CORCEPT THERAPEUTICS INC
Form 10-Q
November 12, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2013

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 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 November 6, 2013 there were 99,814,250 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 and sell Korlym® (mifepristone) 300mg Tablets;*
- *the progress and timing of our research, development and clinical programs and the timing of regulatory activities for mifepristone for the treatment of the psychotic features of psychotic depression;*
- *our estimates regarding enrollment in and the dates by which we expect to report results of our clinical trials and the anticipated results of these trials;*
- *our ability to achieve marketing approval of Korlym in the European Union (EU) and realize the benefits of Orphan Drug Designation there;*
- *our ability to realize the benefits of Orphan Drug Designation of Korlym in the United States;*
- *the timing of the market introduction of future product candidates, including any 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 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.*

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 except per share data)

	September 30, 2013 (Unaudited)	December 31, 2012 (See Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 63,175	$ 93,032
Trade receivables, net	1,019	557
Inventory	1,025	853
Prepaid expenses and other current assets	1,004	620
Total current assets	66,223	95,062
Strategic inventory	4,530	3,810
Property and equipment, net of accumulated depreciation	184	150
Other assets	120	144
Total assets	$ 71,057	$ 99,166
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 2,337	$ 3,804
Accrued clinical expenses	1,963	843
Accrued compensation	510	351
Other accrued liabilities	777	695
Long-term obligation current portion	4,500	2,650
Deferred revenue	55	16
Total current liabilities	10,142	8,359
Long-term obligation, net of current portion	30,142	29,030
Commitments		
Stockholders equity:		
Preferred stock, par value $0.001 per share, 10,000 shares authorized and no shares outstanding at September 30, 2013 and December 31, 2012		
Common stock, par value $0.001 per share, 280,000 shares authorized and 99,814 shares issued and outstanding at September 30, 2013 and December 31, 2012	100	100
Additional paid-in capital	312,166	308,283
Accumulated deficit	(281,493)	(246,606)
Total stockholders equity	30,773	61,777
Total liabilities and stockholders equity	$ 71,057	$ 99,166

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 September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Product sales, net	$ 2,634	$ 1,055	$ 6,242	$ 1,930
Operating expenses:				
Cost of sales	40	24	82	72
Research and development	5,155	3,008	13,903	9,218
Selling, general and administrative	7,179	5,694	23,723	18,932
Total operating expenses	12,374	8,726	37,708	28,222
Loss from operations	(9,740)	(7,671)	(31,466)	(26,292)
Interest and other expense	(1,166)	(622)	(3,421)	(632)
Net loss and comprehensive loss	$ (10,906)	$ (8,293)	$ (34,887)	$ (26,924)
Basic and diluted net loss per share	$ (0.11)	$ (0.08)	$ (0.35)	$ (0.30)
Weighted average shares outstanding used in computing basic and diluted net loss per share	99,814	99,082	99,814	90,738

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)

	Nine Months Ended September 30,	
	2013	2012
Operating activities		
Net loss	$ (34,887)	$ (26,924)
Adjustments to reconcile net loss to net cash used in operations:		
Stock-based compensation	3,883	4,264
Accretion of interest expense	3,340	575
Amortization of debt financing costs	27	9
Depreciation and amortization of property and equipment	53	14
Changes in operating assets and liabilities:		
Trade receivables	(462)	(354)
Inventory	(892)	(2,477)
Prepaid expenses and other current assets	(384)	(660)
Other assets	(3)	3
Accounts payable	(1,467)	(2,037)
Accrued clinical expenses	1,120	(39)
Accrued compensation and other liabilities	241	327
Deferred revenue	39	21
Net cash used in operating activities	(29,392)	(27,278)
Investing activities		
Purchases of property and equipment	(87)	(93)
Cash used in investing activities	(87)	(93)
Financing activities		
Proceeds from issuance of common stock and warrants, net of issuance costs		59,504
Proceeds from issuance of long-term obligation, net of issuance costs		29,860
Payment related to long-term obligation	(378)	
Net cash (used in) provided by financing activities	(378)	89,364
Net (decrease) increase in cash and cash equivalents	(29,857)	61,993
Cash and cash equivalents, at beginning of period	93,032	39,635
Cash and cash equivalents, at end of period	$ 63,175	$ 101,628

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. Basis of Presentation and Summary of Significant Accounting Policies

Description of Business and Basis of Presentation

Corcept Therapeutics Incorporated was incorporated in the state of Delaware in May 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, we have been developing our lead product, Korlym®. Mifepristone, the active ingredient in Korlym, is a potent competitive antagonist of the glucocorticoid receptor II (GR-II), which means that it competitively blocks the effects of cortisol throughout the body at one of its two receptors. In February 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 in April 2012. We also have a clinical program for the use of mifepristone 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 and patented three series of novel selective 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 Incorpora

The accompanying unaudited condensed balance sheet as of September 30, 2013 and the condensed statements of comprehensive loss and condensed statements of cash flows for the three- and nine-month periods ended September 30, 2013 and 2012 have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three- and nine-month periods ended September 30, 2013 are not necessarily indicative of the results that may be expected for the year ending December 31, 2013 or any other period. These financial statements and notes should be read in conjunction with the financial statements for the year ended December 31, 2012 included in our Annual Report on Form 10-K. The accompanying balance sheet as of December 31, 2012 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 make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. 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, contingent liabilities, and the timing of payments with respect to our long-term capped royalty obligation, which determine its effective interest rate. We base our estimates on relevant experience and on other specific assumptions that we believe are reasonable.

We update our assumptions and estimates on a recurring basis as new information becomes available. Any changes in estimates are recorded in the period of the change.

Cash and Cash Equivalents

We invest our 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. As of September 30, 2013 and December 31, 2012, 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. This fund invests primarily in short-term U.S. Treasury notes and bills.

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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 or by the entity or entities that issued the securities held by the fund 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. We experienced no loss or lack of access to cash and cash equivalents in our operating or investment accounts during the three- and nine-month periods ended September 30, 2013 and 2012.

