CORCEPT THERAPEUTICS INC
Form 10-Q
August 08, 2014
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# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-Q

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

**For the quarterly period ended June 30, 2014**

**or**

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

**For the transition period from to**

**Commission File Number:**

**000-50679**

# CORCEPT THERAPEUTICS INCORPORATED

**(Exact Name of Corporation as Specified in Its Charter)**

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

**149 Commonwealth Drive**

**Menlo Park, CA 94025**

**(Address of principal executive offices, including zip code)**

**(650) 327-3270**

**(Registrant s telephone number, including area code)**

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

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

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

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

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

On August 4, 2014 there were 101,123,406 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 regulatory activities associated with such programs;*
- *our ability to realize the benefits of Orphan Drug designation of Korlym in the United States;*
- *the timing of the market introduction of future product candidates, including new uses for mifepristone and any compound in our families of selective glucocorticoid receptor II (GR-II) antagonists;*
- *our ability to achieve marketing approval of mifepristone in the European Union (EU) (for which we have requested the brand name Corluxin®) and realize the benefits of Orphan Drug designation there;*
- *our ability to manufacture, market, commercialize and achieve market acceptance for our future product candidates, including mifepristone for the treatment of triple-negative breast cancer or any other indications and any compounds in our families of selective GR-II antagonists;*
- *uncertainties associated with obtaining and enforcing patents;*
- *our estimates for future performance, including revenue and profits; and*
- *our estimates regarding our capital requirements.*

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

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**PART I. FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS**

**CORCEPT THERAPEUTICS INCORPORATED**

**CONDENSED BALANCE SHEETS**

(In thousands except per share data)

| | June 30, 2014 (Unaudited) | December 31, 2013 (See Note 1) |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 33,974 | $ 54,877 |
| Trade receivables | 2,225 | 1,428 |
| Inventory | 1,072 | 1,096 |
| Prepaid expenses and other current assets | 2,166 | 910 |
| Total current assets | 39,437 | 58,311 |
| Strategic inventory | 4,570 | 4,450 |
| Property and equipment, net of accumulated depreciation | 296 | 203 |
| Other assets | 87 | 113 |
| Total assets | $ 44,390 | $ 63,077 |
| **Liabilities and stockholders equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,595 | $ 2,381 |
| Accrued clinical expenses | 1,643 | 3,288 |
| Other accrued liabilities | 1,624 | 1,301 |
| Long-term obligation - current portion | 7,396 | 5,743 |
| Deferred revenue | 44 | 25 |
| Total current liabilities | 13,302 | 12,738 |
| Long-term obligation, net of current portion | 27,636 | 29,322 |
| Commitments | | |
| Stockholders equity: | | |
| Preferred stock, par value $0.001 per share, 10,000 shares authorized and no shares outstanding at June 30, 2014 and December 31, 2013 | | |
| Common stock, par value $0.001 per share, 280,000 shares authorized and 101,123 and 99,849 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively | 101 | 100 |
| Additional paid-in capital | 317,449 | 313,534 |
| Accumulated deficit | (314,098) | (292,617) |
| Total stockholders equity | 3,452 | 21,017 |
| Total liabilities and stockholders equity | $ 44,390 | $ 63,077 |

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

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**CORCEPT THERAPEUTICS INCORPORATED**

**CONDENSED STATEMENTS OF COMPREHENSIVE LOSS**

(Unaudited)

(In thousands, except per share data)

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2014 | 2013 | 2014 | 2013 |
| Product sales, net | $ 5,851 | $ 1,891 | $ 10,255 | $ 3,608 |
| Operating expenses: | | | | |
| Cost of sales | 215 | 23 | 389 | 43 |
| Research and development | 4,252 | 4,491 | 11,537 | 8,748 |
| Selling, general and administrative | 7,965 | 8,160 | 17,769 | 16,544 |
| Total operating expenses | 12,432 | 12,674 | 29,695 | 25,335 |
| Loss from operations | (6,581) | (10,783) | (19,440) | (21,727) |
| Interest and other expense | (971) | (1,114) | (2,041) | (2,254) |
| Net loss and comprehensive loss | $ (7,552) | $ (11,897) | $ (21,481) | $ (23,981) |
| Basic and diluted net loss per share | $ (0.07) | $ (0.12) | $ (0.21) | $ (0.24) |
| Weighted average shares outstanding used in computing basic and diluted net loss per share | 100,980 | 99,814 | 100,751 | 99,814 |

