CORCEPT THERAPEUTICS INC
Form 10-Q
August 09, 2012
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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 June 30, 2012

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

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

On August 2, 2012 there were 99,681,768 shares of common stock outstanding at a par value of $0.001 per share.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (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, or the Securities Act. All statements contained in this Form 10-Q other than statements of historical fact are forward-looking statements. When used in this report or elsewhere by management from time to time, the words believe, anticipate, intend, plan, estimate, expect, may, will, should, seeks and similar expressions are forward-looking statements. Such forward-looking statements are based on current expectations, but the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements made in this Quarterly Report on Form 10-Q may include, but are not limited to, statements about:

- *our ability to manufacture, market, commercialize and achieve market acceptance for Korlym (mifepristone) 300mg Tablets;*
- *our ability to realize the benefits of Orphan Drug Designation of Korlym in the United States and the European Union (EU);*
- *the progress and timing of our research, development and clinical programs and the timing of regulatory activities, including post-approval actions by the United States Food and Drug Administration (FDA) for mifepristone for the treatment of the psychotic features of psychotic depression;*
- *our estimates of the dates by which we expect to report results of our clinical trials and the anticipated results of these trials;*
- *the timing of the market introduction of future product candidates, including any other compound in our families of selective GR-II antagonists;*
- *our ability to manufacture, market, commercialize and achieve market acceptance for our future product candidates, including mifepristone for the treatment of the psychotic features of psychotic depression and any other compound in our families of selective GR-II antagonists;*
- *uncertainties associated with obtaining and enforcing patents;*
- *our estimates for future performance, including revenue and profits; and*
- *our estimates regarding our capital requirements and our needs for, and ability to obtain, additional financing.*

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

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CORCEPT THERAPEUTICS INCORPORATED

CONDENSED BALANCE SHEETS

(In thousands)

	June 30, 2012 (Unaudited)	December 31, 2011 (See Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 34,899	$ 39,635
Trade receivables	355	
Inventory	2,437	
Prepaid expenses and other current assets	608	140
Total current assets	38,299	39,775
Property and equipment, net of accumulated depreciation	59	26
Other assets	260	32
Total assets	$ 38,618	$ 39,833
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 4,235	$ 3,611
Accrued clinical expenses	640	644
Accrued compensation	294	238
Other accrued liabilities	621	533
Deferred revenue	26	
Total current liabilities	5,816	5,026
Commitments (Note 4)		
Stockholders equity:		
Preferred stock		
Common stock	89	84
Additional paid-in capital	259,901	243,281
Accumulated deficit and comprehensive loss	(227,188)	(208,558)
Total stockholders equity	32,802	34,807
Total liabilities and stockholders equity	$ 38,618	$ 39,833

The accompanying notes are an integral part of these condensed financial statements.

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CORCEPT THERAPEUTICS INCORPORATED

CONDENSED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30	
	2012	2011	2012	2011
Product sales, net	$ 875	$	$ 875	$
Operating expenses:				
Cost of sales	48		48	
Research and development	2,668	6,203	6,210	11,127
Selling, general and administrative	5,751	2,666	13,238	4,840
Total operating expenses	8,467	8,869	19,496	15,967
Loss from operations	(7,592)	(8,869)	(18,621)	(15,967)
Interest and other income, net		(1)		1
Other expense	(5)	(12)	(9)	(17)
Net loss and comprehensive loss	$ (7,597)	$ (8,882)	$ (18,630)	$ (15,983)
Basic and diluted net loss per share	$ (0.09)	$ (0.11)	$ (0.22)	$ (0.19)
Weighted average shares outstanding used in computing basic and diluted net loss per share	88,621	84,010	86,521	82,396

The accompanying notes are an integral part of these condensed financial statements.

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CORCEPT THERAPEUTICS INCORPORATED

CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Six Months Ended June 30,	
	2012	**2011**
Operating activities		
Net loss	$ (18,630)	$ (15,983)
Adjustments to reconcile net loss to net cash used in operations:		
Depreciation and amortization of property and equipment	8	1
Expense related to stock options	3,271	1,449
Changes in operating assets and liabilities:		
Trade receivables	(355)	
Inventory	(2,437)	
Prepaid expenses and other current assets	(468)	(37)
Other assets	(228)	72
Accounts payable	624	1,474
Accrued clinical expenses	(4)	(16)
Deferred revenue	26	
Other liabilities	144	(1,462)
Net cash used in operating activities	(18,049)	(14,502)
Investing activities		
Purchases of property and equipment	(41)	
Net cash used in investing activities	(41)	
Financing activities		
Proceeds from issuance of common stock and warrants, including collection of notes receivable, net of issuance costs	13,354	42,154
Net cash provided by financing activities	13,354	42,154
Net increase in cash and cash equivalents	(4,736)	27,652
Cash and cash equivalents, at beginning of period	39,635	24,578
Cash and cash equivalents, at end of period	$ 34,899	$ 52,230

The accompanying notes are an integral part of these condensed financial statements.

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CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Description of Business and Basis of Presentation

Corcept Therapeutics Incorporated was incorporated in the state of Delaware on May 13, 1998, and our facilities are located in Menlo Park, California. Corcept is a pharmaceutical company engaged in the discovery, development and commercialization of drugs for the treatment of severe metabolic and psychiatric disorders. Since our inception in May 1998, we have been developing our lead product, Korlym . Mifepristone, the active ingredient in Korlym, is a potent glucocorticoid receptor II (GR-II) antagonist, which means that it blocks the effects of cortisol throughout the body. On February 17, 2012, the United States Food and Drug Administration (FDA) approved Korlym (mifepristone) 300 mg Tablets in the United States as a once-daily oral medication for treatment of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing s syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. We released Korlym for sale on April 10, 2012. We also have a clinical program for the use of mifepristone, the active ingredient in Korlym, for the treatment of the psychotic features of psychotic depression. We are currently conducting a phase 3 study for this indication. In addition, we have discovered three series of novel selective glucocorticoid receptor II (GR-II) antagonists. Unless otherwise stated, all references in these financial statements to we, us, our, Corcept, the Company, our company and similar designations refer to Corcept Therapeutics Incorporated.

We were considered to be in the development stage prior to the second quarter of 2012 when we recorded significant revenue from our planned principal operations following commercialization of Korlym.

The accompanying unaudited balance sheet as of June 30, 2012, statements of comprehensive loss for the three- and six-month periods ended June 30, 2012 and 2011, and statements of cash flows for the six-month periods ended June 30, 2012 and 2011 have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three- and six-month periods ended June 30, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012 or any other period. These financial statements and notes should be read in conjunction with the financial statements for the year ended December 31, 2011 included in our Annual Report on Form 10-K. The accompanying balance sheet as of December 31, 2011 has been derived from audited financial statements at that date.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to use assumptions and make estimates to form judgments about the carrying value of assets and liabilities reported in the financial statements and accompanying notes, the value of which we cannot readily determine from other sources. Actual results could differ materially from those estimates.

We evaluate our estimates and assumptions on an ongoing basis, including those related to our discounts for prompt payment of sales invoices, chargebacks and rebates, patient assistance, potential product returns, excess/obsolete inventories, allowances for doubtful accounts, accruals of clinical and preclinical expenses and contingent liabilities. We base our estimates on relevant experience and on other specific assumptions that we believe are reasonable.

We update these assumptions and estimates as new information becomes available. Any changes in estimates are recorded in the period of the change.

Cash and Cash Equivalents

We invest our excess cash in bank deposits, money market accounts, corporate debt securities, and obligations of the U.S. government and U.S. government sponsored entities. We consider all highly liquid investments purchased with maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents are carried at fair value, which approximates cost and, as of June 30, 2012 and December 31, 2011, all of our funds were invested in cash and cash equivalents that consist of a money market fund maintained at a major U.S. financial

institution.

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CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

Credit Risks and Concentrations

We have a concentration of credit risk related to our cash and cash equivalents. We are exposed to credit risk in the event of default by the financial institutions holding these funds to the extent of the amount recorded on our balance sheet. We mitigate this risk by investing in a money market fund that invests primarily in short-term U.S. Treasury notes and bills. For the six-month periods ended June 30, 2012 and 2011, we experienced no loss or lack of access to cash and cash equivalents in our operating or investment accounts.

Beginning with the commercialization of Korlym in April 2012, we are also exposed to credit risk in regard to our trade receivables. We have only two customers one specialty pharmacy and one specialty distributor, which are subsidiaries of the same corporate parent. We extend credit to these customers based on their individual creditworthiness and that of their shared parent organization. We monitor our exposure and will record a reserve against uncollectible trade receivables as necessary.

We also have a concentration of risk in regard to the manufacture of our product. As of June 30, 2012, we had one manufacturer of Korlym tablets, which has indicated that it will temporarily suspend commercial production in the fourth quarter of 2012 while it relocates to a new facility. We have a contract with a potential second Korlym tablet manufacturer, to which we have transferred the production process and which has produced regulatory stability batches and established the required analytical testing methods. In June 2012, we submitted a New Drug Application (NDA) supplement to the FDA requesting approval of this manufacturer as a source of Korlym tablets. The Prescription Drug User Fee Act due date for the FDA s response is October 27, 2012. If we are not able to qualify the new manufacturer and our pre-existing supplier is unable to make Korlym tablets in the quantities that we require, we may not have adequate inventory of Korlym tablets to meet demand.

Fair Value Measurements

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

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

Trade Receivables

Trade receivables are recorded net of customer allowances for prompt payment and data services, doubtful accounts and sales returns. See the discussion below under Net Product Sales regarding the methods for estimation of these allowances and sales returns. Our estimate of the allowance for doubtful accounts is determined based on existing contractual payment terms, actual payment patterns of our customers and individual customer circumstances. To date, we have determined that an allowance for uncollectible trade receivables is not required.

Inventory

We consider regulatory approval of product candidates to be uncertain, and product manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. We expense the manufacturing costs for product candidates incurred prior to regulatory approval as research and development expense as we incur them. When regulatory approval of a product is obtained, we begin capitalizing manufacturing costs related to the approved product into inventory.

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CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

We value our inventories at the lower of cost or net realizable value. We determine the cost of inventory using the specific identification method on a first-in, first-out basis. We analyze our inventory levels quarterly and write down inventory that has become obsolete or has a cost basis in excess of its expected net realizable value, as well as any inventory quantities in excess of expected requirements. Any expired inventory is disposed of and the related costs are recognized as cost of sales in the statement of comprehensive loss.

Net Product Sales

We sell Korlym to a specialty pharmacy and a specialty distributor, which subsequently resell Korlym to patients and healthcare providers. We recognize product revenues from sales of Korlym upon delivery to our customers as long as (i) there is persuasive evidence that an arrangement exists between ourselves and the customer, (ii) collectability is reasonably assured and (iii) the price is fixed or determinable. In order to conclude that the price is fixed or determinable, we must be able to (i) calculate gross product revenues from the sales to our customers and (ii) reasonably estimate net product revenues.

