive results;

slow patient enrollment;

patient noncompliance with the protocol;

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

FDA inspections of our clinical operations; and

real or perceived lack of effectiveness or safety of CORLUX.

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

We are a development stage company with no current source of product revenue. We have a limited history of operations and have focused primarily on clinical trials, and if the outcome of our clinical trials supports it, we plan to seek FDA regulatory clearance to market CORLUX for the treatment of the psychotic features of psychotic depression and for the treatment of Cushing's Syndrome. Historically, we have funded our operations primarily from the sale of our equity securities. We have incurred losses in each year since our inception in 1998. As of September 30, 2007, we had an accumulated deficit of \$105.8 million. We do not know when or if we will generate product revenue. Subject to our ability to raise additional funds, we expect our research and development expenses to increase in connection with the clinical trials and other development activities for CORLUX and for other product candidates. We expect to incur significant expenses related to the preparation for commercializing CORLUX and for the product's launch, if the FDA approves our NDA. As a result, we expect that our losses will increase for the foreseeable future. We are unable to predict the extent of any future losses or whether or when we will become profitable.

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



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

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

We have contracted with various contract research organizations, or CROs, to monitor clinical site performance and to perform investigator supervision, data collection and analysis for the majority of our clinical trials. We may not be able to maintain these relationships with the CROs or with the clinical investigators and the clinical sites through the completion of all trial activities without excessive expenditures. Our agreements place substantial responsibilities on these parties, which could result in excessive expenditures for our clinical trials if these parties fail to perform as expected. For example, if any of our clinical trial sites fail to comply with FDA-approved good clinical practices, we may be unable to use the data gathered at

---

**Table of Contents**

those sites. If these CROs, clinical investigators, clinical sites or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, we may be unable to obtain regulatory approval for, or successfully commercialize, CORLUX.

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

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

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

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

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

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

the FDA may not find that the candidate is safe;

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

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

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

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

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



---

**Table of Contents**

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

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

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

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

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

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

Many factors may affect the market acceptance and commercial success of CORLUX for the treatment of the psychotic features of psychotic depression. Although there is no FDA-approved treatment for psychotic depression, there are two treatment approaches currently used by psychiatrists: electroconvulsive therapy, or ECT, and combination medicinal therapy. Even if the FDA approves CORLUX for the treatment of the psychotic features of psychotic depression, physicians may not adopt CORLUX. Physicians will recommend the use of CORLUX only if they determine, based on experience, clinical data, side effect profiles and other factors, that it is preferable to other products or treatments then in use. Acceptance of CORLUX among influential practitioners will be essential for market acceptance of CORLUX.

Other factors that may affect the market acceptance and commercial success of CORLUX for the treatment of the psychotic features of psychotic depression 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;

Edgar Filing: CORCEPT THERAPEUTICS INC - Form 10-Q

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

the extent and success of our sales and marketing efforts;

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

negative publicity concerning CORLUX, RU-486 or mifepristone.

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

## **Table of Contents**

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

The active ingredient in CORLUX, mifepristone, or RU-486, is used to terminate pregnancy. As a result, mifepristone has been and continues to be the subject of considerable ethical and political debate in the United States and elsewhere. Public perception of mifepristone may limit our ability to engage alternative manufacturers and may limit the commercial acceptance of CORLUX by patients and physicians. Even though we intend to create measures to minimize the likelihood of the prescribing of CORLUX to a pregnant woman, physicians may decline to prescribe CORLUX to a woman simply to avoid altogether any risk of unintentionally terminating a pregnancy. We intend to create measures for controlling the distribution of CORLUX to reduce the potential for diversion. However, controlled distribution may negatively impact sales of CORLUX.

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

We currently have no experience in, and we do not own facilities for, nor do we plan to develop facilities for, manufacturing any products. We have agreements with two manufacturers of the active pharmaceutical ingredient, or API, of mifepristone and an agreement with a tablet manufacturer for development quantities of CORLUX. The tablet manufacturer is a single source supplier to us. Our current arrangements with these manufacturers are terminable by either party at any time. Although we anticipate engaging our current tablet supplier to produce commercial quantities of CORLUX, we cannot guarantee that we will enter into an agreement with them on terms acceptable to us. If we are unable, for whatever reason, to obtain the active pharmaceutical ingredient or CORLUX tablets from our contract manufacturers, we may not be able to manufacture our required quantities of CORLUX in a timely manner, if at all.

