CORCEPT THERAPEUTICS INC
Form 10-Q
November 07, 2014
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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, 2014

or

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

For the transition period from to

Commission File Number:

000-50679

CORCEPT THERAPEUTICS INCORPORATED

(Exact Name of Corporation as Specified in Its Charter)

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

149 Commonwealth Drive

Menlo Park, CA 94025

(Address of principal executive offices, including zip code)

(650) 327-3270

(Registrant s telephone number, including area code)

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

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

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

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

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

On November 3, 2014 there were 101,190,167 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, seek 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) 300 mg Tablets;*
- *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;*
- *the progress and timing of our research, development and clinical programs and the regulatory activities associated with such programs;*
- *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 new uses for mifepristone and any compound in our families of selective glucocorticoid receptor II (GR-II) antagonists;*
- *our ability to achieve marketing approval of mifepristone in the European Union (EU) (for which we have requested the brand name Corluxin®) and realize the benefits of Orphan Drug designation there;*
- *our ability to manufacture, market, commercialize and achieve market acceptance for our future product candidates, including mifepristone for the treatment of triple-negative breast cancer or any other indications and any compounds 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, 2014 (Unaudited)	December 31, 2013 (See Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 26,780	$ 54,877
Trade receivables	2,746	1,428
Inventory	1,080	1,096
Prepaid expenses and other current assets	1,769	910
Total current assets	32,375	58,311
Strategic inventory	4,430	4,450
Property and equipment, net of accumulated depreciation	273	203
Other assets	81	113
Total assets	$ 37,159	$ 63,077
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 1,960	$ 2,381
Accrued clinical expenses	276	3,288
Other accrued liabilities	1,539	1,301
Long-term obligation - current portion	8,661	5,743
Deferred revenue	50	25
Total current liabilities	12,486	12,738
Long-term obligation, net of current portion	25,990	29,322
Commitments		
Stockholders equity:		
Preferred stock, par value $0.001 per share, 10,000 shares authorized and no shares outstanding at September 30, 2014 and December 31, 2013		
Common stock, par value $0.001 per share, 280,000 shares authorized and 101,141 and 99,849 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	101	100
Additional paid-in capital	318,687	313,534
Accumulated deficit	(320,105)	(292,617)
Total stockholders equity (net capital deficiency)	(1,317)	21,017
Total liabilities and stockholders equity	$ 37,159	$ 63,077

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,	
	2014	2013	2014	2013
Product sales, net	$ 7,282	$ 2,634	$ 17,537	$ 6,242
Operating expenses:				
Cost of sales	235	40	624	82
Research and development	3,047	5,155	14,583	13,903
Selling, general and administrative	9,103	7,179	26,872	23,723
Total operating expenses	12,385	12,374	42,079	37,708
Loss from operations	(5,103)	(9,740)	(24,542)	(31,466)
Interest and other expense	(903)	(1,166)	(2,946)	(3,421)
Net loss and comprehensive loss	$ (6,006)	$ (10,906)	$ (27,488)	$ (34,887)
Basic and diluted net loss per share	$ (0.06)	$ (0.11)	$ (0.27)	$ (0.35)
Weighted average shares outstanding used in computing basic and diluted net loss per share	101,134	99,814	100,880	99,814

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,	
	2014	**2013**
Operating activities		
Net loss	$ (27,488)	$ (34,887)
Adjustments to reconcile net loss to net cash used in operations:		
Stock-based compensation	3,814	3,883
Accretion of interest expense	2,874	3,340
Amortization of debt financing costs	23	27
Depreciation and amortization of property and equipment	104	53
Changes in operating assets and liabilities:		
Trade receivables	(1,318)	(462)
Inventory	38	(892)
Prepaid expenses and other current assets	(859)	(384)
Other assets	9	(3)
Accounts payable	(421)	(1,467)
Accrued clinical expenses	(3,012)	1,120
Other accrued liabilities	238	241
Deferred revenue	25	39
Net cash used in operating activities	(25,973)	(29,392)
Investing activities		
Purchases of property and equipment	(174)	(87)
Cash used in investing activities	(174)	(87)
Financing activities		
Proceeds from issuance of common stock upon exercise of options and warrants, net of issuance costs	1,338	
Payments related to long-term obligation	(3,288)	(378)
Net cash used in financing activities	(1,950)	(378)
Net decrease in cash and cash equivalents	(28,097)	(29,857)
Cash and cash equivalents, at beginning of period	54,877	93,032
Cash and cash equivalents, at end of period	$ 26,780	$ 63,175

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, psychiatric and oncologic 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 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 the United States in April 2012. In December 2013, we initiated a study of mifepristone for the treatment of triple-negative breast cancer. 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 Incorporated.

The accompanying unaudited condensed balance sheet as of September 30, 2014 and the condensed statements of comprehensive loss for the three- and nine-month periods ended September 30, 2014 and 2013 and the condensed statements of cash flows for the nine-month periods ended September 30, 2014 and 2013 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, 2014 are not necessarily indicative of the results that may be expected for the year ending December 31, 2014 or any other period. These financial statements and notes should be read in conjunction with the financial statements for the year ended December 31, 2013 included in our Annual Report on Form 10-K. The accompanying balance sheet as of December 31, 2013 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 reserves for chargebacks and rebates, patient assistance, potential product returns and 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, 2014 and December 31, 2013, all of our funds were invested in cash and cash equivalents that consist of a money market fund maintained at a major U.S. financial institution.