Since the commercialization of Korlym in April 2012, we have been exposed to credit risk in regard to our trade receivables. From the launch of Korlym through June 30, 2013, approximately 97% of our sales were to one specialty pharmacy customer, from whom we have fully collected all receivables. As discussed in Note 5, ***Significant Agreements Specialty Pharmacy for Korlym***, we have transitioned all of our specialty pharmacy business to a new provider, Centric Health Resources, Inc. (Centric). Among other services, Centric dispenses Korlym to patients for us, with title to the medicine passing from us to the patient upon patient s receipt of the drug. Accordingly, our receivables risk is spread among various third-party payors pharmacy benefit managers, insurance companies, private charities, government programs and individual patients. We extend credit to third-party payors based on their creditworthiness. 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 September 30, 2013, we had one tablet manufacturer for Korlym with an operational facility, AAI Pharma (AAI), which was approved by the FDA in November 2012 for the manufacture of our commercial tablets, subject to the successful manufacture of validation batches. We plan to undertake this validation process at AAI early in 2014 and are currently in negotiations for a long-term commercial manufacturing agreement with AAI. If AAI is unable to prepare Korlym tablets in the quantities and time frame required, we may not be able to manufacture our product in a timely manner. In addition, we have a single-source manufacturer of mifepristone, the active pharmaceutical ingredient (API), in Korlym. In order to mitigate these risks related to the manufacture of our product, we placed strategic orders for additional quantities of API and Korlym tablets, which are now in inventory.

Fair Value Measurements

We categorize financial instruments 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 reported at fair value other than our cash equivalents.

Trade Receivables, net

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. We determine our allowance for doubtful accounts 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.

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CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

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, provided such product is produced by a facility the FDA has approved to manufacture Korlym.

We value our inventories at the lower of cost or net realizable value. We determine the cost of inventory using the specific identification method, which approximates 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.

Inventory amounts that are not expected to be consumed within twelve months following the balance sheet date are classified as strategic inventory, a noncurrent asset.

Property and Equipment

We state property and equipment at cost less accumulated depreciation. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets, ranging from three to five years.

Long-term Obligation

In August 2012, we entered into a Purchase and Sale Agreement (Financing Agreement) with Biopharma Secured Debt Fund II Sub, S.à r.l (Biopharma), a private limited liability company organized under the laws of Luxembourg. Under the terms of the Financing Agreement, we received $30.0 million from Biopharma and are obligated to make payments calculated as a percentage of (i) any licensing or other contingent payments arising from Korlym and any other products containing mifepristone or any of our proprietary selective GR-II antagonists (Covered Products) and (ii) net Covered Product revenues earned in the calendar quarter ended June 30, 2013 and thereafter (together, Korlym Receipts), until such time as we have paid Biopharma a total of $45.0 million.

The accounting for the Financing Agreement requires us to make certain estimates and assumptions, including the timing of royalty payments due to Biopharma, the expected rate of return to Biopharma, the split between current and long-term portions of the obligation and the accretion of related interest expense. Korlym has only been marketed since April 2012 and the magnitude and timing of Korlym revenue is difficult to predict. Therefore, these estimates and assumptions are subject to significant variability and are likely to change as we gain experience marketing Korlym, which will result in changes in our classification of the current and long-term portions of the amounts payable pursuant to the Financing Agreement, as well as the internal rate of return paid to Biopharma and the accretion of interest expense related to this obligation. Actual payment amounts will be based on Korlym Receipts over the term of the Financing Agreement but in no event will the total amount paid to Biopharma exceed $45.0 million.

The amount shown as the current portion of the obligation is an estimate of the total amount under the Financing Agreement that would be paid to Biopharma within twelve months following September 30, 2013. Under the Financing Agreement, our first payment to Biopharma was made in July 2013.

See Note 4, ***Long-term Obligation***, for additional information regarding this agreement.

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CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

Net Product Sales

From our initial launch in April 2012 through June 30, 2013, we sold Korlym primarily to a specialty pharmacy and a specialty distributor, which subsequently resold Korlym to patients and healthcare providers. Korlym is not available in retail pharmacies. As discussed in Note 5, ***Significant Agreements Specialty Pharmacy for Korlym***, Centric, the specialty pharmacy we began using July 1, 2013, operates on a consignment basis, without carrying any Korlym inventory. Accordingly, all of our sales through Centric are made directly to patients.

We recognize product revenues from sales of Korlym upon delivery to patients 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. Prior authorization or confirmation of coverage level by the patient s private insurance plan or government payor is a prerequisite to the shipment of product to a patient. 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 provide cash donations to a non-profit third party organization that supports patients who meet certain eligibility requirements with financial assistance for the treatment of Cushing s syndrome, which treatment may include Korlym. We do not include as net product revenues sales of Korlym tablets funded through this source.

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 our patient co-pay assistance program. 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: Through June 30, 2013, we offered our specialty pharmacy and specialty distributor customers a discount on Korlym sales for payment within 30 days. We also offered them a small discount for providing data services. We expected these customers to earn these discounts and, accordingly, deducted them in full from gross product revenues and trade receivables at the time we recognized such revenues. Because of our change in specialty pharmacies, we no longer offer a prompt-payment discount.

Rebates and Chargebacks: We contract with Medicaid and other government programs 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 amounts 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 specialty distribution customer has 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 hospital customers of our specialty distribution customer who, generally, have the right to return only unopened bottles. Individual patients do not have the right to return product. We have the right to resell returned product, provided the bottles have not been opened or damaged and the product has not expired. The expiration date for the Korlym product sold to date will not occur until May 2014. 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

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CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

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.

See Note 5, ***Significant Agreements Specialty Pharmacy for Korlym***, for additional information regarding our new specialty pharmacy agreement signed in May 2013 with Centric, termination of our previous agreement with CuraScript Specialty Pharmacy (CuraScript) and the product return reserve recorded as of June 30, 2013 as a result of termination of our CuraScript agreement. Because Centric operates on a consignment model and does not carry inventory, our future exposure to product returns will be limited to the specialty distributor channel and is not expected to be material.

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 in February 2012. Prior to receiving FDA approval for Korlym, we expensed all costs related to the manufacturing of the product 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.