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

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

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

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

## **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.

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

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

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

We have exclusively licensed three issued U.S. patents from Stanford University for the use of GR-II antagonists in the treatment of psychotic major depression, which is commonly referred to as psychotic depression, cocaine-induced psychosis and early dementia, including early Alzheimer's disease. We bear the costs of protecting and defending the rights to these patents. In order to maintain the exclusive license to these patents until their expiration, we are obligated to make milestone and royalty payments to Stanford University. We are currently in compliance with our obligations under this agreement. If we become noncompliant, we may lose the right to commercialize CORLUX for the treatment of psychotic depression and Alzheimer's disease 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.

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

Our presently pending and future patent applications may not issue as patents, and any patent issued to us may be challenged, invalidated, held unenforceable or circumvented. For example, the arguments presented by Akzo Nobel could be raised in the United States either before the U.S.

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

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



---

## **Table of Contents**

industry regarding patent and other intellectual property rights. If we become involved in litigation, it could consume a substantial portion of our resources. Regardless of the merit of any particular claim, defending a lawsuit takes significant time, is expensive and diverts management's attention from other business.

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

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

### **Our licensed patent covering the use of mifepristone to treat psychotic depression is a method of use patent rather than a composition of matter patent, which increases the risk that physicians will prescribe another manufacturer's mifepristone for the treatment of psychotic depression rather than CORLUX.**

We have an exclusive license from Stanford University to a patent covering the use of GR-II antagonists, including mifepristone, targeted for the treatment of psychotic depression. A method of use patent covers only a specified use of a particular compound, not a particular composition of matter. All of our issued patents and all but three of our 14 U.S. patent applications relate to use patents. Because none of our issued patents covers the composition of mifepristone or any other compound, we cannot prevent others from commercializing mifepristone or any other GR-II antagonist. If others receive approval to manufacture and market mifepristone or any other GR-II antagonist, physicians could prescribe mifepristone or any other GR-II antagonist for psychotic depression patients instead of CORLUX. Although any such off-label use would violate our licensed patent, effectively monitoring compliance with our licensed patent may be difficult and costly. In addition, if others develop a treatment for psychotic depression that works through a mechanism which does not involve the GR-II receptor, physicians could prescribe that treatment instead of CORLUX.

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

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

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

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

We only have experience with CORLUX and we may determine that CORLUX is not desirable for uses other than for the treatment of the psychotic features of psychotic depression. In that event, we would have to identify and may need to secure rights to a different GR-II antagonist. For example, we may not develop CORLUX for mitigation of the weight gain associated with the use of olanzapine, even though we have reported positive top-line results regarding the proof of concept study described earlier in this Form 10-Q. We may pursue other GR-II antagonists for this use. The compounds developed

## **Table of Contents**

pursuant to our discovery research program may fail to generate commercially viable product candidates in spite of the resources we have dedicated to the program. Even if product candidates are identified, we may abandon further development efforts before we reach clinical trials or after expending significant expense and time conducting clinical trials due to financial constraints, concerns over safety, efficacy of the product candidates or for other reasons. Moreover, governmental authorities may enact new legislation or regulations that could limit or restrict our development efforts. If we are unable to successfully discover and commercialize new uses for GR-II antagonists, we may be unable to generate sufficient revenue to support our operations.

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

The costs required to start or continue many of the programs that our intellectual property allow us to consider for further development are collectively greater than the funds currently available to us. For example, we announced in 2004 that we had successfully discovered three series of compounds that are specific GR-II antagonists but, unlike CORLUX, do not appear to block the progesterone receptor. Further development of these programs and others, such as the use of GR-II antagonists for the mitigation of weight gain associated with olanzapine, may be delayed or cancelled if we determine that such development may jeopardize our ability to complete the clinical development of CORLUX for the treatment of psychotic depression.