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CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

Credit Risks and Concentrations

We have a concentration of credit risk related to our cash and cash equivalents. We are exposed to credit risk in the event of default by the financial institutions holding these funds 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 have never experienced a loss or lack of access to cash and cash equivalents in our operating or investment accounts.

We bear credit risk in regard to our trade receivables, which are spread among various third-party payors pharmacy benefit managers, insurance companies, private charities and government programs and individual patients. We extend credit to third-party payors based on their creditworthiness. We monitor our exposure and record a reserve against uncollectible trade receivables as necessary. To date, we have not incurred any credit losses.

We have a concentration of risk in regard to the manufacture of our product. As of September 30, 2014, we had one tablet manufacturer for Korlym with an operational facility AAI Pharma Services Corp. (AAI). In addition, we have a single-source manufacturer of mifepristone, the active pharmaceutical ingredient (API), in Korlym Produits Chimiques Auxiliaires et de Synthèse SA (PCAS). If either of these companies is unable to manufacture API or Korlym tablets in the quantities and time frame required, we may not be able to manufacture our product in a timely manner. In order to mitigate these risks related to the manufacture of our product, we purchased and hold in inventory additional quantities of mifepristone API and Korlym tablets.

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

Trade receivables are recorded net of customer allowances for co-pay assistance, 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.

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.

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CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

We value our inventories at the lower of cost or net realizable value. We determine the cost of inventory using the specific identification method, 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, which was recorded as a long-term obligation at issuance. We 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 sales 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.

Interest expense related to the Financing Agreement is calculated based on the internal interest rate to Biopharma that would result from these assumed payment streams.

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. The amount of our payment with respect to each quarter will be based on Korlym Receipts recorded in that quarter and may differ from our 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 at $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 12 months following September 30, 2014.

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

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 of July 1, 2013, we began using Dohmen Life Science Services (Dohmen), formerly known as Centric Health Resources, Inc., as our specialty pharmacy. Dohmen operates on a consignment basis, without carrying any Korlym inventory. Accordingly, all of our sales through Dohmen are made directly to patients.

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CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

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 make cash donations to a non-profit third party organization that provides 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 in net product revenues sales of Korlym tablets to uninsured patients 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. Beginning in the third quarter of 2013, we ceased incurring a prompt-payment discount to our specialty pharmacy.

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: Because sales through Dohmen, our specialty pharmacy, are made to individual patients who do not have the right to return the product, our exposure to product returns is 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 and the cost to acquire mifepristone, the active pharmaceutical ingredient (API) in Korlym, as inventory following approval by the FDA in February 2012. Prior to receiving FDA approval for Korlym, we expensed all such costs when incurred as research and development expense. A portion of the product manufactured and the API acquired prior to FDA approval is available for commercial use.

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CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

Research and Development

Research and development expenses consist of costs incurred for research and development activities that we sponsor. 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 value of the award at the grant date as determined using the Black-Scholes option valuation model. For service-based awards, we recognize expense over the requisite service period.

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.

See Note 6 for a detailed discussion of stock-based compensation expense.

2. Fair Value of Financial Instruments

As of September 30, 2014 and December 31, 2013, 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 $25.4 million and $52.9 million as of September 30, 2014 and December 31, 2013, 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.

All cash equivalents and short-term investments held as of September 30, 2014 and December 31, 2013 were in active markets and valued based upon their quoted prices.

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CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

3. Composition of Certain Balance Sheet Items

Inventory

The composition of inventory was as follows:

	September 30, 2014	December 31, 2013
	(in thousands)	
Raw materials	$ 3,596	$ 4,318
Work in progress	18	2
Finished goods	1,896	1,226
Total inventory	5,510	5,546
Less strategic inventory classified as non-current	(4,430)	(4,450)
Total inventory classified as current	$ 1,080	$ 1,096

The finished goods inventory as of September 30, 2014 and December 31, 2013 includes all costs of manufacture and packaging 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 have single-source manufacturers of both the API for Korlym and Korlym tablets, 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:

	September 30, 2014	December 31, 2013
	(in thousands)	
Accrued compensation	$ 574	$ 466
Professional fees	235	369
Commercialization costs	430	288
Government rebates	146	40
Legal fees	91	110
Other	63	28
	$ 1,539	$ 1,301

4. Long-Term Obligation

As discussed in Note 1, ***Basis of Presentation and Summary of Significant Accounting Policies, Long-term Obligation***, under the Financing Agreement with Biopharma, 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. Through September 30, 2014, we have paid Biopharma $4.3 million, with an additional payment of $1.6 million made in October 2014.

Under the terms of the Financing Agreement, our payments are 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 $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.

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CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

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, (EBITDA) 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.

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. We recorded interest expense of $895,000 and $2.9 million for the three- and nine-month periods ended September 30, 2014, respectively, $1.1 million and $3.3 million for the three- and nine-month periods ended 30, 2013, respectively, and total accreted interest of $9.0 million for the period from August 2012 through September 30, 2014, as calculated based on the internal interest rate to Biopharma that would result from these assumed payment streams. The timing of payment amounts 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 at $45.0 million.

The carrying value of the long-term obligation was $34.7 million as of September 30, 2014 and $35.1 million as of December 31, 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.

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CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

The following table provides a summary of the payment obligations under the Financing Agreement as of September 30, 2014 and December 31, 2013, utilizing the payment assumptions discussed above.