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

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**CORCEPT THERAPEUTICS INCORPORATED**

**CONDENSED STATEMENTS OF CASH FLOWS**

(Unaudited)

(In thousands)

| | Six Months Ended June 30, | |
|---|---|---|
| | **2014** | **2013** |
| **Operating activities** | | |
| Net loss | $ (21,481) | $ (23,981) |
| Adjustments to reconcile net loss to net cash used in operations: | | |
| Stock-based compensation | 2,603 | 2,575 |
| Accretion of interest expense | 1,979 | 2,207 |
| Amortization of debt financing costs | 14 | 19 |
| Depreciation and amortization of property and equipment | 65 | 33 |
| Changes in operating assets and liabilities: | | |
| Trade receivables | (797) | (298) |
| Inventory | (94) | (881) |
| Prepaid expenses and other current assets | (1,256) | (181) |
| Other assets | 12 | (3) |
| Accounts payable | 214 | (771) |
| Accrued clinical expenses | (1,645) | 201 |
| Other accrued liabilities | 323 | 269 |
| Deferred revenue | 19 | 21 |
| Net cash used in operating activities | (20,044) | (20,790) |
| **Investing activities** | | |
| Purchases of property and equipment | (158) | (22) |
| Cash used in investing activities | (158) | (22) |
| **Financing activities** | | |
| Proceeds from issuance of common stock and warrants, net of issuance costs | 1,311 | |
| Payments related to long-term obligation | (2,012) | |
| Net cash used in financing activities | (701) | |
| Net decrease in cash and cash equivalents | (20,903) | (20,812) |
| Cash and cash equivalents, at beginning of period | 54,877 | 93,032 |
| Cash and cash equivalents, at end of period | $ 33,974 | $ 72,220 |

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

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**CORCEPT THERAPEUTICS INCORPORATED**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

**1. Basis of Presentation and Summary of Significant Accounting Policies**

**Description of Business and Basis of Presentation**

Corcept Therapeutics Incorporated was incorporated in the state of Delaware in May 1998, and our facilities are located in Menlo Park, California. Corcept is a pharmaceutical company engaged in the discovery, development and commercialization of drugs for the treatment of severe metabolic, psychiatric and oncologic disorders. Since our inception, we have been developing our lead product, Korlym®. Mifepristone, the active ingredient in Korlym, is a potent competitive antagonist of the glucocorticoid receptor II (GR-II), which means that it competitively blocks the effects of cortisol throughout the body at one of its two receptors. In February 2012, the United States Food and Drug Administration (FDA) approved Korlym (mifepristone) 300 mg Tablets as a once-daily oral medication for treatment of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing s syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. We released Korlym for sale in the United States in April 2012. In December 2013, we initiated a study of mifepristone for the treatment of triple-negative breast cancer. In addition, we have discovered and patented three series of novel selective GR-II antagonists. Unless otherwise stated, all references in these financial statements to we, us, our, Corcept, the Company, our company and similar designations refer to Corcept Therapeutics Incorporated.

The accompanying unaudited condensed balance sheet as of June 30, 2014 and the condensed statements of comprehensive loss for the three- and six-month periods ended June 30, 2014 and 2013 and the condensed statements of cash flows for the six-month periods ended June 30, 2014 and 2013 have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three- and six-month periods ended June 30, 2014 are not necessarily indicative of the results that may be expected for the year ending December 31, 2014 or any other period. These financial statements and notes should be read in conjunction with the financial statements for the year ended December 31, 2013 included in our Annual Report on Form 10-K. The accompanying balance sheet as of December 31, 2013 has been derived from audited financial statements at that date.

**Use of Estimates**

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ materially from those estimates.

We evaluate our estimates and assumptions on an ongoing basis, including those related to our reserves for chargebacks and rebates, patient assistance, potential product returns and excess/obsolete inventories, allowances for doubtful accounts, accruals of clinical and preclinical expenses, contingent liabilities, and the timing of payments with respect to our long-term capped royalty obligation, which determine its effective interest rate. We base our estimates on relevant experience and on other specific assumptions that we believe are reasonable.