We calculate gross product revenues based on the price that we charge our customers. We estimate our net product revenues by deducting from our gross product revenues (a) trade allowances, such as discounts for prompt payment and distributor fees, (b) estimated government rebates and chargebacks, (c) reserves for expected product returns and (d) estimated costs of patient assistance programs. We initially record estimates for these deductions at the time we recognize the gross revenue. We update our estimates on a recurring basis as new information becomes available.

Trade Allowances: We offer our customers a discount on Korlym sales for payment within 30 days. We also offer them a small discount for the provision of data services. We expect our customers to earn these discounts and accordingly deduct them in full from gross product revenues and trade receivables at the time we recognize such revenues.

Rebates and Chargebacks: We contract with Medicaid and other government agencies so that Korlym will be eligible for purchase by, or qualify for partial or full reimbursement from, such government programs. We estimate the rebates and chargebacks that we are obligated to provide to government programs and deduct these estimated amounts from our gross product sales at the time the revenues are recognized. We base our estimates of these rebates and chargebacks upon (i) the discount rates applicable to government-funded programs and (ii) information obtained from our vendors regarding the percentage of sales by our customers to patients who are covered by entities or programs that are eligible for such rebates and chargebacks.

Allowances for Patient Assistance Program: We provide financial assistance to eligible patients whose insurance policies require them to pay high deductibles and co-pays. We estimate the cost of assistance to be provided under this program by applying our actual experience regarding such assistance to our estimate of the percentage of our sales in the period that will be provided to patients covered by the program.

Sales Returns: Our customers have the right to return Korlym beginning six months before the labeled expiration date and ending 12 months after the labeled expiration date. This right of return is extended to our specialty distributor channel s hospital customers who, generally, have the right to return only unopened bottles. The expiration date for our current Korlym inventory is two years after the manufacture of the tablets. We estimate the amount of Korlym that we believe will be returned and deduct that estimated amount from gross revenue at the time we recognize such revenue. When estimating future returns, we analyze quantitative and qualitative information including, but not limited to, actual return rates, the amount of product in the distribution channel, the expected shelf life of such product, current and projected product demand, the introduction of competing products that may erode demand, and broad economic and industry-wide indicators. If we cannot reasonably estimate product returns with respect to a particular sale, we defer recognition of revenue from that sale until we can make a reasonable estimate.

Cost of Sales

Cost of sales includes the cost of product (the cost to manufacture Korlym, which includes material, third-party manufacturing costs and indirect personnel and other overhead costs) based on units for which revenue is recognized in the current period, as well as costs of stability testing, logistics and distribution of the product. We began capitalizing Korlym production costs as inventory following approval by the FDA on February 17, 2012. Prior to receiving the FDA approval for Korlym, we expensed all costs related to the manufacturing of the product (including stability costs and manufacturing overhead) as incurred; we classified these costs as research and development expense. A portion of the product

manufactured prior to FDA approval is available for us to use commercially.

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CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

Research and Development

Research and development expenses consist of costs incurred for research and development activities that we sponsor, which costs are expensed as incurred. These costs include direct expenses, such as the cost of clinical trials, pre-clinical studies, manufacturing development, preparations for submissions to the FDA and efforts to prosecute and defend those submissions and the development of second-generation compounds, as well as research and development-related overhead expenses. We also expense as incurred nonrefundable payments to third parties and our cost of acquiring technologies and materials used in research and development that have no alternative future use.

We base our cost accruals for clinical trials, research and preclinical activities on estimates of work completed under service agreements, milestones achieved, patient enrollment and past experience with similar contracts. Our estimates of work completed and associated cost accruals include our assessments of information from third-party contract research organizations and the overall status of clinical trial and other development and administrative activities.

Segment Reporting

We determine our operating segments based on the way we organize our business to make operating decisions and assess performance. We have only one operating segment, which concerns the discovery, development and commercialization of pharmaceutical products.

Stock-Based Compensation

Stock-based compensation for employee and director options

We account for stock-based compensation of option grants to employees and directors under the fair value method, based on the fair value-based measurement of the award at the grant date. For service-based awards, we recognize expense over the requisite service period. For options with performance-based vesting criteria, we begin to recognize expense over the requisite service period when we believe there is a high degree of probability (i.e., greater than 70 percent) of achieving the vesting criteria.

Stock-based compensation expense related to non-employees

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

2. Fair Value of Financial Instruments

As of June 30, 2012 and December 31, 2011, we had invested our financial assets in a money market fund that can be converted to cash at par on demand. We measured these funds, which totaled approximately $34.9 million and $39.6 million as of June 30, 2012 and December 31, 2011, respectively, at fair value, which approximates cost, as of the respective dates and classified them as Level 1 assets in the fair value hierarchy for financial assets.

We realized no gains or losses on investments during the three-month periods ended June 30, 2012 and 2011. We determined the cost of securities sold using the specific identification method.

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CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

3. Composition of Certain Balance Sheet Items

The following tables present the composition of certain balance sheet items as of June 30, 2012 and December 31, 2011. All amounts are in thousands.

Inventory

	June 30, 2012
Raw materials	$ 1,248
Work in progress	1,164
Finished goods	25
Total inventory	$ 2,437

As we had no product approved by the FDA as of December 31, 2011, we had no inventory value on our balance sheet as of that date.

Other Accrued Liabilities

	June 30, 2012	December 31, 2011
Professional fees	$ 351	$ 292
Commercialization costs	30	80
Legal fees	112	46
Manufacturing costs	27	78
Other	101	37
Total	$ 621	$ 533

4. Commitments

During the six months ended June 30, 2012, we placed purchase orders with Produits Chimiques Auxiliaires et de Synthese SA (PCAS) for the acquisition of mifepristone, the active pharmaceutical ingredient (API) in Korlym, for delivery during 2012 for aggregate commitments of approximately $2.8 million, approximately $1.2 million of which we received and recorded as inventory prior to June 30, 2012. See Note 8, for an additional purchase order placed with PCAS in July 2012.

As of June 27, 2012, we signed an amendment to the lease for our office space that reflected an expansion of the space and extended our occupancy through December 2013. The aggregate commitment for base rent through the term of the amendment is approximately $630,000, approximately $202,000 of which will be incurred during the remainder of 2012. The amended lease provides us with an option to extend the lease for one additional year.

5. Capital Stock

On March 3, 2012, two investors exercised warrants for the purchase of our common stock with exercise prices ranging from $2.77 to $2.96 per share. As a result, we issued 93,082 shares of common stock and generated aggregate proceeds of approximately $267,000.

On March 29, 2012, we issued approximately 4.2 million shares of our common stock upon the exercise of warrants that we had issued in a private placement transaction in April 2010 at an exercise price of $2.96 per share and sold new warrants to the same investors to purchase approximately 4.2 million shares of common stock at an exercise price of $4.05 per share. The new warrants are exercisable through March 29, 2015. We generated net proceeds in these transactions of approximately $12.9 million, after the deduction of issuance costs. Venture capital funds, trusts and other entities affiliated with members of our Board of Directors purchased approximately 40 percent of the securities sold in this transaction, with the remainder being purchased by other qualified investors.

See Note 8 Subsequent Events, for a discussion of additional shares of common stock sold in July 2012.

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CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

6. Stock Option Plans

We have three stock option plans the 2000 Stock Option Plan (the 2000 Plan), the 2004 Equity Incentive Plan (the 2004 Plan) and the 2012 Incentive Award Plan (the 2012 Plan).

All option grants under the 2000 Plan are fully vested. In 2004, our board of directors and stockholders approved the 2004 Plan, which became effective upon the completion of our initial public offering (IPO). Subsequent to the IPO, no options were or will be issued under the 2000 Plan. Under the 2004 Plan, stock options were issued to our employees, officers, directors and consultants. The 2004 Plan provided that the exercise price for incentive stock options would be no less than 100 percent of the fair value of our common stock, as of the date of grant. Options granted under the 2004 Plan vest over periods ranging from one to five years. The vesting period of the options is generally equivalent to the requisite service period.

In November 2011, our Board of Directors authorized an increase in the shares available for issuance under the 2004 Plan equal to 4 percent of the shares of our common stock outstanding as of December 31, 2011, pursuant to the terms of the 2004 Plan. Accordingly, as of January 1, 2012, the shares available for issuance under the 2004 Plan increased by a total of 3,369,249 shares.

In February 2012, our Board of Directors and stockholders approved the 2012 Plan, which became effective upon its approval at our Annual Meeting of Stockholders on June 13, 2012. As of the effective date of the 2012 Plan, approximately 5.3 million shares that remained available for issuance of new grants under the 2004 Plan were transferred to the 2012 Plan. After that date, no additional options were or will be issued under the 2004 Plan. Vested options under the 2000 Plan and the 2004 Plan that are not exercised within the remaining contractual life and any options under the 2004 Plan that do not vest because of terminations after the effective date of the 2012 Plan will be added to the pool of shares available for future grants under the 2012 Plan.

Under the 2012 Plan, we can issue options, stock purchase and stock appreciation rights and restricted stock awards to our employees, officers, directors and consultants. The 2012 Plan provides that the exercise price for incentive stock options will be no less than 100 percent of the fair value of our common stock, as of the date of grant. Options granted under the 2012 Plan are expected to vest over periods ranging from one to four years. We expect the vesting period of the options that we grant under the 2012 Plan to be generally equivalent to the requisite service period.

During the six-month period ended June 30, 2012, we issued an aggregate of 135,000 shares of our common stock upon the exercise of stock options.

The following table provides a summary of non-cash stock-based compensation. All figures are in thousands.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Research and development	$ 138	$ 267	$ 256	$ 323
Selling, general and administrative	744	602	3,015	1,126
Total non-cash stock-based compensation	$ 882	$ 869	$ 3,271	$ 1,449

The data in the table above for the six-month period ended June 30, 2012 includes approximately $1.3 million of non-cash stock-based compensation expense, which is classified as selling, general and administrative expense, related to performance-based stock option awards to officers that vested in February 2012 upon the FDA approval of Korlym. The data in the table above for the three- and six-month periods ended June 30, 2011 includes approximately $192,000 of non-cash stock-based compensation expense, which is classified as research and development expense, related to a performance-based stock option award to a consultant that vested in June 2011 upon the filing by the FDA of our NDA for

Korlym. All other stock-based compensation in the periods presented relates to service-based option awards.

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CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

7. Net Loss Per Share

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

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

	June 30,	
	2012	2011
Warrants outstanding	9,026	9,200
Stock options outstanding	10,700	9,874
Total	19,726	19,074

In July 2012, we sold 11.0 million shares of our common stock. (See Note 8 Subsequent Events.)

8. Subsequent Events

Sale of Capital Stock

On July 6, 2012, we sold 11.0 million shares of our common stock in an underwritten public offering for aggregate net proceeds of approximately $46.1 million after deducting expenses of the offering.

Purchase Commitment

In July 2012, we placed an additional purchase order with PCAS for delivery of mifepristone in the fourth quarter of 2012 or early 2013 for a commitment of approximately $843,000.