	September 30, 2014	December 31, 2013
	(in thousands)	
Total repayment obligation	$ 45,000	$ 45,000
Less interest to be accreted in future periods	(6,036)	(8,910)
Less payments made	(4,313)	(1,025)
Less current portion	(8,661)	(5,743)
Long-term obligation, net of current portion	$ 25,990	$ 29,322

The estimated fair value of the long-term obligation, as measured using Level 3 inputs, approximates the carrying amounts as presented on the balance sheet as of September 30, 2014 and December 31, 2013. The estimated fair value was calculated using the income method of valuation. The key assumptions required for the calculation were an estimate of the amount and timing of future product revenues and an estimated cost of capital. Management s estimate of the future product revenues is subject to significant uncertainty due to the fact that Korlym has only been available for slightly more than two years and there is an extended time period associated with the Financing Agreement.

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, 2014 and December 31, 2013, the unamortized issuance costs were $65,000 and $87,000, respectively, and are included in other assets on our balance sheets.

5. Significant Agreements

Pharmaceutical Manufacturing Agreement

In March 2014, we entered into a long-term manufacturing and supply agreement with PCAS for the manufacture of mifepristone, the active pharmaceutical agreement in Korlym®. We have agreed to purchase a minimum percentage of our mifepristone requirements from PCAS; the amount of the commitment will depend on our future needs. The initial term of the agreement is five years from March 20, 2014, with an automatic extension of one year unless either party gives 12 months prior written notice that it does not want an extension. We have the right to terminate the agreement if PCAS is unable to manufacture the product for a consecutive nine-month period.

Tablet Manufacturing Agreement

On April 7, 2014, we entered into a manufacturing agreement with AAI Pharma Services Corp. (AAI) under which AAI will manufacture and package Korlym tablets. The initial term of this agreement is a period of three years from April 7, 2014, with consecutive automatic extensions of two years unless either party gives written notice in the case of AAI, 18 months prior to the end of the applicable term, and in our case 12 months prior to the end of the applicable term that it does not want such an extension. We have the right to terminate the agreement if AAI is unable to manufacture the product for a consecutive four-month period or if the product is withdrawn from the market. There are no minimum purchase obligations under this agreement.

Clinical Trial Agreement

In March 2014, we entered into an agreement with Quotient Clinical Limited, a clinical research organization (CRO), for a Phase 1 study of one of our new compounds. The total commitment under the agreement is approximately $2.6 million, which is expected to be expended over approximately a 1-year period.

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CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

6. Stock Option Plans

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

On February 6, 2014, our Board of Directors authorized an increase of 3,993,300 shares in the number of shares available for issuance under the 2012 Plan, which was equivalent to 4% of the shares of our common stock outstanding as of December 31, 2013, pursuant to the terms of the 2012 Plan.

During the nine-month period ended September 30, 2014, we issued an aggregate of 1.1 million shares of our common stock upon the exercise of stock options.

The following table provides a summary of non-cash stock-based compensation.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
	(in thousands)		*(in thousands)*	
Research and development	$ 183	$ 161	$ 514	$ 466
Selling, general and administrative	1,027	1,148	3,300	3,417
Total non-cash stock-based compensation	$ 1,210	$ 1,309	$ 3,814	$ 3,883

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.

	September 30,	
	2014	2013
	(in thousands)	
Stock options outstanding	14,890	14,621
Warrants outstanding	8,044	8,574
Total	22,934	23,195

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ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Forward-Looking Statements

This Management Discussion should be read in conjunction with the financial statements and notes thereto appearing elsewhere in this report. We make statements in this section that are forward-looking within the meaning of the federal securities laws. For a complete discussion of such forward-looking statements and the potential risks and uncertainties that may impact upon their accuracy, see Forward-Looking Statements included in Risk Factors Item 1A of this Form 10-Q and the Overview and Liquidity and Capital Resources sections of this 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, psychiatric and oncologic 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 1998, we have been developing mifepristone, a competitive glucocorticoid receptor II (GR-II) antagonist. In February 2012, the FDA approved Korlym® (mifepristone) 300 mg Tablets 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 made the drug available to patients in the United States in April 2012.

We have begun a Phase 1 safety and efficacy study of mifepristone in combination with chemotherapy in the treatment of triple-negative breast cancer a form of cancer with a particularly poor prognosis. We have discovered and patented three series of selective GR-II antagonists that, like mifepristone, competitively block GR-II but do not bind to the progesterone receptor and thus do not interfere with pregnancy.

On May 7, 2014, we announced the discontinuation of our Phase 3 study of mifepristone, the active ingredient in Korlym, for treatment of psychotic depression (Study 14) after receiving the report of the study s data monitoring committee that the trial was unlikely to meet its primary endpoint with statistical significance based on an analysis of interim data. We began this study in 2008. See further discussion under Psychotic Depression below.

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.

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

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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). We submitted our Marketing Authorization Application request to the EMA in October 2013.

Triple-Negative Breast Cancer. In January 2014, we began a Phase 1 study of mifepristone in combination with the chemotherapy drug eribulin in the treatment of triple-negative breast cancer.

We plan to conduct our study in two phases. First, the recommended dose for the second phase of the study will be determined in up to 20 patients with metastatic breast cancer. In the subsequent expansion phase, 20 patients with GR-II-positive triple-negative breast cancer will be dosed to determine a preliminary estimate of efficacy. Mifepristone will be administered orally with food once daily and eribulin will be administered intravenously. We began enrolling patients in this study in February 2014 and expect to have results in 2015.