Research and Development

Research and development expense consists of costs incurred for research and development activities that we sponsor. 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 related to option grants to employees and directors under the fair value method, based on the fair value-based measurement of the award at the grant date as determined utilizing the Black-Scholes option valuation model. For service-based awards, we recognize expense over the requisite service period. For options with performance-based vesting criteria, we begin to recognize expense when we believe there is a high degree of probability (i.e., greater than 70%) of achieving the vesting criteria.

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CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

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

As of September 30, 2013 and December 31, 2012, 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 $62.6 million and $92.5 million as of September 30, 2013 and December 31, 2012, 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.

There were no realized gains or losses on investments during the three- and nine-month periods ended September 30, 2013 and 2012. The cost of securities sold is determined based upon specific identification.

3. Composition of Certain Balance Sheet Items

Inventory

The composition of inventory was as follows (in thousands):

	September 30, 2013	December 31, 2012
Raw materials	$ 4,318	$ 3,478
Work in progress		1,165
Finished goods	1,237	20
Total inventory	5,555	4,663
Less strategic inventory classified as non-current	(4,530)	(3,810)
Total inventory classified as current	$ 1,025	$ 853

The finished goods inventory as of December 31, 2012 consisted of tablets that were manufactured prior to FDA approval. The inventory value for this material included only the costs of bottling, packaging and labeling as the costs of raw materials and tablet manufacture were expensed prior to approval. The finished goods inventory as of September 30, 2013 includes all costs of manufacture and packing with the exception of the cost of raw materials that were expensed prior to FDA approval.

In order to be prepared for potential demand for Korlym and because we had single-source manufacturers of both the API for Korlym and Korlym tablets prior to the approval by the FDA of our second tablet manufacturer in November 2012, we have invested in inventory of both of these materials. Inventory amounts that are not expected to be consumed within twelve months following the balance sheet date are referred to as Strategic Inventory and classified as a noncurrent asset.

Other Accrued Liabilities

Other accrued liabilities consisted of the following (in thousands):

	September 30, 2013	December 31, 2012
Professional fees	$ 363	$ 311
Commercialization costs	227	159
Government rebates	86	78
Legal fees	95	31
Other	6	116
	$ 777	$ 695

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CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

4. Long-term Obligation

As discussed in Note 1, ***Basis of Presentation and Summary of Significant Accounting Policies, Long-term Obligation***, in August 2012, we entered into a Financing Agreement with Biopharma under which we received $30.0 million from Biopharma. In return, we are obligated to make payments, calculated as a percentage of our net sales of Korlym, any future mifepristone-based products, 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 $45.0 million.

Under the terms of the Financing Agreement, 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 ended June 30, 2013, subject to quarterly payment caps of $2.25 million during 2013, $3.0 million during 2014, and $3.75 million 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).

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 by incurring indebtedness greater than the sum of earnings before interest, taxes, depreciation and amortization, including such items as non-cash stock-based compensation, for the four calendar quarters preceding such incurrence 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 $45.0 million, less any amounts already paid by us, would become due.

To secure our obligations in connection with this Financing 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 (together, 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 $45.0 million (after deducting any payments we have already made). In addition, pursuant to this agreement, we are not allowed to pay a dividend or other cash distribution, unless we will have cash and cash equivalents in excess of $50.0 million after such payment.

The cash payment of $30.0 million received from Biopharma was recorded as a long-term obligation at issuance. As discussed in Note 1, ***Basis of Presentation and Summary of Significant Accounting Policies, Long-term Obligation***, we make estimates of the timing of payments during the term of this agreement for purposes of calculating the expected rate of return to Biopharma, the accretion of related interest expense and the current portion of our obligation. Interest expense of $1.1 million for three-month period ended September 30, 2013, $3.3 million for the nine-month period ended September 30, 2013 and total accreted interest of $5.0 million for the period from August 16, 2012, the date of funding of the Financing Agreement, through September 30, 2013, was calculated based on the internal interest rate to Biopharma that would result from

these assumed payment streams. Korlym has only been marketed since April 2012 and the magnitude and timing of Korlym revenue is difficult to predict. Therefore, these estimates and assumptions are subject to significant variability and are likely to change as we gain experience marketing Korlym. The timing of payment amounts

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CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

will be based on actual Korlym Receipts recorded in the financial statements over the term of this agreement and may differ from these estimates. While changes in the timing of Korlym revenue may affect the timing of recognition of interest expense and the split between the current and long-term portions of the obligation at any balance sheet date, the aggregate amount to be repaid to Biopharma is fixed.

The carrying value of the long-term obligation was $34.6 million and $31.7 million as of September 30, 2013 and December 31, 2012, respectively, including accreted interest of $5.0 million and $1.7 million, respectively, less the repayment of $378,000 in July 2013. The long-term obligation, including accrued interest, is presented on the balance sheet in two components; the Long-term obligation current portion, which equates to the estimated amount due under the agreement to be paid within twelve months following the balance sheet date, and the remaining amount, which is included in Long-term obligation, net of current portion. The following table provides a summary of the payment obligations under the Financing Agreement as of September 30, 2013 and December 31, 2012, utilizing the payment assumptions discussed above.

	September 30, 2013	December 31, 2012
	(in thousands)	
Total repayment obligation	$ 45,000	$ 45,000
Less interest to be accreted in future periods	(9,980)	(13,320)
Less payment made	(378)	
Less current portion	(4,500)	(2,650)
Long-term obligation, net of current portion	$ 30,142	$ 29,030

The estimated fair value of the long-term obligation, as measured using Level 3 inputs based upon available information regarding similar arrangements, approximates the carrying amounts as presented on the balance sheet as of September 30, 2013 and December 31, 2012.

We capitalized $140,000 of issuance costs related to the Financing Agreement, which are being amortized over the estimated term of the obligation, based on the assumptions discussed above. At September 30, 2013 and December 31, 2012, the unamortized issuance costs were $96,000 and $124,000, respectively, and are included in other assets on our balance sheets.

In accordance with the terms of the Financing Agreement, our first payment to Biopharma was made in July 2013 in the amount of approximately $378,000; our second payment was made in October 2013 in the amount of approximately $647,000.

