CORCEPT THERAPEUTICS INC
Form 10-Q
November 12, 2009
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UNITED STATES

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, 2009

or

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

Commission File Number:

000-50679

CORCEPT THERAPEUTICS INCORPORATED

(Exact Name of Corporation as Specified in Its Charter)

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

149 Commonwealth Drive

Menlo Park, CA 94025

(Address of principal executive offices, including zip code)

(650) 327-3270

(Registrant s telephone number, including area code)

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

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

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

Large Accelerated Filer ¨	Accelerated Filer ¨
Non-accelerated filer ¨ (Do not complete if a smaller reporting company)	Smaller Reporting Company x

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

On November 6, 2009 there were 62,474,686 shares of common stock outstanding at a par value $.001 per share.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended and should be read in conjunction with the Risk Factors section of this Form 10-Q. All statements contained in this Form 10-Q other than statements of historical fact are forward-looking statements. When used in this report or elsewhere by management from time to time, the words believe, anticipate, intend, plan, estimate, expect, may, will, should, seeks and similar expressions are forward-looking statements. Such forward-looking statements are based on current expectations, but the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements may include, but are not limited to, statements about:

- *the progress and timing of our research, development and clinical programs and the timing of regulatory activities;*
- *the timing of the market introduction of CORLUX® and future product candidates, including CORT 108297;*
- *estimates of the dates by which we expect to report results of our clinical trials and the anticipated results of these trials;*
- *our ability to market, commercialize and achieve market acceptance for CORLUX or other future product candidates;*
- *uncertainties associated with obtaining and enforcing patents;*
- *our estimates for future performance; and*
- *our estimates regarding our capital requirements and our needs for, and ability to obtain, additional financing.*

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

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS (UNAUDITED)

CORCEPT THERAPEUTICS INCORPORATED

(A DEVELOPMENT STAGE COMPANY)

CONDENSED BALANCE SHEETS

(In thousands)

	September 30, 2009 (Unaudited)	December 31, 2008 (See Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 10,716	$ 14,716
Short-term investments		3,593
Prepaid expenses and other current assets	686	1,270
Total current assets	11,402	19,579
Property and equipment, net of accumulated depreciation	12	20
Other assets	206	176
Total assets	$ 11,620	$ 19,775
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 892	$ 1,304
Accrued clinical expenses	955	989
Accrued compensation	214	243
Obligations under capital lease, short-term	9	10
Other accrued liabilities	288	316
Total current liabilities	2,358	2,862
Obligations under capital lease, long-term		6
Commitments		
Stockholders equity:		
Preferred stock		
Common stock	50	50
Additional paid-in capital	154,381	153,031
Notes receivable from stockholders	(101)	(6,101)
Deficit accumulated during the development stage	(145,068)	(130,072)
Accumulated other comprehensive income		(1)
Total stockholders equity	9,262	16,907
Total liabilities and stockholders equity	$ 11,620	$ 19,775

See accompanying notes.

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CORCEPT THERAPEUTICS INCORPORATED

(A DEVELOPMENT STAGE COMPANY)

CONDENSED STATEMENTS OF OPERATIONS

(Unaudited)

(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from inception (May 13, 1998) to September 30, 2009
	2009	2008	2009	2008	
Collaboration revenue	$	$ 66	$ 29	$ 66	$ 1,014
Operating expenses:					
Research and development*	3,127	3,300	10,653	9,426	110,462
General and administrative*	1,543	1,668	4,463	4,312	39,348
Total operating expenses	4,670	4,968	15,116	13,738	149,810
Loss from operations	(4,670)	(4,902)	(15,087)	(13,672)	(148,796)
Interest and other income, net	4	291	97	747	5,322
Other expense	(2)	(954)	(6)	(965)	(1,594)
Net loss	$ (4,668)	$ (5,565)	$ (14,996)	$ (13,890)	$ (145,068)
Basic and diluted net loss per share	$ (0.09)	$ (0.11)	$ (0.30)	$ (0.30)	
Weighted average shares outstanding used in computing basic and diluted net loss per share	49,765	48,754	49,764	45,831	

* Includes non-cash stock-based compensation consisting of the following:

Research and development	$ 66	$ 70	$ 198	$ 202	$ 5,211
General and administrative	399	328	1,158	1,022	9,167
Total non-cash stock-based compensation	$ 465	$ 398	$ 1,356	$ 1,224	$ 14,378

See accompanying notes.

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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, 2009
	2009	2008	
Operating activities			
Net loss	$ (14,996)	$ (13,890)	$ (145,068)
Adjustments to reconcile net loss to net cash used in operations:			
Depreciation and amortization of property and equipment	8	10	108
Expense related to stock options, net of reversals	1,339	1,220	14,003
Expense related to stock issued for services or in conjunction with license agreement	11	4	90
Expense related to stock issued below fair value			522
Interest accrued on convertible promissory note			104
Settlement of liquidated damages in stock			1,281
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	584	(1,400)	(686)
Other assets	(30)	(107)	(206)
Accounts payable	(412)	(112)	892
Accrued clinical	(34)	(98)	955
Other liabilities	(57)	505	502
Net cash used in operating activities	(13,587)	(13,868)	(127,503)
Investing activities			
Purchases of property and equipment			(61)
Purchases of short-term and long-term investments		(6,532)	(118,320)
Maturities of short-term investments	3,594	5,930	118,320
Net cash provided by (used in) investing activities	3,594	(602)	(61)
Financing activities			
Proceeds from issuance of common stock and warrants, including collection of notes receivable, net of issuance costs	6,000	19,361	96,409
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		6	
Principal payments of obligations under capital leases	(7)	(10)	(50)
Net cash provided by financing activities	5,993	19,357	138,280

Net increase (decrease) in cash and cash equivalents	(4,000)	4,887	10,716
Cash and cash equivalents, at beginning of period	14,716	11,433	
Cash and cash equivalents, at end of period	$ 10,716	$ 16,320	$ 10,716

See accompanying notes.

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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, Corcept, we, our, or it) was incorporated in the state of Delaware on May 13, 1998, and it facilities are located in Menlo Park, California. Corcept is a pharmaceutical company engaged in the discovery and development of drugs for the treatment of severe metabolic and psychiatric 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, 2009, statements of operations for the three- and nine-month periods ended September 30, 2009 and 2008, and statements of cash flows for the nine-month periods ended September 30, 2009 and 2008 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, 2009 are not necessarily indicative of the results that may be expected for the year ending December 31, 2009 or any other period. These financial statements and notes should be read in conjunction with the financial statements for the year ended December 31, 2008 included in the Company s Annual Report on Form 10-K. The accompanying balance sheet as of December 31, 2008 has been derived from audited financial statements at that date. The Company has evaluated subsequent events through the time of filing this Form 10-Q on November 12, 2009, which is the date that these financial statements have been filed with the Securities and Exchange Commission (SEC). No material subsequent events have occurred since September 30, 2009 that required recognition or disclosure in these financial statements, except for the items disclosed in footnote 10 Subsequent Events.

Management Plans Regarding 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. We plan to continue to finance our operations through the sale of our equity and/or the issuance of debt or by engaging in strategic relationships with potential partners. 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. Our ability to continue our operations through the complete development and commercialization of our products is dependent upon the successful execution of our financing and/or any partnership strategies. Our most advanced programs are the two Phase 3 trials of CORLUX in Cushing s Syndrome and in psychotic depression.