Psychotic Depression. On May 5, 2014, an independent data monitoring committee informed us that its analysis of data from the first 226 patients to enroll in our Phase 3 trial of mifepristone for the treatment of psychotic depression (Study 14) showed that the study had failed to reach its primary endpoint a rapid and sustained reduction in the patients psychotic symptoms with statistical significance. The committee advised us that continuing the study to its full enrollment of 450 patients would be unlikely to generate a statistically significant result. On May 7, 2014, we announced our decision to discontinue Study 14 and redeploy resources to more promising programs.

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 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 in each of the three series. One additional composition of matter patent application is 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, metabolic syndrome, muscular dystrophy, obesity, 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 study the most promising of them in humans.

In September 2014, we commenced enrollment in a Phase 1 clinical study with CORT125134, one of these new compounds. The primary objectives of the study are to assess the safety, tolerability and pharmacokinetics of CORT125134 in healthy human volunteers.

We plan to advance at least one additional new compound to the clinic over the next year.

General

Our activities to date have included:

- product development, including drug formulation and manufacturing, 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.

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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, 2014, we had an accumulated deficit of $320.1 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 expenses related to the commercial launch of Korlym. We may continue to incur net losses 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.

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. We made Korlym available commercially in the United States in April 2012.

For the three- and nine-month periods ended September 30, 2014, we recorded net product sales of $7.3 million and $17.5 million, respectively, as compared to $2.6 million and $6.2 million in the respective periods in 2013. To calculate net product sales, we deducted from gross sales estimates of prompt-pay discounts (which we ceased to incur with respect to our specialty pharmacy customer beginning in the third quarter of 2013), distribution service fees, rebates and chargebacks owed to government payors and patient assistance program costs, which amounts are not material for any of the periods presented.

We make cash donations to a non-profit third party organization that provides 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 in net product revenues sales of Korlym tablets to uninsured patients 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 was available for us to use commercially.

Cost of sales was $235,000 and $624,000 for the three- and nine-month periods ended September 30, 2014, respectively, which equaled 3.2 percent and 3.6 percent of net product sales for each of the respective periods. Cost of sales was $40,000 and $82,000, respectively, for the three- and nine-month periods ended September 30, 2013, which equaled 1.5 percent and 1.3 percent of net product sales for the respective periods. Direct product cost for tablets sold during the three- and nine-month periods ended September 30, 2014 represented approximately 2.7 percent and 2.9 percent of net product sales, respectively, as compared to less than 1 percent of net product sales for each of the three- and nine-month periods ended September 30, 2013. The remainder of the cost of sales during each period related to stability testing and distribution costs. Product sold during the three- and nine-month periods ended September 30, 2014, included the cost to manufacture the Korlym tablets and indirect personnel and other overhead costs but did not include the cost of the active pharmaceutical ingredient (API) as that had been expensed prior to FDA approval of Korlym. Product sold during the three- and nine- month periods ended September 30, 2013, did not include either the cost to manufacture the Korlym tablets or the API costs as these tablets had been fully manufactured prior to FDA approval.

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Although the cost of manufacturing Korlym reflected in our cost of sales through September 30, 2014 does 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 these periods, we do not expect that the inclusion of these previously expensed cost components in future periods will materially increase our cost of sales, because we expect that the added costs will be offset by production efficiencies. In addition, as 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, our cost of sales of Korlym as a percentage of net product sales may fluctuate from period to period.

Research and development expenses Research and development expenses include (1) personnel costs related to our development activities, including facilities costs and non-cash stock-based compensation, (2) 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) costs of manufacturing development, including the development and activities to qualify a tablet manufacturing site, (7) costs of manufacture and / or acquisition of clinical trial materials and material used in registration and validation batches included in regulatory submissions prior to product approval 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 decreased 40.9 percent to $3.0 million for the three-month period ended September 30, 2014 from $5.2 million for the comparable period in 2013. For the nine-month period ended September 30, 2014, research and development expenses increased 4.9 percent to $14.6 million from $13.9 million for the comparable period in 2013.

During the three-month period ended September 30, 2014, as compared to the corresponding period in 2013, there was a decrease of $149,000 in staffing and consultancy costs. During the nine-month period ended September 30, 2014, as compared to the corresponding period in 2013, there was an increase of $1.3 million in staffing and consultancy costs, which included $815,000 related to bonuses to staff working in these functions that were awarded and paid in February 2014. After adjusting for the effect of these bonuses, there was a net increase of $502,000 in staffing and consulting costs in the nine months ended September 30, 2014 as compared to the same period in 2013. The increase in costs between the year-to-date periods was primarily to support increased activity in the psychotic depression study (Study 14), preparations for a previously anticipated submission to the FDA of an sNDA for approval of mifepristone in psychotic depression and increased activities in our oncology study. Study 14 was discontinued in May 2014.

Clinical trial costs reflected a net decrease of $1.2 million during the three-month period and an increase of $548,000 during the nine-month period ended September 30, 2014, as compared to the respective periods in 2013. During the three- and nine-month periods ended September 30, 2014 as compared to 2013, there were decreases of $1.7 million and $361,000, respectively, related to our Phase 3 study with mifepristone for the treatment of psychotic depression study, which were offset by increases of $327,000 and $1.1 million, respectively, related to our oncology study. During the three-month period ended September 30, 2014, as compared to the respective period in 2013, there was an increase of $178,000 in other clinical trial activities, primarily related to the initiation of our Phase 1 study with CORT125134. During the nine-month period ended September 30, 2014 there was a decrease of $178,000 in other clinical trials as compared to the corresponding period in 2013 as the costs related to this Phase 1 study were more than offset by the reduction in costs related to other clinical trials as work on these studies was completed.