Financing Transaction with Biopharma

On August 2, 2012, we executed a transaction (Transaction) with Biopharma Secured Debt Fund II Sub, S.àr.l, a private limited liability company organized under the laws of Luxembourg (Biopharma). Under the terms of the Transaction, we will receive $30 million at the closing, which is anticipated to occur on or about August 16, 2012. In return, we are obligated to make payments, calculated as a percentage of our net sales of Korlym, any future mifepristone-based products and our selective GR-II antagonists (together referred to as Covered Products) and any upfront, milestone or other contingent payments with respect to Covered Products. Biopharma s right to receive payments will expire once it has received cumulative payments of $45 million.

Under the terms of the Transaction, our payments are entirely variable, with no fixed minimums. If there are no net sales, upfront, milestone or other contingent payments in a period with respect to Covered Products, then no payment will be due for that period.

We are obligated to make payments as follows:

20 percent of our net product sales of Covered Products, beginning with the calendar quarter ending June 30, 2013, subject to quarterly payment caps of $2,250,000 during 2013, $3,000,000 during 2014 and $3,750,000 during 2015. There is no quarterly cap on payments with respect to net product sales in 2016 and later.

20 percent of payments received for upfront, milestone or other contingent fees under co-promotion and out-license agreements for Covered Products (without application of quarterly caps), provided however, that any amounts received under such agreements after the Transaction s effective date of August 2, 2012 but before June 30, 2013 would be deferred and made simultaneously with the payment for the calendar quarter ending June 30, 2013.

The percentage used to calculate our payments to Biopharma would increase to 50 percent and any applicable payment caps would lapse if we (i) fail to provide Biopharma with certain information regarding our promotion and sales of Covered Products, (ii) do not devote a commercially reasonable amount of resources to the promotion and marketing of the Covered Products or (iii) violate the Indebtedness Covenant and, in each case, fail to cure within the applicable cure period.

Upon the occurrence of a Corcept change of control transaction or the licensing of Korlym to a third-party for promotion and sale in the United States, the entire $45 million, less any amounts already paid by us, would become due.

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CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

To secure our obligations in connection with this Transaction, we granted Biopharma a security interest in our rights in patents, trademarks, trade names, domain names, copyrights, know-how and regulatory approvals related to the Covered Products, all books and records relating to the foregoing and all proceeds of the foregoing (the Collateral). If we (i) fail to deliver a royalty payment when due and do not remedy that failure within 30 days, (ii) fail to maintain a first-priority perfected security interest in the Collateral in the United States and do not remedy that failure within five business days of receiving notice of such failure or (iii) become subject to an event of bankruptcy, then Biopharma may attempt to recover up to $45 million (after deducting any payments we have already made).

Committed Equity Financing Facility

In addition, effective August 7, 2012, we terminated our Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge). The termination of the CEFF has no effect on the warrant that was issued to Kingsbridge for 330,000 shares of our common stock, which can be exercised at any time through September 25, 2013 for an exercise price of $3.525 per share.

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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, development and commercialization of drugs for the treatment of severe metabolic and psychiatric disorders. Our focus is on disorders associated with the steroid hormone cortisol. Elevated levels and abnormal release patterns of cortisol have been implicated in a broad range of human disorders.

Since our inception in May 1998, we have been developing mifepristone, a potent glucocorticoid receptor II (GR-II) antagonist. On February 17, 2012, the FDA approved Korlym (mifepristone) 300 mg Tablets in the United States as a once-daily oral medication for treatment of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing s syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. We released Korlym for sale on April 10, 2012. We also have an on-going phase 3 study of mifepristone, the active ingredient in Korlym, for treatment of the psychotic features of psychotic depression. We have discovered three series of novel selective GR-II antagonists.

Unless otherwise stated, all references in this document to we, us, our, Corcept, the Company, our company and similar designations refe Corcept Therapeutics Incorporated.

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

As discussed above, the FDA approved our NDA for Korlym on February 17, 2012. This approval allows us to market Korlym in the United States for the approved indication. We are carrying out our commercial launch plans, including hiring a small number of medical science liaisons (MSLs), to launch Korlym in the United States.

We have Orphan Drug Designations for Korlym from the FDA for the approved indication and from the European Commission for the treatment of endogenous Cushing s syndrome. Orphan Drug Designation in the United States 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 for the approved indication 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. Benefits of Orphan Drug Designation in the EU are similar to those in the U.S., but include ten years of marketing exclusivity for the approved indication in all 27 member states, free scientific advice during drug development, access to a centralized review process and a reduction or complete waiver of fees levied by the European Medicines Agency.

Psychotic Depression. We are also developing mifepristone, the active ingredient in Korlym, for the treatment of the psychotic features of psychotic depression under an exclusive patent license from Stanford University. The FDA has granted fast track status to evaluate the safety and efficacy of mifepristone for the treatment of the psychotic features of psychotic depression.

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

As expected, the group of patients who took 1200 milligrams (mg) of mifepristone in Study 06 developed higher drug plasma levels than did the groups of patients who received lower doses. Further, there was no discernable difference in the incidence of adverse events between patients who received placebo in Study 06 and those who received 300 mg, 600 mg or 1200 mg of mifepristone in that study. In August 2011, we published our analysis of these data in *The Journal of Clinical Psychopharmacology*. Based on this information, we are testing a mifepristone dose of 1200 mg once per day for seven days in Study 14.

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

Enrollment in Study 14 is ongoing. Our goal is to complete enrollment by the end of 2013. To help reach this goal, we plan to increase the number of clinical sites from eight to approximately 20 over the next year.

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

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

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

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

Several of our new compounds have demonstrated positive results in animal models for the prevention and reversal of anti-psychotic-induced weight gain. One of them, CORT 108297, is in phase 1b/2a clinical trials. We have identified other selective GR-II antagonists from our proprietary series that we believe may have utility as therapeutic agents in a variety of diseases. Our intent is to continue our discovery research program with the goal of identifying new selective GR-II antagonists and to manufacture and conduct pre-clinical development on one or more of these compounds and to submit Investigational New Drug (IND) applications with respect to the most promising of them, as we deem appropriate.

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 percent fat diet and high sucrose liquid. The results of these preclinical data were published in April 2011 in the journal *Nutrition and Metabolism*.

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

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General

Our activities to date have included:

- product development, including drug formulation and manufacturing, as well as designing, funding and overseeing clinical trials and conducting non-clinical investigatory activities, such as toxicological testing;
- discovery research;
- regulatory affairs;
- intellectual property prosecution and expansion; and
- commercialization of Korlym, including hiring and training medical science liaisons, retention and management of third-party distribution partners, establishment of product reimbursement and patient assistance programs, and marketing activities.

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.

As of June 30, 2012, we had an accumulated deficit of $227.2 million. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for mifepristone, discovery research, non-clinical activities such as toxicology and carcinogenicity studies, manufacturing process development and regulatory activities, as well as selling, general and administrative expenses, including preparations for the commercial launch of Korlym, which occurred in April 2012. We may continue to incur net losses over at least the next few years as we continue our mifepristone and selective GR-II antagonist clinical development programs, apply for regulatory approvals, continue discovery and initiate development of other selective GR-II antagonists for various indications, acquire and / or develop treatments in other therapeutic areas, establish sales and marketing capabilities and expand our operations.

Our business is subject to significant risks, including the risks inherent in our research and development efforts, the results of our mifepristone and other clinical trials, uncertainties associated with securing financing, uncertainties associated with obtaining and enforcing patents, our investment in manufacturing set-up, the management of our supply chain, 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

Net Product Sales Net product sales includes product revenue resulting from sales to our customers, reduced by 1) trade allowances, such as discounts for prompt payment and distributor fees, 2) estimated government rebates and chargebacks, 3) reserves for expected product returns and 4) estimated costs of our patient assistance program.

In April 2012, we made Korlym commercially available in the United States to our specialty distributor and specialty pharmacy customers. For the three months ended June 30, 2012, we recognized approximately $875,000 in net product sales compared with none in the comparable period in 2011. To calculate net product sales, we deducted from gross sales estimates of prompt-pay discounts, distribution service fees, rebates and chargebacks owed to government payors and patient assistance programs, which amounts are not material for the quarter ended June 30, 2012.

Based on our limited experience marketing Korlym, it is difficult for us to predict the magnitude of product sales for any future quarter or for the year-ended December 31, 2012.

Cost of sales Cost of sales includes the cost of product (the cost to manufacture Korlym, which includes material, third-party manufacturing costs and indirect personnel and other overhead costs) based on units for which revenue is recognized in the current period, as well as costs of stability testing, logistics and distribution of the product. We began capitalizing Korlym production costs as inventory following approval by the FDA on February 17, 2012. Prior to receiving the FDA approval for Korlym, we expensed all costs related to the manufacturing of the product (including stability costs and manufacturing overhead) as incurred; we classified these costs as research and development expense. A portion of the product manufactured prior to FDA approval is available for us to use commercially.

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Cost of sales was approximately $48,000 for the three months ended June 30, 2012, which equals 5.5 percent of net product sales, the majority of which represented costs related to stability testing. The amount and timing of stability testing varies from period to period as determined by FDA regulations and our production schedule and is not proportional with sales volumes. In addition, the cost of manufacturing Korlym reflected in our cost of sales in 2012, and for some period thereafter, will not reflect the full cost of production because we have previously expensed the majority of the raw materials, labor and overhead costs incurred to produce the product sold during this period. We expect that our cost of sales as a percentage of net product sales of Korlym will fluctuate from quarter to quarter during 2012 and for some period thereafter as product manufactured prior to FDA approval, and therefore fully expensed, is consumed.

Research and development expenses Research and development expenses include 1) the personnel costs related to our development activities, including facilities costs and non-cash stock-based compensation, 2) the costs of discovery research, 3) costs associated with IND-enabling activities and pre-clinical studies, 4) costs of clinical trials, including trial preparation, enrollment, site monitoring and data management and analysis expenses, 5) regulatory costs, 6) the costs of manufacturing development, including the development and activities to qualify a second tablet manufacturing site, 7) the costs of manufacture and / or acquisition of clinical trial materials and material used in registration and validation batches included in the NDA submission for Korlym and 8) other costs associated with the preparation and prosecution of the Korlym NDA or other FDA submissions related to Korlym or other product candidates.

Research and development expenses decreased 57 percent to $2.7 million for the three-month period ended June 30, 2012 from $6.2 million for the comparable period in 2011. For the six-month period ended June 30, 2012, research and development expenses decreased 44 percent to $6.2 million from $11.1 million for the comparable period in 2011.

During the second quarter of 2012 as compared to the corresponding period in 2011, there was an increase of approximately $108,000 in staffing costs, which includes increases of approximately $63,000 for stock-based compensation expenses related to employees working in research and development functions. During the six-month period ended June 30, 2012 as compared to the corresponding period in 2011, there was an increase of approximately $712,000 in staffing costs, which includes bonuses paid on FDA approval of Korlym in the amount of approximately $441,000 and increases of approximately $125,000 for stock-based compensation expenses related to employees working in research and development functions. During the second quarter and first half of 2012 as compared to the corresponding periods in 2011, there were decreases of approximately $1.2 million and $1.9 million, respectively, in consultancy costs, due primarily to the additional resources required during 2011 for the preparation, submission and prosecution of the NDA, which was submitted in April 2011 and filed by the FDA in June 2011. Additionally, stock-based compensation expense decreased approximately $192,000 during both the second quarter and first half of 2012 as compared to the corresponding periods of 2011 due to non-cash stock-based compensation costs related to a stock option award to a consultant that vested in its entirety on the acceptance of the NDA by the FDA in June 2011.