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

**Cash and Cash Equivalents**

We invest our cash in bank deposits, money market accounts, corporate debt securities and obligations of the U.S. government and U.S. government sponsored entities. We consider all highly liquid investments purchased with maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents are carried at fair value, which approximates cost. As of June 30, 2014 and December 31, 2013, all of our funds were invested in cash and cash equivalents that consist of a money market fund maintained at a major U.S. financial institution.

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**CORCEPT THERAPEUTICS INCORPORATED**

**NOTES TO CONDENSED FINANCIAL STATEMENTS, continued**

**Credit Risks and Concentrations**

We have a concentration of credit risk related to our cash and cash equivalents. We are exposed to credit risk in the event of default by the financial institutions holding these funds or by the entity or entities that issued the securities held by the fund to the extent of the amount recorded on our balance sheet. We mitigate this risk by investing in a money market fund that invests primarily in short-term U.S. Treasury notes and bills. We experienced no loss or lack of access to cash and cash equivalents in our operating or investment accounts during the three- and six-month periods ended June 30, 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 and 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 June 30, 2014, we had one tablet manufacturer for Korlym with an operational facility AAI Pharma Services Corp. (AAI). In addition, we have a single-source manufacturer of mifepristone, the active pharmaceutical ingredient (API), in Korlym - Produits Chimiques Auxiliaires et de Synthèse SA (PCAS). If either of these companies is unable to manufacture API or Korlym tablets in the quantities and time frame required, we may not be able to manufacture our product in a timely manner. In order to mitigate these risks related to the manufacture of our product, we 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.

**Trade Receivables**

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

**Inventory**

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

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**CORCEPT THERAPEUTICS INCORPORATED**

**NOTES TO CONDENSED FINANCIAL STATEMENTS, continued**

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

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

**Property and Equipment**

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

**Long-term Obligation**

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

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

The accounting for the Financing Agreement requires us to make certain estimates and assumptions, including the timing of royalty payments due to Biopharma, the expected rate of return to Biopharma, the split between current and long-term portions of the obligation and the accretion of related interest expense. Korlym has only been marketed since April 2012 and the magnitude and timing of Korlym revenue is difficult to predict. Therefore, these estimates and assumptions are subject to significant variability and are likely to change as we gain experience marketing Korlym, which will result in changes in our classification of the current and long-term portions of the amounts payable pursuant to the Financing Agreement, as well as the internal rate of return paid to Biopharma and the accretion of interest expense related to this obligation. The amount of our payment with respect to each quarter will be based on Korlym Receipts recorded in that quarter and may differ from our estimates. While changes in the timing of Korlym revenue may affect the timing of recognition of interest expense and the split between the current and long-term portions of the obligation at any balance sheet date, the aggregate amount to be repaid to Biopharma is fixed at $45.0 million.

The amount shown as the current portion of the obligation is an estimate of the total amount under the Financing Agreement that would be paid to Biopharma within 12 months following June 30, 2014.

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

**Net Product Sales**

From our initial launch in April 2012 through June 30, 2013, we sold Korlym primarily to a specialty pharmacy and a specialty distributor, which subsequently resold Korlym to patients and healthcare providers. Korlym is not available in retail pharmacies. As of July 1, 2013, we began using Dohmen Life Science Services (Dohmen), formerly known as Centric Health Resources, Inc., as our specialty pharmacy. Dohmen operates on a consignment basis, without carrying any Korlym inventory. Accordingly, all of our sales through Dohmen are made directly to patients.

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**CORCEPT THERAPEUTICS INCORPORATED**

**NOTES TO CONDENSED FINANCIAL STATEMENTS, continued**

We recognize product revenues from sales of Korlym upon delivery to patients as long as (i) there is persuasive evidence that an arrangement exists between ourselves and the customer, (ii) collectability is reasonably assured and (iii) the price is fixed or determinable. Prior authorization or confirmation of coverage level by the patient s private insurance plan or government payor is a prerequisite to the shipment of product to a patient. In order to conclude that the price is fixed or determinable, we must be able to (i) calculate gross product revenues from the sales to our customers and (ii) reasonably estimate net product revenues.

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

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

*Trade Allowances:* Through June 30, 2013, we offered our specialty pharmacy and specialty distributor customers a discount on Korlym sales for payment within 30 days. We also offered them a small discount for providing data services. We expected these customers to earn these discounts and, accordingly, deducted them in full from gross product revenues and trade receivables at the time we recognized such revenues. Beginning in the third quarter of 2013, we ceased incurring a prompt-payment discount to our specialty pharmacy.