5. Significant Agreements Specialty Pharmacy for Korlym

On May 21, 2013, we entered into a services agreement with Centric Health Resources, Inc. (Centric) to provide exclusive specialty pharmacy and patient services programs for Korlym beginning July 1, 2013. Under the terms of this agreement, Centric acts as the exclusive specialty pharmacy distributor of Korlym in the United States, subject to certain exceptions. Among other services, Centric provides services related to pharmacy operations; patient intake, access and reimbursement; patient support; claims management and accounts receivable; and data and reporting.

We provide Korlym to Centric, which it dispenses to patients. Centric does not take title to the product, which passes directly from us to the patient at the time the patient receives the medicine.

The initial term of the agreement is a period of three years, with successive automatic renewal terms of three years unless either party gives at least 180 days prior notice of non-renewal.

The agreement contains customary termination provisions, representations, warranties and covenants. Subject to certain limitations, we have agreed to indemnify Centric for certain third party claims related to the product, and we have each agreed to indemnify the other for certain breaches of representations, warranties, covenants, and other specified matters.

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CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

As of May 20, 2013, we gave notice to CuraScript, our previous specialty pharmacy provider, of our intent to terminate our agreement with them effective July 20, 2013. As of June 30, 2013, we recorded a return reserve estimate of $300,000 for inventory that CuraScript had purchased from us but had the right to return as a result of this termination. This amount was reflected as an adjustment to net revenue in our Statement of Comprehensive Loss for the nine-month period ended September 30, 2013. In the future, our exposure to product returns will be limited to the specialty distributor channel and is not expected to be material.

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).

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Research and development	$ 161	$ 160	$ 466	$ 416
Selling, general and administrative	1,148	833	3,417	3,848
Total non-cash stock-based compensation	$ 1,309	$ 993	$ 3,883	$ 4,264

The data in the table above for the nine-month period ended September 30, 2012 includes $1.3 million of non-cash stock-based compensation expense, 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 our first commercial product. All other stock-based compensation in the periods presented relates to service-based option awards.

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 the period. The computation of net loss per share for each period, including the number of weighted-average shares outstanding, is shown on the face of the Statements of Comprehensive Loss.

We have excluded the impact of common stock equivalents relating to shares underlying outstanding stock options and warrants from the calculation of diluted net loss per common share because all such securities are antidilutive for all periods presented.

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

	September 30,	
	2013	2012
Stock options outstanding	14,621	10,891
Warrants outstanding	8,574	9,026

Total	23,195	19,917

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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, competitive glucocorticoid receptor II (GR-II) antagonist. In February 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 first made the drug available to patients in the United States in April 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 and patented three series of selective GR-II antagonists that, like Korlym, competitively block GR-II but, unlike Korlym, do not bind to the progesterone receptor and thus do not interfere with pregnancy.

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.

The FDA approval of Korlym allows us to market Korlym in the United States for its approved indication. Since Korlym s approval in February 2012, we have been carrying out our commercialization plans, including deploying medical science liaisons (MSLs) and sales representatives. We have also developed digital marketing capabilities and patient assistance programs to support physicians and patients. Korlym first became available to patients in April 2012. We finished hiring and the initial training of our team of MSLs in the third quarter of 2012 and of our sales representatives in the fourth quarter of 2012.

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 United States, but include ten years of marketing exclusivity for the approved indication in all 28 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 (EMA). The EMA has accepted our plan to study the use of Korlym in children with Cushing s syndrome. We expect that the completion of this study will extend our period of marketing exclusivity by two years in the EU. We submitted our Marketing Authorization Application request to the EMA in October 2013.

In May 2013, we entered into an agreement with IDIS Limited (IDIS) to distribute Korlym on a named-patient basis in all countries outside of the United States. A named-patient program provides access to drugs for a single patient or group of patients in countries where they are not commercially available. Products offered through such a program can be investigational or can be approved in one country but not the patient s home country. Regulations covering named-patient programs vary by country. IDIS s right to distribute Korlym in a particular country will terminate automatically upon Korlym s approval by regulatory authorities in that country and its availability there on a commercial basis. IDIS received approval from the Medicines Healthcare Products Regulatory Agency to distribute Korlym on a named-patient basis in the third quarter of 2013.

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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 average drug plasma levels than did the groups of patients who received lower doses. Further, there was no discernible 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.

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 the change in dose, as well as the other modifications to the protocol described above, should allow us to demonstrate the efficacy of mifepristone in the treatment of the psychotic symptoms of psychotic depression.

Enrollment in Study 14 is ongoing. 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. In the fourth quarter of 2012, we began adding clinical sites and had 27 active sites as of November 6, 2013**.** We expect to perform an interim analysis of data from this study and report results of that analysis in the second quarter of 2014.

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,

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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 mifepristone, competitively antagonize the cortisol receptor (GR-II) but, unlike mifepristone, they do not 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 composition of matter patents to us on each of the three series. Two additional composition of matter patent applications are pending.

Several of our new compounds have demonstrated positive results in animal or *in vitro* models for the prevention and reversal of alcohol dependence; amyotrophic lateral sclerosis (Lou Gehrig s disease); Alzheimer s disease; anti-psychotic-induced weight gain; breast, ovarian and prostate cancer in combination with a chemotherapeutic agent; electroconvulsive shock-induced retrograde amnesia; the metabolic syndrome; muscular dystrophy; obesity; ovarian and prostate cancer; prevention of glucocorticoid-induced neurological damage in premature infants; and stress disorders. We intend to continue our discovery research program with the goal of identifying new selective GR-II antagonists, to manufacture and conduct pre-clinical development of one or more of these compounds and to submit Investigational New Drug (IND) applications for the most promising of them.

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-human clinical investigatory activities, such as toxicological testing;
- commercialization of Korlym, including hiring and training medical science liaisons and sales representatives, retention and management of third-party distribution partners, establishment of third-party coverage and reimbursement and patient assistance programs and marketing activities;
- regulatory affairs;
- discovery research; and
- intellectual property prosecution and expansion.