Korlym manufacturing costs categorized as research and development expense decreased approximately $1.1 million and $1.6 million, respectively, during the second quarter and first half of 2012 as compared to the corresponding periods in 2011, due primarily to capitalizing to inventory the costs of Korlym s active pharmaceutical ingredient and of the manufacture of Korlym tablets for commercial sale following the date of FDA approval. See discussion below under the caption Critical Accounting Policies and Estimates .

Clinical trial costs decreased approximately $901,000 and $1.4 million, respectively, during the second quarter and first half of 2012, as compared to the corresponding periods of 2011. During the second quarter and first half of 2012 as compared to the corresponding periods in 2011, there were decreases of approximately $1.1 million and $1.3 million, respectively, related to clinical studies with CORT 108297, decreases of approximately $184,000 and $110,000, respectively, related to our phase 3 study with mifepristone for the treatment of psychotic depression, and decreases of approximately $190,000 and $394,000, respectively, related to the clinical trials with Korlym in the treatment of Cushing s syndrome. These decreases were partially offset by increases of approximately $564,000 and $415,000, respectively, for the second quarter and first half of 2012 as compared to the corresponding periods of 2011 related to drug-drug interaction and other NDA-supportive studies with Korlym.

In addition, costs related to financial support for medical conferences and seminars in support of our Cushing s syndrome program decreased approximately $241,000 and $391,000, respectively, in the second quarter and first half of 2012 as compared to the corresponding periods of 2011, because subsequent to product approval the nature of our activities at medical meetings has changed, and now such costs relate to marketing activities that are classified as a component of selling, general and administrative expenses. Costs relating to IND-enabling activities and research efforts regarding our new GR-II antagonists decreased approximately $150,000 and $200,000 during the second quarter and first half of 2012, respectively, as compared to the corresponding periods in 2011.

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

Project	Three-Months Ended June 30, 2012	Three-Months Ended June 30, 2011	Six-Months Ended June 30, 2012	Six-Months Ended June 30, 2011
	(in thousands)		*(in thousands)*	
Korlym	$ 823	$ 3,291	$ 2,238	$ 5,565
Mifepristone for Psychotic Depression	373	596	896	977
Selective GR-II antagonists	593	1,743	1,664	2,868
Unallocated activities, including NDA supportive studies and manufacturing, regulatory and pre-clinical activities	741	306	1,156	1,394
Stock-based compensation	138	267	256	323
Total research and development expense	$ 2,668	$ 6,203	$ 6,210	$ 11,127

We expect that research and development expenditures will decrease during the remainder of 2012 as compared to 2011 as increases in costs associated with the continuation of our phase 3 study of mifepristone for the treatment of psychotic depression, and the continued development of our other proprietary selective GR-II antagonists will be more than offset by decreases in the costs related to the completion of our phase 3 study in Cushing s syndrome. Research and development expenses in 2013 and future years will be largely dependent on our strategic priorities and 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 more 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 depend on the success of our efforts and any difficulties that we may encounter. 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.

Selling, general and administrative expenses Selling, general and administrative expenses include 1) personnel and consultancy costs related to administrative and commercialization activities, including facilities costs and non-cash stock-based compensation, 2) expenses of third-party vendors that we engaged to execute our commercial plans related to Korlym, including conducting market research, providing market analytics, developing reimbursement support services and, distribution and other logistical needs related to our commercialization of Korlym and 3) legal, accounting and other professional fees.

For the three-month period ended June 30, 2012, selling, general and administrative expenses increased to $5.8 million from $2.7 million for the comparable period in 2011. For the six-month period ended June 30, 2012, selling, general and administrative expenses increased to $13.2 million from $4.8 million for the comparable period in 2011.

During the second quarter and first half of 2012 as compared to the corresponding periods in 2011, staffing and consultancy costs increased approximately $1.1 million and $4.8 million, respectively, due primarily to additional resources necessary to engage in commercialization of Korlym. These increases included approximately $142,000 and $1.9 million, respectively, for the second quarter and first half periods related to increases in non-cash stock-based compensation costs for stock options granted to employees, directors and consultants, of which approximately $1.3 million consisted of performance-based stock option awards to officers that vested in February 2012 upon the FDA approval of Korlym. We also awarded approximately $1.6 million in cash bonuses in the first quarter of 2012 to employees working in selling, general and administrative functions in recognition of the FDA s approval of Korlym.

In addition, other professional services costs related to commercialization activities and other corporate matters increased approximately $1.8 million and $3.2 million, respectively, during the second quarter and first half of 2012 as compared to the corresponding periods of 2011.

We expect that selling, general and administrative expenses will increase during the remainder of 2012 as compared to 2011 in regard to activities directly associated with product commercialization and the need to continue building our administrative infrastructure to support these activities. The level of selling, general and administrative activities and related expenses in 2013 and future years will be largely dependent on our assessment of the staff and other services necessary to support product commercialization and our continued clinical development activities and the availability of additional funds. See also, Liquidity and Capital Resources.

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Liquidity and Capital Resources

We have incurred operating losses since inception, and at June 30, 2012, we had an accumulated deficit of $227.2 million. Since our inception, we have relied primarily on the proceeds from public and private sales of our equity securities to fund our operations.

At June 30, 2012, we had cash and cash equivalents of $34.9 million, compared to $39.6 million at December 31, 2011. Net cash used in operating activities for the six-month periods ended June 30, 2012 and 2011 was $18.0 million and $14.5 million, respectively. We used cash in each period primarily for research and development activities, including efforts toward the submission and prosecution of the NDA for Korlym and to develop administrative infrastructure to support the commercialization of Korlym.

On July 6, 2012, we sold 11.0 million shares of our common stock in an underwritten public offering for net proceeds of approximately $46.1 million after deducting expenses of the offering.

As discussed in Note 8 of our financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, we entered into a Transaction with Biopharma on August 2, 2012 under which we will receive $30 million at closing, which we expect to occur on or about August 16, 2012. Pursuant to the Transaction, beginning with the quarter ending June 30, 2013, we will make quarterly payments equal to (i) 20 percent of our net product sales of Covered Products, subject to certain quarterly payment caps through 2015 and (ii) 20 percent of any upfront, milestone or other contingent payments we receive under co-promotion or out-licensing agreements with respect to Covered Products (without application of caps), until we have made cumulative payments of $45 million. Under the terms of the Transaction, our payments are entirely variable, with no fixed minimums. If there are no net sales, upfront, milestone or other contingent payments in a period with respect to Covered Products, then no payment will be due for that period.

We expect cash used in operating activities to increase during the remainder of 2012 as compared to spending levels in 2011 due to the commercialization of Korlym, the continuation and scale-up of our phase 3 clinical trial of mifepristone for the treatment of psychotic depression and the continued development of our selective GR-II antagonists, which will be only partially offset by sales of Korlym. We expect our funding requirements for operating activities may increase in 2013 and possibly beyond as costs associated with the continuation of our development program for Cushing s syndrome, continuation and expansion of our development programs for psychotic depression and our selective GR-II antagonists, research activities, commercialization activities and selling, general and administrative expenses may be only partially offset by revenues from sales of Korlym.

We may choose to raise additional funds at some time in the future 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.

In March 2008, we entered into a CEFF with Kingsbridge, under which the determination of the timing and amount of any CEFF financings were to be made solely by us, subject to certain conditions. Under the terms of the CEFF, Kingsbridge had agreed to provide at our sole option, subject to certain conditions, up to $60 million of capital in exchange for newly issued shares of our common stock. Through June 30, 2012, we raised a total of approximately $2.6 million from sales of approximately 1.0 million shares of stock under the CEFF. As discussed in Note 8 of our financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, effective August 7, 2012, we terminated the CEFF. No further securities will be sold under this agreement.

While we monitor the cash balance in our checking account and transfer the funds in only as needed, these cash balances and our money market fund could be impacted if the underlying financial institution were to fail or were subject to other adverse conditions in the financial markets. To date, we have experienced no loss or lack of access to cash in our checking accounts or money market fund.

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

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Contractual Obligations and Commercial Commitments

During the six months ended June 30, 2012, we placed purchase orders with Produits Chimiques Auxiliaires et de Synthese SA (PCAS) for the acquisition of mifepristone, the active pharmaceutical ingredient (API) in Korlym, for delivery during 2012 for aggregate commitments of approximately $2.8 million, approximately $1.2 million of which was received and recorded as inventory prior to June 30, 2012. In July 2012, we placed an additional purchase order with PCAS for delivery of mifepristone in the fourth quarter of 2012 or early 2013 for a commitment of approximately $843,000.

In addition, as of June 27, 2012, we signed an amendment to the lease for our office space that reflected an expansion of the space and extended our occupancy through December 2013. The aggregate commitment for base rent through the term of the amendment is approximately $630,000, approximately $202,000 of which will be incurred during the remainder of 2012. The amended lease provides us with an option to extend the lease for one additional year.

As discussed above under the caption Liquidity and Capital Resources , on August 2, 2012, we entered into a Transaction with Biopharma. Under the terms of the Transaction, we will receive $30 million from Biopharma on the closing, which we expect to occur on or about August 16, 2012. In consideration of the $30 million payment, we are obligated to make payments to Biopharma totaling $45 million, calculated as a percentage of our net sales of Covered Products and any upfront, milestone or other contingent payments with respect to Covered Products. The payments we are required to make are entirely variable, with no fixed minimums. Biopharma s right to receive to receive the payments will expire once it has received cumulative payments of $45 million.

Our first such payment will be due with respect to net sales of Covered Products during the quarter ended June 30, 2013 and any upfront, milestone or other contingent payments that we have received with respect to licensing or co-promotion agreements concerning Covered Products from the date of the Transaction through June 30, 2013. A further description of the terms of this transaction is set forth in Note 8 of our financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Off-Balance Sheet Arrangements

None.

Critical Accounting Policies and Estimates

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Our critical accounting policies and estimates are discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011. During the three months ended June 30, 2012, we did not make any significant changes to our critical accounting policies and estimates other than the adoption of accounting policies for product sales, inventory and cost of sales that were adopted in April 2012 in connection with our initial commercialization of Korlym. Below is a description of the accounting policies and estimates in regard to these matters.

Net Product Sales

We sell Korlym to a specialty pharmacy and a specialty distributor, which subsequently resell Korlym to patients and healthcare providers. We recognize product revenues from sales of Korlym upon delivery to our customers as long as (i) there is persuasive evidence that an arrangement exists between ourselves and the customer, (ii) collectability is reasonably assured and (iii) the price is fixed or determinable. In order to conclude that the price is fixed or determinable, we must be able to (i) calculate gross product revenues from the sales to our customers and (ii) reasonably estimate net product revenues.

We calculate gross product revenues based on the price that we charge our customers. We estimate our net product revenues by deducting from our gross product revenues (a) trade allowances, such as discounts for prompt payment and distributor fees, (b) estimated government rebates and chargebacks, (c) reserves for expected product returns and (d) estimated costs of patient assistance programs. We initially record estimates for these deductions at the time we recognize the gross revenue. We update our estimates on a recurring basis as new information becomes available.