In addition, there were decreases in spending of $508,000 and $581,000 during the three- and nine-month periods ended September 30, 2014, respectively, as compared to the respective periods in 2013, related to the development of new compounds, and decreases in spending of $106,000 and $489,000 in the respective periods related to development of other products.

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

Project	Three Months Ended September 30, 2014	2013	Nine Months Ended September 30, 2014	2013
	(in thousands)		*(in thousands)*	
Development programs:				
Psychotic Depression	$ 560	$ 2,602	$ 5,816	$ 5,805
Cushing s syndrome	639	815	1,782	2,119
Cancer	524		1,695	
Selective GR-II antagonists	849	1,167	3,581	4,015
Unallocated activities, including NDA supportive studies and manufacturing, regulatory and pre-clinical activities	292	410	1,195	1,498
Stock-based compensation	183	161	514	466
Total research and development expense	$ 3,047	$ 5,155	$ 14,583	$ 13,903

We expect research and development expenditures during the fourth quarter of 2014 to be significantly less than they were in 2013, due primarily to reductions in spending on psychotic depression with the termination of our Study 14 during the second quarter of 2014. Research and development expenses in 2015 and beyond will depend on our strategic priorities. See also Liquidity and Capital Resources .

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

Selling, general and administrative expenses Selling, general and administrative expenses include (1) 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 of marketing materials 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, 2014, selling, general and administrative expenses increased 26.8 percent to $9.1 million from $7.2 million for the comparable period in 2013. For the nine-month period ended September 30, 2014, selling, general and administrative expenses increased 13.3 percent to $26.9 million from $23.7 million for the comparable period in 2013.

During the three-month period ended September 30, 2014, as compared to the corresponding period in 2013, there were increases of $295,000 in staffing and consultancy costs and $336,000 in professional services related to commercial activities. During the nine-month period ended September 30, 2014, as compared to the corresponding period in 2013, staffing and consultancy costs increased by $3.3 million, primarily due to the payment of $2.5 million in bonuses awarded in February 2014. This increase was partially offset by a decrease in other professional services related to commercial activities of $1.1 million in the respective comparable period.

Selling, general and administrative expenses included stock-based compensation expense related to option grants to individuals performing these functions of $1.0 million and $3.3 million during the three- and nine-month periods ended September 30, 2014, respectively, compared to $1.1 million and $3.4 million in the respective periods of 2013.

We expect that selling, general and administrative expenses for the fourth quarter of 2014 will be approximately the same as during the respective period of 2013. The level of selling, general and administrative activities and related expenses in 2015 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. See also Liquidity and Capital Resources.

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Interest and other expense Interest and other expense for the three- and nine-month periods ended September 30, 2014 was $903,000 and $2.9 million, respectively, as compared to $1.2 million and $3.4 million for the respective periods in 2013. Costs in this category consisted primarily of interest expense related to our Biopharma financing agreement for all periods presented. Interest expense for the fourth quarter of 2014 and future years related to this obligation will decrease from the levels of 2013 as the outstanding balance of the obligation is reduced by the quarterly payments.

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.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
	(in thousands, except for per share data)			
GAAP net loss	$(6,006)	$ (10,906)	$ (27,488)	$ (34,887)
Significant non-cash expenses:				
Stock-based compensation	1,210	1,309	3,814	3,883
Accretion of interest expense related to long-term obligation	895	1,133	2,874	3,340
Non-GAAP net loss, as adjusted for significant non-cash expenses	$ (3,901)	$ (8,464)	$ (20,800)	$ (27,664)
GAAP basic and diluted net loss per share	$ (0.06)	$ (0.11)	$ (0.27)	$ (0.35)
Non-GAAP basic and diluted net loss per share, as adjusted for significant non-cash expenses	$ (0.04)	$ (0.08)	$ (0.21)	$ (0.28)
Shares used in computing basic and diluted net loss per share	101,134	99,814	100,880	99,814

Liquidity and Capital Resources

We have incurred operating losses since inception, and at September 30, 2014, we had an accumulated deficit of $320.1 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, 2014, we had cash and cash equivalents of $26.8 million, compared to $54.9 million at December 31, 2013. Net cash used in operating activities for the nine-month periods ended September 30, 2014 and 2013 were $26.0 million and $29.4 million, respectively. We used cash in each period primarily for the commercialization of Korlym and for research and development activities. In addition, we made payments under the Biopharma Financing Agreement of $3.3 million in the aggregate during the nine-month period ended September 30, 2014. During the nine-month period ended September 30, 2013, we made only one payment under this agreement in the amount of $378,000, which payment was made in July 2013. No payments were required under this agreement prior to that time.

We expect net cash used during the remainder of 2014 and future periods will be significantly lower than in corresponding period of 2013 as cash generated from the sale of Korlym will increase more than our expenditures related to the commercialization of Korlym, the continuation of our Phase 1 trial of mifepristone for triple-negative breast cancer, development of our selective GR-II antagonists and payments under our

Biopharma Financing Agreement.

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As discussed below under the caption Contractual Obligations and Commercial Commitments, we are required to make aggregate payments under the Biopharma Financing Agreement of $45.0 million, with $4.3 million paid through September 30, 2014 and an additional payment of $1.6 million made in October 2014. Future individual payment amounts will be variable.

We believe that we will reach cash-flow breakeven without needing to raise additional funds. However, 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 never experienced a loss or lack of access to cash in our checking account or money market fund.