Historically, we have financed our operations and internal growth primarily through private placements of our preferred and common stock, the public sale of common stock and through our Financing Agreement with Biopharma, rather than through collaborative or partnership agreements.

As of September 30, 2013, we had an accumulated deficit of $281.5 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 and regulatory activities, as well as selling, general and administrative expenses, including the commercial launch of Korlym. We may continue to incur net losses over at least the next few years as we continue our mifepristone and selective GR-II antagonist discovery and clinical development programs, apply for regulatory approvals, 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 products.

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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 through a specialty pharmacy that sold to individual patients and a specialty distributor that sells to hospital pharmacies. For the three- and nine-month periods ended September 30, 2013, we recognized $2.6 million and $6.2 million, respectively, in net product sales compared to $1.1 million and $1.9 million for the three- and nine-month periods ended September 30, 2012. 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 co-pay program costs, which amounts are not material for any of the periods presented.

We provide cash donations to a non-profit third party organization that supports patients who meet certain eligibility requirements with financial assistance for the treatment of Cushing s syndrome, which treatment may include Korlym. We do not include as net product revenues sales of Korlym tablets funded through this source.

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

Cost of sales was $40,000 and $82,000, respectively, for the three- and nine-month periods ended September 30, 2013, which equals 1.5 percent and 1.3 percent of net product sales for the respective periods. Cost of sales was $24,000 and $72,000, respectively, for the three- and nine-month periods ended September 30, 2012, which equals 2.2 percent and 3.7 percent, of net product sales for the respective periods. The majority of these costs during all periods presented related to distribution costs and 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 a fixed percentage of our sales volumes.

In addition, the cost of manufacturing Korlym reflected in our cost of sales in 2012 and 2013, 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 of Korlym as a percentage of net product sales will fluctuate from period to period during the remainder of 2013 and for some time thereafter as product manufactured prior to FDA approval, which is already 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 regulatory submissions and 8) other costs associated with the preparation and prosecution of the regulatory submissions related to Korlym or other product candidates.

Research and development expenses increased 71 percent to $5.2 million for the three-month period ended September 30, 2013 from $3.0 million for the comparable period in 2012. For the nine-month period ended September 30, 2013, research and development expenses increased 51 percent to $13.9 million from $ 9.2 million for the comparable period in 2012.

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During the three-month period ended September 30, 2013, as compared to the corresponding period in 2012, there was an increase of $409,000 in staffing and consultancy costs to support the increased psychotic depression study activities, preparations for a submission to the EMA for approval of mifepristone for Cushing s syndrome in Europe and other research and development activities. During the nine-month period ended September 30, 2013, as compared to the corresponding period in 2012, there was a net increase of $342,000 in staffing and consultancy costs. The nine-month period ended September 30, 2012 included cash bonuses awarded on FDA approval of Korlym to employees working in research and development in the amount of $474,000. After adjusting for the effect of these bonuses, there was a net increase of $816,000 in staffing and consulting costs between the nine-month period ended September 30, 2013 and the comparable period in 2012, approximately $51,000 of which represented increases in non-cash stock-based compensation costs.

Clinical trial costs related to our phase 3 product candidates reflected net increases of $1.6 million and $2.4 million, respectively, during the three- and nine-month periods ended September 30, 2013, as compared to the corresponding periods of 2012. During the three- and nine-month periods ended September 30, 2013 as compared to the corresponding periods of 2012, there were increases of $1.7 million and $3.5 million, respectively, related to our phase 3 study with mifepristone for the treatment of psychotic depression, which were partially offset by decreases of $155,000 and $848,000, respectively, related to drug-drug interaction and other NDA-supportive studies with Korlym that occurred in the prior periods. During the three- and nine-month periods ended September 30, 2013 as compared to the corresponding periods in 2012, there was an increase of $29,000 and a decrease of $235,000, respectively, related to the clinical trials with Korlym in the treatment of Cushing s syndrome.

During the three-month period ended September 30, 2013, as compared to the corresponding period in 2012, there were also increases of $187,000 related to research and development efforts regarding our new GR-II antagonists and $143,000 related to other products. During the nine-month period ended September 30, 2013, as compared to the corresponding period in 2012, there were also net increases of $1.2 million related to research and development of our new GR-II antagonists, $578,000 related to other products and $220,000 in academic research grants to further basic scientific research regarding GR-II antagonism.

During the three- and nine-month periods ended September 30, 2013 as compared to the corresponding periods in 2012, there were decreases of $253,000 and $233,000, respectively, related to our manufacturing costs of Korlym due to the completion of certain manufacturing process development efforts.

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

Project	Three Months Ended September 30, 2013	2012	Nine Months Ended September 30, 2013	2012
	(in thousands)		*(in thousands)*	
Development programs:				
Psychotic Depression	$ 2,602	$ 756	$ 5,805	$ 1,652
Cushing s syndrome	815	717	2,119	2,954
Selective GR-II antagonists	1,167	887	4,015	2,552
Unallocated activities, including NDA-supportive studies and manufacturing, regulatory and pre-clinical activities	410	488	1,498	1,644
Stock-based compensation	161	160	466	416
Total research and development expense	$ 5,155	$ 3,008	$ 13,903	$ 9,218

We expect that research and development expenditures will likely increase during the remainder of 2013 as compared to 2012, due to the cost of expanding enrollment in our phase 3 study of mifepristone in the treatment of psychotic depression and increased spending on the development of our next-generation selective GR-II antagonists. Research and development expenses in 2014 and beyond will depend on our strategic priorities. 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 of medicine 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.

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Selling, general and administrative expenses Selling, general and administrative expenses include 1) internal personnel, a contracted sales force and other 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 engage to execute our commercial plans related to Korlym, including marketing and promotion, strategy development, market research and analytics, reimbursement support services, pharmacovigilance, distribution and other logistical needs, 3) medical educational grants and donations and 4) legal, accounting and other professional fees.

For the three-month period ended September 30, 2013, selling, general and administrative expenses increased 26 percent to $7.2 million from $5.7 million for the comparable period in 2012. For the nine-month period ended September 30, 2013, selling, general and administrative expenses increased 25 percent to $23.7 million from $18.9 million for the comparable period in 2012.