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Trade Allowances: We offer our customers a discount on Korlym sales for payment within 30 days. We also offer them a small discount for the provision of data services. We expect our customers to earn these discounts and accordingly deduct them in full from gross product revenues and trade receivables at the time we recognize such revenues.

Rebates and Chargebacks: We contract with Medicaid and other government agencies so that Korlym will be eligible for purchase by, or qualify for partial or full reimbursement from, such government programs. We estimate the rebates and chargebacks that we will be obligated to provide to government programs and deduct these estimated amounts from our gross product sales at the time the revenues are recognized. We base our estimates of these rebates and chargebacks upon (i) the discount rates applicable to government-funded programs and (ii) information obtained from our vendors regarding the percentage of sales by our customers to patients who are covered by entities or programs that are eligible for such rebates and chargebacks.

Allowances for Patient assistance Program: We provide financial assistance to eligible patients whose insurance policies require them to pay high deductibles and co-pays. We estimate the cost of assistance to be provided under this program by applying our actual experience regarding such assistance to our estimate of the percentage of our sales in the period that will be provided to patients covered by the program.

Sales Returns: Our customers have the right to return Korlym beginning six months before the labeled expiration date and ending 12 months after the labeled expiration date. This right of return is extended to our specialty distributor channel s hospital customers who, generally, have the right to return only unopened bottles. The expiration date for our current Korlym inventory is two years after the manufacture of the tablets. We estimate the amount of Korlym that we believe will be returned and deduct that estimated amount from gross revenue at the time we recognize such revenue. When estimating future returns, we analyze quantitative and qualitative information including, but not limited to, actual return rates, the amount of product in the distribution channel, the expected shelf life of such product, current and projected product demand, the introduction of competing products that may erode demand, and broad economic and industry-wide indicators. If we cannot reasonably estimate product returns with respect to a particular sale, we defer recognition of revenue from that sale until such time as a reasonable estimate can be made.

Inventory and Cost of Sales

We consider regulatory approval of product candidates to be uncertain, and product manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. We expense manufacturing costs for product candidates incurred prior to regulatory approval as research and development expenses as we incur them. When regulatory approval of a product is obtained, we begin capitalizing manufacturing costs related to the approved product into inventory.

We value our inventories at the lower of cost or net realizable value. We determine the cost of inventory using the specific identification method on a first-in, first-out basis. We analyze our inventory levels quarterly and write down inventory that has become obsolete or has a cost basis in excess of its expected net realizable value, as well as any inventory quantities in excess of expected requirements. Any expired inventory is disposed of and the related costs are recognized as cost of sales in the statement of comprehensive loss.

Cost of sales includes the cost of product (the cost to manufacture Korlym, which includes material, third-party manufacturing costs and indirect personnel and other overhead costs) based on units for which revenue is recognized in the current period, as well as costs of stability testing, logistics and distribution of the product. We began capitalizing Korlym production costs as inventory following approval by the FDA on February 17, 2012. Prior to receiving the FDA approval for Korlym, we expensed all costs related to the manufacturing of the product (including stability costs and manufacturing overhead) as incurred; we classified these costs as research and development expense. A portion of the product manufactured prior to FDA approval is available for us to use commercially.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

The primary objective of our investment activities is to preserve principal. As of June 30, 2012, our cash and cash equivalents consisted primarily of a money market fund maintained at a major U.S. financial institution that invests primarily in United States Treasury securities. 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 percent increase or decrease in market interest rates would not have a material impact on the total value of our portfolio as of June 30, 2012.

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ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures. Our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of our disclosure controls and procedures, as defined under Rules 13a-15(e) and 15d-15(e) of the Exchange Act as of June 30, 2012. Based on that evaluation, 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 control over financial reporting. There were no changes in our internal control over financial reporting during the quarter ended June 30, 2012, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting other than our adoption of accounting policies for product sales, trade receivables, inventory and cost of sales in April 2012 in connection with our commercialization of Korlym.

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

Risks Related to the Commercialization of Korlym

and Development of Mifepristone and Our Other Proprietary GR-II Antagonists

We depend heavily on the success of Korlym, which we only recently began to sell. If we are unable to commercialize Korlym successfully, or experience significant delays in doing so, we may not generate revenues as quickly as or at the levels that we or investors expect and our stock price will likely decline.

We anticipate that for the foreseeable future our ability to generate meaningful revenues and achieve profitability will be solely dependent on the successful commercialization of Korlym. Many factors could harm our efforts to commercialize Korlym, including:

- an inability to generate meaningful revenue due to low product usage, inadequate reimbursement or other factors;
- an inability to manufacture Korlym or the active ingredient in Korlym in commercial quantities and at an acceptable cost;
- political concerns relating to other uses of mifepristone, or RU-486, that could limit the market acceptance of Korlym;
- negative, inconclusive or otherwise unfavorable results from any post-approval studies we conduct;
- previously unknown, serious side effects that may be identified;
- rapid technological change making Korlym obsolete; and
- competition from companies with greater financial, technical and marketing resources than ours.

Even if we are able to commercialize Korlym successfully, we cannot predict the rate at which success will occur.

As our current ability to generate revenue is wholly dependent upon the commercialization of Korlym, its rate of sale will directly and materially impact our results of operations. There are inherent difficulties in predicting the volumes at which Korlym will be sold and the potential for slower than anticipated adoption and manufacturing, distribution or other delays are heightened by our relative inexperience commercializing Korlym or other products. Failure of our revenue to meet the expectations of investors could cause our stock price to decline. See also the discussion below under The failure of our financial results to meet estimates published by research analysts or other investor expectations could cause our stock price to decline.

Physicians may accept Korlym slowly or may never accept it, which would adversely affect our financial results.

Many factors may affect the market acceptance and commercial success of Korlym.

Even though the FDA has approved Korlym, physicians may not adopt it as a treatment for their eligible patients. Physicians will prescribe Korlym only if they determine, based on experience, clinical data, side effect profiles and other factors, that it is preferable to other products or treatments currently in use, even if those products are not approved for Cushing s syndrome. Because Cushing s syndrome is rare, most physicians are inexperienced in the care of patients with the illness and it may be difficult to persuade them to prescribe a new treatment, such as Korlym, even with clinical trial results that suggest that it may be a compelling alternative treatment for them to consider. Acceptance of Korlym among influential practitioners may be essential for market acceptance of Korlym.

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

- the effectiveness of Korlym, including any side effects, as compared to alternative treatment methods;
- the rate of adoption of Korlym by physicians and by target patient populations;
- the cost-effectiveness of Korlym and the availability of third-party insurance coverage and reimbursement, in particular from government payors such as Medicare and Medicaid, for patients using Korlym;
- the product labeling required by the FDA for Korlym;
- the extent and success of our efforts to manufacture, commercialize, market, distribute and sell Korlym; and
- negative publicity concerning Korlym, RU-486, Mifeprex® or mifepristone.

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

If we are unable to obtain acceptable prices or adequate coverage and reimbursement for Korlym 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 medications in both domestic and international markets depends 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. Our near-term dependence on the commercial success of Korlym makes us particularly susceptible to any such cost containment or reduction efforts. Accordingly, even though Korlym has been approved for commercial sale, unless government and other third-party payors provide adequate and timely coverage and reimbursement, physicians may not prescribe it and patients may not purchase it. In addition, meaningful delays in insurance coverage for individual patients may increase our costs and reduce our revenues. Further, we may need to obtain approvals from hospital formularies before Korlym can be reimbursed for in-patient treatment. If we fail to obtain such approvals, this will reduce the level of revenues that we are able to attain.

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

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

- annual, non-deductible fees on any entity that manufactures or imports certain prescription drugs and biologics;
- increases in Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program for both branded and generic drugs;

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

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

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

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

The PPACA provisions on comparative clinical effectiveness research extended the initiatives of the American Recovery and Reinvestment Act of 2009, also known as the stimulus package, which included $1.1 billion in funding to study the comparative effectiveness of health care treatments. This stimulus funding was designated for, among other things, conducting, supporting or synthesizing research that compares and evaluates the risks and benefits, clinical outcomes, effectiveness and appropriateness of products. The PPACA also appropriated additional funding to comparative clinical effectiveness research. Although Congress has indicated that this funding is intended to improve the quality of health care, it remains unclear how the research will impact current Medicare coverage and reimbursement or how new information will influence other third-party payor policies.

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Since its passage, a number of state governors have strenuously opposed the mandatory purchase of insurance, referred to as the individual mandate, and aspects of voluntary Medicaid expansion under PPACA, and initiated lawsuits challenging its constitutionality. On June 28, 2012, the United States Supreme Court upheld the constitutionality of the individual mandate, and invalidated requirements that states forfeit certain federal funding if they do not expand Medicaid coverage as prescribed by PPACA. The Court left the remainder of PPACA intact. Congress has also proposed a number of legislative initiatives, including possible repeal of the PPACA. At this time, it remains unclear whether there will be any changes made to the PPACA, whether to certain provisions or its entirety.

In addition, other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. Most recently, on August 2, 2011, the Budget Control Act of 2011 among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2 percent per fiscal year, starting in 2013.

The PPACA and regulations and policies implementing this legislation, as well as other healthcare reform measures that may be adopted in the future, may have a material adverse effect on our industry generally and on our ability to successfully develop and commercialize our products.

The Orphan Drug Designation for Korlym may not provide protection from competition and other benefits as anticipated.

In July 2007, we received Orphan Drug Designation from the FDA for Korlym for the treatment of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing s syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. Drugs that receive Orphan Drug Designation obtain seven years of marketing exclusivity for the approved indication from the date of drug approval, as well as tax credits for clinical trial costs, marketing application filing fee waivers and assistance from the FDA in the drug development process.

In October 2011, the European Commission granted to us Orphan Drug Designation for Korlym for the treatment of endogenous Cushing s syndrome (hypercortisolism) in the EU. Benefits of Orphan Drug Designation in the EU are similar to those in the United States, but include ten years of marketing exclusivity for the approved indication in all 27 member states, free scientific advice during drug development, access to a centralized review process and a reduction or complete waiver of fees levied by the European Medicines Agency.

Although we have received Orphan Drug Designation in both the United States and the EU, we cannot be assured that we will recognize the potential benefits of these designations. Even after an orphan drug is approved for its orphan indication, the FDA can subsequently approve a different drug for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. In addition, the FDA may, during the seven-year orphan drug exclusivity period, approve the same drug for a different indication.

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

If another drug with mifepristone as its active ingredient is approved in the EU for Cushing s Syndrome before Korlym, we will not receive the ten years of marketing exclusivity from the date of drug approval in the EU and other benefits that we anticipate. Any delay in our commercialization of Korlym may have a negative impact on the revenue that we might be able to realize from the exclusivity provided during the applicable periods.

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We may face competition from companies that attempt to develop mifepristone or other compounds for the treatment of Cushing s syndrome, which could limit our future revenues from the commercialization of Korlym and which could have a negative impact on future revenues from the commercialization of Korlym for any indication. These companies may have significantly more resources than we do.