As reflected in the accompanying financial statements as of September 30, 2009, we had cash, cash equivalents and investments balances of $10.7 million, working capital of $9.0 million and an accumulated deficit of $145.1 million. In October, we sold shares of our common stock and warrants, in a private placement, for gross proceeds of approximately $18.0 million. An additional $250,000 in proceeds was raised in late October 2009 under our Committed Equity Financing Facility (CEFF) with Kingsbridge. Following these financings, management believes that the Company has sufficient funds to maintain our operations through the end of 2010, including the completion of our Phase 3 trial in Cushing s Syndrome, the submission of our New Drug Application (NDA) for the use of CORLUX in Cushing s Syndrome, the continuation of enrollment in our Phase 3 trial in psychotic depression, and the filing of an Investigational New Drug Application (IND) for CORT 108297, one of our proprietary, selective GR-II antagonists.

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.

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CORCEPT THERAPEUTICS INCORPORATED

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS, Continued

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. The estimates are updated on a recurring basis as new information becomes available.

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

Cash, Cash Equivalents and Short-term Investments

The Company invests its excess cash in bank deposits, money market funds maintained at major U.S. financial institutions, commercial paper and corporate debt securities issued by major corporations with high credit ratings from the major rating services, and obligations of the U.S. government and U.S. government sponsored entities. The Company considers all highly liquid investments purchased with maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents and short-term investments are carried at fair value.

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

Fair Value Measurements

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

The Company has determined that there were no nonfinancial assets or nonfinancial liabilities that required measurement at fair value.

Revenue Recognition

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

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CORCEPT THERAPEUTICS INCORPORATED

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS, Continued

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, and manufacturing development. Such costs are expensed as services are performed. 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.

Recently Issued Accounting Standards

In May 2009, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 165, *Subsequent Events* (SFAS No. 165). This standard, which is covered in Topic 855 of the Accounting Standards Codification discussed below, is intended to establish general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. Specifically, this standard sets forth the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements, the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements, and the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. We began applying the provisions of SFAS No. 165 in the second quarter of 2009 and its adoption did not affect our financial statements, other than the disclosures required by SFAS No. 165.

In June 2009, the FASB issued SFAS No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepting Accounting Principles A Replacement of FASB Statement No. 162* (SFAS 168) that established the FASB Accounting Standards Codification (ASC) , which was launched on July 1, 2009, as the single source of authoritative nongovernmental U.S. GAAP. The ASC did not change U.S. GAAP, but is intended to simplify user access to all authoritative U.S. GAAP by providing all the authoritative literature related to a particular topic in one place. Rules and interpretive releases of the Securities and Exchange Commission (SEC) under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. On the effective date of this Statement, the ASC superseded all then existing accounting and reporting standard documents. All other non-grandfathered non-SEC accounting literature not included in the ASC became non-authoritative. The ASC is effective for interim and annual periods ending after September 15, 2009. The Company adopted this guidance in the third quarter of 2009; the adoption did not have an impact on our financial condition or results of operations.

In October 2009, FASB adopted Update 2009-13 *Multiple-Deliverable Revenue Arrangements,* which is an update to ASC Topic 650 *Revenue Recognition.* ASU 2009-13 eliminates the residual method of allocation and the requirement to use the relative selling price method when allocating revenue in a multiple deliverable arrangement. When applying the relative selling price method, the selling price for each deliverable shall be determined using vendor specific objective evidence of selling price, if it exists, otherwise third-party evidence of selling price. If neither vendor specific objective evidence nor third-party evidence of selling price exists for a deliverable, the vendor shall use its best estimate of the selling price for that deliverable when applying the relative selling price method. ASU 2009-13 is to be applied on a prospective basis for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, with earlier application permitted. The adoption of ASU 2009-13 is not expected to have an impact on our financial statements as we currently have no such arrangements.

In September 2009, the EITF discussed Issue No. 08-9, *Milestone Method of Revenue Recognition*. Under the milestone method, the additional consideration earned from achievement of the milestone is viewed as being indicative of the value provided to the customer through either (a) the efforts performed by the vendor or (b) a specific outcome resulting from the vendor s performance to achieve that specific milestone. Under the milestone method an entity recognizes contingent arrangement consideration earned from the achievement of a milestone in its entirety in the period in which the milestone is achieved. The proposed model requires that a milestone be substantive before this method can be applied; that is, there is a substantial uncertainty about the achievement of the milestone, substantive effort is required to achieve the milestone, and none of the payment for the milestone is refundable. The EITF did not reach a consensus on this issue. The task force will continue deliberations on this issue at future meetings. The adoption of such a standard is not expected to have an impact on our financial statements as we currently have no such arrangements.

On September 30, 2009, FASB issued Proposed Accounting Standards Update EITF09-2 Research and Development (Topic 730): *Research and Development Assets Acquired In an Asset Acquisition*. As a result of the amendments in this

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CORCEPT THERAPEUTICS INCORPORATED

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NOTES TO CONDENSED FINANCIAL STATEMENTS, Continued

proposed Update, all tangible and intangible research and development assets acquired in an asset acquisition shall be capitalized regardless of whether those assets have a future alternative use. Acquired intangible research and development assets would be considered indefinite-lived assets until completion or abandonment of the related research and development activities. Once the research and development efforts are completed or abandoned, the entity would determine the useful lives of the assets. In addition, any contingent consideration arrangements related to the acquisition of an asset group (regardless of whether the asset group includes research and development assets) would continue to be accounted for in accordance with existing U.S. generally accepted accounting principles. Comments on this exposure draft were to have been received by October 24, 2009. If adopted, the amendments in this proposed Update would be effective for acquisitions of assets occurring in fiscal years beginning on or after December 15, 2009. The amendments would be applied on a prospective basis. Earlier application is not permitted. The adoption of such a standard is not expected to have an impact on our financial statements as we currently have no such arrangements.

2. Fair Value

As of September 30, 2009, our financial assets were invested in a money market fund, which can be converted to cash at par on demand. These funds, which totaled $10.4 million, were measured at fair value as of September 30, 2009 and were classified as Level 1 assets in the fair value hierarchy for financial assets.

All cash equivalents held as of September 30, 2009 were in active markets and there are no Level 2 or Level 3 financial assets or liabilities.

3. Financial Instruments

All cash, cash equivalents and investments were classified as available-for-sale securities as of September 30, 2009 and December 31, 2008. The following table provides summary of cash, cash equivalents and short-term investments as of those dates. All figures are in thousands.

September 30, 2009	Cost	Unrealized Gain	Unrealized Loss	Fair Value
Cash	$ 339	$	$	$ 339
Money market funds	10,377			10,377
	$ 10,716	$	$	$ 10,716
Reported as Cash and cash equivalents	$ 10,716	$	$	$ 10,716

December 31, 2008	Cost	Unrealized Gain	Unrealized Loss	Fair Value
Cash	$ 1,434	$	$	$ 1,434
Money market funds	13,282			13,282
Commercial paper	1,390	2		1,392
Corporate debt securities	2,204		(3)	2,201
	$ 18,310	$ 2	$ (3)	$ 18,309

Reported as:				
Cash and cash equivalents	$ 14,716	$	$	$ 14,716
Short-term investments	3,594	2	(3)	3,593
	$ 18,310	$ 2	$ (3)	$ 18,309

As of September 30, 2009 and December 31, 2008, there were no mortgage-backed securities and no auction rate securities in the portfolio.

All short-term investments at December 31, 2008 had remaining maturities of less than one year and matured in the normal course of time with no realized gain or loss.

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CORCEPT THERAPEUTICS INCORPORATED

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS, Continued

The net realized loss on sales of available-for-sales investments was not material for any period presented. Realized gains and losses are calculated based on the specific identification method.