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

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

*Sales Returns:* Because sales through Dohmen, our specialty pharmacy, are made to individual patients who do not have the right to return the product, our exposure to product returns is 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.

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**CORCEPT THERAPEUTICS INCORPORATED**

**NOTES TO CONDENSED FINANCIAL STATEMENTS, continued**

**Research and Development**

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

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

**Segment Reporting**

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

**Stock-Based Compensation**

*Stock-based compensation for employee and director options*

We account for stock-based compensation related to option grants to employees and directors under the fair value method, based on the 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.

**Recently Issued Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09. ASU 2014-09 supersedes the revenue recognition requirements in Revenue Recognition (Topic 605), and requires entities to recognize revenue in a way that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In applying this new guidance to contracts within its scope, an entity will: (1) identify the contract(s) with a customer, (2) identify the performance obligation in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract, and (5) recognize revenue when (or as) the entity satisfies a performance obligation. Additionally, this new guidance will require significantly expanded revenue recognition disclosures. This guidance, which will become effective for us as of January 1, 2017, is to be applied retrospectively. Early application is not permitted. We are currently evaluating the new standard, but do not anticipate a material impact to our financial statements once implemented.

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**CORCEPT THERAPEUTICS INCORPORATED**

**NOTES TO CONDENSED FINANCIAL STATEMENTS, continued**

**2. Fair Value of Financial Instruments**

As of June 30, 2014 and December 31, 2013, we had invested our financial assets in a money market fund that can be converted to cash at par on demand. We measured these funds, which totaled $33.6 million and $52.9 million as of June 30, 2014 and December 31, 2013, respectively, at fair value, which approximates cost, as of the respective dates and classified them as Level 1 assets in the fair value hierarchy for financial assets.

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

**3. Composition of Certain Balance Sheet Items**

*Inventory*

The composition of inventory was as follows:

| | June 30, 2014 | December 31, 2013 |
|---|---|---|
| | *(in thousands)* | |
| Raw materials | $ 3,488 | $ 4,318 |
| Work in progress | 1,257 | 2 |
| Finished goods | 897 | 1,226 |
| Total inventory | 5,642 | 5,546 |
| Less strategic inventory classified as non-current | (4,570) | (4,450) |
| Total inventory classified as current | $ 1,072 | $ 1,096 |

The finished goods inventory as of June 30, 2014 and December 31, 2013 includes all costs of manufacture and packaging with the exception of the cost of raw materials that were expensed prior to FDA approval.

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

*Other Accrued Liabilities*

Other accrued liabilities consisted of the following:

| | June 30, 2014 | December 31, 2013 |
|---|---|---|
| | *(in thousands)* | |
| Accrued compensation | $ 561 | $ 466 |

| | | |
|---|---|---|
| Professional fees | 345 | 369 |
| Commercialization costs | 328 | 288 |
| Government rebates | 119 | 40 |
| Legal fees | 193 | 110 |
| Other | 78 | 28 |
| | $ 1,624 | $ 1,301 |

**4. Long-Term Obligation**

As discussed in Note 1, ***Basis of Presentation and Summary of Significant Accounting Policies, Long-term Obligation***, under the Financing Agreement with Biopharma, we are obligated to make payments calculated as a percentage of our net sales of Korlym, any future mifepristone-based products, our selective GR-II antagonists (together referred to as Covered Products) and any upfront, milestone or other contingent payments with respect to Covered Products. Biopharma s right to receive payments will expire once it has received cumulative payments of $45.0 million. Through June 30, 2014, we made aggregate payments to Biopharma in the amount of $3.0 million, with an additional payment in the amount of $1.3 million made in July 2014.

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**CORCEPT THERAPEUTICS INCORPORATED**

**NOTES TO CONDENSED FINANCIAL STATEMENTS, continued**

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.

20 percent of payments received for upfront, milestone or other contingent fees under co-promotion and out-license agreements for Covered Products (without application of quarterly caps).

The percentage used to calculate our payments to Biopharma would increase to 50 percent and any applicable payment caps would lapse if we (i) fail to provide Biopharma with certain information regarding our promotion and sales of Covered Products, (ii) do not devote a commercially reasonable amount of resources to the promotion and marketing of the Covered Products or (iii) violate the indebtedness covenant by incurring indebtedness greater than the sum of earnings before interest, taxes, depreciation and amortization, including such items as non-cash stock-based compensation, (EBITDA) for the four calendar quarters preceding such incurrence and, in each case, fail to cure within the applicable cure period.