We may experience competition from Novartis, which has received approval in the EU to market its somatostatin analogue, pasireotide, for the treatment of patients with Cushing s disease (a subset of the patients with Cushing s syndrome) who have failed or are not candidates for surgery. In the United States, Novartis completed its phase 3 trial of pasireotide in Cushing s disease and submitted an NDA to the FDA in June 2011. It withdrew this NDA in October 2011 due to an unspecified issue related to its chemistry, manufacturing and controls, but has stated that it plans to resubmit its NDA. In April 2012, Novartis initiated an expanded access study that makes pasireotide available internationally and in the United States to certain patients with Cushing s disease who would otherwise not be able to participate in a clinical trial of the drug.

In addition, we are aware that Laboratoire HRA Pharma has begun a Phase 2 clinical trial in Europe and the United States evaluating the use of mifepristone to treat a subtype of Cushing s syndrome, and that Exelgyn Laboratories may be planning to develop a Cushing s syndrome product, although it has stated that it has not conducted any clinical trials to date. See also the discussion above under The Orphan Drug Designation for Korlym may not provide protection from competition and other benefits as anticipated. If another product for treatment of Cushing s syndrome or Cushing s disease is approved for commercialization, our potential future revenue could be reduced.

We will need to develop medical education, sales and marketing capabilities to successfully commercialize Korlym and our other proprietary, selective GR-II antagonists.

We currently have a limited number of employees with experience in marketing or selling pharmaceutical products. To achieve commercial success for any approved product, we must either develop sales and marketing capabilities internally or enter into arrangements with third parties to market and sell our current and future products, and we may not be successful in doing so. We are seeking to hire experienced medical science liaisons and other personnel to commercialize Korlym in the United States, which will be expensive and time consuming. Although we received approval to market and sell Korlym in February 2012, our efforts to staff, deploy and train a marketing and medical education organization remain in an early stage. Any failure or delay in the development or failure to maintain effectively our internal capabilities for the marketing and sales of Korlym would adversely impact the commercialization of the product. If our efforts to develop an internal commercial marketing and sales team are not successful, cost-effective and timely, we may not achieve profitability.

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

We expect that the development of our commercial organization and the likely future expansion of our research and development efforts will strain our administrative, operational and management 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:

- 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;
- hire and train additional qualified personnel;

manage our clinical trials effectively; and

manage our research and development efforts effectively.

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

Public perception of the active ingredient in Korlym, mifepristone (also known as RU-486), may limit our ability to market and sell Korlym.

The active ingredient in Korlym, mifepristone (RU-486), is approved by FDA in another drug for the termination of early 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 Korlym by patients and physicians. Even though we have taken measures to minimize the likelihood of the prescribing of Korlym to a pregnant woman, physicians may choose not to prescribe Korlym to a woman simply to avoid any risk of unintentionally terminating a pregnancy. We have taken measures to control the distribution of Korlym to reduce the potential for diversion and this controlled distribution may negatively impact sales of Korlym.

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We have no manufacturing capabilities and we currently depend on third parties to manufacture the active ingredient and the tablets for Korlym, both of which are single-source suppliers. If these suppliers are unable or unwilling to continue manufacturing Korlym and we are unable to contract quickly with alternative sources, or if these third-party manufacturers fail to comply with FDA regulations or otherwise fail to meet our requirements, 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 depend on third-party contract manufacturers to supply the active pharmaceutical ingredient, or API, in Korlym and to manufacture the Korlym tablet. In addition, we expect to use third-party manufacturers and suppliers if and when our product candidates are approved. The facilities used by our contract manufacturers to manufacture our products must be approved by the FDA pursuant to inspections. We do not control the manufacturing processes of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as current good manufacturing practices, or cGMPs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our products or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our products. In addition, sanctions could be imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could harm our business.

We have an agreement with only one approved manufacturer of the API in Korlym. This agreement is due to expire in November 2012 and we have initiated discussions about extension of the agreement. We have a memorandum of understanding with a second API manufacturer. However, there are no activities currently being conducted at this second manufacturer s site to develop or qualify the manufacturing processes or facilities and we did not request approval of material produced by this second manufacturer when we submitted our NDA for Cushing s syndrome.

We have an agreement with a tablet manufacturer that we included in our NDA submission for Korlym. This tablet manufacturer is a single-source supplier to us and has indicated that it will temporarily suspend commercial production in the fourth quarter of 2012 while it relocates to a new facility. However, we have a contract with a potential second tablet manufacturer to whom we have transferred the production process. This manufacturer has produced regulatory stability batches and established all required analytical testing methods. In June 2012, we submitted an NDA supplement to the FDA requesting this second tablet manufacturer s approval as a source of Korlym tablets. The Prescription Drug User Fee Act due date for the FDA s response is October 27, 2012. Nevertheless, we cannot give you any assurance as to the actual outcome or timing of the FDA s review of this supplement or approval of this vendor as an alternate supplier. If we are unable to secure an alternate tablet supplier on a timely basis, and if our current single-source supplier were to fail to manufacture tablets on a timely basis in the quantities that we require, or fail to maintain manufacturing capabilities that meet FDA standards, we would likely experience a lengthy delay in our manufacturing processes. We cannot assure you that our single source-supplier or any alternate tablet supplier will be able or willing to meet our future demands.

Our current arrangements with these manufacturers are terminable by such manufacturers. If we are unable, for whatever reason, to obtain the API or Korlym tablets from our contract manufacturers, we may not be able to manufacture our required quantities or identify alternate manufacturers of mifepristone or Korlym tablets in a timely manner or on reasonable terms, if at all, which would harm our business.

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If we or others identify previously unknown, serious side effects of mifepristone, we may be required to perform lengthy additional clinical trials, change the labeling of Korlym or withdraw it from the market, any of which would hinder or preclude our ability to generate revenues.

The FDA s approval of Korlym requires that we conduct a study of the interactions between Korlym and ketoconazole, an anti-fungal agent sometimes used to treat patients with Cushing s syndrome. It also requires us to study drug utilization to better characterize the reporting rates of adverse events associated with the long-term use of Korlym. If we or others identify previously unknown, serious side effects of mifepristone:

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

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 Korlym or other product candidates, or by patients using Korlym. A product liability claim may damage our reputation by raising questions about Korlym or any of 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 Korlym is used to terminate pregnancy. Therefore, clinicians using the medicine in our clinical trials and physicians prescribing the medicine to women with childbearing potential must take necessary and strict precautions to ensure 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 company beginning to commercialize its first pharmaceutical product. 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 Korlym or any of our product candidates, or result in meaningful underinsured or uninsured liability. 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.

Even if we receive regulatory approval for our product candidates, we will be subject to ongoing and continued regulatory review, and if we are unable to maintain regulatory approval of Korlym, or if we fail to comply with regulatory requirements, we will be unable to generate revenue or may be subject to penalties and our business will be harmed.

Even after we obtain U.S. regulatory approval for a product, the FDA may still impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. For example, a product s approval may contain requirements for potentially costly post-approval studies and surveillance, including Phase 4 clinical trials, to monitor the safety and efficacy of the product. The FDA s approval of Korlym was subject to limitations on the indicated uses for which the product may be marketed and requirements for post-marketing follow-up studies and information reporting. In addition, the FDA s approval of Korlym requires that we conduct a study of the interactions

between Korlym and ketoconazole, an anti-fungal agent sometimes used to treat patients with Cushing s syndrome. It also requires us to conduct a drug utilization study to better characterize the reporting rates of adverse events associated with the long-term use of Korlym.

We will also be subject to ongoing obligations and continued regulatory review by the FDA and other regulatory authorities in the United States and other countries with respect to the research, testing, manufacturing, labeling, distribution, adverse event reporting, storage, selling, advertising, promotion, recordkeeping and marketing of products. These requirements include submissions of safety and other post-marketing information and reports, annual updates on manufacturing activities and continued compliance with cGMPs and cGCPs for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with FDA regulations and other applicable foreign and U.S. regulatory requirements may result in, among other things, warning letters, civil and criminal penalties, injunctions, holds on clinical trials, product seizure or detention, refusal to permit the import or export of products, restrictions on product marketing, withdrawal of the product from the market, voluntary or mandatory product recalls, total or partial suspension of production, refusal to approve pending NDAs or supplements to approved NDAs, and suspension or revocation of product approvals.

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The FDA s policies may change and additional governmental regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may place at risk any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

The sale of our products is subject to regulatory approvals, and our business is subject to extensive regulatory requirements, and if we are unable to obtain regulatory approval for future product candidates, including mifepristone for the treatment of the psychotic features of psychotic depression, we will be limited in our ability to commercialize such product candidates and our business will be harmed.

We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. Obtaining regulatory approval of a new drug is an uncertain, lengthy and expensive process, and success is never guaranteed. Despite the time, resources and effort expended, failure can occur at any stage. In order to receive approval from the FDA for each product candidate, we must demonstrate that the new drug product is safe and effective for its intended use and that our manufacturing processes for the product candidate comply with the FDA s cGMPs. cGMPs include requirements related to production processes, quality control and assurance, and recordkeeping. The FDA has substantial discretion in the approval process for human medicines. The FDA may require substantial additional clinical testing or find our drug products do not satisfy the standards for approval. Our inability or the inability of our suppliers to comply with applicable FDA and other regulatory requirements can result in, among other things, delays in or denials of new product approvals, warning letters, fines, consent decrees restricting or suspending manufacturing operations, injunctions, civil penalties, recall or seizure of products, total or partial suspension of sales, and/or criminal prosecution. Any of these or other regulatory actions could materially adversely affect our business and our financial condition.

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

If we receive regulatory approval for our future product candidates, including mifepristone for the treatment of psychotic depression, we will 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 restrictions and obligations, such as a Risk Evaluation and Mitigation Strategy. If we are not able to maintain regulatory compliance, we may not be permitted to market our product candidates and/or may be subject to product recalls or seizures.

Any regulatory approvals that we receive for our future 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, we will be subject to ongoing and continuing regulatory requirements. See also the discussion above under Even if we receive regulatory approval for our product candidates, we will be subject to ongoing and continued regulatory review, and if we are unable to maintain regulatory approval of Korlym, or if we fail to comply with regulatory requirements, we will be unable to generate revenue or may be subject to penalties and our business will be harmed.

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

In the United States, we are subject to FDA regulations governing the promotion of health care products. Although physicians are permitted, based on their medical judgment, to prescribe drugs for indications other than those approved by the FDA, manufacturers are prohibited from promoting their products for such off-label uses. In the United States, we will market Korlym for treatment of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing s syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery and provide promotional materials and training programs to physicians regarding the use of Korlym for this indication. Although we believe our marketing materials and training programs for physicians do not constitute off-label promotion of Korlym, the FDA may disagree. If the FDA determines that our promotional materials, training or other activities by our employees or agents constitute off-label promotion of Korlym, it could request that we modify our training or promotional materials or other activities or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal or state enforcement authorities might take action if they believe that the alleged improper promotion led to the submission and payment of claims for an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. Even if it is later determined that we are not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our position and have to divert significant management resources from other matters.