4. Other Accrued Liabilities

Other Accrued Liabilities includes the following (in thousands):

	September 30, 2009	December 31, 2008
Professional fees	$ 194	$ 145
Legal fees	75	149
Other	19	22
Total	$ 288	$ 316

5. Commitments

On January 15, 2009, we signed an agreement for the manufacture of materials and pre-clinical testing in regard to our selective GR-II antagonist, CORT 108297, for a commitment of approximately $835,000, which is expected to be expended during 2009.

In June 2009, we amended our agreements with two vendors that are providing services in connection with our ongoing Phase 3 clinical trial in psychotic depression to reduce the amounts of commitments under these agreements by approximately $5.0 million in accordance with the reduction in the near-term scope of activities in this trial. However, we view the reduction in these commitments as a temporary measure as it is our intent to continue the conduct of this trial to its conclusion, assuming the availability of sufficient capital for this purpose.

See footnote 10 Subsequent Event for a discussion of additional commitments for two NDA-supportive studies signed in October 2009.

6. Capital Stock and Stock Note Receivable

On February 6, 2009, we collected the note receivable of $6.0 million that had been issued in connection with the private equity financing in March 2008. The note was collected in full, including all accrued interest to that date and expenses associated with the note. Upon receipt of the funds, we released our interest in the collateral that had been held as security for the note.

See footnote 10 Subsequent Event for a discussion of sales of shares of the Company s common stock and warrants in October 2009.

7. Stock Option Plans

Effective January 1, 2009, the Board of Directors authorized an increase of 995,264 shares in the shares available under the 2004 Equity Incentive Plan (the 2004 Plan), which amount was based on 2% of the shares of the Company s common stock outstanding as of December 31, 2008 pursuant to the terms of the 2004 Plan. In addition, on March 26, 2009, the Board approved an amendment to the 2004 Plan, which was approved by the Company s stockholders on June 11, 2009 at the 2009 Annual Meeting of stockholders, to 1) add 1,000,000 to the shares available and 2) to allow increases to the number of available shares on January 1, 2010 and each January 1 thereafter for 4 more years, by the least of (a) 4% of the number of common shares issued and outstanding on the immediately preceding December 31, (b) 4,000,000 shares and (c) a number of shares set by the Board.

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CORCEPT THERAPEUTICS INCORPORATED

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS, Continued

8. 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 September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Net loss as reported	$ (4,668)	$ (5,565)	$ (14,996)	$ (13,890)
Change in unrealized gain		(28)	1	(31)
Comprehensive net loss	$ (4,668)	$ (5,593)	$ (14,995)	$ (13,921)

9. Net Loss Per Share

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

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

	September 30,	
	2009	2008
Warrants outstanding	4,792	4,792
Stock options outstanding	6,946	4,332
Total	11,738	9,124

See footnote 10 Subsequent Event for a discussion of sales of shares of the Company s common stock and warrants in October 2009, which will dilute the per share data in the future.

10. Subsequent Event

In October 2009, the Company sold, in a private placement, approximately 12.6 million shares of its common stock and warrants to purchase approximately 4.4 million shares of its common stock. The securities were sold at a price of $1.43 per unit , which consisted of one share of common stock and a warrant to purchase 0.35 shares of common stock (the October 2009 Financing). The warrants have a three year term and an exercise price of $1.66 per share. The October 2009 Financing generated gross proceeds of approximately $18.0 million, before the deduction of issuance costs of approximately $700,000.

In late October 2009, we also sold 102,149 shares of common stock to Kingsbridge under the Committed Equity Financing Facility (CEFF) at an average price of $2.45 per share, for proceeds of $250,000.

In October 2009, we signed agreements with a contract research organization for the conduct of two of the NDA-supportive studies for aggregate commitments of approximately $1.0 million, the majority of which will be expended during remainder of 2009.

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ITEM 2.

MANAGEMENT S DISCUSSION AND ANALYSIS OF

FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

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

Cushing s Syndrome

Cushing s Syndrome is a disorder caused by prolonged exposure of the body s tissues to high levels of the hormone cortisol. Sometimes called hypercortisolism, it is relatively uncommon and most often affects adults aged 20 to 50. An estimated 10 to 15 of every one million people are newly diagnosed with this syndrome each year, approximately 3,000 new patients in the United States. This results in an estimated prevalence of 20,000 patients with Cushing s Syndrome in the United States (U.S.)

The Investigational New Drug application (IND) for the evaluation of CORLUX for the treatment of Cushing s Syndrome was opened in September 2007. The United States Food and Drug Administration (FDA) has indicated that our single 50-patient open-label study may provide a reasonable basis for the submission of a New Drug Application (NDA) for this indication. This trial was opened for enrollment in December 2007. Our goal is the completion of enrollment by the end of 2009. We expect to have accumulated a full data set on all 50 patients by mid-2010 and plan to submit our NDA by year-end 2010.

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

Psychotic Depression

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

In March of 2008, we commenced enrollment in Study 14, our ongoing Phase 3 trial in psychotic depression. The protocol for this trial incorporates what we have learned from our three previously completed Phase 3 trials to address the established relationship between increased drug plasma levels and clinical response and attempts to decrease the random variability observed in the results of the psychometric instruments used to measure efficacy. In one of the previously completed Phase 3 trials, Study 06, we prospectively tested and confirmed that patients whose plasma levels rose above a predetermined threshold statistically separated from both those patients whose plasma levels were below the threshold and those patients who received placebo; this threshold was established from data produced in earlier studies. As expected, patients who took 1200 mg of CORLUX in Study 06 developed higher drug plasma levels than patients who received lower doses. Further, there was no discernable difference in the incidence of adverse events between placebo and any of the three CORLUX dose groups in Study 06. Based on this information, we are using a CORLUX dose of 1200 mg once per day for seven days in Study 14. In addition, we also are utilizing a third party centralized rating service to independently evaluate the patients for entry into the study as well as for their level of response. We believe the centralization of this process will improve the consistency of rating across clinical trial sites and reduce the background noise that was illustrated in earlier studies and is endemic to many psychopharmacologic studies. We believe that this change in dose, as well as the other modifications to the protocol, should allow us to demonstrate the efficacy of CORLUX in the treatment of the psychotic symptoms of psychotic depression. In March 2009, we announced that, in order to conserve financial resources, we were scaling back our planned rate of spending on this trial and extended the timeline for its completion. As of early July 2009, we completed the implementation of this strategy, which included reducing the number of clinical sites to eight.

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Management of Weight Gain Induced by Antipsychotics

In 2005, we published the results of studies in rats that demonstrated that CORLUX both reduced the weight gain associated with the ongoing use of olanzapine and mitigated the weight gain associated with the initiation of treatment with olanzapine (the active ingredient in Zyprexa). This study was paid for by Eli Lilly and Company (Lilly).

During 2007 we announced positive results from our clinical proof-of-concept study in lean healthy male volunteers evaluating the ability of CORLUX to mitigate weight gain associated with the use of Zyprexa. The results show a statistically significant reduction in weight gain in those subjects who took Zyprexa plus CORLUX compared to those who took Zyprexa alone. Also, the addition of CORLUX to treatment with Zyprexa had a beneficial impact on secondary metabolic measures such as fasting insulin, and triglycerides and abdominal fat, as indicated by waist circumference. Lilly provided Zyprexa and financial support for this study. In January 2009 we announced positive results from a similar proof-of-concept study evaluating the ability of CORLUX to mitigate weight gain associated with the use of Johnson & Johnson s Risperdal. This study, which began in 2008, confirmed the earlier results seen with CORLUX and Zyprexa, demonstrating a statistically significant reduction in weight and secondary metabolic endpoints of fasting insulin, triglycerides and abdominal fat, as indicated by waist circumference. The results from the study of CORLUX and Risperdal were presented at several scientific conferences, including the American Diabetes Association meeting in June 2009.

