
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 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
(State or other jurisdiction of
incorporation or organization)

77-0487658
(I.R.S. Employer
Identification No.)

149 Commonwealth Drive
Menlo Park, CA 94025
(Address of principal executive offices, including zip code)

(650) 327-3270
(Registrant's telephone number, including area code)

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

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

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

| | | | |
|-------------------------|--|---------------------------|-------------------------------------|
| Large Accelerated Filer | <input type="checkbox"/> | Accelerated Filer | <input checked="" type="checkbox"/> |
| Non-accelerated filer | <input type="checkbox"/> (Do not check if a smaller reporting company) | Smaller Reporting Company | <input type="checkbox"/> |

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

On May 5, 2014 there were 100,893,846 shares of common stock outstanding at a par value of \$0.001 per share.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

- our ability to manufacture, market and sell Korlym[®] (mifepristone) 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 timing of regulatory activities for mifepristone for the treatment of triple-negative breast cancer or other indications;
- 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).

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CORCEPT THERAPEUTICS INCORPORATED

CONDENSED BALANCE SHEETS

(In thousands except per share data)

| | March 31, 2014 (Unaudited) | December 31, 2013 (See Note 1) |
|---|----------------------------------|--------------------------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 43,618 | \$ 54,877 |
| Trade receivables | 1,922 | 1,428 |
| Inventory | 1,127 | 1,096 |
| Prepaid expenses and other current assets | 1,453 | 910 |
| Total current assets | 48,120 | 58,311 |
| Strategic inventory | 4,330 | 4,450 |
| Property and equipment, net of accumulated depreciation | 285 | 203 |
| Other assets | 96 | 113 |
| Total assets | <u>\$ 52,831</u> | <u>\$ 63,077</u> |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 3,666 | \$ 2,381 |
| Accrued clinical expenses | 3,380 | 3,288 |
| Other accrued liabilities | 1,271 | 1,301 |
| Long-term obligation - current portion | 6,896 | 5,743 |
| Deferred revenue | 29 | 25 |
| Total current liabilities | 15,242 | 12,738 |
| Long-term obligation, net of current portion | 28,218 | 29,322 |
| Commitments | | |
| Stockholders' equity: | | |
| Preferred stock, par value \$0.001 per share, 10,000 shares authorized and no shares outstanding at March 31, 2014 and December 31, 2013 | — | — |
| Common stock, par value \$0.001 per share, 280,000 shares authorized and 100,689 and 99,849 shares issued and outstanding at March 31, 2014 and December 31, 2013, respectively | 101 | 100 |
| Additional paid-in capital | 315,817 | 313,534 |
| Accumulated deficit | (306,547) | (292,617) |
| Total stockholders' equity | 9,371 | 21,017 |
| Total liabilities and stockholders' equity | <u>\$ 52,831</u> | <u>\$ 63,077</u> |

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

CORCEPT THERAPEUTICS INCORPORATED
CONDENSED STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited)
(In thousands, except per share data)

| | Three Months Ended | |
|--|---------------------------|--------------------|
| | March 31, | |
| | 2014 | 2013 |
| Product sales, net | \$ 4,405 | \$ 1,717 |
| Operating expenses: | | |
| Cost of sales | 174 | 20 |
| Research and development | 7,285 | 4,257 |
| Selling, general and administrative | 9,805 | 8,383 |
| Total operating expenses | 17,264 | 12,660 |
| Loss from operations | (12,859) | (10,943) |
| Interest and other expense | (1,071) | (1,141) |
| Net loss and comprehensive loss | <u>\$ (13,930)</u> | <u>\$ (12,084)</u> |
| Basic and diluted net loss per share | <u>\$ (0.14)</u> | <u>\$ (0.12)</u> |
| Weighted average shares outstanding used in computing basic and diluted net loss per share | <u>100,521</u> | <u>99,814</u> |

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

CORCEPT THERAPEUTICS INCORPORATED
CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

| | Three Months Ended | |
|--|---------------------------|------------------|
| | March 31, | |
| | 2014 | 2013 |
| Operating activities | | |
| Net loss | \$ (13,930) | \$ (12,084) |
| Adjustments to reconcile net loss to net cash used in operations: | | |
| Stock-based compensation | 1,378 | 1,310 |
| Accretion of interest expense | 1,044 | 1,115 |
| Amortization of debt financing costs | 8 | 11 |
| Depreciation and amortization of property and equipment | 28 | 14 |
| Changes in operating assets and liabilities: | | |
| Trade receivables | (494) | (586) |
| Inventory | 89 | (13) |
| Prepaid expenses and other current assets | (543) | 48 |
| Other assets | 9 | (3) |
| Accounts payable | 1,285 | (1,541) |
| Accrued clinical expenses | 92 | (260) |
| Other accrued liabilities | (30) | 375 |
| Deferred revenue | 4 | 60 |
| Net cash used in operating activities | <u>(11,060)</u> | <u>(11,554)</u> |
| Investing activities | | |
| Purchases of property and equipment | (110) | (18) |
| Cash used in investing activities | <u>(110)</u> | <u>(18)</u> |
| Financing activities | | |
| Proceeds from issuance of common stock and warrants, net of issuance costs | 906 | — |
| Payments related to long-term obligation | (995) | — |
| Net cash used in financing activities | <u>(89)</u> | <u>—</u> |
| Net decrease in cash and cash equivalents | <u>(11,259)</u> | <u>(11,572)</u> |
| Cash and cash equivalents, at beginning of period | 54,877 | 93,032 |
| Cash and cash equivalents, at end of period | <u>\$ 43,618</u> | <u>\$ 81,460</u> |

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

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 in the United States as a once-daily oral medication for treatment of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. We released Korlym for sale in 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 March 31, 2014 and the condensed statements of comprehensive loss and condensed statements of cash flows for the three-month periods ended March 31, 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-month period ended March 31, 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 March 31, 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.

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

Credit Risks and Concentrations

We have a concentration of credit risk related to our cash and cash equivalents. We are exposed to credit risk in the event of default by the financial institutions holding these funds or by the entity or entities that issued the securities held by the fund to the extent of the amount recorded on our balance sheet. We mitigate this risk by investing in a money market fund that invests primarily in short-term U.S. Treasury notes and bills. We experienced no loss or lack of access to cash and cash equivalents in our operating or investment accounts during the three-month periods ended March 31, 2014 and 2013.

We are exposed to credit risk in regard to our trade receivables with this risk being spread among various third-party payors – pharmacy benefit managers, insurance companies, private charities, government programs – and individual patients. We extend credit to third-party payors based on their creditworthiness. We monitor our exposure and will record a reserve against uncollectible trade receivables as necessary. 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 March 31, 2014, we had one tablet manufacturer for Korlym with an operational facility – AAI Pharma Services Corp. (AAI). AAI was approved by the FDA in November 2012 for the manufacture of our commercial tablets, subject to the successful manufacture of validation batches. The manufacture of these batches began in April 2014. 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 manufacturers 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 placed orders for additional quantities of mifepristone API and Korlym tablets, which are now in inventory.

Fair Value Measurements

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

No assets or liabilities in our financial statements are required to be reported at fair value other than our cash equivalents and the obligation under our Financing Agreement with Biopharma Secured Debt Fund II Sub, S.à.r.l (Biopharma).

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.

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 and are obligated to make payments calculated as a percentage of (i) any licensing or other contingent payments arising from Korlym and any other products containing mifepristone or any of our proprietary selective GR-II antagonists (Covered Products) and (ii) net Covered Product revenues earned in the calendar quarter ending June 30, 2013 and thereafter (together, Korlym Receipts), until such time as we have paid Biopharma a total of \$45.0 million.

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

The amount shown as the current portion of the obligation is an estimate of the total amount under the Financing Agreement that would be paid to Biopharma within 12 months following March 31, 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.

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

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

Trade Allowances: Through June 30, 2013, we offered our specialty pharmacy and specialty distributor customers a discount on Korlym sales for payment within 30 days. We also offered them a small discount for providing data services. We expected these customers to earn these discounts and, accordingly, deducted them in full from gross product revenues and trade receivables at the time we recognized such revenues. 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 now limited to the specialty distributor channel and is not expected to be material.

Cost of Sales

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

Research and Development

Research and development 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

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

submissions and the development of second-generation compounds, as well as research and development-related overhead expenses. We also expense as incurred nonrefundable payments to third parties and our cost of acquiring technologies and materials used in research and development that have no alternative future use.

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

Segment Reporting

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

Stock-Based Compensation

Stock-based compensation for employee and director options

We account for stock-based compensation related to option grants to employees and directors under the fair value method, based on the fair value-based measurement of the award at the grant date as determined utilizing the Black-Scholes option valuation model. For service-based awards, we recognize expense over the requisite service period.

Stock-based compensation expense related to non-employees

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

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

2. Fair Value of Financial Instruments

As of March 31, 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 \$42.7 million and \$52.9 million as of March 31, 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 March 31, 2014 and December 31, 2013 were in active markets and valued based upon their quoted prices.

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

3. Composition of Certain Balance Sheet Items*Inventory*

The composition of inventory was as follows:

| | March 31, 2014 | December 31, 2013 |
|--|-----------------------|----------------------|
| | <i>(in thousands)</i> | |
| Raw materials | \$ 4,373 | \$ 4,318 |
| Work in progress | 11 | 2 |
| Finished goods | 1,073 | 1,226 |
| Total inventory | 5,457 | 5,546 |
| Less strategic inventory classified as non-current | (4,330) | (4,450) |
| Total inventory classified as current | <u>\$ 1,127</u> | <u>\$ 1,096</u> |

The finished goods inventory as of March 31, 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 had 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:

| | March 31, 2014 | December 31, 2013 |
|-------------------------|-----------------------|----------------------|
| | <i>(in thousands)</i> | |
| Accrued compensation | \$ 527 | \$ 466 |
| Professional fees | 176 | 369 |
| Commercialization costs | 258 | 288 |
| Government rebates | 141 | 40 |
| Legal fees | 62 | 110 |
| Other | 107 | 28 |
| | <u>\$ 1,271</u> | <u>\$ 1,301</u> |

4. Long-Term Obligation

As discussed in Note 1, *Basis of Presentation and Summary of Significant Accounting Policies, Long-term Obligation*, in August 2012, we entered into a Financing Agreement with Biopharma under which we received \$30.0 million from Biopharma. In return, we are obligated to make payments, calculated as a percentage of our net sales of Korlym, any future mifepristone-based products, our selective GR-II antagonists (together referred to as Covered Products) and any upfront, milestone or other contingent payments with respect to Covered Products. Biopharma's right to receive payments will expire once it has received cumulative payments of \$45.0 million. Through March 31, 2014, we made aggregate payments to Biopharma in the amount of \$2.0 million, with an additional payment in the amount of \$1.0 million made in April 2014.

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

We are obligated to make payments as follows:

- 20 percent of our net product sales of Covered Products, beginning with the calendar quarter ended June 30, 2013, subject to quarterly payment caps of \$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.

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.