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In addition, there are health care fraud and abuse regulations and enforcement by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

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

- federal false claims laws, which prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as allegedly providing free product to or entering into sham consulting arrangements with customers to induce such customers to purchase, order or recommend the company s products in violation of the Anti-Kickback Statute and federal false claims laws and regulations; reporting to pricing services inflated average wholesale prices that were then used by certain governmental programs to set reimbursement rates; engaging in the promotion of off-label uses that caused customers to submit claims to and obtain reimbursement from governmental payors for non-covered off-label uses; and submitting inflated best price information to the Medicaid Drug Rebate Program;

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

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

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

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

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

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical development is a long, expensive and uncertain process, and data obtained from clinical trials and supportive studies are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The results from early clinical trials may not be predictive of results to be obtained in later clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Clinical trials may not demonstrate sufficient safety and efficacy to obtain the necessary regulatory approvals or a commercially

viable product. To gain regulatory approval from the FDA to market mifepristone for the psychotic features of psychotic depression, our ongoing phase 3 clinical trial must demonstrate the safety and efficacy of mifepristone for that indication. The ongoing phase 3 clinical trial of mifepristone for the treatment of the psychotic features of psychotic depression may not demonstrate efficacy or safety results sufficient for approval, and we may need to conduct other studies in support of a potential NDA in that indication. If our ongoing phase 3 clinical trial is not completed or conducted as planned or if mifepristone does not prove to be safe and effective or does not receive required regulatory approvals, the commercialization of mifepristone for the psychotic features of psychotic depression would be delayed or prevented, and our ability to generate revenues would be impaired.

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Moreover, the commencement and completion of clinical trials may be delayed by many factors that are beyond our control, including:

- delays obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with contract research organizations, or CROs, and clinical trial sites;
- obtaining institutional review board, or IRB, approval at each site;
- slower than anticipated patient enrollment;
- scheduling conflicts with participating clinicians and clinical institutions;
- lack of funding;
- negative or inconclusive results;
- 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 manufacturing operations; and
- real or perceived lack of effectiveness or safety of mifepristone.

We could encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the clinical trial sites in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

We may decide, or the FDA or other regulatory authorities may require us, to pursue additional clinical or preclinical studies on mifepristone for the treatment of the psychotic features of psychotic depression. Additional trials or studies would require additional funding, the availability of 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 mifepristone for treating the psychotic features of psychotic depression. Even if we are able to conduct all of the clinical trials and supportive studies that we consider appropriate for an optimal NDA, we may never receive regulatory approval to market mifepristone for psychotic depression.

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

In connection with our ongoing phase 3 trial evaluating mifepristone for the psychotic features of psychotic depression, Study 14, we engaged MedAvante to provide centralized psychiatric rating services. MedAvante is providing centralized psychometric assessments via high resolution video-conferencing. The use of MedAvante s centralized rating services is intended 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 we 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 with the patients enrolled in our study.

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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 mifepristone in treating the psychotic features of psychotic depression.

During screening for Study 14, there has been a higher than anticipated incidence of potential patients who do not meet appropriate criteria for entrance into the trial for diagnostic and other clinical reasons. Although we believe that this is the result of improved accuracy in the screening process resulting from the use of the MedAvante centralized rating services as an additional step in the selection of patients appropriate for inclusion in the study, MedAvante s diagnostic screening may not actually improve trial performance. In addition, in mid-2009, in order to lower expenses and to conserve financial resources, we scaled back our planned rate of spending on this trial and extended the timeline for its completion. Our current plan is to increase the number of clinical sites from eight to approximately 20, which will increase our rate of spending on the trial, with an unknown effect on the likelihood of success.

We depend on third parties to conduct and manage many of our clinical trials and to perform related data collection and analysis and, if these third parties do not successfully carry out their contractual duties or meet expected timelines, we may face costs and delays that may prevent or delay us from obtaining regulatory approval for or commercializing our product candidates, which could substantially harm our business.

We rely on clinical investigators and clinical sites to enroll patients and other third parties such as clinical research organizations, or CROs, to manage many of our trials and to perform related data collection and analysis. We control only certain aspects of these third parties activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with current good clinical practices, or cGCP, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities through periodic inspections of trial sponsors, clinical investigators and clinical sites. If we or any of the third parties working on or conducting our trials fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approval of our marketing applications, if at all. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with cGCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, 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 mifepristone for the psychotic features of psychotic depression or other development programs.

We have an agreement with a CRO that is conducting our ongoing phase 3 trial evaluating mifepristone 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. The conduct of future clinical trials may also be conducted through the use of CROs and third party clinical sites. 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. If any of our relationships with CROs or other third parties terminates, we may not be able to enter into arrangements with alternative CROs or third parties on commercially reasonable terms, or at all. 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 they need to be replaced 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 regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may be unable to obtain regulatory approval for, or successfully commercialize, mifepristone for the psychotic features of psychotic depression.

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

We may seek to commercialize our products and product candidates in international markets with the help of one or more partners or on our own. Outside the United States, we may commercialize a product only if we receive a marketing authorization and, in many cases, pricing approval, from the appropriate regulatory authorities, whose approval processes include 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. Other than seeking and receiving Orphan Drug Designation in the EU, 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.

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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, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our product candidates in any foreign market.

The fast track designation for the development program of mifepristone 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 mifepristone 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 mifepristone will receive regulatory approval for the treatment of the psychotic features of psychotic depression.

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

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. If approved for commercial use as a treatment for the psychotic features of psychotic depression, mifepristone 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 by physicians for off-label use to treat the psychotic features of psychotic depression, which is the clinical target of mifepristone. Antipsychotics include Abilify® (Bristol-Myers Squibb), Clozaril® (Novartis), Geodon® and Navane® (Pfizer), Haldol® (Ortho-McNeil), Mellaril® (Mylan), Risperdal® (Janssen Pharmaceuticals), Seroquel® (AstraZeneca), Stelazine® and Thorazine® (GlaxoSmithKline) and Zyprexa® (Eli Lilly). Mifepristone may not compete effectively with these established treatments. We are aware of one clinical trial conducted by Organon, for a new chemical entity for the treatment of psychotic depression. Organon was the pharmaceutical division of Akzo Nobel, which was purchased by Schering Plough which was then subsequently acquired by Merck & Co. Organon s new chemical entity is a GR-II antagonist; we believe that its commercial use would be covered by our patent.

Our present and potential competitors include major pharmaceutical companies such as the makers of the drugs identified above, 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 mifepristone. Many of our competitors and related private and public research and academic institutions have greater experience, more financial and marketing 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, mifepristone 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 mifepristone or render mifepristone obsolete or non-competitive. If we are unable to establish mifepristone as a superior and cost-effective treatment for the psychotic features of psychotic depression, or any future use, we may be unable to generate the revenues necessary to support our business.

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

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

The use of GR-II antagonists may not be effective to treat these conditions or any other indications. Moreover, we could discover that the use of GR-II antagonists in these patient populations has unacceptable side effects or is otherwise not safe. Due to the risks of efficacy and side effects inherent in developing novel compounds, we are likely to enter multiple compounds into development, which would increase our rate of spending with no assurance that we will be successful in developing new drugs that are safe and effective.

In addition, 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, and our product development efforts may not lead to commercially viable products.

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

We only have significant clinical experience with mifepristone and we may determine that mifepristone is not desirable for uses other than for the treatment of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing s syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery and the psychotic features of psychotic depression. For example, we do not intend to develop mifepristone for mitigation of the weight gain associated with the use of Zyprexa, Risperdal or other atypical antipsychotics, even though we have reported positive results in the proof of concept studies described in Part I, Item 1, Business Overview Mifepristone Proof-of-Concept Studies for Other Metabolic Disorders of our Annual Report on Form 10-K for the year ended December 31, 2011. We are pursuing other GR-II antagonists for this use. The compounds developed pursuant to our early clinical, preclinical and discovery research programs, including CORT 108297, may fail to become viable product candidates regardless 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 the safety or efficacy of the product candidates, manufacturing difficulties or 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.

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.

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

We face intense competition for qualified personnel from numerous companies, as well as universities and nonprofit research organizations in the highly competitive San Francisco Bay 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.

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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.

The occurrence of a catastrophic disaster or other similar events could cause damage to our own 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 also 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 Capital Needs and Financial Results

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

We may have to perform more clinical trials, in addition to our ongoing phase 3 trial, prior to submitting an NDA for mifepristone for the treatment of the psychotic features of psychotic depression. If so, we may need to raise additional funds to complete the development of mifepristone for that indication. In addition, we may need to raise additional funds to continue and expand the development of our proprietary, selective GR-II antagonists in various indications. We may also raise additional funds for other research and development activities, including clinical trials, and working capital and for other general corporate purposes, or to acquire or invest in businesses, products and technologies that are complementary to our own.

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Factors impacting our cash position and future prospects of liquidity include the following:

- the amount and timing of revenues from the commercialization of Korlym;
- the pace at which physicians adopt Korlym as a treatment;
- the willingness of insurance companies, the government and other third-party payors to provide coverage for Korlym at reasonable rates;
- changes in the reimbursement policies of third-party insurance companies or government agencies;
- the costs, timing of site selection and enrollment of our clinical trials;
- the results of our research efforts and clinical trials;
- the need to perform additional clinical trials and other supportive studies;
- the need to establish second sources for the manufacture of Korlym API and tablets;
- the timing of the submission of an NDA to the FDA, the acceptance of the NDA submission, and the outcome of the FDA approval process for the marketing of mifepristone for the treatment of the psychotic features of psychotic depression;
- the timing of commercialization of mifepristone for the treatment 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; and
- changes in our research and development plans for our proprietary, selective GR-II antagonists.

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 and future operating plans.

We cannot be certain that additional funding will be available on acceptable terms or at all. Even though we have raised funds a number of times in the past, market and economic conditions may make it difficult for us to raise any or sufficient additional capital. Our sales of common stock

and warrants and the exercises of warrants have been dilutive to stockholders and any exercise of outstanding warrants and additional equity financing will cause further dilution to stockholders. Debt financing, if available, may involve restrictive covenants. If we obtain funds through collaborations with others, these arrangements may be on unfavorable terms or may require us to relinquish certain rights to Korlym, our technologies or product candidates, which we would otherwise seek to develop on our own. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or we may be required to discontinue operations.

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

We have a limited history of operations and have focused primarily on clinical trials. We are beginning to commercialize Korlym and, if the outcome of our clinical trials supports it, we plan to seek FDA regulatory clearance to market mifepristone for the treatment of the psychotic features of psychotic depression. Historically, we have funded our operations primarily from the sale of our equity securities. We have incurred losses in each year since our inception in 1998. As of June 30, 2012, we had an accumulated deficit of $227.2 million. We only began to sell our first commercial product, Korlym, in the United States in April 2012. Based on this limited experience marketing Korlym, it is difficult for us to predict the magnitude or timing of future product sales. Subject to our ability to raise additional funds, we expect our research and development expenses to increase in connection with the clinical trials and other development activities for mifepristone for the psychotic features of psychotic depression and for other product candidates. We expect to incur significant expenses related to commercializing Korlym. As a result, we expect that our losses will increase at least until Korlym is generating material amounts of revenue. We are unable to predict the extent of any future losses or whether or when we will become profitable.