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

Research

In early 2003, we initiated a discovery research program to identify and patent selective GR-II antagonists to develop a pipeline of products for proprietary use. Three distinct series of GR-II antagonists were identified. These compounds appear to be as potent as our lead product CORLUX in blocking cortisol but, unlike CORLUX, they do not appear to block the PR (progesterone), ER (estrogen), AR (androgen) or GR-I (mineralocorticoid) receptors. Composition of matter patents on two of the three series have been granted, or are in condition for grant, in Europe. The patent on one series has issued in the U.S. Substantive prosecution of the application has occurred in another of the series and is moving toward allowance. Examination has not yet begun in the U.S. on the third.

New Chemical Entity CORT 108297

In 2007, we commenced a human microdosing study of one of our newly identified selective GR-II antagonists, CORT 108297, with Xceleron Limited utilizing their Accelerator Mass Spectrometry technology. In this microdosing study, we evaluated CORT 108297, a compound which develops particularly high plasma and brain concentrations in an animal model. On May 1, 2008, we announced the results from this study, which demonstrated that CORT 108297 was extremely well absorbed, demonstrated good bioavailability and had a half-life that appears compatible with once-a-day oral dosing. In addition, further pharmacokinetic testing of CORT 108297 in a rat model indicated that a ten-fold increase in oral dose (5 milligrams per kilograms to 50 milligrams per kilograms) led to a proportional increase in the amount of compound detected in plasma.

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

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

The manufacturing and pre-clinical development of CORT 108297 began late in 2008 and continues through 2009 as preparatory steps to the submission of an IND with the FDA, which we expect to submit by the end of 2009.

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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 and common stock and the public sale of common stock rather than through collaborative or partnership agreements. Therefore, we have no research funding or collaborative payments payable to us, except for the limited revenue that has been collected under the agreements with Lilly discussed above.

We are in the development stage and have incurred significant losses since our inception. We have not generated any revenue other than the revenue under the agreements with Lilly, and do not expect to generate significant revenue for the next few years. As of September 30, 2009, we had an accumulated deficit of $145.1 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 manufacturing set-up, the lengthy and expensive regulatory approval process and competition from other products. Our ability to successfully generate revenues in the foreseeable future is dependent upon our ability, alone or with others, to finance our operations and develop, obtain regulatory approval for, manufacture and market our lead product.

Results of Operations

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

No revenue was recognized under the agreements during the three-month period ended September 30, 2009; approximately $29,000 of revenue was recognized during the nine-month period then ended. During the three and nine-month periods ended September 30, 2008, we recognized approximately $66,000 of revenue. There will be no revenue under the agreements in the future as all activities required by these agreements were completed by mid-2009.

Research and development expenses Research and development expenses include the personnel costs related to our development activities, including facilities costs and non-cash stock-based compensation, as well as the costs of discovery research, pre-clinical activities, clinical trial preparations, enrollment and monitoring expenses, regulatory costs, the costs of manufacturing development and the costs of manufacture and/or acquisition of clinical trial materials.

Research and development expenses decreased 5% to $3.1 million for the three-month period ended September 30, 2009 from $3.3 million for the comparable period in 2008. Compared to the year earlier period, there was a cost increase of approximately $460,000 related to research and

preclinical work with our selective GR-II antagonists, including preparations for the submission of the IND for CORT 108297, expected later this year. There was also a cost increase of approximately $215,000 related to the study of CORLUX for the treatment of Cushing s Syndrome. These were offset by a decrease of approximately $455,000 in clinical trial costs related to our psychotic depression program, as we scaled back our ongoing Phase 3 trial and completed reporting activities for the previous Phase 3 trials. There was a decrease of approximately $240,000 in manufacturing expenses as the year-earlier period included the acquisition and manufacture of the initial supply of materials for the CORLUX clinical trials and completion of certain manufacturing process development activities related to CORLUX. There was also a decrease of approximately $85,000 in consulting expenses.

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For the nine-month period ended September 30, 2009, research and development expenses increased 13% to $10.7 million from $9.4 million for the comparable period in 2008. The increase in expenses reflects increases of approximately $1.4 million in costs related to research and preclinical work with our selective GR-II antagonists, including CORT 108297, $945,000 related to the clinical trials that commenced enrollment during 2008 in Cushing s Syndrome and the mitigation of weight gain caused by Risperdal, $260,000 due to increases in staffing costs and $35,000 of consulting expenses. Offsetting these increases was a decrease in manufacturing expenses related to CORLUX of approximately $1.3 million due to the acquisition and manufacture during 2008 of the initial supply of materials for the CORLUX clinical trials and completion of certain manufacturing process development activities related to CORLUX.

Below is a summary of our research and development expenses by major program. All figures are in thousands.

	Three Months Ended September 30,		Nine Months Ended September 30,	
Program	**2009**	**2008**	**2009**	**2008**
Psychotic Depression	$ 992	$ 1,620	$ 4,094	$ 4,330
Cushing s Syndrome	720	410	2,103	1,051
Weight Gain Mitigation	(12)	251	563	651
Other research on selective GR-II antagonists	1,025	473	3,057	1,578
Unallocated manufacturing, regulatory, pre-clinical activities	336	476	638	1,614
Stock-based compensation	66	70	198	202
Total research and development expense	$ 3,127	$ 3,300	$ 10,653	$ 9,426

We expect that research and development expenditures will decrease slightly during the fourth quarter of 2009 as compared to the same period in 2008 as increases in the costs associated with the continued development of our proprietary selective GR-II antagonists and the continuation of our Phase 3 study in Cushing s Syndrome will be more than offset by decreases in the costs of our psychotic depression program due to the previously announced scaling back of resources devoted to our ongoing Phase 3 study, including reducing the number of clinical sites to eight. During the fourth quarter of 2009, research and development expenditures will also decrease compared to the same quarter of 2008, due to the completion of our proof-of-concept weight gain mitigation study of CORLUX in combination with Risperdal, which contributed to costs in the fourth quarter of 2008. Research and development expenses in 2010 and future years will be largely dependent on the availability of additional funds to finance clinical development plans. See also, Liquidity and Capital Resources .

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

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

General and administrative expenses decreased 7% to $1.5 million for the three-month period ended September 30, 2009 from $1.7 million for the comparable period in 2008. This change between periods reflects a decrease of approximately $315,000 in legal expenses due primarily to a reduction in patent-related legal costs, which was offset by increases of approximately $105,000 in professional fees and consultancy expenses due primarily to preparations for the initial year of auditor attestation of the effectiveness of our internal controls in accordance with Sarbanes Oxley (SOX) section 404 and an increase of approximately $90,000 in staffing costs due primarily to the recruitment of a new chief financial officer, who commenced work with us in November 2008. Approximately $55,000 of the staffing increase in the third quarter was non-cash stock-based compensation. On October 2, 2009, the SEC announced the deferral of the requirement of auditor attestation for non-accelerated filers, such as Corcept, until fiscal years ending on or after June 15, 2010.

For the nine-month period ended September 30, 2009, general and administrative expenses increased 4% to $4.5 million from $4.3 million for the nine-month period ended September 30, 2008. This increase reflects higher staffing costs of approximately $320,000, due primarily to the recruitment of our new chief financial officer. The increase in staffing costs in the year-to-date period included a net increase in stock-based compensation of $125,000, which reflects the cost of stock options granted to our new chief financial officer, other employees and directors.