The cash payment of \$30.0 million received from Biopharma was recorded as a long-term obligation at issuance. As discussed in Note 1, **Basis of Presentation and Summary of Significant Accounting Policies, Long-term Obligation**, we make estimates of the timing of payments during the term of this agreement for purposes of calculating the expected rate of return to Biopharma, the accretion of related interest expense and the current portion of our obligation. Interest expense of \$1.0 million for the three-month period ended March 31, 2014, \$1.1 million for the same period ended March 31, 2013 and total accreted interest of \$7.1 million for the period from August 2012 through March 31, 2014, is calculated based on the internal interest rate to Biopharma that would result from these assumed payment streams. Korlym has only been marketed since April 2012 and the magnitude and timing of Korlym revenue is difficult to predict. Therefore, these estimates and assumptions are subject to significant variability and are likely to change as we gain experience marketing Korlym. The timing of payment amounts will be based on actual Korlym Receipts recorded in the financial statements over the term of this agreement and may differ from these estimates. While changes in the timing of Korlym revenue may affect the timing of recognition of interest expense and the split between the current and long-term portions of the obligation at any balance sheet date, the aggregate amount to be repaid to Biopharma is fixed.

The carrying value of the long-term obligation was \$35.1 million as of March 31, 2014 and 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.

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 March 31, 2014 and December 31, 2013, utilizing the payment assumptions discussed above.

| | March 31, 2014 | December 31, 2013 |
|--|---------------------------|------------------------------|
| | <i>(in thousands)</i> | |
| Total repayment obligation | \$ 45,000 | \$ 45,000 |
| Less interest to be accreted in future periods | (7,866) | (8,910) |
| Less payments made | (2,020) | (1,025) |
| Less current portion | (6,896) | (5,743) |
| Long-term obligation, net of current portion | <u>\$ 28,218</u> | <u>\$ 29,322</u> |

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 March 31, 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 been available for less than two years and the 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 March 31, 2014 and December 31, 2013, the unamortized issuance costs were \$80,000 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 ingredient in Korlym®. We have agreed to purchase a certain minimum percentage of our mifepristone requirements from PCAS, the amount of which will be variable depending on 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 to the other that it does not want such an extension. We have the right to terminate the agreement if PCAS is unable to manufacture the product for a consecutive nine-month period.

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.

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 three-month period ended March 31, 2014, we issued an aggregate of 840,000 shares of our common stock upon the exercise of stock options.

CORCEPT THERAPEUTICS INCORPORATED**NOTES TO CONDENSED FINANCIAL STATEMENTS, continued**

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

| | Three Months Ended | |
|---|---------------------------|-----------------|
| | March 31, | |
| | 2014 | 2013 |
| | <i>(in thousands)</i> | |
| Research and development | \$ 162 | \$ 148 |
| Selling, general and administrative | 1,216 | 1,162 |
| Total non-cash stock-based compensation | <u>\$ 1,378</u> | <u>\$ 1,310</u> |

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.

| | March 31, | |
|---------------------------|-----------------------|---------------|
| | 2014 | 2013 |
| | <i>(in thousands)</i> | |
| Stock options outstanding | 14,675 | 14,141 |
| Warrants outstanding | 8,574 | 8,904 |
| Total | <u>23,249</u> | <u>23,045</u> |

8. Subsequent Events*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.

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 statements 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 potent, competitive glucocorticoid receptor II (GR-II) antagonist. In February 2012, the FDA approved Korlym® (mifepristone) 300 mg Tablets in the United States as a once-daily oral medication for treatment of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. We first made the drug available to patients in the United States in April 2012.

We have also 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 refer to Corcept Therapeutics Incorporated.

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

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

We 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

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approval, as well as tax credits for clinical trial costs, marketing application filing fee waivers and assistance from the FDA in the drug development process. Benefits of Orphan Drug Designation in the EU are similar to those in the United States, but include ten years of marketing exclusivity for the approved indication in all 28 member states, free scientific advice during drug development, access to a centralized review process and a reduction or complete waiver of fees levied by the European Medicines Agency (EMA). The EMA has accepted our plan to study the use of Korlym in children with Cushing's syndrome. We expect that the completion of this study will extend our period of marketing exclusivity by two years in the EU, provided our orphan protection is still in place at that time. 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 initial results in the first half of 2015.

Psychotic Depression. Since our inception in 1998, we have been developing mifepristone, the active ingredient in Korlym, for the treatment of psychotic depression under an exclusive patent license from Stanford University. 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.

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

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

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

Selective GR-II Receptor Antagonists. In 2003, we initiated a discovery research program to identify and patent selective GR-II antagonists with the intent of developing a pipeline of products for proprietary use. Three

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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; the metabolic syndrome; muscular dystrophy; obesity; ovarian and prostate cancer; prevention of glucocorticoid-induced neurological damage in premature infants; and stress disorders. We intend to continue our discovery research program with the goal of identifying new selective GR-II antagonists, to manufacture and conduct pre-clinical development of one or more of these compounds and to study the most promising of them in humans. We plan to advance one or more compounds to the clinic in 2014.

General

Our activities to date have included:

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

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

As of March 31, 2014, we had an accumulated deficit of \$306.5 million. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for mifepristone, discovery research, non-clinical activities such as toxicology and carcinogenicity studies, manufacturing and regulatory activities, as well as selling, general and administrative expenses, including expenses related to the commercial launch of Korlym. We may continue to incur net losses over at least the next year 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.

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For the three-month period ended March 31, 2014, we recorded \$4.4 million in net product sales, as compared to \$1.7 million in the comparable period 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 provide cash donations to a non-profit third party organization that supports patients who meet certain eligibility requirements with financial assistance for the treatment of Cushing's syndrome, which treatment may include Korlym. We do not include as net product revenues sales of Korlym tablets funded through this source.

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

Cost of sales was \$174,000 for the three-month period ended March 31, 2014, as compared to \$20,000 for the comparable period in 2013, which equals 4.0 percent and 1.2% percent of net product sales for the respective periods. Direct product cost for tablets sold during the three-month period ended March 31, 2014 represented approximately 3.2% of net product sales as compared to less than 1% of net product sales for the three-month period ended March 31, 2013. The remainder of the cost of sales during each period related to stability testing and distribution costs. Product sold during the three-month period ended March 31, 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-month period ended March 31, 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.

The cost of manufacturing Korlym reflected in our cost of sales through March 31, 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. In addition, 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. We expect that our cost of sales of Korlym as a percentage of net product sales will fluctuate from period to period during 2014 as product manufactured prior to FDA approval is consumed.

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 and (8) other costs associated with the preparation and prosecution of the regulatory submissions related to Korlym or other product candidates.

Research and development expenses increased 71 percent to \$7.3 million for the three-month period ended March 31, 2014 from \$4.3 million for the comparable period in 2013.

During the three-month period ended March 31, 2014, as compared to the corresponding period in 2013, there was an increase of \$1.2 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 \$423,000 in staffing and consulting costs in the first quarter of 2014 as compared to the same period in 2013, primarily to support increased activity in the psychotic depression study, preparations for a previously anticipated submission to the FDA of an sNDA for approval of mifepristone in psychotic depression, increased activities in our oncology study and other research and development activities.

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Clinical trial costs reflected net increases of \$1.7 million during the first quarter of 2014, as compared to the comparable period in 2013. During the three-month period ended March 31, 2014 as compared to 2013, there were increases of \$1.4 million related to our Phase 3 study with mifepristone for the treatment of psychotic depression study and \$554,000 related to our oncology study. In addition, there was an increase in spending of \$397,000 related to the development of new compounds, which was partially offset by decreases in spending of \$200,000 related to other products.

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

| Project | Three-Months Ended March 31, | |
|--|---|-----------------|
| | 2014 | 2013 |
| | <i>(in thousands)</i> | |
| Development programs: | | |
| Psychotic Depression | \$ 3,395 | \$ 1,506 |
| Cushing's syndrome | 641 | 538 |
| Cancer | 767 | — |
| Selective GR-II antagonists | 1,857 | 1,464 |
| Unallocated activities, including NDA supportive studies and manufacturing, regulatory and pre-clinical activities | 463 | 601 |
| Stock-based compensation | 162 | 148 |
| Total research and development expense | <u>\$ 7,285</u> | <u>\$ 4,257</u> |

We expect research and development expenditures during the remainder of 2014 to be approximately the same as they were in 2013, as reductions in our spending on psychotic depression are offset by increases in spending on development of our next-generation compounds. Research and development expenses in 2015 and beyond will depend on our strategic priorities and the availability of funding. 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 March 31, 2014, selling, general and administrative expenses increased 17 percent to \$9.8 million from \$8.4 million for the comparable period in 2013.

During the three-month period ended March 31, 2014, as compared to the corresponding period in 2013, staffing and consultancy costs reflected an increase of \$2.7 million, which included \$2.5 million related to cash bonuses awarded in February 2014 to employees and officers working in selling, general and administrative functions. During the three-month period ended March 31, 2014, as compared to the corresponding period in 2013, there was also an increase of \$251,000 related to our contracted sales force. These increases were offset by a decrease in other professional services costs related to commercial activities of \$914,000 in marketing and promotional activities and a decrease in our legal costs of \$285,000.

Selling, general and administrative expenses included stock-based compensation expense related to option grants to individuals performing these functions of \$1.2 million during each of the three-month periods ended March 31, 2014 and 2013.

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We expect that selling, general and administrative expenses will be slightly higher during the remainder of 2014 as compared to 2013 because of activities directly associated with the commercialization of Korlym. 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 and the availability of additional funds. See also, "Liquidity and Capital Resources."

Interest and other expense – Interest and other expense was \$1.1 million for each of the three-month periods ended March 31, 2014 and 2013, which consisted primarily of interest expense related to our Biopharma financing agreement. Interest expense for the remainder of 2014 and future years related to this obligation will decrease from the levels of 2013 due to quarterly payments against the outstanding obligation.

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 | |
|--|--|-------------|
| | March 31, | |
| | 2014 | 2013 |
| | <i>(in thousands, except for per share data)</i> | |
| GAAP net loss | \$ (13,930) | \$ (12,084) |
| Significant non-cash expenses: | | |
| Stock-based compensation | | |
| Research and development | 162 | 148 |
| Selling, general and administrative | 1,216 | 1,162 |
| Total stock-based compensation | 1,378 | 1,310 |
| Accretion of interest expense related to long-term obligation | 1,044 | 1,115 |
| Non-GAAP net loss, as adjusted for significant non-cash expenses | \$ (11,508) | \$ (9,659) |
| GAAP basic and diluted net loss per share | \$ (0.14) | \$ (0.12) |
| Non-GAAP basic and diluted net loss per share, as adjusted for significant non-cash expenses | \$ (0.11) | \$ (0.10) |
| Shares used in computing basic and diluted net loss per share | 100,521 | 99,814 |

Liquidity and Capital Resources

We have incurred operating losses since inception, and at March 31, 2014, we had an accumulated deficit of \$306.5 million. Since our inception, we have relied primarily on the proceeds from public and private sales of our equity securities and our Financing Agreement with Biopharma to fund our operations.

At March 31, 2014, we had cash and cash equivalents of \$43.6 million, compared to \$54.9 million at December 31, 2013. Net cash used in operating activities for the three-month periods ended March 31, 2014 and 2013 were \$11.1 million and \$11.6 million, respectively. We used cash in each period primarily for the commercialization of Korlym and for research and development activities. In addition, we made a payment under the Biopharma Financing Agreement of \$995,000 during the three-month period ended March 31, 2014. No payments had been required under this agreement during the comparable period in 2013 as payments as the first payment was not required to be made until August 2013.