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

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

We have only limited product liability insurance coverage, with limits 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.

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

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

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

If resources are made available to continue operations beyond the second quarter of 2008, we plan to use those resources to expand our research and development efforts and develop a sales and marketing organization when appropriate. In that event, we expect to experience growth, which may strain our operations, product development and other managerial and operating resources. Future growth will impose significant added responsibilities on members of management, including



## **Table of Contents**

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

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

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

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

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

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

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 thioridazine, Schering Corporation's Trilafon and Eli Lilly's Zyprexa. CORLUX may not compete effectively with these established treatments. We are aware of one clinical trial conducted by the pharmaceutical division of Akzo Nobel, for a new chemical entity for the treatment of psychotic depression. This new chemical entity is a GR-II antagonist, the commercial use of which would be covered by our patent. As discussed above, in 2004, Akzo Nobel filed an observation in our exclusively licensed European patent application with claims directed to psychotic depression, in which Akzo Nobel challenged the claims of that patent application. In 2005, we filed a rebuttal to the EPO that responded to the points raised by Akzo Nobel. In February 2006, the EPO allowed our patent application. In July 2006, the patent was issued. We are not aware of any public disclosures by any company, other than Akzo Nobel, regarding the development of new products to treat psychotic depression.

## **Table of Contents**

We are aware that Laboratoire HRA Pharma has received an orphan drug designation for the use of mifepristone to treat a subtype of Cushing's Syndrome. If this product is approved for commercialization before CORLUX, our potential future revenue could be reduced by the possibility of off-label use of mifepristone for psychotic depression or for Cushing's Syndrome.

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

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

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

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

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

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

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

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

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

## **Table of Contents**

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

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

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

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

We cannot assure you that an active trading market for our common stock will exist at any time. Holders of our common stock may not be able to sell shares quickly or at the market price if trading in our common stock is not active. During the 52-week period ended November 6, 2007 our average daily trading volume has been approximately 120,000 shares and the intra-day sales prices per share of our common stock ranged from \$0.68 to \$6.85. As of November 6, 2007, our officers, directors and principal stockholders control approximately 70% of our common stock. The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

our cash and short-term investment position;

actual or anticipated timing and results of our clinical trials;

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

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

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

actual or anticipated variations in quarterly operating results;

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

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

changes in financial estimates or recommendations by securities analysts;

conditions or trends in the biotechnology and pharmaceutical industries;

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

changes in the market valuations of similar companies;

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

additions or departures of key personnel;

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

developments concerning our collaborations;

trading volume of our common stock;

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

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

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

sales of our common stock by us or our stockholders.

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



## **Table of Contents**

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

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

If we are unable to meet any of the Nasdaq listing requirements in the future, the Nasdaq Stock Market staff could determine to delist our common stock, the delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease. Such delisting could also adversely affect our ability to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees.

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

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

### **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.

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

As of November 6, 2007, our officers, directors and principal stockholders control approximately 70% of our common stock. As a result, these stockholders, acting together, will be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders and may prevent or delay a change in control. This significant concentration of share ownership may adversely affect the trading price of our common stock because investors often perceive disadvantages to owning stock in companies with controlling stockholders. As of November 6, 2007, Paperboy Ventures LLC owns approximately 21% of our common stock. Allen Andersson, the chairman of Paperboy Ventures LLC, is a member of our board of directors. Paperboy Ventures' ownership interest and board representation may allow it to exert significant control over us and the risks described above regarding our officers, directors and principal stockholders acting as a group are equally applicable to Paperboy Ventures acting alone.

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

Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and regulations of the SEC and the Nasdaq Stock Market, have and will continue to result in increased costs to us. The new rules could make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, or our board committees, or as executive officers. At present, we cannot predict or estimate the amount of the additional costs related to these new rules and regulations or the timing of such costs.