During this period, there were also increases in professional fees and consultancy costs of approximately $200,000, primarily related to the costs associated with periodic filings with the SEC and the preparations for the initial year of auditor attestation under SOX section 404. These increases were offset by a decrease of approximately $415,000 in legal expenses due primarily to the reduction in patent legal costs.

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The amount of general and administrative expenses during the remainder of 2009 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, Liquidity and Capital Resources .

Interest and other income, net Interest and other income, net of investment management fees, was approximately $5,000 and $95,000, respectively, for the three- and nine-month periods ended September 30, 2009, compared to $290,000 and $745,000, respectively, for the comparable periods in 2008. Interest income for the three- and nine-month periods ended September 30, 2008 included approximately $145,000 and $260,000, respectively, that was earned on the note receivable issued in connection with our private placement of our common stock and warrants in March 2008 (the March 2008 Financing), which we collected in February 2009. The remainder of the decrease was attributable to lower yields on the investment portfolio and a lower level of invested funds.

Other expense Other expense was approximately $2,000 and $5,000, respectively for the three- and nine-month periods ended September 30, 2009, compared to $955,000 and $965,000, respectively, for the same periods in 2008. Other expense in 2009 is comprised of interest expense on capitalized leases and state tax on capital, which is based on our projected capital and asset positions as of each year-end. Other expense for the three- and nine-month periods ended September 30, 2008 included approximately $945,000 of liquidated damages incurred related to the March 2008 financing.

Liquidity and Capital Resources

We have incurred operating losses since inception, and at September 30, 2009, we had an accumulated deficit of $145.1 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 February 6, 2009, we collected a note receivable of $6.0 million that had been issued in March 2008 in connection with the March 2008 Financing. The note was collected in full, including all accrued interest to that date and expenses associated with the note.

At September 30, 2009, we had cash, cash equivalents and investments balances of $10.7 million, compared to $18.3 million at December 31, 2008. Net cash used in operating activities for the nine-month period ended September 30, 2009, was approximately $13.6 million, as compared to $13.9 million used in the same period of 2008. The use of cash in each period was primarily a result of our research and development activities and amounts incurred to support our administrative infrastructure. We expect cash used in operating activities during the remainder of 2009 will be approximately the same as during that period of 2008 as the increased spending on the continuation of our Cushing s Syndrome study and the development of our selective GR-II antagonists should be offset by the decreased spending on psychotic depression and weight gain mitigation. We expect our funding requirements for operating activities will increase during later years due to the continuation and expansion of our development programs for Cushing s Syndrome, psychotic depression and our selective GR-II antagonists, research activities, commercialization activities and general and administrative expenses.

On October 16, 2009 we sold common stock and warrants in a private placement generating gross proceeds of approximately $18.0 million. Also, in late October, we sold common stock to Kingsbridge under the CEFF generating an additional $250,000. With the completion of our $18.0 million financing which closed October 16, 2009 and the sales to Kingsbridge, we believe that we have sufficient capital resources to maintain our operations through the end of 2010, including the planned completion of enrollment of our Phase 3 Cushing s Syndrome trial, the continuation of enrollment in our Phase 3 psychotic depression trial, and the submission of an IND for CORT 108297, one of our proprietary, selective GR-II antagonists.

We will have to perform additional clinical trials prior to submission of NDAs for CORLUX for the treatment of Cushing s Syndrome or the psychotic features of psychotic depression. We will need to raise additional funds to prepare for the commercialization of CORLUX for either of these indications and to continue and expand the development of our proprietary selective GR-II antagonists.

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

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In March 2008, we entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge), a private investment group. Under the terms of the agreement, Kingsbridge committed to provide up to $60 million of capital in exchange for newly-issued shares of our common stock for a period of up to three years after the Securities and Exchange Commission declares effective the registration statement filed by us covering the resale of the shares of common stock issuable in connection with the CEFF and the shares of common stock underlying the warrant issued to Kingsbridge. The maximum number of shares that can be sold by us under this agreement is approximately 9.6 million shares. Under the terms of the agreement, the determination of the exact timing and amount of any CEFF financings will be made solely by us, subject to certain conditions. The agreement currently requires a minimum stock price of $1.50 per share to allow us to issue shares to Kingsbridge under the CEFF. Based on the volume weighted average price on the NASDAQ Capital Market for our common stock for the period from March 25, 2008, the date of the signing of the Kingsbridge CEFF, through November 6, 2009, the maximum amount of net proceeds that could be raised under the CEFF is approximately $17 million. Over the 60 trading day period ended November 6, 2009, the price for our common stock on the NASDAQ Capital Market has ranged from $1.00 to $3.10. The actual amount of funds that can be raised under this agreement will be dependent on the number of shares actually sold under the agreement and the market value of our stock during the pricing periods of each sale.

At any point in time we may have approximately $150,000 to $1.5 million in our bank operating account with a third party financial institution. While we monitor the cash balance in our operating account and transfer the funds in only as needed, these cash balances could be impacted if the underlying financial institution were to fail or could be subject to other adverse conditions in the financial markets. On October 23, 2008, the Federal Deposit Insurance Corporation (FDIC) implemented its Temporary Liquidity Guarantee Program. Under this program, non-interest bearing commercial accounts are insured to an unlimited amount through June 30, 2010, thus mitigating our exposure to any possible bank failure. To date, we have experienced no loss or lack of access to cash in our operating accounts.

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

Contractual Obligations and Commercial Commitments

On January 15, 2009, we signed an agreement for the manufacture of materials and pre-clinical testing in regard to our selective GR-II antagonist, CORT 108297, with a commitment of approximately $835,000, which is expected to be expended during 2009.

In June 2009, we amended our agreements with two vendors that are providing services in connection with our ongoing Phase 3 clinical trial in psychotic depression to reduce the amounts of commitments under the agreements with these organizations by approximately $5.0 million in accordance with the reduction in the near-term scope of activities under these trials. However, we view the reduction in these commitments as a temporary measure as it is our intent to continue the conduct of this trial to its conclusion, assuming the availability of sufficient capital for this purpose.

In October 2009, we signed agreements with a contract research organization for the conduct of two of the NDA-supportive studies for aggregate commitments of approximately $1.0 million, the majority of which will be expended during the remainder of 2009.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, with the exception of the operating lease for our office space.

Critical Accounting Policies and Estimates

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the

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carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Our critical accounting policies and estimates are discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008. During the three-month period ended September 30, 2009, we have not made any significant changes to our critical accounting polices and estimates.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Market Risk

The primary objective of our investment activities is to preserve principal. As of September 30, 2009, our cash and cash equivalents consisted of money market funds maintained at major U.S. financial institutions. To minimize our exposure to interest rate 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 impact on the total value of our portfolio as of September 30, 2009.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Exchange Act. Based on their evaluation as of September 30, 2009, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective in reaching a reasonable level of assurance that the information required to be disclosed by us in this Quarterly Report on Form 10-Q was 1) recorded, processed, summarized and reported within the time periods specified in the SEC s rules and Form 10-Q and 2) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met.

Changes in internal controls. There were no changes in our internal control over financial reporting during the quarter ended September 30, 2009, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently involved in any material legal proceedings.