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We expect net cash used during the remainder of 2014 will be lower than in corresponding periods of 2013 as the cash expected to be generated from increasing sales of Korlym will be greater than the change in expenditures related to the continued commercialization of Korlym, the initiation of our Phase 1 trial of mifepristone for triple-negative breast cancer, the continued development of our selective GR-II antagonists and payments under our Biopharma Financing Agreement.

Our funding requirements for operating activities may increase in 2015 and beyond if we decide to expand our development programs for oncology or our selective GR-II antagonists, in which case expenses may be only partially offset by revenues from sales of Korlym.

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, of which \$2.0 million was paid through March 31, 2014, with an additional payment of \$1.0 million in April 2014. Future individual payment amounts will be variable.

We may choose to raise additional funds to finance our strategic priorities. We cannot be certain that additional funding will be available on acceptable terms or at all. Further, any additional equity financing may be dilutive to stockholders, and any debt financing, if available, may involve restrictive covenants. If we obtain funds through collaborations with others, these arrangements may be on unfavorable terms or may require us to relinquish certain rights to our technologies or product candidates that we would otherwise seek to develop on our own.

While we monitor the cash balance in our checking account and transfer the funds in only as needed, these cash balances and our money market fund could be influenced if the underlying financial institution were to fail or were subject to other adverse conditions in the financial markets. To date, we have experienced no loss or lack of access to cash in our checking 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 three months ended March 31, 2014, with the exception of 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 and the execution of a long-term manufacturing and supply agreement with PCAS for the manufacture of mifepristone. We have agreed to purchase a certain minimum percentage of our mifepristone requirements from PCAS, the amount of which will be variable depending on future needs.

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 three months ended March 31, 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 March 31, 2014, the fair value of our cash and cash equivalents was \$43.6 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 March 31, 2014.

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 March 31, 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 March 31, 2014, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently involved in any material legal proceedings.

ITEM 1A. RISK FACTORS

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

Risks Related to the Commercialization of Korlym and Development of Mifepristone and Our Other Proprietary GR-II Antagonists

We depend heavily on the success of Korlym, which we began to sell in the United States in April 2012. If we are unable to increase revenues of Korlym to the levels that investors expect, or experience significant delays in doing so, our stock price will likely decline.

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

- an inability to generate meaningful revenue due to low product usage, inadequate coverage and reimbursement or other factors;
- competition from Novartis's Signifor and from other companies with greater financial, technical and marketing resources than ours;
- an inability to manufacture Korlym or the active ingredient in Korlym in commercial quantities and at an acceptable cost;
- 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 are able to commercialize Korlym successfully, we cannot predict the rate at which success will occur.

As our current ability to generate revenue is wholly dependent upon the commercialization of Korlym, its rate of sale will directly and materially affect our results of operations. There are inherent difficulties in predicting the volumes of Korlym that will be sold, which are heightened by our 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."

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

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

Even though the FDA has approved Korlym, physicians may not adopt it as a treatment for their eligible patients. Physicians will prescribe Korlym only if they determine, based on experience, clinical data, side effect

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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, in particular from government payors such as Medicare and Medicaid, for patients using Korlym;
- the product labeling required by the FDA for Korlym;
- the extent and success of our efforts to manufacture, commercialize, market, distribute and sell Korlym; and
- negative publicity concerning Korlym, RU-486, Mifeprex® or mifepristone.

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

We will face competition from companies that attempt to develop mifepristone or other compounds for the treatment of Cushing's syndrome, which could limit our future revenues from the commercialization of Korlym and which could have a negative impact on future revenues from the commercialization of Korlym for any indication. These companies may have significantly more resources than we do. The Orphan Drug Designation for Korlym may not provide protection from competition and other benefits as anticipated.

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

In 2011, the European Commission granted us Orphan Drug Designation for mifepristone for the treatment of endogenous Cushing's syndrome (hypercortisolism) in the EU. Benefits of Orphan Drug Designation in the EU are similar to those in the United States, but include ten years of marketing exclusivity for the approved indication in all 28 Member States, free scientific advice during drug development, access to a centralized review process and a reduction or complete waiver of fees levied by the EMA. The EMA has accepted our plan to study the use of Korlym in children with Cushing's syndrome which we expect will, upon completion, extend our period of marketing exclusivity by two years in the EU. We submitted our Marketing Authorization Application request to the EMA in October 2013.

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

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

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. Any delay in our commercialization of Korlym may have a negative impact on the revenue that we might be able to realize from the exclusivity provided during the applicable periods.

If we cannot continue to obtain acceptable prices or adequate coverage and reimbursement for Korlym from third-party payors, we will be unable to generate significant revenues.

There is significant uncertainty related to the availability of third-party insurance coverage and reimbursement for newly approved medications. The commercial success of our medications in both domestic and international markets depends on whether third-party coverage and reimbursement is available for them. Government payors, including Medicare and Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new medicines, and, as a result, they may not cover or provide adequate payment for our medications. Our near-term dependence on the commercial success of Korlym makes us particularly susceptible to any such cost containment or reduction efforts. Accordingly, even though Korlym has been approved for commercial sale, unless government and other third-party payors continue to provide adequate and timely coverage and reimbursement, physicians may not prescribe it and patients may not purchase it. In addition, meaningful delays in insurance coverage for individual patients may increase our costs and reduce our revenues. Further, we may need to obtain approvals from hospital formularies before Korlym can be covered for in-patient treatment. If we fail to obtain such approvals, this will reduce the level of revenues that we are able to attain.

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

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

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\$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.

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 any future growth effectively.

To that end, we must be able to:

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

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

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

The active ingredient in Korlym, mifepristone (RU-486), is approved by the FDA in another drug for the termination of early pregnancy. As a result, mifepristone has been and continues to be the subject of considerable ethical and political debate in the United States and elsewhere. Public perception of mifepristone may limit our ability to engage alternative manufacturers and may limit the commercial acceptance of Korlym by patients and physicians. Even though we have taken measures to minimize the likelihood of the prescribing of Korlym to a pregnant woman, physicians may choose not to prescribe Korlym to a woman simply to avoid any risk of unintentionally terminating a pregnancy. We have taken measures to control the distribution of Korlym to reduce the potential for diversion and this controlled distribution may negatively impact sales of Korlym.

We have no manufacturing capabilities and we currently depend on third parties to manufacture the active ingredient and the tablets for Korlym, both of which are single-source suppliers. If these suppliers are unable or unwilling to continue manufacturing Korlym and we are unable to contract quickly with alternative sources, or if these third-party manufacturers fail to comply with FDA regulations or otherwise fail to meet our requirements, our business will be harmed.

We currently have no experience in, and we do not own facilities for, nor do we plan to develop facilities for, manufacturing any products. We depend on 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 to manufacture Korlym tablets. In November 2012, the FDA approved AAI as a qualified site for the manufacture of Korlym tablets, subject to the successful manufacture of validation batches. The manufacturing of the validation batches began in April 2014. We entered into a long-term agreement with AAI in April 2014. If either of these manufacturers is unable or unwilling to meet our future demands in the quantities and time frame 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, for whatever reason, to obtain the API or Korlym tablets from our contract manufacturers, we may not be able to manufacture our required quantities or identify alternate manufacturers of mifepristone or Korlym tablets in a timely manner or on reasonable terms, if at all, which would harm our business. 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

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to study drug utilization to better characterize the reporting rates of adverse events associated with the long-term use of Korlym. If we or others identify previously unknown, serious side effects of mifepristone:

- regulatory authorities may withdraw their approvals;
- we may be required to conduct additional clinical trials, make changes in labeling, implement changes to or obtain re-approvals of our manufacturing facilities;
- we may experience a significant drop in the sales of Korlym;
- our reputation in the marketplace may suffer; and
- we may become the target of lawsuits, including class action lawsuits.

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

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

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

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

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

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

We are also subject to ongoing obligations and continued regulatory review by the FDA and other regulatory authorities in the United States and other countries with respect to the research, testing, manufacturing, labeling, distribution, adverse event reporting, storage, selling, advertising, promotion, recordkeeping and marketing of products. These requirements include submissions of safety and other post-marketing information and reports, annual updates on manufacturing activities and continued compliance with current good manufacturing practices, or cGMPs, and current good clinical practices, or cGCPs, for any clinical trials that we conduct post-approval. cGMPs and cGCPs are regulations and guidelines enforced by the FDA and comparable

foreign regulatory authorities through periodic inspections of manufacturing sites, trial sponsors, clinical investigators and clinical sites. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with FDA regulations and other applicable foreign and U.S. regulatory requirements may result in, among other things, warning letters, civil and criminal penalties, injunctions, holds on clinical trials, product seizure or detention, refusal to permit the import or export of products, restrictions on product marketing, withdrawal of the product from the market, voluntary or mandatory product recalls, total or partial suspension of production, refusal to approve pending NDAs or supplements to approved NDAs, and suspension or revocation of product approvals.

The FDA's policies may change and additional governmental regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may place at risk 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 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 will be required to report detailed payment data and submit legal attestation to the accuracy of such data during Phase 2 of the program (which begins in May 2014 and extends for at least 30 days). 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

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- 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.

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.

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

- delays obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with contract research organizations, or CROs, and clinical trial sites;
- obtaining institutional review board, or IRB, approval at each site;
- slower than anticipated patient enrollment;
- scheduling conflicts with participating clinicians and clinical institutions;
- lack of funding;
- negative or inconclusive results;
- patient noncompliance with the protocol;
- adverse medical events or side effects among patients during the clinical trials;
- negative or problematic FDA inspections of our clinical operations or manufacturing operations; and
- real or perceived lack of effectiveness or safety of mifepristone.

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

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.

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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.

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 one or more of the new compounds to the clinic in 2014, 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.

We only have significant clinical experience with mifepristone and we may determine that mifepristone is not desirable for uses other than for the treatment of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery and, potentially, for the treatment of 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 described above in Part I, Item 1, Business – Overview – Mifepristone 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

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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.

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.

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

- the amount and timing of revenues from the commercialization of Korlym;
- the pace at which physicians adopt Korlym as a treatment;
- the willingness of insurance companies, the government and other third-party payors to provide coverage for Korlym at reasonable rates;
- changes in the 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 terms or may require us to relinquish certain rights to Korlym, our technologies or product candidates, which we would otherwise seek to develop on our own. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or we may be required to discontinue operations.

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

We have a limited history of operations and have focused primarily on clinical trials. We have begun to commercialize Korlym and, if the outcome of our clinical trials supports it, we plan to seek FDA regulatory clearance to market mifepristone for the treatment of 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 March 31, 2014, we had an accumulated deficit of \$306.5 million. We began to sell our first commercial product, Korlym, in the United States in April 2012. Based on this limited experience marketing Korlym, it is difficult for us to predict the magnitude or timing of future product sales. We expect our research and development expenses to increase in connection with the clinical trials and other development activities for mifepristone 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.

Failure to meet our obligations under our Financing Agreement with Biopharma Secured Debt Fund II Sub, S.à.r.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.

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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.

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.

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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 secrets and other proprietary information, and we may not have adequate remedies for the breach. We also realize that our trade secrets may become known through means not currently foreseen. Notwithstanding our efforts to protect our trade secrets and proprietary information, our competitors may independently develop similar or alternative products that are equal or superior to our product candidates without infringing on any of our proprietary information or trade secrets.