During the three-month period ended September 30, 2013, as compared to the corresponding period in 2012, there was a net increase of $405,000 in staffing and consultancy costs, which included an increase of $315,000 related to non-cash stock-based compensation costs. During the nine-month period ended September 30, 2013, as compared to the corresponding period in 2012, staffing and consultancy costs reflected a net decrease of $668,000. The nine-month period ended September 30, 2012 included $1.6 million related to cash bonuses awarded to employees and officers working in selling, general and administrative functions and $1.3 million of non-cash stock-based compensation related to awards that vested in February 2012 upon the FDA approval of Korlym. After adjusting for these items, there was a $2.2 million increase in staffing and consultancy costs during the period as compared to 2012, due primarily to additional resources necessary to commercialize Korlym, of which $892,000 represented increases in non-cash stock-based compensation costs.

During the three- and nine-month periods ended September 30, 2013, as compared to the corresponding periods of 2012, there were increases in other professional services costs related to commercialization activities of $890,000 and $3.4 million, respectively, which included $686,000 and $1.9 million, respectively, related to our contracted sales force and $182,000 and $858,000, respectively, related to market research and marketing materials. In addition, there were increases of $326,000 and $2.3 million between the respective periods in other support costs, such as education, training and conference costs, medical education grants and donations, facilities and technology costs, travel and fleet vehicle costs, legal, insurance and other service fees.

We expect that selling, general and administrative expenses will be higher during the remainder of 2013 than in the comparable period of 2012 in regard to activities directly associated with product commercialization. The level of selling, general and administrative activities and related expenses in 2014 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.

Interest and other expense Interest and other expense for the three- and nine-month periods ended September 30, 2013 was $1.2 million and $3.4 million, respectively, as compared to $622,000 and $632,000, respectively, for the comparable periods in 2012. These increases were primarily due to the inclusion in the three- and nine-month periods ended September 30, 2013 of interest expense related to our Financing Agreement with Biopharma, which was entered into in August 2012.

Non-GAAP Financial Measures

We prepare our condensed financial statements and footnotes thereto, which are included in Part I, Item 1 of this Quarterly Report on Form 10-Q, in accordance with U.S. Generally Accepted Accounting Principles (GAAP). To supplement our financial results presented on a GAAP basis, we use non-GAAP measures of net loss that exclude significant non-cash expenses related to stock-based compensation expense and the accretion of interest expense under our capped royalty financing transaction. We use this non-GAAP measure of net loss to manage our business and believe that it may help investors better evaluate our past financial performance and potential future results. Non-GAAP measures should not be considered in isolation or as a substitute for comparable GAAP accounting and investors should read them in conjunction with our financial statements and notes thereto prepared in accordance with GAAP. The non-GAAP measure of net loss we use may be different from, and not directly comparable to, similarly titled measures used by other companies.

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
	(in thousands, except for per share data)			
GAAP net loss	$ (10,906)	$ (8,293)	$ (34,887)	$ (26,924)
Significant non-cash expenses:				
Stock-based compensation				
Research and development	161	160	466	416
Selling, general and administrative	1,148	833	3,417	3,848
Total stock-based compensation	1,309	993	3,883	4,264
Accretion of interest expense related to long-term obligation	1,133	575	3,340	575
Non-GAAP net loss, as adjusted for significant non-cash expenses	$ (8,464)	$ (6,725)	$ (27,664)	$ (22,085)
GAAP basic and diluted net loss per share	$ (0.11)	$ (0.08)	$ (0.35)	$ (0.30)
Non-GAAP basic and diluted net loss per share, as adjusted for significant non-cash expenses	$ (0.08)	$ (0.07)	$ (0.28)	$ (0.24)
Shares used in computing basic and diluted net loss per share	99,814	99,082	99,814	90,738

Liquidity and Capital Resources

We have incurred operating losses since inception, and at September 30, 2013, we had an accumulated deficit of $281.5 million. Since our inception, we have relied primarily on the proceeds from public and private sales of our equity securities and our Financing Agreement with Biopharma to fund our operations.

At September 30, 2013, we had cash and cash equivalents of $63.2 million, compared to $93.0 million at December 31, 2012. Net cash used in operating activities for the nine-month periods ended September 30, 2013 and 2012 was $29.4 million and $27.3 million, respectively. We used cash in each period primarily for the commercialization of Korlym and for research and development activities.

We expect cash used in operating activities will be higher during the remainder of 2013 than in the comparable period of 2012 due to the continued commercialization of Korlym, the continuation 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 2014 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, commercial activities and selling, general and administrative expenses may be only partially offset by revenues from sales of Korlym.

In addition, in accordance with the Biopharma Financing Agreement, our first payment to Biopharma was made in July 2013 in the amount of approximately $378,000; a second payment in the amount of approximately $647,000 was made in October 2013. Future individual payment amounts will be variable.

We may choose to raise additional funds to finance our strategic priorities. 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 that we would otherwise seek to develop on our own.

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 influenced 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.

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Contractual Obligations and Commercial Commitments

Our contractual payment obligations and purchase commitments as of December 31, 2012 are disclosed in our Annual Report on Form 10-K for the year ended December 31, 2012, and have not changed materially during the nine months ended September 30, 2013.

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, 2012. During the three months ended September 30, 2013, we did not make any significant changes to our critical accounting policies and estimates.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk of loss. As of September 30, 2013, the fair value of our cash and cash equivalents was $63.2 million and consisted primarily of money market funds maintained at major U.S. financial institutions. To minimize our exposure to interest rate risk, we have limited the maturities of our investments to less than two years with an average maturity not to exceed one year. Due to the short-term nature of these instruments, a 10% increase or decrease in market interest rates would not have a material impact on the total value of our portfolio as of September 30, 2013. However, our money market fund invests primarily in short-term U.S. Treasury notes and bills, the value and liquidity of which may be adversely affected in the event of any failure by the U.S. Treasury to service its debts in a timely manner.

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 September 30, 2013. 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 September 30, 2013, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently involved in any material legal proceedings.