ITEM 1A. RISK FACTORS

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

Risks Related to Our Business

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

We have invested a significant portion of our time and financial resources since our inception in the development of CORLUX for the treatment of the psychotic features of psychotic depression and, more recently, for the treatment of Cushing s Syndrome. We currently do not have any commercial products and we anticipate that for the foreseeable future our ability to generate meaningful revenues and achieve profitability will be solely dependent on the successful development, approval and commercialization of CORLUX for the treatment of Cushing s Syndrome or for the psychotic features of psychotic depression. We are conducting a single Phase 3 trial in Cushing s Syndrome. Neither we, nor anyone else, have completed a clinical trial in Cushing s Syndrome. We have completed three Phase 3 clinical trials evaluating CORLUX for psychotic depression. None of these trials met its primary or key secondary endpoints; we have begun a fourth Phase 3 trial in this indication. 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 Cushing s Syndrome or for the treatment of the psychotic features of psychotic depression;

an inability to manufacture CORLUX or the active ingredient in CORLUX in commercial quantities and at an acceptable cost; 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 Cushing s Syndrome, for the treatment of the psychotic features of psychotic depression or for any other indications does not demonstrate safety and efficacy, our business will be harmed.

To gain regulatory approval from the FDA to market CORLUX, our Phase 3 clinical trials must demonstrate the safety and efficacy of CORLUX for the particular indication. Our first three Phase 3 studies evaluating CORLUX for the treatment of the psychotic features of psychotic depression did not meet their primary or key secondary endpoints. In addition to the ongoing Phase 3 clinical trials of CORLUX for the treatment of Cushing s Syndrome and for the treatment of the psychotic features of psychotic

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depression, we will need to conduct other studies in support of a potential NDA. Clinical development is a long, expensive and uncertain process and is subject to delays, and data obtained from clinical trials and supportive studies are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. While we obtained favorable results in our Phase 2 clinical trials in psychotic depression, these results were not replicated in a robust enough way in our completed Phase 3 clinical trials and are not sufficient to use by themselves as the pivotal clinical trials in an application for FDA approval of this indication. In addition, we cannot assure you that supportive studies and tests will produce favorable results.

Although our pivotal Phase 3 clinical trial in Cushing s Syndrome only requires 50 patients, both site selection and enrollment could be an extended process. Delays in selection and initiation of clinical trial sites and/or patient enrollment could extend the time and cost for completion of the trial.

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

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

Any delays in the process of identifying and recruiting the clinical sites or identifying and screening the patients for enrollment in the study could delay the completion of the study or increase the cost.

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

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 previously completed Phase 3 trials evaluating CORLUX for treatment of the psychotic features of psychotic depression did not meet their primary endpoints, the FDA is requiring us to pursue at least one additional clinical trial to demonstrate the safety and/or efficacy of CORLUX for this indication. The FDA generally requires two positive Phase 3 studies or one positive Phase 3 study with other supportive data to be completed prior to the submission of an NDA.

Further, we may decide, or the FDA or other regulatory authorities may require us, to pursue additional clinical, pre-clinical or manufacturing studies to satisfactorily complete our NDA. For example, the FDA may require us to perform a bioequivalance study comparing our recently reformulated CORLUX clinical trial materials to the materials used in our earlier clinical trials. Additional trials or studies will require additional funding which is not assured. Also, it is possible that additional trials or studies that we decide are necessary or desirable will delay or prevent the completion of the development of CORLUX for treating Cushing s Syndrome or the psychotic features of psychotic depression. We anticipate continued dialogue with the FDA to define any additional data needed to complete an NDA.

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;

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

real or perceived lack of effectiveness or safety of CORLUX.

Even after we conduct all of the clinical trials and supportive studies that we consider appropriate for an optimal NDA, we may not receive regulatory approval to market CORLUX.

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We will need additional capital in order to complete the development and commercialization of CORLUX and our other proprietary, selective GR-II antagonists. Additional capital may not be available to us at all or on favorable terms.

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

We anticipate that our existing capital resources will be sufficient to fund our current operating plan through the end of 2010. However, our expectations are based on our currently planned clinical development and research programs for CORLUX and for certain of our proprietary, selective GR-II antagonists, which may change as a result of many factors, including:

- the costs, timing of site selection and enrollment of our clinical trials;
- the results of our research efforts and clinical trials;
- the need to perform additional clinical trials and other supportive studies;
- the need to establish a second source for CORLUX tableting;
- the timing of the approval by the FDA, if any, to market CORLUX for the treatment of Cushing s Syndrome or for the treatment of the psychotic features of psychotic depression;
- developments or disputes concerning patents or proprietary rights, including announcements of claims of infringement, interference or litigation against us or our licensors;
- actual or anticipated fluctuations in our operating results;
- changes in our growth rates;
- changes in our research development plans for our proprietary, selective GR-II antagonists;
- the timing of commercialization of CORLUX and future product candidates; and
- changes in the reimbursement policies of third-party insurance companies or government agencies.

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

We cannot be certain that additional funding will be available on acceptable terms or at all. Even though we raised approximately $18.0 million in October 2009, through a private placement of our common stock and warrants, and an additional $250,000 in late October under our CEFF

with Kingsbridge, market and economic conditions may make it difficult for us to raise any additional capital. The sale of common stock and warrants during the fourth quarter of 2009 has been dilutive to stockholders and any exercise of outstanding warrants and additional equity financing could cause further dilution to stockholders. Debt financing, if available, may involve restrictive covenants. If we obtain funds through collaborations with others, these arrangements may be on unfavorable terms or may require us to relinquish certain rights to our technologies or product candidates, including potentially our lead product candidate that we would otherwise seek to develop on our own. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or we may be required to discontinue operations.

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

Kingsbridge will not be obligated to purchase shares under the CEFF unless certain conditions are met, which include a minimum price for our common stock, currently set at $1.50 per share; the accuracy of representations and warranties made to Kingsbridge; compliance with laws; the effectiveness and continued effectiveness of the resale registration statement; and the continued listing of our stock on the Nasdaq Capital Market. Over the 60 trading day period ended November 6, 2009, the price for our common stock on the NASDAQ Capital Market has ranged from $1.00 to $3.10. The actual amount of funds that can be raised under this agreement will be dependent on the number of shares actually sold under the agreement and the market value of our stock during the pricing periods of each sale.

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On June 10, 2008, the SEC declared effective our registration statement with the SEC covering the resale of approximately 3.6 million of the shares issuable under the CEFF and the shares issuable upon the exercise of the warrant issued to Kingsbridge. This registration statement covers approximately 37% of the 9.6 million shares of our common stock issuable pursuant to the CEFF and all of the 330,000 shares of our common stock issuable upon exercise of the warrant issued to Kingsbridge.

We intend to file additional registration statements covering the resale of additional shares of our common stock issuable pursuant to the CEFF beginning on the later of 60 days after Kingsbridge and its affiliates have resold substantially all of the securities registered for sale under this initial registration statement or six months after the effective date of this registration statement. These subsequent registration statements are subject to our ability to prepare and file them and may be subject to review and comment by the Staff of the SEC, as well as consent by our independent registered accounting firm. Therefore, the timing of these subsequent registration statements becoming effective cannot be assured. The effectiveness of these subsequent registration statements is a condition precedent to our ability to sell the shares of common stock subject to these subsequent registration statements to Kingsbridge under the CEFF. We cannot assure you that these registration statements will be declared effective or, if declared effective, that they will remain continuously effective thereafter.

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

We are entitled in certain circumstances, to deliver a blackout notice to Kingsbridge to suspend the use of the resale registration statement and prohibit Kingsbridge from selling shares thereunder. If we deliver a blackout notice in the 15 trading days following the settlement of a draw down, or if the resale registration statement is not effective in circumstances not permitted by our agreement with Kingsbridge, then we must make a payment to Kingsbridge, or issue Kingsbridge additional shares in lieu of the payment, calculated on the basis of the number of shares held by Kingsbridge (exclusive of shares that Kingsbridge may hold pursuant to exercise of the Kingsbridge warrant) and the change in the market price of our common stock during the period in which the use of the resale registration statement is suspended. If the trading price of our common stock declines during a suspension of the resale registration statement, the blackout or other payment could be significant.