Our licensed patent covering the use of mifepristone to treat triple-negative breast cancer covers 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 for the treatment of Cushing's syndrome or triple-negative breast cancer or if patients acquire mifepristone from other sources, such as the internet or underground market.

We have exclusively licensed three issued 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.

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 May 5, 2014, our average daily trading volume was approximately 309,000 shares and the intra-day sales prices per share of our common stock on The NASDAQ Stock Market ranged from \$1.47 to \$4.49. As of May 5, 2014, our officers, directors and principal stockholders controlled 34 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.

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 wide 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.

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

As of May 5, 2014, our officers, directors and principal stockholders control 34 percent of our common stock. As a result, these stockholders, acting together, will be able to significantly influence all matters requiring

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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.

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

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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 May 5, 2014, the intra-day sales prices per share of our common stock on The NASDAQ Stock Market ranged from \$1.47 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.à.r.l, could adversely affect our financial results and liquidity.” These provisions in our charter and bylaws and under Delaware law and the Financing Agreement could reduce the price that investors might be willing to pay for shares of our common stock in the future and result in the market price being lower than it would be without these provisions.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

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ITEM 6. EXHIBITS

| <u>Exhibit Number</u> | <u>Description of Document</u> |
|-----------------------|--|
| 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 [†] | Consulting agreement with Robert I. Roe, M.D., dated January 7, 2014. |
| 10.2 [#] | Manufacturing and Supply Agreement with Produits Chimiques Auxiliaires et de Synthese SA, dated March 20, 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 March 31, 2014, formatted in Extensible Business Reporting Language (XBRL): (i) unaudited Condensed Balance Sheets at March 31, 2014 and December 31, 2013, (ii) unaudited Condensed Statements of Comprehensive Loss for the Three-Month Periods Ended March 31, 2014 and 2013, (iii) unaudited Condensed Statements of Cash Flows for the Three-Month Periods Ended March 31, 2014 and 2013, and (iv) Notes to Condensed Financial Statements. |

[†] Management contract or compensatory plan or arrangement

[#] Confidential treatment requested

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: May 12, 2014

/s/ Joseph K. Belanoff

Joseph K. Belanoff, M.D.
Chief Executive Officer

Date: May 12, 2014

/s/ G. Charles Robb

G. Charles Robb
Chief Financial Officer

Exhibit Index

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[#] Confidential treatment requested

CORCEPT THERAPEUTICS INCORPORATED**CONSULTING AGREEMENT**

This Agreement is made and entered into as of the 1st day of January, 2014 (the "Effective Date") by and between Corcept Therapeutics Incorporated ("Corcept"), a Delaware corporation located at 149 Commonwealth Drive, Menlo Park, CA 94025, and Robert L. Roe ("Consultant"), an individual, located at Palo Alto, CA 94304.

Recital

As part of its ongoing program of research, development and commercialization, Corcept desires to retain qualified individuals to advise Corcept with respect to its strategy and implementation in these areas. In furtherance thereof, Corcept and Consultant desire to enter into this Agreement.

Agreement

In consideration of the foregoing and the mutual promises contained in this Agreement, Consultant and Corcept hereby agree as follows:

1. Engagement of Services

The consulting services that are the subject of this Agreement ("Services") are described in the attached Schedule 1. These Services may be modified from time to time by Corcept having due regard for Consultant's obligations and commitments. Consultant will perform the Services for Corcept in good faith and to the best of Consultant's ability at places and times agreeable to Corcept and Consultant.

2. Compensation

In consideration for the Services and the terms of this Agreement, Consultant shall be paid the following compensation:

Corcept shall pay Consultant a fee of \$2,800 per Consulting Day, payable monthly within thirty (30) days of receipt of the invoice. A Consulting Day shall be defined as a minimum eight hour day of Services. If Consultant works less than a full Consulting Day, Consultant's fee for that day shall be calculated at a rate of \$350.00 per hour. Also, options to purchase Corcept common stock which Consultant received during his tenure as an employee of Corcept shall (i) if not yet vested, continue to vest during the term of this Agreement at the rate set forth in the applicable option grants and (ii) if vested, shall remain exercisable until three years following the termination of this Agreement (including any extensions or renewals of this Agreement to which the parties may agree in writing), or if earlier, the original expiration date of such options.

3. Additional Activities

(a) Consultant agrees that during the term of this Agreement, Consultant will not, directly or indirectly, either as an employee, employer, consultant, agent, principal, partner, stockholder, corporate officer, director, or in any other individual or representative capacity,

engage, participate in or perform services (“Non-Corcept Consultant Services”) for any business that is in competition with the business then being conducted or planned by Corcept. For the avoidance of doubt, Consultant may disclose in writing any on-going or contemplated Non-Corcept Consultant Services to the Chief Executive Officer or Chief Financial Officer of Corcept, who shall promptly notify Consultant, in writing, whether such services are or would be in competition with the business then being conducted or planned by Corcept.

(b) Consultant agrees that during the term of this Agreement, and for a period ending one year after the date of termination of this Agreement, Consultant will not (i) induce any employee of Corcept to leave the employ of Corcept or (ii) solicit the business of any client or customer of Corcept, other than on behalf of Corcept.

(c) If any restriction set forth in Sections 3(a) and 3(b) above is found by any court of competent jurisdiction to be unenforceable because it extends for too long a period of time or over too great a range of activities or in too broad a geographic area, it shall be interpreted to extend only over the maximum period of time, range of activities or geographic area as to which it may be enforceable.

4. Proprietary Information and Assignment

(a) Consultant understands that during the term of this Agreement Consultant may produce, obtain, make known or learn about certain information which has commercial value in the business in which Corcept is engaged and which is treated by Corcept as confidential. This information may also have been created, discovered or developed by Corcept or otherwise received by Corcept from third parties subject to a duty to maintain the confidentiality of such information (“Third Parties”). All such information, together with any Confidential Information disclosed under the **January 1, 2014** Confidentiality and Nondisclosure Agreement between Corcept and Consultant, hereinafter called “Proprietary Information,” includes Inventions (as defined in Section 5(a) below) and all other trade secrets, ideas, processes, programs, and all tangible and intangible information relating to formulations, products, processes, know-how, designs, formulas, methods, developmental or experimental work, improvements, discoveries, pending or potential patent claims and any information derived therefrom, plans for research, new products, marketing and selling, business plans, budgets and unpublished financial statements, licenses, prices and costs, suppliers and customers, and information regarding the skills and compensation of other employees or consultants of Corcept.

(b) Consultant hereby acknowledges Corcept’s ownership of the Proprietary Information and Consultant hereby assigns to Corcept any right, title or interest Consultant may have or acquire in any such Proprietary Information. At all times during the term of this Agreement and thereafter, Consultant will keep in strictest confidence and trust all Proprietary Information, and Consultant will not use, reproduce, disclose, lecture upon or publish any Proprietary Information without the written consent of Corcept, except (i) as may be necessary in the ordinary course of performing the Services and (ii) as permitted by agreement between Corcept and any Third Party in the case of property that is solely any such Third Party’s, unless Consultant is expressly authorized to act otherwise by Corcept.

5. Inventions During the Term of Agreement

(a) All Inventions (as defined below) and all original works of authorship (including without limitation, computer code and the documentation and notes related thereto) made or conceived by Consultant during the term of this Agreement shall be works made for hire and shall become and remain the sole and exclusive property of Corcept. Consultant shall promptly notify Corcept in writing of all Inventions and original works of authorship pertaining to scientific, medical or business matters so conceived or made by Consultant. “**Inventions**” means any and all ideas and discoveries, including, without limitation, findings, reports, disclosures, developments, improvements, concepts, processes, methods, formulas, compositions, procedures, algorithms, devices, drawings, specifications, models, source code, object code, software, diagrams, flow charts, techniques, articles and machines, as well as improvements thereof or know-how related thereto, whether copyrightable or patentable or not, relating to the business or planned business of Corcept or person or business entity directly or indirectly controlled by or controlling Corcept or in which any of the aforesaid have at least a 50% ownership interest.

(b) To the extent that ownership of such Inventions and original works of authorship do not automatically vest in Corcept, Consultant agrees to and hereby assigns and transfers to Corcept Consultant’s entire right, title and interest in and to all Inventions, whether or not patent or copyright applications are filed thereon. Consultant shall, at Corcept’s request and expense, promptly execute a written assignment to Corcept of title to any such Invention and Consultant shall preserve any such Invention as part of the Proprietary Information of Corcept. Consultant also hereby assigns and transfers to, or as directed by, Corcept all right, title and interest in and to any and all Inventions, full title to which is required to be in the United States by a contract between Corcept and the United States or any of its agencies. Consultant further agrees as to all Inventions to assist Corcept in every proper way and to execute those documents and take such acts as are reasonably requested by Corcept to obtain, sustain and from time to time enforce patents, copyrights, and other rights and protections for the Inventions in the United States and any other country.

(c) In the event Corcept is unable, after reasonable effort, to secure Consultant’s signature on any document needed to apply for or prosecute any patent, copyright, or other right or protection for an Invention, Consultant hereby irrevocably designates and appoints Corcept and its duly authorized officers and agents as its agent and attorney-in-fact, to act for and on Consultant’s behalf to execute, verify and file any such applications and to do all other lawfully permitted acts to further the prosecution and issuance of patents, copyrights, and other rights and protections thereon with the same legal force and effect as if executed by Consultant.

6. No Unauthorized Use of Third Party Technology

Consultant represents that, except as may be specified in a schedule prepared, signed and delivered by Consultant at the time of signing this Agreement, Consultant has not brought and will not bring to Corcept or use in the performance of the services any device, material, document, trade secret or the like of any third party that is not generally available to the public, unless Consultant has obtained express written authorization from such third party for their possession and use, including those items listed in the schedule.

7. No Conflicting Obligations

(a) Consultant represents that Consultant's performance of all the terms of this Agreement and the Services does not and will not breach any agreement to keep in confidence any information of another entity that Consultant has acquired or may acquire in confidence or in trust prior to the date or during the term of this Agreement.

(b) Consultant agrees to submit to Corcept any proposed publication which contains any discussion relating to Corcept or work performed by Consultant for Corcept under this Agreement. Consultant further agrees that no such publication shall be made without the prior written consent of Corcept.

8. Independent Contractor/Taxes.

Consultant is not an agent or employee of Corcept and is not authorized to act on behalf of Corcept. Except as required by a final determination by the Internal Revenue Service or state taxing authority and upon due notice to the other party, Consultant and Corcept agree that they will each treat Consultant as an independent contractor for tax purposes and file all tax and information returns and pay all applicable taxes on that basis.

9. Term and Termination

The Agreement shall be in full force and effect through **December 31, 2014**. This Agreement may thereafter be extended only by written agreement of the parties. The obligations and liabilities of Corcept and Consultant may be earlier terminated as follows:

(a) Upon thirty (30) days' written notice by either Consultant or Corcept.

(b) Immediately upon written notice by Corcept to Consultant in the event of a material breach by Consultant of any of the covenants contained herein or misconduct by Consultant having a materially adverse effect on the business of Corcept.