---

## **Table of Contents**

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

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

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the company's internal controls over financial reporting in their annual reports on Form 10-K. This requirement will first apply to our annual report on Form 10-K for our fiscal year ending December 31, 2007. In addition, the independent registered public accounting firm auditing the company's financial statements must attest to and report on the effectiveness of the company's internal controls over financial reporting, which requirement will first apply to our annual report on Form 10-K for our fiscal year ending December 31, 2008. Uncertainty exists regarding our ability to comply with these requirements by applicable deadlines. If we are unable to complete the required assessment as to the adequacy of our internal control reporting or if our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal controls over financial reporting as the required deadline and future year ends, investors could lose confidence in the reliability of our financial reporting.

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

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

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

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

On August 16, 2007, we agreed to sell an aggregate of 4,790,473 shares of common stock, par value \$0.001, at a price of \$2.10 per share, for aggregate proceeds of approximately \$10.1 million.

**Table of Contents**

We completed the initial closing of the Offering on August 17, 2007, selling 3,599,997 shares of common stock, par value \$0.001, at the purchase price of \$2.10 per share for gross proceeds of \$7.6 million. The Purchasers in the initial closing included Paperboy Ventures, LLC, Sutter Hill Ventures and Alta Partners, LLP, all venture capital firms that are currently significant shareholders of the Company. The Purchasers also included various entities affiliated with G. Leonard Baker, Jr., Joseph C. Cook, Jr., David L. Mahoney and James N. Wilson, who are members of the Company's board of directors, and other qualified investors. Allen Andersson, a member of the Company's board of directors, is the chairman of Paperboy Ventures. Mr. Baker is a partner and managing director of Sutter Hill Ventures. Alix Marduel, M.D., a member of the Company's board of directors, is a managing director of Alta Partners.

On September 24, 2007, after receiving approval at a special meeting of stockholders, we completed the second closing under the agreement selling an additional 1,190,476 shares of common stock, par value \$0.001, at the purchase price of \$2.10 per share to Paperboy Ventures LLC for additional proceeds of \$2.5 million.

This financing is exempt from registration pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(2) the Securities Act of 1933, as amended, and Regulation D under the Securities Act of 1933, as amended.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

We held a special meeting of stockholders on September 24, 2007 to consider and vote on a proposal to approve the issuance and sale of 1,190,476 shares of the Company's common stock to Paperboy Ventures, LLC, pursuant to the Common Stock Purchase Agreement, dated August 16, 2007 among the Company and the purchaser parties thereto as required by Nasdaq Rule 4350.

The total number of shares voted at the special meeting was 29,189,384. The voting on the proposal is set forth below:

For	28,544,623
Against	629,161
Abstain	15,600

**ITEM 5. OTHER INFORMATION**

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

**Table of Contents**

**ITEM 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Description of Document</b>
3.1 <sup>(1)</sup>	Amended and Restated Certificate of Incorporation
3.2 <sup>(2)</sup>	Amended and Restated Bylaws
4.1 <sup>(1)</sup>	Specimen Common Stock Certificate
4.2 <sup>(1)</sup>	Amended and Restated Registration Rights Agreement by and among Corcept Therapeutics Incorporated and certain holders of preferred stock, dated as of May 8, 2001
4.3 <sup>(1)</sup>	Amendment No. 1 to Amended and Restated Registration Rights Agreement by and among Corcept Therapeutics Incorporated and certain holders of preferred stock, dated as of March 16, 2004
10.1 <sup>(3)</sup>	Common Stock Purchase Agreement by and among Corcept Therapeutics Incorporated and each of those persons and entities listed on the Schedule of Purchasers thereto, dated as of March 30, 2007
10.2 <sup>(4)</sup>	Severance and Change in Control Agreement between Corcept Therapeutics Incorporated and Joseph K. Belanoff, M. D., dated July 24, 2007
10.3 <sup>(4)</sup>	Severance and Change in Control Agreement between Corcept Therapeutics Incorporated and Robert L. Roe , M. D., dated July 24, 2007
10.4 <sup>(4)</sup>	Severance and Change in Control Agreement between Corcept Therapeutics Incorporated and Anne M. LeDoux, dated July 24, 2007
10.5 <sup>(4)</sup>	Severance and Change in Control Agreement between Corcept Therapeutics Incorporated and James N. Wilson, dated July 24, 2007
10.6 <sup>(5)</sup>	Common Stock Purchase Agreement by and among Corcept Therapeutics Incorporated and each of those persons and entities listed in the Schedule of Purchasers thereto, dated as of August 16, 2007.
10.7	Form of Indemnification Agreement for directors and officers approved by the Board of Directors on September 24, 2007
31.1	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Joseph K. Belanoff, M.D.
31.2	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Anne M. LeDoux.
32.1	Certification pursuant to 18 U.S.C. Section 1350 of Joseph K. Belanoff, M.D.
32.2	Certification pursuant to 18 U.S.C. Section 1350 of Anne M. LeDoux.