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

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

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

We have incurred losses since inception and anticipate that we will incur continued losses for at least several years.

We are a development stage company with no current source of product revenue. We have a limited history of operations and have focused primarily on clinical trials, and if the outcome of our clinical trials supports it, we plan to seek FDA regulatory clearance to market CORLUX for the treatment of Cushing s Syndrome and for the treatment of the psychotic features of psychotic depression. Historically, we have funded our operations primarily from the sale of our equity securities. We have incurred losses in each year since our inception in 1998. As of September 30, 2009, we had an accumulated deficit of $145.1 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

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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 at least the next several years. We are unable to predict the extent of any future losses or whether or when we will become profitable.

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

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

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

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

In Study 14, our ongoing clinical trial evaluating CORLUX for the psychotic features of psychotic depression, we have engaged MedAvante to provide centralized psychiatric rating services. If patients are uncomfortable or unwilling to participate in the centralized rating process or if MedAvante is unable to provide services in a satisfactory manner over the course of the trial, we may not see any improvement in the accuracy and consistency of the psychiatric assessments. In addition, the use of centralized psychiatric rating services by a third-party, such as MedAvante, as an additional screening element may continue to slow the pace of enrollment in Study 14.

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

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

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

Thus far we have seen a higher than anticipated incidence of potential patients who do not meet appropriate criteria for entrance into our trial for diagnostic and other clinical reasons during the screening of patients for Study 14. We believe that this is the result of improved accuracy in the screening process resulting from the use of the MedAvante centralized rating services as an additional step in the selection of patients appropriate for inclusion in the study. While we anticipate that the

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incidence of patients who do not meet the appropriate criteria for enrollment in the trial will decrease over time as the investigators improve their ability to identify potential patients for inclusion in the study and we identify which clinical trial sites have the greatest access to our targeted patient population, we cannot assure you that this will be the case. In addition, in March 2009, we announced that, in order to conserve financial resources, we scaled back our planned rate of spending on this trial and extended the timeline for its completion. We have completed the implementation of this strategy which included reducing the number of clinical sites to eight. A continued lower enrollment rate could result in delays in the timing of anticipated completion of the trial and increased study costs over the longer term.

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

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

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

- the FDA may not find that the candidate is safe;
- the FDA may not find data from the clinical or preclinical testing to be sufficient; or
- the FDA may not approve our or our third party manufacturers processes or facilities.

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

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

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

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

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

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

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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.

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

In July 2007, we received Orphan Drug Designation from the FDA for CORLUX for the treatment of endogenous Cushing s Syndrome. Although we have received Orphan Drug Designation from the FDA, we cannot be assured that we will recognize the potential benefits of this designation. If another drug is approved for this indication before CORLUX, we may not garner the seven years of marketing exclusivity from the date of drug approval and other benefits which we anticipate.

Even if we receive approval for the marketing and sale of CORLUX for the treatment of Cushing s Syndrome or psychotic depression, CORLUX may never be accepted as a treatment for the approved indications.

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

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

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

- the effectiveness of CORLUX, including any side effects, as compared to alternative treatment methods;
- the product labeling or product insert required by the FDA for CORLUX;
- the cost-effectiveness of CORLUX and the availability of third-party insurance coverage and reimbursement, in particular from government payors such as Medicare and Medicaid, for patients using CORLUX;
- the timing of market entry of CORLUX relative to competitive products;
- the intentional restriction of distribution of CORLUX to physicians treating the target patient population;
- the extent and success of our sales and marketing efforts;

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

negative publicity concerning CORLUX, RU-486 or mifepristone.

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

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

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

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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 or identify alternate manufacturers of mifepristone or CORLUX tablets in a timely manner or on reasonable terms, if at all.

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

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

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

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

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

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

- regulatory authorities may withdraw their approvals;
- we may be required to reformulate our future products, conduct additional clinical trials, make changes in labeling of such products or implement changes to or obtain re-approvals of our manufacturing facilities;
- we may experience a significant drop in the sales of the affected products;

our reputation in the marketplace may suffer; and

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

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.

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

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

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

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

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

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

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

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

In addition to patents, we rely on a combination of confidentiality, nondisclosure and other contractual provisions, laws protecting trade secrets and security measures to protect our trade secrets and proprietary information. Nevertheless, these measures may not adequately protect our trade secrets or other proprietary information. If they do not adequately protect our rights, third parties could use our proprietary information, which could diminish our ability to compete in the market. In addition, employees, consultants and others who participate in the development of our product candidates may breach their agreements with us regarding our trade secrets and other proprietary information, and we may not have adequate remedies for the breach. We also realize that our trade secrets may become known through means not currently foreseen. Notwithstanding

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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 Cushing s Syndrome or psychotic depression rather than CORLUX or patients may acquire mifepristone from other sources, such as the internet or black market.

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

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

The composition of matter patents on our families of novel selective glucocorticoid antagonists may not be issued and we would not be able to prevent competition from others.

We have filed composition of matter patent claims on three families of novel selective glucocorticoid antagonists but not all of these have been issued. These have been filed internationally, with applications for two of the three families already granted in Europe. In the United States, an application for one of the three families has been issued and the application for another one of the families is in active prosecution and moving toward allowance. Examination has not yet begun in the U.S. on our third novel selective GR-II family. We cannot be certain that these patents will be issued to us. If these patents are not issued we may not be able to prevent others from developing competing compounds. The competing products could be prescribed by physicians instead of those developed by us.

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

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

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

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

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

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.

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.

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

We are aware that Laboratoire HRA Pharma has received an Orphan Drug Designation in the United States and Europe for the use of mifepristone to treat a subtype of Cushing s Syndrome and has begun a Phase II clinical trial in Europe and the United States for this indication. We are also aware that Exelgyn Laboratories recently received a recommendation for Orphan Drug Designation for Cushing s Syndrome in Europe, but they have stated that they have not yet conducted any clinical trials. We are aware that Novartis is developing a somatostatin analogue that is in Phase 3 trials for various endocrine disorders, including Cushing s disease, which is a subset of the patients with Cushing s Syndrome. If a 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.

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

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

Combination medicinal therapy consists of the use of antipsychotic and antidepressant medicines, not currently approved for the treatment of psychotic depression. The antipsychotics are prescribed for off-label use by physicians to treat the psychotic features of psychotic depression, which is the clinical target of CORLUX. Antipsychotics include Bristol-Myers Squibb s Abilify, Novartis Clozaril, Pfizer s Geodon and Navane, Ortho-McNeil s Haldol, Janssen Pharmaceutica s Risperdal, AstraZeneca s Seroquel, GlaxoSmithKline s Stelazine and Thorazine, Mylan s Mellaril, 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 Organon, for a new chemical entity for the treatment of psychotic depression. Organon was the pharmaceutical division of Akzo Nobel, which was purchased by Schering Plough. Organon s 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 it 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. As of the time of filing of this report, we are not aware of any other public disclosures by any company, regarding the development of new products to treat psychotic depression.

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

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

Rapid technological change could make our product candidates obsolete.

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

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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 small, specialty sales forces to market and sell CORLUX in the United States for the treatment of Cushing s Syndrome and for the treatment of the psychotic features of psychotic depression, as each indication is approved for marketing by the FDA. However, our sales and marketing efforts may not be successful or cost-effective. 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.