10. Effect of Termination

Upon any termination of this Agreement, each party shall be released from all obligations and liabilities to the other occurring or arising after the date of such termination, except that any termination of this Agreement shall not relieve Consultant of Consultant's obligations under Sections 3, 4, 5, 6 and 7 hereof, nor shall any such termination relieve either party from any liability arising from any breach of this Agreement. Upon termination of this Agreement for any reason, Consultant shall promptly deliver to Corcept all documents, notes, drawings, specifications, calculations, laboratory materials, data and other materials of any nature pertaining to Consultant's work with Corcept, and documents or data of any description (or any reproduction of any documents or data) containing or pertaining to any Proprietary Information. In the event of such termination, Consultant shall cooperate with Corcept in completing and signing Corcept's termination statement for Consultant.

11. Legal and Equitable Remedies

Because Consultant's services are personal and unique and because Consultant may have access to and become acquainted with Proprietary Information of Corcept, Corcept shall have the right to enforce this Agreement and any of its provisions by injunction, specific performance or other equitable relief without prejudice to any other rights and remedies that Corcept may have for a breach of this Agreement.

12. General Terms

(a) This Agreement constitutes the final, complete and exclusive agreement between Corcept and Consultant, superseding any previous oral or written communication, representation, understanding or agreement, including the **January 1, 2014** Confidentiality and Nondisclosure Agreement between the parties.

(b) This Agreement shall inure to the benefit of the successors and assigns of Corcept, and shall be binding upon Consultant's successors and permitted assigns.

(c) To the extent that any part of this Agreement shall be found to be illegal or unenforceable for any reason, such part shall be modified or deleted in such a manner so as to make the Agreement legal and enforceable under applicable laws.

(d) This Agreement shall be governed by the laws of the State of California, notwithstanding its conflict of laws principles.

(e) This Agreement may not be amended, modified, released, discharged, abandoned, or otherwise changed, in whole or in part, except by a written instrument signed by both parties.

(f) Any notices required or permitted hereunder shall be given to the appropriate party at the address specified below or at such other address as the party shall specify in writing. Such notice shall be deemed given upon personal delivery, or sent by certified or registered mail, postage prepaid, three (3) days after the date of mailing, to the appropriate address below.

(g) Corcept has specifically contracted for Consultant's services, Consultant shall not assign any of its rights or delegate any of its obligations under this Agreement without the prior written consent of Corcept. Any such attempted assignment or delegation without proper consent shall be void.

(h) The waiver of any term or condition contained in this Agreement by any party to this Agreement shall not be construed as a waiver of a subsequent breach or failure of the same term or condition or a waiver of any other term or condition contained in this Agreement.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first written above.

CORCEPT THERAPEUTICS INCORPORATED

Robert L. Roe

(Name of Institution/Corporation/Vendor)

Address: 149 Commonwealth Drive
Menlo Park, CA 94025

Address: Palo Alto, CA 94304

By: /s/ G. Charles Robb _____

By: /s/ Robert L. Roe _____

G. Charles Robb

(Print Name)

Robert L. Roe

(Print Name)

Chief Financial Officer

(Title)

(Title)

1/7/14

(Date)

07 – January - 2014

(Date)

Schedule 1

CONSULTING SERVICES

Consulting Services to be provided shall include advice regarding clinical and pre-clinical development activities, interactions with the FDA and other regulatory bodies, general management consulting, assistance with the management of third-party clinical trials, the hiring and training of a Chief Medical Officer and other personnel, and any other matters to which the parties may agree.

September 5, 2012

Manufacturing and Supply Agreement

between

CORCEPT THERAPEUTICS INCORPORATED

149 Commonwealth Drive
Menlo Park, CA 94025
USA

- Here in after referred to as "Corcept"

and

Produits Chimiques Auxiliaires et de Synthèse SA

23 rue Bossuet
91161 Longjumeau Cedex
France

- Here in after referred to as "PCAS"

- Here in after collectively referred to as "Party/Parties"

Whereas

- I. Corcept has certain patents and know-how with respect to the drug known as Mifepristone.
- II. PCAS has know-how and currently manufactures the product Mifepristone and wishes to manufacture the Product for Corcept and Corcept wishes PCAS to continue to produce and manufacture the Product and wishes to purchase the Product from PCAS, subject to the terms and conditions set forth in this Agreement.

Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [***]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

NOW THEREFORE IT IS HEREBY AGREED AS FOLLOWS:

1. Definitions

- Affiliates** shall mean a corporation or other entity or person that directly or indirectly controls, is controlled by, or is under common control of a Party. For purpose of this definition, control shall mean direct or indirect possession of 50% or more of the capital shares of such corporation and effective control of 50% or more of the voting stock thereof.
- Batch** shall mean a specific quantity of material produced in a contiguous process or series of processes that is expected to be homogeneous within specified limits. The initial Batch size for each Product is set forth in **Appendix II** attached hereto and incorporated herein by reference.
- Confidential Information** shall mean all proprietary or confidential information and materials provided to one Party by the other Party pursuant to this Agreement;
- Finished Product** shall mean the finished form of pharmaceutical preparations containing the Product for human use.
- GMP** shall mean the recognized pharmaceutical regulations and requirements of regulatory authorities such as those defined by the U.S. FDA's regulations at 21 CFR Parts 210 and 211, those defined by EudraLex, "The Rules Governing Medicinal Product in the European Union," and specifically Volume 4, "Guidelines for Good Manufacturing Practices for Medicinal Product for Human and Veterinary Use" and applicable Annexes (Directives 2001/83/EC and amendments including Directives 2003/94/EC dated October 2003 and 2004/27/EC dated March 2004 and/or others that may be appropriate for the particular project), as the foregoing may be amended from time to time.

Manufacturing and Supply Agreement

| | |
|--------------------------------|---|
| Marketing Authorization | shall mean the United States or European Medicines Agency new drug application, or abbreviated application, as applicable, for the Product. |
| Master Batch Record | shall mean the batch record used under this Agreement to govern the manufacture of Product. |
| Material Change | shall have the meaning set forth in Section 7.1. |
| Product | shall mean Mifepristone, designated by the chemical formula 11b-[p-(dimethylamino)phenyl]-17b-hydroxy-17a-(1-propynyl)estra-4,9-dien-3-one, and produced under GMP in the form of a powder in bulk for use in for Finished Product. |
| Raw Materials | shall mean any component materials used to manufacture the Product. |
| Release to Corcept | shall mean the date upon which all of the following have occurred for a Batch of Product: (i) PCAS has manufactured the Product according to the Master Batch Record; (ii) PCAS has fulfilled its testing/analytical obligations as further set forth herein and provided to Corcept documentation of the results thereof; and (iii) the results of PCAS's testing and analysis show that the Product meets the Specifications. |
| Specifications | shall mean the Specifications for the Product set by Corcept and defined in Appendix I hereto. |

Manufacturing and Supply Agreement

2. Subject

- 2.1. PCAS agrees to manufacture at FDA registered facilities, to store and to deliver to Corcept the Product as specified in **Appendix I** and according to the Specifications and Applicable Laws, including without limitation GMP as specified in the then-current US guidelines and regulations (e.g., US CFR 21 and ICH Q7A) and the Guide to GMP for Medicinal Product promulgated under European Directive 91/356/EEC, all as in effect from time to time hereafter. PCAS will supply Product for use in producing Finished Product. PCAS shall not Materially Change the manufacturing process for the Product in a manner that requires a change to a Marketing Authorization or change the facility where a Product is manufactured without the prior written consent of Corcept.
- 2.2. The Parties agree that it is in mutual best interest to incorporate PCAS' facility in Aramon, France, as a manufacturing facility for the Product. Respective efforts will be made by both Parties in good faith to expedite such incorporation.
- 2.3. Corcept agrees to take delivery of the Product on the terms and conditions set forth in this Agreement.

3. Supply, Forecast, Orders

- 3.1. Corcept will, within [***] days of execution of this Agreement and [***] thereafter, advise PCAS of its estimated requirements for Product for the ensuing [***] ("**Forecasts**").
- 3.2. Corcept shall purchase from PCAS a minimum percentage of forecast for a given period as stated below with regards to [***] demand
 - 3.2.1. [***]
 - 3.2.2. [***]
- 3.3. Corcept will purchase from PCAS a minimum of [***] of Corcept's total purchase requirement per annum.
- 3.4. Corcept will place firm and irrevocable orders, from time to time, at least [***] before the required delivery.

Manufacturing and Supply Agreement

- 3.5. PCAS agrees to maintain [***] of Product at facility as consignment rolling stock and at ownership of Corcept. PCAS shall use its best endeavors and make all reasonable effort to fulfill any excess requirements above forecast.
- 3.6. PCAS shall confirm the firm orders within [***] days after receipt of a firm order by Corcept.
- 3.7. If PCAS delivers less than the full quantity ordered in accordance with Section 3.4 and/or delays the delivery date due to a Force Majeure as specified in Section 12, PCAS shall state the reasons which led to the reduction of quantity or delay of supply past the given delivery date and will provide a revised delivery date. The Parties will reasonably cooperate to find a solution to ensure the supply of Product to Corcept.
- 3.8. On an annual basis, the Parties shall review and discuss in good faith the topics of this Section 3 and make reasonable and appropriate adjustments.

4. Price/Quantities

- 4.1. The price payable by Corcept to PCAS for the Product supplied hereunder shall be the price listed in **Appendix II**.
- 4.2. In case changes to the Specifications and quality requirements requested by Corcept have an impact on manufacturing costs, a price adjustment will be agreed as set forth in Section 8.3.
- 4.3. The price for Product will be adjusted annually starting in 2015 based on the US Government reported Producer Price Index —“Pharmaceutical preparation mfg—pcu325412325412”, with the base year being 2014 and the price adjustment will take effect once a year on January 1st, and shall apply to orders made during that calendar year.

5. Terms of Payment

- 5.1. Payments for Product in accordance with the terms of this Agreement will be made in U.S. dollars.
- 5.2. Payment is due thirty (30) days after the latest of:
 - 5.2.1. Receipt of delivery, unless it is agreed by the Parties to hold shipment,
 - 5.2.2. Release to Corcept,
 - 5.2.3. Receipt by Corcept of an invoice.

6. Terms of Delivery

Title of all Product shall pass to Corcept at PCAS manufacturing plant. PCAS shall deliver according to Incoterms 2010 CIP to the location specified by Corcept via Airfreight. Corcept shall indicate the place of destination once the Product has been Released to Corcept.

7. Specification, Quality Control, Warranty

- 7.1. **PCAS Changes to Manufacturing Process.** Except as required by applicable federal, state, provincial or local law and/or respective regulations as established by the FDA and/or other regulatory authority (collectively, “**Applicable Law(s)**”), including without limitation GMP, PCAS shall not change the manufacturing process of a Product or change the facility or equipment used to manufacture a Product in a manner that requires a change to a Marketing Authorization without the prior written consent of Corcept. PCAS shall notify Corcept of all changes, including Material Changes, as soon as practicable after PCAS learns of such change. A “**Material Change**” is one that either Party deems in its sole discretion requires a submission to the FDA or other regulatory authority or that impacts or potentially impacts the manufacture of Product pursuant to this Agreement.
- 7.2. **Corcept Requested Changes.** Corcept shall inform PCAS in writing of any modifications to the Specifications or the manufacturing process or equipment used to manufacture the Product Corcept wishes to propose. Any proposed change shall require PCAS’s prior written consent if it imposes material new obligations upon PCAS or results in increased costs of PCAS that are not otherwise borne by Corcept (including without limitation pursuant to Section 7.3), which consent shall not be unreasonably withheld or delayed. PCAS shall make all such changes as promptly as practicable (after, where PCAS’s consent is required pursuant to the preceding sentence, obtaining PCAS’s consent thereto or, where Corcept’s consent must be obtained for the costs of implementing such change pursuant to Section 7.3, obtaining such consent of Corcept); provided, however, that such changes are consistent with Applicable Law, including without limitation GMP.
- 7.3. **Costs of Changes.**

(a) Unless otherwise agreed by the Parties, any and all direct costs associated with changes requested by PCAS and changes required by applicable law that apply generally to PCAS’s facility where the applicable manufacturing occurs shall be borne by PCAS.