Contractual Obligations and Commercial Commitments

Our contractual payment obligations and purchase commitments as of December 31, 2013 are disclosed in our Annual Report on Form 10-K for the year ended December 31, 2013, and have not changed materially during the nine-months ended September 30, 2014, with the exception of (1) the initiation of an agreement with a CRO for a Phase 1 study of one of our new compounds with a total commitment of approximately $2.6 million that is expected to be expended over the next one-year period, (2) the execution of a long-term manufacturing and supply agreement with PCAS for the manufacture of mifepristone and (3) the execution of a long-term agreement with AAI Pharma for the manufacture of Korlym tablets. We have agreed to purchase a minimum percentage of our mifepristone requirements from PCAS; the amount of this commitment will depend on our future needs. There are no minimum purchase obligations under the agreement with AAI Pharma.

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, 2013. During the nine months ended September 30, 2014, 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, 2014, the fair value of our cash and cash equivalents was $25.4 million and consisted primarily of a money market fund maintained at a major U.S. financial institution that invests primarily in short-term U.S. Treasury notes and bills. 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, 2014.

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ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures. Our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of our disclosure controls and procedures, as defined under Rules 13a-15(e) and 15d-15(e) of the Exchange Act as of September 30, 2014. 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, 2014, 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 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 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 insurance 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;
- 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;
- 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 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 limited experience 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.

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

Even though the FDA has approved Korlym, physicians may not adopt it as a treatment for their eligible patients. Physicians will prescribe Korlym only if they determine, based on experience, clinical data, side effect profiles and other factors, that it is preferable to other products or treatments currently in use, even if those products are not approved for Cushing s syndrome. Because Cushing s syndrome is rare, most physicians are inexperienced in the care of patients with the illness and it may be difficult to persuade them to prescribe a newer treatment, such as Korlym, even with clinical trial results that suggest 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 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. We may face competition from companies that attempt to develop mifepristone or other compounds for the treatment of Cushing s syndrome, which could limit our future revenues from the commercialization of Korlym and which could have a negative impact on future revenues from the commercialization of Korlym for any indication. These companies may have significantly more resources than we do.

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 or EMA can subsequently approve a different drug for the same condition if it concludes that the later drug is safer, more effective or makes a major contribution to patient care. In addition, the FDA or EMA may, during the orphan drug exclusivity period, approve the same drug for a different indication or different drug for the same indication. Upon expiration of the orphan drug exclusivity period, we may be subject to competition from manufacturers offering a generic form of mifepristone at a lower price, in which case our business could be harmed.

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 determine 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.

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 mifepristone to treat 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 our drug, we will not receive the ten years of marketing exclusivity from the date of drug approval in the EU and other potential benefits.

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.

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 cost containment 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 may need to obtain approvals from hospital formularies before Korlym can be covered for in-patient treatment. Failure to obtain such approvals 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.

The PPACA, which was passed in 2010, 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;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer s Medicaid rebate liability;
- expansion of access to commercial health insurance coverage through new state-based health insurance marketplaces, or exchanges;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical research;
- new requirements for manufacturers to discount drug prices to eligible patients by 50 percent at the pharmacy level and for mail order services in order for their outpatient drugs to be covered under Medicare Part D;
- an increase in the number of entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and
- establishment of a licensure framework for follow-on biologic products.

The PPACA provisions on comparative clinical effectiveness research extended the initiatives of the American Recovery and Reinvestment Act of 2009, also known as the stimulus package, which included $1.1 billion in funding to study the comparative effectiveness of health care treatments. This stimulus funding was designated for, among other things, conducting, supporting or synthesizing research that compares and

evaluates the risks and benefits, clinical outcomes, effectiveness and appropriateness of products. The PPACA also appropriated additional funding to comparative clinical effectiveness research. Although Congress has indicated that this funding is intended to improve the quality of health care, it remains unclear how the research will impact current Medicare coverage and reimbursement or how new information will influence other third-party payor policies. It also is unclear what the full impact of PPACA s extension of coverage to previously uninsured individuals will be on the demand for our products.

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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 two percent per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2024 unless additional Congressional action is taken. 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 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 further 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 growth effectively.

To that end, we must be able to:

- integrate additional management, clinical development, administrative and sales and marketing personnel;
- expand the size and composition of our management team;
- develop our administrative, accounting and management information systems and controls;
- hire and train additional qualified personnel;
- manage our 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

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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 a single-source, third-party contract manufacturer, PCAS, to supply the active pharmaceutical ingredient, or API, in Korlym. We entered into a long-term agreement with PCAS in March 2014. We also depend on a single-source, third-party contract manufacturer, AAI, to produce Korlym tablets. In April 2014, we entered into a long-term agreement with AAI. If either of these manufacturers is unable or unwilling to meet our future demands required, we may not be able to manufacture our product in a timely manner. Our current arrangements with these manufacturers are terminable by such manufacturers, subject to certain notice provisions. If we are unable 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. In addition, we expect to use third-party manufacturers and suppliers if and when our other 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. If our suppliers 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.

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.

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

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

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

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

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

Even after we obtain U.S. regulatory approval for a product, the FDA may still impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. For example, a product s approval may contain requirements for potentially costly post-approval studies and surveillance, including Phase 4 clinical trials, to monitor the safety and efficacy of the product. The FDA s approval of Korlym was subject to limitations on the indicated uses for which the product may be marketed and requirements for post-marketing follow-up studies and information reporting. In addition, the FDA s approval of Korlym requires that we conduct a study of the interactions between Korlym and ketoconazole, an anti-fungal agent sometimes used to treat patients with Cushing s syndrome. It also requires us to conduct a drug utilization study to better characterize the reporting rates of adverse events associated with the long-term use of Korlym.