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

<sup>(2)</sup> Incorporated by reference to the Registrants Current Report on Form 8-K filed September 27, 2007.

<sup>(3)</sup> Incorporated by reference to the Registrant's Current Report on Form 8-K filed on April 3, 2007.

<sup>(4)</sup> Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, which was filed with the SEC on August 14, 2007.

<sup>(5)</sup> Incorporated by reference to the Registrant's Current Report on Form 8-K filed August 21, 2007.



**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: November 14, 2007

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

**Chief Executive Officer**

Date: November 14, 2007

*/s/ Anne M. LeDoux*  
**Anne M. LeDoux**

**Vice President and Controller**

**(Principal Accounting Officer)**

**Table of Contents**

**Exhibit Index**

<b>Exhibit Number</b>	<b>Description of Document</b>
3.1 <sup>(1)</sup>	Amended and Restated Certificate of Incorporation
3.2 <sup>(2)</sup>	Amended and Restated Bylaws
4.1 <sup>(1)</sup>	Specimen Common Stock Certificate
4.2 <sup>(1)</sup>	Amended and Restated Registration Rights Agreement by and among Corcept Therapeutics Incorporated and certain holders of preferred stock, dated as of May 8, 2001
4.3 <sup>(1)</sup>	Amendment No. 1 to Amended and Restated Registration Rights Agreement by and among Corcept Therapeutics Incorporated and certain holders of preferred stock, dated as of March 16, 2004
10.1 <sup>(3)</sup>	Common Stock Purchase Agreement by and among Corcept Therapeutics Incorporated and each of those persons and entities listed on the Schedule of Purchasers thereto, dated as of March 30, 2007
10.2 <sup>(4)</sup>	Severance and Change in Control Agreement between Corcept Therapeutics Incorporated and Joseph K. Belanoff, M. D., dated July 24, 2007
10.3 <sup>(4)</sup>	Severance and Change in Control Agreement between Corcept Therapeutics Incorporated and Robert L. Roe , M. D., dated July 24, 2007
10.4 <sup>(4)</sup>	Severance and Change in Control Agreement between Corcept Therapeutics Incorporated and Anne M. LeDoux, dated July 24, 2007
10.5 <sup>(4)</sup>	Severance and Change in Control Agreement between Corcept Therapeutics Incorporated and James N. Wilson, dated July 24, 2007
10.6 <sup>(5)</sup>	Common Stock Purchase Agreement by and among Corcept Therapeutics Incorporated and each of those persons and entities listed in the Schedule of Purchasers thereto, dated as of August 16, 2007.
10.7	Form of Indemnification Agreement for directors and officers approved by the Board of Directors on September 24, 2007.
31.1	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Joseph K. Belanoff, M.D.
31.2	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Anne M. LeDoux.
32.1	Certification pursuant to 18 U.S.C. Section 1350 of Joseph K. Belanoff, M.D.
32.2	Certification pursuant to 18 U.S.C. Section 1350 of Anne M. LeDoux.

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

(2) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on September 27, 2007.

(3) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on April 3, 2007.

(4) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, which was filed with the SEC on August 14, 2007.



<sup>(5)</sup> Incorporated by reference to the Registrant's Current Report on Form 8-K filed August 21, 2007.