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(b) For all changes requested by Corcept, PCAS will provide notice to Corcept which notice shall include information regarding any increase in PCAS's cost of manufacture of Product caused by Corcept's proposed changes under Section 7.2 including, without limitation, whether the added cost will recur in future Batches. The Parties will discuss the allocation of such costs for up to thirty (30) days to determine whether an increase in the Product price pursuant to Section 4.1 should apply. If the Parties cannot reach a decision as to an increase to the Purchase Price (if any), then the matter shall be submitted for resolution as provided in Section 19.2 with the additional following conditions: (i) the matter may be referred to either the CEO or CFO of each Party under Section 19.2(a); (ii) if such officers do not resolve such issue within the time period provided in Section 19.2(a), such matter shall be submitted for resolution pursuant to Section 19.2(b) and each Party shall submit its proposed resolution of each open issue in writing to the arbitrator, and (iii) the arbitrator shall be required to select the most commercially reasonable position advanced by one of Parties on each open issue. For avoidance of doubt, the arbitrator shall not be permitted to devise its own resolution to such open issues but instead must select the most commercially reasonable position advanced by either Party.

- 7.4. Upon Release to Corcept, Corcept will have a period of sixty (60) days in which to notify PCAS of its rejection of a delivered Product due to failure in whole or in part to conform to the Specifications; provided that in the case of latent defects written notice must be given to PCAS within sixty (60) days after discovery thereof. In the event Corcept has not lodged a notice of rejection of the Product within sixty (60) days after delivery, then Corcept shall be deemed to have accepted that quantity of the Product as conforming to the Specifications, subject to Corcept's right to reject Product due to latent defects as set forth above.
- 7.5. In the event a shipment of Product is rejected by Corcept, in whole or in part, PCAS shall promptly conduct appropriate tests as set forth in the Specifications on samples PCAS retains from the relevant Batch to confirm Corcept's test results. PCAS shall not be responsible for any failure of the Product to satisfy the Specifications shown by the test results arising from inappropriate storage conditions of the Product at Corcept's facilities or the facilities of any third-party to whom Corcept has directed PCAS to deliver the Product or unduly prolonged customs clearance by Corcept, or any other cause excused under Section 12 of this Agreement. If PCAS testing agrees with Corcept's test results, PCAS shall promptly replace the Product, including paying for any freight, duties, taxes and insurance charges in connection with the delivery of such new Product, and shall promptly reimburse Corcept for the actual costs incurred by Corcept, in shipping, insurance premiums, duties, taxes or other reasonable out-of-pocket charges directly incurred in connection with the transportation and return or destruction of the affected Product.
- 7.6. If PCAS testing does not confirm that Corcept's rejection is justified, it shall immediately notify Corcept in writing, and technical representatives of Corcept and PCAS, respectively, shall meet to attempt to resolve the issues of disagreement. If the Parties cannot resolve the issue, they hereby agree to each

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submit a sample - one in a container sealed and provided by Corcept, one in a container sealed and provided by PCAS for this purpose, to an independent laboratory to be mutually agreed upon for the purpose of confirming whether the Product meets Specifications. Such independent laboratory shall perform an analysis using the Specifications. The analytical result of the independent laboratory will be final and binding on the Parties. Costs connected with such test by the independent laboratory will be borne by the Party whose opinion was found to be in error. If the independent testing agrees with Corcept's test results, PCAS shall promptly replace the Product, including paying for any freight, duties, taxes and insurance charges in connection with the delivery of such new Product, and shall promptly reimburse Corcept for the actual costs incurred by Corcept, in shipping, insurance premiums, duties, taxes or other reasonable out-of-pocket charges directly incurred in connection with the transportation and return or destruction of the affected Product. If the independent testing agrees with PCAS's test results, the Product shall be deemed to have met the Specifications, and Corcept shall be deemed to have accepted the Product, subject to Corcept's right to reject Product due to latent defects as set forth above.

- 7.7. **Subcontracting.** PCAS shall not subcontract any aspect of the manufacture of Product without obtaining prior written consent from Corcept to do so. If Corcept consents to any subcontracting by PCAS, (a) the Third-party subcontractor will adhere to GMP and other applicable laws and regulations and will conduct all activities related to the Product in FDA-approved facilities; (b) any such Third-party subcontractor to whom PCAS discloses Confidential Information shall enter into an appropriate written agreement obligating such Third-party to be bound by obligations of confidentiality and restrictions on use of such Confidential Information that are no less restrictive than the obligations in Section 14; (c) PCAS will retain or obtain exclusive control of any and all intellectual property (and patent rights covering such intellectual property) made by such Third-party in performing such services for PCAS; and (d) PCAS shall at all times be responsible for the performance of such subcontractor.

8. Regulatory Matters; Records

- 8.1. **Access to PCAS's Facilities by Corcept Representatives.** Upon reasonable prior written notice, and during normal business hours, and at mutually agreed upon times, PCAS will permit Corcept to inspect PCAS's manufacturing facilities once per calendar year to ensure GMP compliance, unless product quality issues require further action as reasonably determined by Corcept. Such audits shall be performed in a manner that does not unreasonably interfere with PCAS's conduct of business. Corcept representatives and agents conducting such audits shall be bound by obligations of confidentiality with respect to the information obtained during such audits. PCAS shall address to Corcept's reasonable satisfaction, promptly after receiving notice of any issues identified

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during such inspection or audit, all quality or other compliance issues discovered during such inspections. Corcept and representatives of its financial auditor may also inspect PCAS's facilities once per year, on reasonable notice, to verify the amount of any Product or Finished Product held by PCAS.

- 8.2. **Inspections by Governmental or Regulatory Authority.** PCAS shall be responsible for handling and responding to any FDA or other governmental body inspections or inquiries received by PCAS regarding the manufacturing of any Product during the term of this Agreement, provided that for any such inquiries that relate to or that may reasonably impact the Product, PCAS shall notify Corcept within two (2) business days after receiving notice of such inspection or inquiry and provide a copy of the relevant communication from such governmental body. Corcept shall have the right to have its representatives or agents present during such inspection or response to such inquiry, which representatives may include one person from each of its manufacturing, quality and regulatory functions (for a total of three (3) representatives at each such inspection or response, provided that PCAS shall not unreasonably withhold its consent for Corcept to have additional representatives present at such event). Corcept shall have the right to approve PCAS's responses and correspondence with such governmental body to the extent relating to or reasonably deemed to impact the Product. PCAS will cooperate with Corcept in preparing for any such inspection or inquiry response that may relate to or reasonably be deemed to impact Corcept or use of Product in the Finished Product, and will notify Corcept of any routine (e.g., biennial) regulatory inspections with in one (1) business day after the arrival of relevant inspectors, or upon notification of the relevant meeting or discussion. Corcept shall be responsible for handling and responding to any FDA or other governmental body inspections or inquiries received by Corcept regarding other aspects of the Product during the Term, provided that PCAS shall have the right to review and comment on the portions of Corcept's responses and correspondence with such governmental bodies that relate to PCAS's facilities or operations. Each Party shall promptly notify the other regarding any such inquiries or inspections, in advance of the occurrence thereof to the extent reasonably practicable. PCAS shall provide to Corcept and any governmental body any information reasonably requested by Corcept and/or such governmental body concerning any governmental inspection relating to any Product (with all information provided to Corcept being subject to the confidentiality provisions in Section 14 herein, and with PCAS being able to redact any information provided to Corcept to remove third-party confidential information that does not relate to the Product). Each Party agrees to cooperate with and assist the other Party in fulfilling its obligations pursuant to this Section 8.2. PCAS will provide Corcept with a complete copy of any documentation provided by or to the governmental body with respect to any such inspection or inquiry, which may be redacted to omit information not relevant to Product.

8.3. **Complaints, Recalls, and Insurance**

(a) Complaints. Finished Product complaints received by Corcept with respect to Finished Product that upon investigation are caused directly or indirectly by Product manufactured by PCAS hereunder that may require investigation by PCAS shall be faxed to PCAS within five (5) days after receipt to:

If to PCAS' VLG site:

Site Quality Manager
PCAS
35, avenue Jean Jaures
92390 Villeneuve-la-Garenne, France
Fax: 011-33-1-4685-9171

If to PCAS' Expansia site:

Site Quality Manager
PCAS
Route d'Avignon
30390 Aramon, France
Fax: 011-3-4-6657-0148

As more fully described in the Quality Agreement, PCAS shall investigate all complaints primarily associated with the manufacture of Product and all complaints related to Product (including complaints of latent defects), and shall complete such investigation within thirty (30) days or within any longer time period agreed by Corcept, such agreement not to be unreasonably withheld. PCAS shall update Corcept on a monthly basis during such time period regarding PCAS's progress in such investigation, and shall provide to Corcept prior to the end of such time period a report of its investigation and any conclusions. The Parties shall cooperate in investigating complaints that are not primarily associated with the manufacture of Product but that may reasonably be related to the manufacture of Product. Corcept may participate in any such investigation and shall have the right to approve any conclusions thereof. Corcept shall, as between the Parties, be responsible for investigating all other complaints associated with the Product.

(b) Recall Procedures. If any Raw Materials, Product, or Finished Product containing Product manufactured by PCAS must be recalled or subject to a market withdrawal or field correction due to the failure to meet any applicable Specifications, requirements of the FDA or other applicable governmental body or any other requirements under Applicable Law, Corcept shall have the sole right to effect and initiate such recall, market withdrawal or field correction (a "**Recall**"). In the event that a Recall is initiated, whether by a statutory or regulatory authority in any jurisdiction or by Corcept, PCAS shall reimburse Corcept for all costs and expenses incurred in procuring or complying with the requirements of such Recall (including without limitation all of Corcept's internal and out-of-pocket costs and expenses of implementing such recall and replacing the relevant Product Batches or Finished Product) to the extent that such Recall

Manufacturing and Supply Agreement

is initiated as a result of PCAS's breach of this Agreement (which shall include but not be limited to PCAS's noncompliance with Applicable Laws or the Specifications, or the nonconformity of Product or the manufacture of Product with the Specifications, GMP, or any Applicable Laws), intentional misconduct or negligence, or defective manufacturing, processing, testing, packing, or storage of Product prior to delivery to Corcept, and, in addition, PCAS shall refund to Corcept an amount equal to the cost to Corcept of all Recalled Product or Finished Product. Corcept shall be responsible for all other costs and expenses associated with a Recall. PCAS shall reasonably cooperate with Corcept in connection with any Recall.