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 allows us to consider for further development are collectively greater than the funds currently available to us. For example, we have successfully discovered three series of compounds that are selective GR-II antagonists but, unlike mifepristone, do not appear to block the progesterone receptor. Further development of these proprietary compounds 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 mifepristone for the treatment of psychotic depression.

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

In the United States and globally, market and economic conditions have been volatile over the past few years, with significantly tighter credit conditions in the markets in which we conduct our operations. The U.S. and global economies have experienced a recession and face continued concerns about the systemic impact of adverse economic conditions, such as unstable global financial markets, adverse effects on the cost and availability of capital, high corporate, consumer and governmental debt levels and high unemployment. Concern about the stability of the markets generally, and the strength of counterparties specifically, has led and may again lead many lenders and institutional investors to reduce, and in some cases, cease, to provide credit to businesses. Renewed or increased turbulence in the global markets and economies may adversely affect our liquidity and financial condition.

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

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

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

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

Failure to meet our obligations under our Transaction with Biopharma Secured Debt Fund II Sub, S.àr.l, could adversely affect our financial results and liquidity.

Pursuant to our Transaction with Biopharma in August 2012, we are obligated to make payments to Biopharma equal to 20 percent of our net product sales of Korlym, any future mifepristone-based products and our next-generation selective GR-II antagonists (Covered Products), subject to certain quarterly caps, as well as an un-capped 20 percent of any upfront, milestone or other contingent payments we receive with respect to Covered Products, until such payments to Biopharma total $45 million.

Pursuant to this agreement, we may not: (i) incur indebtedness greater than the sum of Earnings Before Interest, Taxes, Depreciation and Amortization, including such items as non-cash stock-based compensation, (EBITDA) for the four calendar quarters preceding such incurrence (the Indebtedness Covenant); (ii) pay a dividend or other cash distribution, unless we have cash and cash equivalents in excess of $50 million after such payment; (iii) amend or restate our certificate of incorporation or bylaws unless such amendments or restatements do not affect Biopharma s interests under the Transaction; and (iv) encumber any of the collateral securing our performance under the agreement.

The percentage used to calculate our payments to Biopharma would increase to 50 percent and any applicable payment caps would lapse if we (i) fail to provide Biopharma with certain information regarding our promotion and sales of Covered Products, (ii) do not devote a commercially reasonable amount of resources to the promotion and marketing of the Covered Products or (iii) violate the Indebtedness Covenant and, in each case, fail to cure within the applicable cure period.

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Upon a Corcept change of control transaction, as defined in the agreement, Biopharma will be automatically entitled to receive any amounts not previously paid, up to our maximum of $45 million repayment obligation. As defined in the agreement, Change in Control includes, among other things, (i) a greater than 50 percent change in the ownership or Board composition of Corcept and (ii) the licensing of Korlym to a third party for sale in the United States.

To secure our obligations under the agreement, we granted Biopharma a security interest in our rights in patents, trademarks, trade names, domain names, copyrights, know-how and regulatory approvals related to the Covered Products, all books and records relating to the foregoing and all proceeds of the foregoing. If we (i) fail to deliver a royalty payment when due and do not remedy that failure within 30 days, (ii) fail to maintain a first-priority perfected security interest in the Collateral in the United States and do not remedy that failure within five business days of receiving notice of such failure or (iii) become subject to an event of bankruptcy, then Biopharma may attempt to recover up to $45 million (after deducting any payments we have already made).

There can be no assurance that we will not breach the covenants or other terms of, or that an event of default will not occur under this agreement and, if a breach or event of default occurs, there can be no assurance that we will be able to cure the event within the time permitted. Any failure to pay our obligations when due, any breach or default of our covenants or other obligations, or any other event that causes an acceleration of payment at a time when we do not have sufficient resources to meet these obligations, could have a material adverse effect on our business, results of operations, financial condition and future viability.

The acceleration of the payment obligation in the event of a change of control transaction may make us less attractive to potential acquirers, and the payment of such funds out of our available cash or acquisition proceeds would reduce acquisition proceeds for our stockholders.

Risks Relating to Our Intellectual Property

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

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

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

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

which would impair our ability to compete.

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

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

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

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 may make it more difficult for us to prove patent infringement if physicians prescribe another manufacturer s mifepristone for the treatment of Cushing s syndrome or psychotic depression or if patients acquire mifepristone from other sources, such as the internet or black market.

We have an exclusive license from Stanford University to a patent covering the use of GR-II antagonists, including mifepristone, for the treatment of psychotic depression. A method of use patent covers only a specified use of a particular compound, not a particular composition of matter. Because none of our issued patents covers the composition of mifepristone, we cannot prevent others from commercializing mifepristone in indications not covered by our method of use patents. If others receive approval to manufacture and market mifepristone or any other GR-II antagonist, physicians could prescribe mifepristone or any other GR-II antagonist for patients with psychotic depression instead of mifepristone. 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 the psychotic features of psychotic depression that works through a mechanism which does not involve the GR-II receptor, physicians could prescribe that treatment instead of mifepristone.

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 will not be able to obtain mifepristone from this source or others, should another company receive approval to market mifepristone for another indication.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our clinical and commercialization activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our product research, development and commercialization efforts could be delayed.

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Risks Related to Our Stock

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

We cannot assure you that an active trading market for our common stock will exist at any time. Holders of our common stock may not be able to sell shares quickly or at the market price if trading in our common stock is not active. During the 52-week period ended August 1, 2012, our average daily trading volume was approximately 344,000 shares and the intra-day sales prices per share of our common stock on the NASDAQ Stock Market ranged from $2.50 to $4.90. As of August 1, 2012, our officers, directors and principal stockholders controlled approximately 35 percent of our common stock. The trading price of our common stock has been and is likely to continue to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

- the pace of market acceptance of Korlym or the timing and level of reimbursement attained;
- 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, including potential product returns and timing of revenue recognition;
- 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;

success of additional financing efforts; and

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

In addition, the stock market in general, the NASDAQ Stock 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.

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The failure of our financial results to meet estimates published by research analysts or other investor expectations could cause our stock price to decline.

There are inherent difficulties in predicting the amount of Korlym that will be sold. For example, the rate of physician adoption of Korlym is uncertain. Furthermore, the timing of a single large order for Korlym could substantially affect our revenue, making our levels of revenue potentially volatile and the identification of revenue trends difficult. Due to such uncertainty, we have not provided any revenue forecasts to investors or research analysts. Research analysts who cover our business have, however, put forth a wide range of revenue estimates, based entirely on their own investigation and analysis. We have not guided or commented on these estimates and you should rely on them at your own discretion. Announcement of financial results that fail to meet analyst estimates or the expectations of investors could cause our stock price to decline.

Research analysts may not continue to provide or initiate coverage of our common stock or may issue negative reports, which 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, whether as a result of equity financings by us or due to the release of trading restrictions, 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 provides that if we fail to file or cause to be declared effective the registration statement covering the resale of these shares prior to specified deadlines, or fail to maintain the effectiveness of such registration statement (subject to limited permissible suspension periods), we will be required to pay the holders of such shares and warrants liquidated damages at the rate of 1 percent of the purchase price of these shares and warrants per month, up to a total of 10 percent. The registration statement covering the resale of the shares and shares underlying the warrants sold in this transaction was declared effective by the SEC in November 2008. Since this registration statement was not declared effective within the time frame specified in the registration rights agreement, we became obligated to pay liquidated damages of approximately $1.3 million in 2008 to the investors in this financing, which obligation was settled in the form of stock in lieu of cash in November 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.

In addition, in March 2008, we entered into a CEFF with Kingsbridge, under which we granted to Kingsbridge a warrant for the purchase of 330,000 shares of common stock. Through June 30, 2012, we sold approximately 1.0 million shares of stock to Kingsbridge under the CEFF. As discussed in Note 8 of our financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, we terminated our CEFF with Kingsbridge effective August 7, 2012 and no further securities will be sold thereunder. However, under the registration rights agreement issued in connection with the CEFF, we are required to continue to use commercially reasonable efforts to maintain the effectiveness of the registration statement covering the shares sold under this agreement and to be issued upon the exercise of the warrant for a period of up to two years following the termination of the CEFF, subject to earlier termination on certain events. During this period, if the effectiveness of the registration statement lapses through actions that were within our control, we may be obligated to pay Kingsbridge for all shares issued under the CEFF and still owned by Kingsbridge at any time during the period of ineffectiveness the difference between (a) the volume weighted average price as of the day prior to the period of ineffectiveness and (b) the volume weighted average price as of the day following the period of ineffectiveness.

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 August 1, 2012, our officers, directors and principal stockholders control approximately 35 percent 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.

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

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

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

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

We are a small company with limited resources.

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

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

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

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

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

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 Stock Market could determine to delist our common stock, the delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease. Such delisting could also adversely affect our ability to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees.

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

Provisions in our charter and bylaws may delay or prevent an acquisition of us or a change in our management. Some of these provisions 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 percent or more of our outstanding voting stock, from merging or combining with us. These provisions in our charter, bylaws and under Delaware law could reduce the price that investors might be willing to pay for shares of our common stock in the future and result in the market price being lower than it would be without these provisions.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

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ITEM 6. EXHIBITS

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation, as amended.
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the registrant s Current Report on Form 8-K filed on September 27, 2007).
10.1#	Commercial Outsourcing Services Agreement with Integrated Commercialization Solutions, Inc., dated as of April 14, 2011.
10.2#	Amended and Restated Exclusive Pharmacy Product Purchase and Services Agreement with CuraScript, Inc., dated August 8, 2012.
10.3#	Amended and Restated Exclusive Wholesale Product Purchase Agreement with CuraScript SD Specialty Distribution, dated August 8, 2012.
10.4	Corcept Therapeutics Incorporated 2012 Incentive Award Plan (incorporated by reference to Appendix A to the registrant s Definitive Proxy Statement on Schedule 14A filed with the SEC on May 21, 2012).
31.1	Rule 13a-14(a)/15d-14(a) Certifications of Joseph K. Belanoff, M.D., Chief Executive Officer of the registrant.
31.2	Rule 13a-14(a)/15d-14(a) Certifications of G. Charles Robb, Chief Financial Officer of the registrant.
32.1	18 U.S.C. Section 1350 Certifications of Joseph K. Belanoff, M.D., Chief Executive Officer of the registrant.
32.2	18 U.S.C. Section 1350 Certifications of G. Charles Robb, Chief Financial Officer of the registrant.
101*	The following materials from the registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2012, formatted in Extensible Business Reporting Language (XBRL): (i) unaudited Condensed Balance Sheets at June 30, 2012 and December 31, 2011, (ii) unaudited Condensed Statements of Comprehensive Loss for the Three- and Six-Month Periods Ended June 30, 2012 and 2011, (iii) unaudited Condensed Statements of Cash Flows for the Six-Month Periods Ended June 30, 2012 and 2011, and (iv) Notes to Condensed Financial Statements.

Confidential treatment requested

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

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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: August 9 2012

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

Chief Executive Officer

Date: August 9, 2012

/s/ G. Charles Robb
G. Charles Robb

Chief Financial Officer

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