ITEM 1A. RISK FACTORS

An investment in our common stock involves significant risks. You should carefully consider the risks described below and the other information in this 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 began to sell in the United States in April 2012. If we are unable to increase revenues of Korlym to the levels that we or investors expect, or experience significant delays in doing so, 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 coverage and reimbursement or other factors;
- competition from Novartis s Signifor and from other companies with greater financial, technical and marketing resources than ours;
- 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; and
- rapid technological change making Korlym obsolete.

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 affect our results of operations. There are inherent difficulties in predicting the volumes of Korlym that will be sold, which 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 If our operating and financial performance in any given period does not meet the guidance that we provide to the public, estimates published by research analysts or other investor expectations, our stock price may 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

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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 treatment for them to consider.

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 possible preference of some physicians for more familiar, long-standing off-label treatments for Cushing s syndrome or for Novartis drug, Signifor, for the treatment of Cushing s disease;
- 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.

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 are eligible to obtain seven years of marketing exclusivity for the approved indication from the date of drug approval, with limited exceptions, 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 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 28 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 (EMA). The EMA has accepted our plan to study the use of Korlym in children with Cushing s syndrome which we expect will, upon completion, extend our period of marketing exclusivity by two years in the EU. We submitted our Marketing Authorization Application request to the EMA in October 2013.

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.

Notwithstanding Korlym s Orphan Drug Designation in both the United States and the EU, in 2012 Novartis received approval in both jurisdictions to market its somatostatin analogue Signifor for adult patients with Cushing s disease (a subset of Cushing s syndrome that afflicts approximately 70 percent of all Cushing s syndrome patients) for whom pituitary surgery is not an option or has not been curative. Novartis also

announced that is undertaking an investigational study of an experimental compound (LC1699) to see whether it can safely reduce the level of urinary free cortisol in patients with Cushing s disease and to examine the compound s safety and efficacy. Novartis has substantially more resources and experience than we do and may provide significant competition.

Further, we are aware that Laboratoire HRA Pharma has received Orphan Drug Designation in the United States and the EU for the use of mifepristone to treat a subtype of Cushing s syndrome. HRA had begun a Phase 2 clinical trial in Europe and the United States for this indication which has been terminated. 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 the EU, but it has stated that it has not yet conducted any clinical trials.

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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 potential benefits. 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.

We will 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 will experience competition from Novartis, which markets Signifor (pasireotide), an injectable somatostatin analogue, in the United States and the EU for the treatment of adult patients with Cushing s disease (a subset of the patients with Cushing s syndrome) for whom pituitary surgery is not an option or has not been curative.

In addition, we are aware 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.

If we cannot continue 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 continue to 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 will 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 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;

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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.

In addition, other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. In August 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, which went into effect on April 1, 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

These new laws and the regulations and policies implementing them, 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.

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

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 continue to hire experienced field and internal personnel to commercialize Korlym in the United States, which is expensive and time consuming. 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.

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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 sales and marketing efforts effectively;
- manage our supply chain effectively;
- 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 the 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.

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 only one approved manufacturer of Korlym s API, with whom our agreement expires in January 2014. We intend to continue the relationship and are in the process of negotiating a new 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.

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In November 2012, the FDA approved AAI as a qualified site for the manufacture of Korlym tablets, subject to the successful manufacture of validation batches. We are now negotiating a long-term commercial supply agreement with AAI. We cannot assure you that AAI will be able or willing to meet our future demands. If AAI is unable to prepare Korlym tablets in the quantities and time frame required, we may not be able to manufacture our product in a timely manner. If our suppliers 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.

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.

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.

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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 current good manufacturing practices, or cGMPs, and current good clinical practices, or cGCPs, for any clinical trials that we conduct post-approval. cGMPs and cGCPs are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities through periodic inspections of manufacturing sites, trial sponsors, clinical investigators and clinical sites. 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.

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.

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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 are marketing 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.

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

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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. Manufacturers were required to begin data collection on August 1, 2013 and will be required to report such data to the Centers for Medicare & Medicaid Services (known as CMS) by March 31, 2014, and by the 90th day of each calendar year thereafter; 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.

Certain states also mandate implementation of commercial compliance programs to ensure compliance with these laws and/or the tracking and reporting of gifts, compensation, and other remuneration to physicians and certain other designated health care professionals and providers.

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 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 may 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.

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.

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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. We have increased the number of clinical sites from eight to 27 sites as of November 6, 2013, which will increase our rate of spending on the trial, with an unknown effect on the likelihood of success.

In order to meet our goal of enrolling a sufficient number of patients in Study 14 to perform a successful interim analysis and report the results of that analysis in the second quarter of 2014, we will need to maintain the current pace of enrollment which will be costly and which we may not succeed in doing.

The pace of enrollment in Study 14 is subject to a number of factors, including our ability to identify, qualify and enlist new trial sites, our ability to identify potential study subjects and enroll them in the trial, and the ability and willingness of patients in the trial to complete the study protocol. Furthermore, we will need to work with our existing third-party service providers and may need to retain additional personnel to support our effort to increase the rate of Study 14 enrollment, which will be costly, and we may not be successful in these efforts. Finally, even if we succeed in maintaining the rate of enrollment in Study 14, this will not necessarily allow us to demonstrate the efficacy of the medicine.

If we conduct an interim analysis of the data from Study 14, the results may not show efficacy. If the interim results are inconclusive and we continue the study, conducting an interim analysis will make achieving a positive result more difficult.

If we choose to perform an interim analysis of the data from Study 14, its results may be negative or inconclusive. If they are negative, then we will terminate the trial and either incur the substantial additional expense and delay of undertaking a new trial, or discontinue the study of mifepristone for the psychotic features of psychotic depression, which may reduce our future revenue. If the results are inconclusive, and we choose to continue the trial, we will incur additional expense and delay the possibility of our obtaining regulatory approval of a treatment for this disease.

In addition, performing an interim analysis makes the measure of statistical significance in any continued trial more rigorous and more difficult to meet. Therefore, a continued trial following an interim analysis is generally less likely to achieve a statistically meaningful positive outcome, making it more difficult to achieve a positive result.