- 8.4. **Quality Agreement.** The Parties intend to enter into a quality agreement acceptable to both Parties (the "**Quality Agreement**") as soon as practicable after the Effective Date. The Quality Agreement will detail the obligations and responsibilities of the Parties with respect to quality assurance, quality control and regulatory compliance aspects of the manufacture of Product; provided, however, that in the event of conflict between the terms of this Agreement and the Quality Agreement, (i) the provisions of the Quality Agreement will prevail with respect to all matters pertaining to, or governed by, GMP and (ii) in all other respects, the provisions of this Agreement will prevail.

9. Indemnification

- 9.1. **By PCAS.** PCAS hereby agrees to indemnify and defend Corcept and its directors, officers, employees, Affiliates, agents, representatives, successors and assigns (collectively, the "Corcept Indemnified Parties") against, and agrees to hold each of them harmless from, any and all claims, losses, liabilities, obligations, damages, costs, penalties, judgments, disbursements and expenses, including without limitation reasonable attorneys' fees ("Losses") incurred by any Corcept Indemnified Party as a result of third-party claims, actions or proceedings (collectively, "Third-party Claims") based upon, attributable to or resulting from: (a) any misrepresentation or breach of warranty made by PCAS in this Agreement, (b) any breach of any covenant or agreement made or to be performed by PCAS pursuant to this Agreement, and (c) the negligence or willful misconduct by a PCAS Indemnified Party in connection with this Agreement; except in each case, to the extent such Losses are attributable to Corcept's breach of this Agreement or arising from the negligence or willful misconduct of Corcept.
- 9.2. **By Corcept.** Corcept hereby agrees to indemnify and defend PCAS and its directors, officers, employees, Affiliates, agents, representatives, successors and assigns (collectively, the "PCAS Indemnified Parties") against, and agrees to hold each of them harmless from, any and all Losses incurred by any PCAS Indemnified Party as a result of Third-party Claims based upon, attributable to or resulting from the performance of this Agreement and services hereunder by PCAS other than for Losses for which PCAS is obligated to indemnify Corcept Indemnified Parties under Section 9.1 above.

9.3. Indemnification Procedures.

(a) The indemnified Party shall give the indemnifying Party prompt notice of any such claim, demand, action or lawsuit (“Indemnification Claim”) (including a copy thereof) served upon it and shall fully cooperate with the indemnifying Party and its legal representatives in the investigation of any matter that is the subject of indemnification pursuant to this Section 9 by the indemnifying Party. The indemnifying Party may enter into a settlement agreement with a third-party claimant but shall not admit liability to a third-party claimant or take any action in such settlement that may otherwise adversely affect the indemnified party without the prior written permission of the indemnified Party, which permission shall not be unreasonably withheld. The indemnified Party shall reasonably cooperate with the indemnifying Party in any investigation and defense pursuant to this Section 9. The indemnitee shall have the right, but not the obligation, to be represented in any investigation or defense by counsel of its own choosing and at its own expense.

(b) The failure of the indemnified Party to give reasonably prompt notice of any Indemnification Claim shall not release, waive or otherwise affect the indemnifying Party’s obligations with respect thereto, except to the extent that the indemnifying Party can demonstrate actual loss and prejudice as a result of such failure.

9.4. EXCEPT AS MAY BE SPECIFICALLY PROVIDED ELSEWHERE IN THIS AGREEMENT TO THE CONTRARY, IN NO EVENT SHALL EITHER Party BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, OR FOR LOST PROFITS, BUSINESS OR REVENUES OF ANY PERSON, HOWEVER CAUSED OR BASED ON ANY THEORY OF LIABILITY ARISING OUT OF THE INDEMNITY PROVIDED IN SECTION 9.1 OR 9.2 REGARDLESS OF THE NOTICE OF THE POSSIBILITY OR THE FORESEEABILITY OF SUCH DAMAGES. EXCEPT AS SPECIFICALLY PROVIDED TO THE CONTRARY, EACH Party SHALL HAVE ALL REMEDIES TO WHICH THEY MAY BE ENTITLED UNDER THIS AGREEMENT, AT LAW OR IN EQUITY.

10. Term

10.1. This Agreement shall become effective on **3/19/2014** for an initial period of five (5) years. It shall be automatically extended for a one (1) year period unless either Party gives twelve (12) months’ prior written notice that it does not want such an extension.

11. Termination for Cause

- 11.1. In the event that either Party should commit a material breach of any of its obligations under this Agreement, and shall have not cured such breach within sixty (60) days after receipt of written notice of breach from the other Party, then such other Party shall have the right to terminate this Agreement forthwith by written notice.
- 11.2. Either Party at its sole option may immediately terminate this Agreement upon written notice, but without prior advance notice, to the other Party in the event that (i) the other Party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by such other Party; or (iii) this Agreement is assigned by such other Party for the benefit of creditors.

In the event that PCAS would not able to manufacture the Product according to the Specifications stated in **Appendix I** or for any reason (including but not limited to cases of Force Majeure) to supply the Product for a total and consecutive nine (9) months period (whether in the quantities ordered or at all), Corcept shall have the right to terminate this Agreement forthwith by written notice.

- 11.3. Either party shall retain the right to terminate this Agreement with 24 months written notice for any cause.
- 11.4. **Effect of Termination.** Upon termination or expiration of this Agreement, in its entirety or with respect to any particular Product:
 - (a) **Cessation of Activities.** Except as provided in Section 11.4(b), PCAS shall stop the manufacturing of Product; each Party shall return to the other any Confidential Information of such other Party concerning the Product subject to such termination or expiration.
 - (b) **Firm Orders.** If this Agreement is terminated by Corcept pursuant to Section 11.1, at Corcept's option, firm orders with respect to the Product not yet started shall be cancelled, or, if requested by Corcept in writing, PCAS will, with respect to the Product subject to such termination, complete or cause the completion of the manufacturing of any work-in-process that is subject to a valid and effective firm order on the date on which the termination is effective. Once such work-in-process is completed, the resulting Product shall be shipped in accordance with Corcept's firm orders and paid for by Corcept in accordance with Sections 4 and 5.
 - (c) **Files and Records.** PCAS will store the originals of all manufacturing and process development documents, or electronic copies thereof, according to cGMPs in a safe and secure facility for at least two (2) years after the expiration of the last Batch produced under this Agreement. In addition, PCAS shall retain

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samples of all Batches of Product for period of two (2) years after the expiration date the particular Batch in question. PCAS shall allow the FDA or other regulatory agencies and authorities access to such documents if requested. Additionally, for a period of twelve (12) months following termination or expiration of this Agreement, PCAS shall make any information available to Corcept in PCAS's control that is reasonably related to Product and that may be useful Corcept support any investigational studies or commercial marketing of Product. PCAS will provide such documents to Corcept thirty (30) days prior to the end of any record retention period. Additionally, at the end of any record retention period specified in this section, PCAS will provide all original records to Corcept, unless otherwise instructed, in writing, by Corcept.

- 11.5. **Survival.** The Parties agree that the following provisions shall survive the termination of this Agreement; the definitions of Section 1 to the extent such Definitions pertain to terms in surviving provisions, and Sections 9 (as to claims arising with respect to activities conducted during the term of this Agreement), 11 and 14-20. Termination or expiration of this Agreement shall not affect any rights accruing prior to the effective date thereof.

12. Force Majeure

- 12.1. Neither Party shall be responsible for a failure or delay in its performance of its obligations hereunder due to causes beyond its control such as wars, insurrection, inability to obtain supplies, strikes, acts of God, governmental actions or controls (whether or not contemplated on the date of signature of this Agreement) or other cause beyond the control of such Party. A Party whose performance has been delayed by causes beyond its control shall use its best efforts to overcome the effect thereof as soon as possible.

13. Hardship

- 13.1. If, at any time during the term of this Agreement, there is a substantial change in the economic, technological or market situation which will make the performance of this Agreement unrealistic or exceedingly unfair by either Party, aggrieved Party can request a meeting with the other Party to discuss the situation, but there is no obligation to adjust the terms of this Agreement.

14. Confidentiality

- 14.1. Each Party will hold in strict confidence, and shall not disclose to any third-party without the other Party's prior written consent, all proprietary or Confidential Information provided to it by such other Party pursuant to this Agreement. PCAS further agrees that it shall not use Corcept's Confidential Information for any purpose other than the manufacturing of Product for Corcept under this Agreement.

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- 14.2. Each Party may disclose Confidential Information only to its directors, officers, employees, consultants, independent contractors or, as to Corcept, its licensees, sublicensees and collaborators, in each case who have need to know Confidential Information for the purposes of this Agreement or, as to PCAS Information disclosed to Corcept, developing and/or commercializing Product, and each Party will be responsible for ensuring that all such persons to whom Confidential Information is disclosed will also observe such obligations of confidentiality and non-use as provided herein. In particular, the receiving Party shall not file any patent application containing any claim the subject matter of which contains, is based upon, or is derived from the Confidential Information of the disclosing Party. The receiving Party shall not use Confidential Information for any purpose or in any manner which would constitute a violation of any applicable laws or regulations. No rights or licenses to trademarks, copyrights, patents or any other proprietary rights are implied or granted under this Agreement. The receiving Party further agrees that it shall not disclose the Confidential Information to any Affiliate unless each such Affiliate agrees in writing to be bound by the terms of this Agreement and names the disclosing Party as a third-party beneficiary of such written agreement
- 14.3. The above confidentiality obligations shall not apply or shall cease to apply to any information which the receiving Party can demonstrate by documentary proof:
- (a) is already in the possession of the receiving Party other than under confidentiality restrictions at the time it is disclosed by the disclosing Party;
 - (b) is in the public domain at the time it is disclosed by the disclosing Party through no fault of the receiving Party;
 - (c) enters the public domain through sources independent of the receiving Party and through no fault of the receiving Party;
 - (d) is lawfully obtained by the receiving Party without any confidentiality restrictions from a third-party who has a right to disclose such information to the receiving Party;
 - (e) has been at any time developed by the receiving Party independently of disclosure from the disclosing party.
- 14.4. Notwithstanding any other provision of this Agreement, disclosure of Confidential Information by the receiving party shall not be prohibited if such disclosure: (a) is in response to a valid order of a court or other governmental body of the United States or any political subdivision thereof, or (b) is otherwise required by Applicable Law or the rules of a securities exchange.

Manufacturing and Supply Agreement

- 14.5. Neither Party (nor any of their respective Affiliates) shall issue any press release or make any public announcement with respect to this Agreement and the transactions contemplated hereby without obtaining the prior written consent of the other Party (such consent not to be unreasonably withheld or delayed), except as may be required by Applicable Law or rules of a securities exchange upon the advice of counsel, in which case such press release or public announcement shall be made only if the disclosing party provides the non-disclosing Party with a reasonable opportunity to first review the release or other public announcement, to the extent practicable. Confidential Information (including all copies thereof) of the disclosing party shall at all times remain the property of the disclosing party and shall be returned to the disclosing party upon request, and in any event, upon completion or termination of this Agreement, unless otherwise required to be retained pursuant to the terms of this agreement, or by operation of law.
- 14.6. These confidentiality obligations shall survive termination or expiration of this Agreement for a period of ten (10) years.