We are 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.

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The FDA s policies may change and additional governmental regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may place at risk the FDA marketing approval for Korlym and any other marketing approval that we may obtain, 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 triple-negative breast cancer, 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, while we have received FDA marketing approval for Korlym, we may be unable to maintain such approval and we may never receive such regulatory approval for any of our product candidates. Obtaining regulatory approval of a new drug is an uncertain, lengthy and expensive process, and success is never guaranteed. Despite the time, resources and effort expended, failure can occur at any stage. In order to receive approval from the FDA for each product candidate, we must demonstrate that the new drug product is safe and effective for its intended use and that our manufacturing processes for the product candidate comply with the FDA s cGMPs. cGMPs include requirements related to production processes, quality control and assurance, and recordkeeping. The FDA has substantial discretion in the approval process for human medicines. The FDA may require substantial additional clinical testing or find our drug products do not satisfy the standards for approval. Our inability or the inability of our suppliers to comply with applicable FDA and other regulatory requirements can result in, among other things, delays in or denials of new product approvals, warning letters, fines, consent decrees restricting or suspending manufacturing operations, injunctions, civil penalties, recall or seizure of products, total or partial suspension of sales, and/or criminal prosecution. Any of these or other regulatory actions could materially adversely affect our business and our financial condition.

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

If we receive regulatory approval for our future product candidates, including mifepristone for the treatment of triple-negative breast cancer, 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. 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

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

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

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

- federal sunshine laws that require transparency regarding financial arrangements with health care providers, such as the reporting and disclosure requirements imposed by the PPACA on drug manufacturers regarding any transfer of value made or distributed to prescribers and other health care providers, and ownership or investment interests held by physicians and their immediate family members. The period between August 1, 2013 and December 31, 2013 was the first reporting period, and manufacturers were required to report aggregate payment data by March 31, 2014, and were required to report detailed payment data and submit legal attestation to the accuracy of such data by June 30, 2014. Payment data for the first reporting period was released to the public on September 30, 2014. Thereafter, manufacturers must submit reports by the 90th day of each calendar year;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; 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; state laws that require pharmaceutical companies to comply with the pharmaceutical industry s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or

marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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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 eventually 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 profile of their medication candidate, despite promising results in earlier trials. Clinical trials may not demonstrate sufficient safety and efficacy to obtain regulatory approval. For example, in May 2014, we discontinued our Phase 3 study of mifepristone for treatment of psychotic depression (Study 14) after receiving the report of a data monitoring committee that the trial was unlikely to reach its primary endpoints based on an analysis of interim data.

Our ongoing Phase 1 study of mifepristone in combination with chemotherapy to treat triple-negative breast cancer is too small to demonstrate definitively the safety or efficacy of mifepristone for that indication. Even if the trial generates positive results, those results would have to be confirmed in at least one substantially larger, more expensive, and lengthier trial if we are to have sufficient basis for seeking regulatory approval.

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.

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Over the course of clinical development of any product candidate, we may decide, or the FDA or other regulatory authorities may require us, to pursue clinical or preclinical studies in addition to those we had initially anticipated. 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 our development programs. Even if we are able to conduct all of the clinical trials and supportive studies that we consider appropriate, we may never receive regulatory approval to market mifepristone for the treatment of triple-negative breast cancer or any other product candidates or indications.

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 (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 treatment of triple-negative breast cancer or other development programs.

We have an agreement with the CRO that is conducting our Phase 1 trial of mifepristone for the treatment of triple-negative breast cancer 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 treatment of triple-negative breast cancer.

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 MAA 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.

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

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 triple-negative breast cancer or for other indications.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. 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 triple-negative breast cancer, 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 or new therapeutic uses for mifepristone. We own or have exclusively licensed issued U.S. patents covering the use of GR-II antagonists to treat triple-negative breast cancer, mental disorders by optimizing mifepristone levels in plasma serum, 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 six U.S. method of use patent applications covering GR-II antagonists for the treatment of a number of other metabolic and psychiatric disorders, six U.S. composition of matter patents covering specific GR-II antagonists, and one additional U.S. composition of matter patent application is 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. For example, although we plan to advance at least two of the new compounds to the clinic over the next year, we may fail to do so.

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

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We only have significant clinical experience with mifepristone and we may determine that mifepristone is not desirable for uses other than for the treatment of Cushing s syndrome and, potentially, triple-negative breast cancer. 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. We may pursue 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. For example, we do not currently employ a Chief Medical Officer to manage our clinical development efforts, although our efforts to hire such an executive are ongoing. 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 and 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. Korlym and 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 Korlym and our product candidates obsolete or uneconomical, which could materially adversely affect our business, financial condition and results of operations.

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

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

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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 the treatment of triple-negative breast cancer 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 need to raise additional funds to continue and expand the development of mifepristone for the treatment of triple-negative breast cancer and 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 and outcome of our Phase 1 study of mifepristone for the treatment of triple-negative breast cancer and further clinical development related to this indication;

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

actual or anticipated fluctuations in our operating results;

changes in our growth rates; and

changes in our research and development plans for our proprietary, selective GR-II antagonists.

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

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

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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 we may incur net losses in the future.

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 triple-negative breast cancer and, potentially, other indications. 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, 2014, we had an accumulated deficit of $320.1 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 and for other product candidates. We expect to incur significant expenses related to commercializing Korlym. 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 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 triple-negative breast cancer.