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 cGCPs. 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.

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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 and the submission of our Marketing Authorization request to the EMA in October 2013, we have not taken any actions to obtain foreign approvals. We may not develop our product candidates in the clinic in order to obtain foreign regulatory approvals on a timely basis, if at all.

Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA, 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 disease or condition and the medicine demonstrates the potential to address unmet medical needs for this disease or 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.

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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 electroconvulsive therapy (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.

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, psychosis associated with cocaine addiction, psychosis associated with Interferon-alpha therapy, migraine headaches, and to increase the therapeutic response to ECT. In addition, we have eight U.S. method of use patent applications covering GR-II antagonists for the treatment of a number of other metabolic and psychiatric disorders, four U.S. composition of matter patents covering specific GR-II antagonists, and two additional U.S. composition of matter patent applications are pending. 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.

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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, potentially, for 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, *Other Metabolic Disorders* of our Annual Report on Form 10-K for the year ended December 31, 2012. We are pursuing other GR-II antagonists for this use. The compounds developed pursuant to our early clinical, preclinical and discovery research programs 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.

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

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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.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security 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.

Risks Related to Our Capital Needs and Financial Results

We may need additional capital in order to complete the development and commercialization of mifepristone for psychotic depression or other indications or for the development and commercialization of our 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.

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 coverage and 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 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.

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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 could cause further dilution to stockholders. Debt financing, if available, may involve restrictive covenants. If we obtain funds through collaborations with others, these arrangements may be on unfavorable terms or may require us to relinquish certain rights to 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 year.

We have a limited history of operations and have focused primarily on clinical trials. We have begun 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 September 30, 2013, we had an accumulated deficit of $281.5 million. We 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. 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 generate sufficient revenue or 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.

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. Any failure by the U.S. Treasury to service its debts in a timely manner would likely cause significant market disruptions and curtail or eliminate our access to our funds, which are invested primarily in short-term U.S. Treasury notes and bills.

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.

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If we acquire other selective 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 Financing Agreement with Biopharma Secured Debt Fund II Sub, S.àr.l, could adversely affect our financial results and liquidity.

Pursuant to our Financing Agreement with Biopharma entered into 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 $45.0 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, for the four calendar quarters preceding such incurrence, which we refer to as the Indebtedness Covenant; (ii) pay a dividend or other cash distribution, unless we have cash and cash equivalents in excess of $50.0 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.

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 repayment obligation of $45.0 million. As defined in the agreement, Change of Control includes, among other things, (i) a greater than 50 percent change in the ownership of Corcept, (ii) certain changes in Board composition of Corcept and (iii) 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, which we refer to as 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 $45.0 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.

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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 thirteen 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 four composition of matter patents and have two composition of matter patents 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.

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.

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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.

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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 November 6, 2013, our average daily trading volume was approximately 284,000 shares and the intra-day sales prices per share of our common stock on The NASDAQ Stock Market ranged from $1.27 to $2.23. As of November 6, 2013, our officers, directors and principal stockholders controlled approximately 36 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 coverage and reimbursement attained;
- our cash and short-term investment position;
- actual or anticipated timing and results of our clinical trials;
- new products or services introduced or announced by us or our competitors;
- 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;
- 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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If our operating and financial performance in any given period does not meet the guidance that we provide to the public, estimates published by research analysts or other investor expectations, our stock price may decline.

In the fourth quarter of 2013, we began providing guidance as to our expected full-year 2013 net revenue. This guidance is comprised of forward-looking statements subject to the risks and uncertainties described in this report and in our other public filings and public statements. Our guidance is only an estimate of what management believes is realizable as of the date of the release of such guidance. Our actual results may vary from our guidance and the variations may be material.

There are a number of reasons why we might fail to meet our financial guidance or other expectations about our business, including, but not limited to, the following. 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. Research analysts who cover our business have put forth a wide range of revenue estimates, based on their own investigation and analysis. We believe research analysts will consider the guidance we have provided as one factor in determining their own annual revenue estimates. Estimating our net revenue for future periods is difficult and you should rely on our guidance and the estimates of research analysts at your own discretion. If, in the future, our operating or financial results for a particular period do not meet our guidance, analyst estimates or the expectations of investors, or if we reduce our guidance for future periods, our stock price may 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.

We have entered into registration rights agreements in connection with certain of our securities offerings, which may require us to pay liquidated damages if we do not meet our obligations under those agreements. For instance, 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.

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

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

As of November 6, 2013, our officers, directors and principal stockholders control approximately 36 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 our company, including the provisions of the PPACA requiring the reporting of aggregate spending related to health care professionals, the provisions of the 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 and payment acceleration provisions under the Biopharma Financing Agreement may make an acquisition of us or a change in our management more expensive or 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. In addition, our payment obligations to Biopharma accelerate in the event of a change of control transaction. See Risk Factors Failure to meet our obligations under our Financing Agreement with Biopharma Secured Debt Fund II Sub, S.à r.l, could adversely affect our financial results and liquidity. These provisions in our charter and bylaws and under Delaware law and the Financing Agreement 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.

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ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation, as amended (incorporated by reference to Exhibit 3.1 to the registrant s Quarterly Report on Form 10-Q filed on August 9, 2012).
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	Amendment to Manufacturing Agreement with Produits Chimiques Auxiliaires et de Synthese SA, dated November 7, 2013.
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 September 30, 2013, formatted in Extensible Business Reporting Language (XBRL): (i) unaudited Condensed Balance Sheets at September 30, 2013 and December 31, 2012, (ii) unaudited Condensed Statements of Comprehensive Loss for the Three- and Nine-month periods Ended September 30, 2013 and 2012, (iii) unaudited Condensed Statements of Cash Flows for the Nine-Month Periods Ended September 30, 2013 and 2012, and (iv) Notes to Condensed Financial Statements.

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SIGNATURES

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

CORCEPT THERAPEUTICS INCORPORATED

Date: November 12, 2013

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

Chief Executive Officer

Date: November 12, 2013

/s/ G. Charles Robb
G. Charles Robb
Chief Financial Officer

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