15. Non-Assignability

- 15.1. This Agreement and the rights and obligations hereunder shall not be assignable by either Party without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, no consent shall be required in the case of an assignment to an Affiliate or in a merger, sale of shares, or sale of substantially all of such Party's assets to which this Agreement relates. Any purported assignment not in compliance herewith is void.

16. Severability

- 16.1. Should one of the provisions of this Agreement become or prove to be null and void, such event shall be without effect on the validity of this Agreement as a whole. Both Parties will, however, endeavor to replace the void provision with a valid one, which in its economic effect comes as close as possible to effectuating the intention of the void provision.

17. Waiver

- 17.1. If either Party should at any time refrain from enforcing its rights arising from a breach or default by the other Party of any of the provisions of this Agreement, such waiver shall not be construed as a continuing waiver regarding that breach or default or other breaches or defaults of the same or other provisions of this Agreement.

18. Entire Agreement and Notification

- 18.1. The terms and conditions herein together with Appendix I and Appendix II and the Quality Agreement constitute the entire Agreement between the Parties with respect to the subject matter hereof.
- 18.2. No modification or amendment of this Agreement shall be binding upon either Party hereto unless in writing and signed by duly authorized officers of the Parties. **Appendix I** and **Appendix II** of this Agreement form an integral part of this Agreement.

19. Governing Law; Dispute Resolution

- 19.1. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware without giving effect to the conflict of laws principles thereof.

19.2. Dispute resolution.

(a) Any controversy, claim or dispute (a "Dispute") arising out of this Agreement shall be settled if possible through good faith negotiations between the Parties. If after ten (10) business days following receipt of a Party's written notification of a Dispute such Dispute has not been resolved, the Dispute shall be brought to the attention of the CEO of each Party and such CEO or his/her designee will negotiate in good faith for up to thirty (30) days to define and implement a final resolution. The intent of this Section 19.2 is to encourage the Parties to work together to resolve any Dispute without having to rely on arbitration or any other legal proceeding. However, nothing in this Section 19.2 shall prevent or inhibit either Party to institute any other action to resolve such Dispute(s).

(b) Except as provided in Section 7.3(b), if negotiations pursuant to Section 19.2(a) are unsuccessful, such controversy, claim or dispute shall be finally resolved by binding arbitration before three arbitrators in a proceeding conducted in the English language administered by the American Arbitration Association in accordance with its Commercial Arbitration Rules and held in New York, NY. Each Party shall select one arbitrator, and the two arbitrators so selected shall select a third, who shall preside. The arbitrator conducting the arbitration must and shall agree to render an opinion within twenty (20) days after the final hearing before the panel. The award shall be made in accordance with California law, and shall be reasoned. The award may be entered by any court of competent jurisdiction.

Manufacturing and Supply Agreement

To the full extent permissible under Applicable Laws, the Parties hereby expressly agree to waive the right to appeal from the decision of the arbitrator, there shall be no appeal to any court or other authority (government or private) from the decision of the arbitrator(s), and the Parties shall not dispute nor question the validity of such decision or award before any regulatory or other authority in any jurisdiction where enforcement action is taken by the Party in whose favor the decision or award is rendered, except in the case of fraud. The arbitrator shall, upon the request of any Party, issue a written opinion of the findings of fact and conclusions of law and shall deliver a copy to each of the Parties. Without limiting any other remedies that may be available under applicable law, the arbitrator(s) shall have no authority to award provisional remedies of any nature whatsoever, or punitive, special, consequential, or any other similar form of damages.

(c) Preliminary Injunctions. Notwithstanding anything in this Agreement to the contrary, a Party may seek a temporary restraining order or a preliminary injunction from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis, pending the decision of the arbitrator(s) on the ultimate merits of any Dispute.

(d) Patent Disputes. Notwithstanding anything in this Agreement to the contrary, any and all issues regarding the scope, construction, validity, infringement and enforceability of one or more Patents or Patent Applications shall be determined in a court of competent jurisdiction under the local patent laws of the jurisdictions having issued the Patents or Patent Applications in question.

(e) Confidentiality. All proceedings and decisions of the arbitrator(s) shall be deemed Confidential Information of each of the Parties, and shall be subject to Section 14.

20. Insurance

- 20.1. For so long as this Agreement is in effect, each Party shall procure and maintain, at its own expense, insurance policies, including product liability insurance, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated. Such policies shall provide protection against claims, demands and causes of action arising out of any defects, alleged or otherwise, of Product and Finished Product.

21. Representations

- 21.1. PCAS represents and warrants that it has all right, power and authority to enter into and perform this Agreement, that it has been granted all rights and licenses necessary to manufacture the Product and that nothing contained in any other agreement or legal right prohibits or restricts PCAS from entering into and performing any part of this Agreement. PCAS represents and warrants that its

Manufacturing and Supply Agreement

manufacture of the Product will not infringe any patent rights or infringe or misappropriate any other intellectual property rights held by third parties. PCAS represents and warrants that PCAS has the rights that fully allow PCAS to manufacture the Product for Corcept in perpetuity and cannot be rescinded or cancelled. PCAS represents, warrants and covenants that upon delivery to Corcept during the Term of the Agreement, all Product shall have a remaining retest dating of at least four years.

- 21.2. PCAS represents and warrants as of the date of this Agreement and continuously during its term that it has never been and none of its employees, affiliates and agents has ever been (i) debarred, (ii) convicted or a crime for which a person can be debarred, (iii) threatened to be debarred, or (iv) indicted for a crime or otherwise engaged in conduct for which a person can be debarred under Section 335(a) of 335(b) of the US Federal Food, Drug, and Cosmetic Act or any similar statute of any other jurisdiction. PCAS agrees that it will promptly notify Corcept in the event of any facts inconsistent with this representation.
- 21.3. The Parties acknowledge that to the best of each party's reasonable knowledge, Mifepristone is not covered by any composition of matter patent.

22. Notices

Any notices, reports, consents or requests required or permitted under this Agreement shall be in writing and deemed to have been given (i) when actually received; (ii) when delivered personally; (iii) when sent by confirmed facsimile; (iv) ten (10) business days after having been sent by registered or certified mail, return receipt requested, postage prepaid; or (v) five (5) business days after deposit with an internationally recognized commercial overnight courier specifying next day delivery (if available, or two (2) day delivery otherwise) with written verification of receipt. All communications shall be sent to the addresses set forth below:

If to PCAS:

Produits Chimiques Auxiliaires et Synthèse SA
23 rue Bossuet
91161 Longjumeau Cedex
France
Attention: Chief Executive Officer

Telephone: 33-1-6909-7785
Fax: 33-1-6974-8104

Manufacturing and Supply Agreement

If to Corcept:

Corcept Therapeutics Incorporated
149 Commonwealth Drive
Menlo Park, CA 94025
USA
Attention: Charlie Robb, Chief Financial Officer

Telephone: 1-(650)
Fax: 1-(650) 327-3218

Manufacturing and Supply Agreement

Duly authorized for and on behalf of Corcept

Duly authorized for and on behalf of PCAS

March 19, 2014
Date

March 24, 2014
Date

/s/ Joseph K. Belanoff
Signature

/s/ V. Touraille
Signature

Joseph K. Belanoff
Name

Vincent Touraille
Name

CEO
Position

CEO
Position

March 26, 2014
Date

/s/ Didier Combis
Signature

Didier Combis
Name

Director Pharma Synthesis
Position

Manufacturing and Supply Agreement

Appendix I

| Corcept MANUFACTURING SPECIFICATION | | |
|---|-----------------------|--------|
| Specification No: DRAFT | Page: 22 of 23 | |
| Effective Date: | Supersedes: MAP003.01 | |
| Name: C-1073, mifepristone, (11b-[p-(dimethylamino)phenyl]-17b-hydroxy-17a-(1-propynyl)estra-4,9-dien-3-one (IUPAC) | | |
| SPECIFICATIONS | | |
| Test | Acceptance Criteria | Method |
| [***] | [***] | [***] |

[***]

| Corcept MANUFACTURING SPECIFICATION | |
|---|--|
| Specification No: DRAFT | |
| Effective Date: | |
| Name: C-1073, mifepristone, (11b-[p-(dimethylamino)phenyl]-17b-hydroxy-17a-(1-propynyl)estra-4,9-dien-3-one (IUPAC) | |

Recommended Packaging: [***]

Recommended Storage: [***]

Sampling Requirements: [***]

| Specifications Approval | | |
|-----------------------------|------------------|------|
| | Signature | Date |
| Author | /s/ David Penake | |
| Corcept QA/QC Approval | /s/ Carl Wilson | |
| Corcept Regulatory Approval | /s/ Sue Rinne | |

| Document Change History | |
|-------------------------|--------|
| Version | Change |
| .01 | [***] |

[***] Certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Manufacturing and Supply Agreement

Appendix II

Prices:

| Product Volume to be Delivered within Calendar Year | | | | | |
|---|-------------|------------|------------|------------|--------|
| \$/€ Exchange Rate | >40 - 150kg | >150-300kg | >300-450kg | >450-600kg | >600kg |
| *** | *** | *** | *** | *** | *** |

| Product Volume to be Delivered within Calendar Year | | | | | |
|---|-------------|------------|------------|------------|--------|
| \$/€ Exchange Rate | >40 - 150kg | >150-300kg | >300-450kg | >450-600kg | >600kg |
| *** | *** | *** | *** | *** | *** |

| Product Volume to be Delivered within Calendar Year | | | | | |
|---|-------------|------------|------------|------------|--------|
| \$/€ Exchange Rate | >40 - 150kg | >150-300kg | >300-450kg | >450-600kg | >600kg |
| *** | *** | *** | *** | *** | *** |

| |
|---|
| Example 1: Corcept purchases 250kg for delivery within a calendar year at the current exchange rate 1.2-1.4 \$/euro |
| *** |

| |
|---|
| Example 2: Corcept purchases 400kg for delivery within a calendar year at the current exchange rate 1.2-1.4 \$/euro |
| *** |

| |
|---|
| Example 1: Corcept purchases 500kg for delivery within a calendar year at the current exchange rate 1.2-1.4 \$/euro |
| *** |

IMPORTANT NOTES:

Current Batch Sizes:

*** Certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

CERTIFICATION

I, Joseph K. Belanoff, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2014 of Corcept Therapeutics Incorporated;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Joseph K. Belanoff

Joseph K. Belanoff, M.D.

Chief Executive Officer

May 12, 2014

CERTIFICATION

I, G. Charles Robb, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2014 of Corcept Therapeutics Incorporated;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ G. Charles Robb

G. Charles Robb
Chief Financial Officer
May 12, 2014

Corcept Therapeutics IncorporatedCERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Corcept Therapeutics Incorporated (the "Company") on Form 10-Q for the period ended March 31, 2014, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joseph K. Belanoff, M.D., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Joseph K. Belanoff

Joseph K. Belanoff, M.D.

Chief Executive Officer

May 12, 2014

This certification is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Corcept Therapeutics Incorporated under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, irrespective of any general incorporation language contained in such filing.

Corcept Therapeutics IncorporatedCERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Corcept Therapeutics Incorporated (the "Company") on Form 10-Q for the period ended March 31, 2014, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, G. Charles Robb, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ G. Charles Robb

G. Charles Robb
Chief Financial Officer
May 12, 2014

This certification is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Corcept Therapeutics Incorporated under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, irrespective of any general incorporation language contained in such filing.