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

To that end, we must be able to:

manage our research and development efforts effectively;

manage our clinical trials effectively;

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

expand the size and composition of our management team;

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

hire and train additional qualified personnel.

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

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

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

Our ability to operate successfully and manage our potential future growth depends significantly upon retaining key research, technical, sales, marketing, managerial and financial personnel, and attracting and retaining additional highly qualified personnel in these areas. We face intense

competition for such personnel from numerous companies, as well as universities and nonprofit research organizations in the highly competitive northern California business area. Although we believe that we have been successful in attracting and retaining qualified personnel to date, we may not be able to attract and retain sufficient qualified personnel in the future. The inability to attract and retain these personnel could result in delays in the research, development and commercialization of our potential products.

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

If appropriate opportunities become available, we may attempt to acquire other GR-II antagonists, particularly GR-II antagonists that do not terminate pregnancy. We may also be able to acquire other technologies or potential products that are complementary to our operating plan. We currently have no commitments, agreements or plans for any acquisitions. The process of acquiring rights to another GR-II 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

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development of our business. In addition, we may fail to realize the anticipated benefits of any acquired potential product or technology. Future acquisitions could dilute our stockholders ownership interest in us and could cause us to incur debt, expose us to future liabilities and result in amortization or other expenses related to goodwill and other intangible assets.

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

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

Risks Related to Our Stock

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

We cannot assure you that an active trading market for our common stock will exist at any time. Holders of our common stock may not be able to sell shares quickly or at the market price if trading in our common stock is not active. During the 52-week period ended November 6, 2009, our average daily trading volume has been approximately 32,000 shares and the intra-day sales prices per share of our common stock on the NASDAQ Capital Market has ranged from $0.73 to $3.10. As of November 6, 2009, our officers, directors and principal stockholders control approximately 60% 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;
- general market and economic conditions, including those seen as a result of the recent worldwide financial credit crisis;

changes in financial estimates or recommendations by securities analysts;

conditions or trends in the biotechnology and pharmaceutical industries;

changes in the market valuations of similar companies;

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

additions or departures of key personnel;

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

developments concerning collaborations;

trading volume of our common stock;

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

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

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

sales of our common stock by us or our stockholders.

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

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

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

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

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

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

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

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

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

See the discussion above under Risks Related to our Business regarding risks associated with the Committed Equity Financing Facility (CEFF), including the risks regarding registration rights under that agreement.

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

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

As of November 6, 2009, our officers, directors and principal stockholders control approximately 60% 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.

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 Capital 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.

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

We are a small company with limited resources.

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

In addition, as directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the company s internal control over financial reporting in their annual reports on Form 10-K. This requirement first applied to our annual report on Form 10-K for the year ended December 31, 2007. This same legislation also requires that the independent registered public accounting firm auditing our financial statements must attest to and report on the effectiveness of our internal controls over financial reporting. The SEC postponed the initial compliance date for this requirement for smaller reporting companies and, under a recent rule change by the SEC that is effective December 15, 2009, the requirement for the auditor s attestation and report will first apply to our annual report on Form 10-K for our fiscal year ending December 31, 2010. Uncertainty exists regarding our ability to comply with these requirements by applicable deadlines and to maintain compliance in future years. If we are unable to complete the required assessment as to the adequacy of our internal control over financial reporting in 2009 or in future years or if our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal control over financial reporting as of the required deadline in 2010 and as of future year ends, investors could lose confidence in the reliability of our financial reporting.

Changes in or interpretations of accounting rules and regulations, 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 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

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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 October 12, 2009, we entered into a Securities Purchase Agreement (Purchase Agreement) with the purchasers named therein (Purchasers). Pursuant to the Purchase Agreement, we agreed to sell an aggregate of 12,596,475 shares (Shares) of common stock, par value $0.001, and warrants (Warrants) with an exercise price of $1.66 per share to purchase an aggregate of 4,408,773 shares of common stock, par value $0.001, to the Purchasers. The Shares and Warrants were sold at a purchase price of $1.43 per unit, which consisted of one Share of common stock and a Warrant to purchase 0.35 shares of common stock, for aggregate gross proceeds of approximately $18 million (Offering). The Offering closed on October 16, 2009. Investors participating in the Offering include Longitude Venture Partners, L.P., Sutter Hill Ventures and Alta Partners, LLP, venture capital firms that are all significant shareholders, as well as various entities and individuals related to these firms. Purchasers who were not previously shareholders included Ingalls & Snyder and Federated Kaufmann Funds. The Purchasers also include trusts and other entities related to members of the Company s Board of Directors, including G. Leonard Baker, Jr., Joseph C. Cook, Patrick G. Enright, David L. Mahoney and Edward E. Penhoet, Ph.D., and other accredited investors. Mr. Enright is a managing director of Longitude Venture Partners, L.P. Mr. Baker is a partner and managing director of Sutter Hill Ventures. Dr. Penhoet is a director of Alta Partners, LLP.

In connection with the Purchase Agreement, on October 12, 2009, we entered into a Registration Rights Agreement (Registration Rights Agreement) with the Purchasers. Pursuant to the Registration Rights Agreement, we agreed to prepare and file a registration statement with the Securities and Exchange Commission (SEC) on or prior to November 16, 2009 for purposes of registering the resale of the Shares, the shares of common stock issuable upon exercise of the Warrants, and any shares of common stock issued as a dividend or other distribution with respect to the Shares or shares underlying the Warrants. We agreed to use our reasonable best efforts to cause this registration statement to be declared effective by the SEC within 90 days after the closing of the offering (105 days in the event the registration statement is reviewed by the SEC). We also agreed, among other things, to indemnify the selling holders under the registration statements from certain liabilities and to pay all fees and expenses (excluding underwriting discounts and selling commissions and all legal fees of any selling holder) incident to our obligations under the Registration Rights Agreement. We expect to use the net proceeds from the Offering to fund the completion of enrollment in its Phase 3 trial of CORLUX for Cushing s Syndrome and the submission of its Cushing s Syndrome NDA, as well as for general corporate purposes, including working capital.

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

The securities sold and issued in connection with the Purchase Agreement have not been registered under the Securities Act of 1933, as amended, or any state securities laws and may not be offered or sold in the United States absent registration with the Securities and Exchange Commission or an applicable exemption from the registration requirements.

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ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

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

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description of Document
4.1	Form of Warrant issued in connection with the Securities Purchase Agreement by and among Corcept Therapeutics Incorporated and the purchasers named therein, dated October 12, 2009.
4.2	Registration Rights Agreement by and among Corcept Therapeutics Incorporated and the investors signatory thereto, dated October 12, 2009.
10.1	Securities Purchase Agreement by and among Corcept Therapeutics Incorporated and the purchasers named therein, dated October 12, 2009.
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 Caroline M. Loewy.
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 Caroline M. Loewy.

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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 12, 2009

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

Chief Executive Officer

Date: November 12, 2009

/s/ CAROLINE M. LOEWY
Caroline M. Loewy
Chief Financial Officer
(Principal financial officer)

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Exhibit Index

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4.1	Form of Warrant issued in connection with the Securities Purchase Agreement by and among Corcept Therapeutics Incorporated and the purchasers named therein, dated October 12, 2009.
4.2	Registration Rights Agreement by and among Corcept Therapeutics Incorporated and the investors signatory thereto, dated October 12, 2009.
10.1	Securities Purchase Agreement by and among Corcept Therapeutics Incorporated and the purchasers named therein, dated October 12, 2009.
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 Caroline M. Loewy.
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 Caroline M. Loewy.