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. Renewed concerns about the recent recession and 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 may cause 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.

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

If we acquire other 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.

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Failure to meet our obligations under our Financing Agreement with Biopharma Secured Debt Fund II Sub, S.àr.l (Biopharma), 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).

We cannot assure 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, we cannot assure that we will be able to cure the event within the time permitted. Any failure to pay our obligations when due, any breach or default of our covenants or other obligations, or any other event that causes an acceleration of payment at a time when we do not have sufficient resources to meet these obligations, could have a material adverse effect on our business, results of operations, financial condition and future viability.

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

Risks Relating to Our Intellectual Property

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

Our success depends in part on our ability to obtain and maintain adequate patent protection for the use of mifepristone for the treatment of triple-negative breast cancer 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.

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

We have exclusively licensed three issued U.S. patents from Stanford University for the use of GR-II antagonists, including mifepristone, 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 have also exclusively licensed from the University of Chicago allowed U.S. patent claims for the use of mifepristone in the treatment of triple-negative breast cancer, which claims are covered in U.S. Patent Application No. 13/071,363 Methods and Compositions Related to Glucocorticoid Receptor Antagonists and Breast Cancer. On August 8, 2013 the U.S. Patent and Trademark Office notified the University of Chicago that certain claims in the application had been allowed, although the patent has not yet issued.

We bear the costs of prosecuting, 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 both universities. If we become noncompliant with our obligations under our agreements, we may lose the right to commercialize mifepristone for the treatment of cocaine-induced psychosis, early dementia and triple-negative breast cancer 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 cocaine-induced psychosis or early dementia. If the University of Chicago were to terminate our license, we would not be able to commercialize mifepristone for the treatment of triple-negative breast cancer.

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 (now a division of 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.

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

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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 patents covering the use of mifepristone to treat triple-negative breast cancer, psychotic depression, cocaine-induced psychosis and early dementia, including Alzheimer s disease, cover only mifepristone s method of use and not its composition of matter, which may make it more difficult for us to prove patent infringement if physicians prescribe another manufacturer s mifepristone or if patients acquire mifepristone from other sources, such as the internet or underground market.

We have exclusively licensed three U.S. patents from Stanford University for the use of GR-II antagonists, including mifepristone, for the treatment of psychotic depression, cocaine-induced psychosis and early dementia, including Alzheimer s disease. We also have an exclusive license from the University of Chicago to certain allowed patent claims covering the use of mifepristone to treat triple-negative breast cancer. A method of use patent covers only a specified use of a particular compound, not a particular composition of matter. Because none of the patents we have licensed from Stanford University and none of the allowed patent rights we have licensed from the University of Chicago cover the composition of mifepristone, we cannot prevent others from commercializing mifepristone in indications not covered by these or our other method of use patents. Although any such off-label use would violate our patents, effectively monitoring compliance with our patents may be difficult and costly.

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 underground 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 3, 2014, our average daily trading volume was approximately 414,000 shares and the intra-day sales prices per share of our common stock on The NASDAQ Stock Market ranged from $1.60 to $4.49. As of November 3, 2014, our officers, directors and principal stockholders controlled 35 percent of our common stock. The trading price of our common stock has been and is likely to continue to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

- the pace of market acceptance of Korlym or the timing and level of 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;
- 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.

We have provided guidance as to our expected 2014 net revenue. 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 risks and uncertainties described in this report and in our other public filings and public statements. In particular, 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 range of revenue estimates, based on their own analyses. 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.

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 penalties 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. We may be obligated to pay liquidated damages if we do not meet our obligations under those agreements.

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 3, 2014, our officers, directors and principal stockholders control 35 percent of our common stock. As a result, these stockholders, acting together, will be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders and may prevent or delay a change in control. This significant concentration of share ownership may adversely affect the trading price of our common stock because investors often perceive disadvantages to owning stock in companies with controlling stockholders.

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

New laws and regulations, as well as changes to existing laws and regulations, affecting 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 have increased and will continue to increase our legal compliance costs.

Section 404 of the Sarbanes-Oxley Act of 2002 requires that we evaluate and determine the effectiveness of our internal controls over financial reporting and provide a management report on the internal control over financial reporting. 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. If we are unable to complete the required assessment as to the adequacy of our internal control over financial reporting in future years or if our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal control over financial reporting as of future year ends, investors could lose confidence in the reliability of our financial reporting.

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

Accounting methods and policies for business and marketing practices of pharmaceutical companies are subject to continual review, interpretation and guidance from relevant accounting authorities, including the SEC. 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.

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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. During the 52-week period ended November 3, 2014, the intra-day sales prices per share of our common stock on The NASDAQ Stock Market ranged from $1.60 to $4.49. 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.àr.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.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

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ITEM 6. EXHIBITS

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation, as amended (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	Third Amendment to the Commercial Outsourcing Services Agreement with Integrated Commercialization Solutions, Inc., effective as of August 11, 2014.
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, 2014, formatted in Extensible Business Reporting Language (XBRL): (i) unaudited Condensed Balance Sheets at September 30, 2014 and December 31, 2013, (ii) unaudited Condensed Statements of Comprehensive Loss for the three- and nine-month periods ended September 30, 2014 and 2013, (iii) unaudited Condensed Statements of Cash Flows for the nine-month periods ended September 30, 2014 and 2013, 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 7, 2014

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

Chief Executive Officer

Date: November 7, 2014

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

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