Upon the occurrence of a Corcept change of control transaction or the licensing of Korlym to a third-party for promotion and sale in the United States, the entire $45.0 million, less any amounts already paid by us, would become due.

To secure our obligations in connection with this Financing Agreement, we granted Biopharma a security interest in our rights in patents, trademarks, trade names, domain names, copyrights, know-how and regulatory approvals related to the Covered Products, all books and records relating to the foregoing and all proceeds of the foregoing (together, the Collateral). If we (i) fail to deliver a royalty payment when due and do not remedy that failure within 30 days, (ii) fail to maintain a first-priority perfected security interest in the Collateral in the United States and do not remedy that failure within five business days of receiving notice of such failure or (iii) become subject to an event of bankruptcy, then Biopharma may attempt to recover up to $45.0 million (after deducting any payments we have already made). In addition, pursuant to this agreement, we are not allowed to pay a dividend or other cash distribution, unless we will have cash and cash equivalents in excess of $50.0 million after such payment.

As discussed in Note 1, ***Basis of Presentation and Summary of Significant Accounting Policies, Long-term Obligation***, we make estimates of the timing of payments during the term of this agreement for purposes of calculating the expected rate of return to Biopharma, the accretion of related interest expense and the current portion of our obligation. We recorded interest expense of $935,000 and $2.0 million for the three- and six-month periods ended June 30, 2014, respectively, $1.1 million and $2.2 million for the three- and six-month periods ended June 30, 2013, respectively, and total accreted interest of $8.1 million for the period from August 2012 through June 30, 2014, as calculated based on the internal interest rate to Biopharma that would result from these assumed payment streams. The timing of payment amounts will be based on actual Korlym Receipts recorded in the financial statements over the term of this agreement and may differ from these estimates. While changes in the timing of Korlym revenue may affect the timing of recognition of interest expense and the split between the current and long-term portions of the obligation at any balance sheet date, the aggregate amount to be repaid to Biopharma is fixed at $45.0 million.

The carrying value of the long-term obligation was $35.0 million as of June 30, 2014 and $35.1 million as of December 31, 2013. The long-term obligation, including accrued interest, is presented on the balance sheet in two components; the Long-term obligation - current portion, which equates to the estimated amount due under the agreement to be paid within twelve months following the balance sheet date, and the remaining amount, which is included in Long-term obligation, net of current portion.

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**CORCEPT THERAPEUTICS INCORPORATED**

**NOTES TO CONDENSED FINANCIAL STATEMENTS, continued**

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

| | June 30, 2014 | December 31, 2013 |
|---|---|---|
| | *(in thousands)* | |
| Total repayment obligation | $ 45,000 | $ 45,000 |
| Less interest to be accreted in future periods | (6,931) | (8,910) |
| Less payments made | (3,037) | (1,025) |
| Less current portion | (7,396) | (5,743) |
| Long-term obligation, net of current portion | $ 27,636 | $ 29,322 |

The estimated fair value of the long-term obligation, as measured using Level 3 inputs, approximates the carrying amounts as presented on the balance sheet as of June 30, 2014 and December 31, 2013. The estimated fair value was calculated using the income method of valuation. The key assumptions required for the calculation were an estimate of the amount and timing of future product revenues and an estimated cost of capital. Management s estimate of the future product revenues is subject to significant uncertainty due to the fact that Korlym has 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 June 30, 2014 and December 31, 2013, the unamortized issuance costs were $72,000 and $87,000, respectively, and are included in other assets on our balance sheets.

**5. Significant Agreements**

*Pharmaceutical Manufacturing Agreement*

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

*Tablet Manufacturing Agreement*

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

*Clinical Trial Agreement*

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

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**CORCEPT THERAPEUTICS INCORPORATED**

**NOTES TO CONDENSED FINANCIAL STATEMENTS, continued**

**6. Stock Option Plans**

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

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

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

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2014 | 2013 | 2014 | 2013 |
| | *(in thousands)* | | *(in thousands)* | |
| Research and development | $ 169 | $ 157 | $ 331 | $ 305 |
| Selling, general and administrative | 1,057 | 1,108 | 2,272 | 2,270 |
| Total non-cash stock-based compensation | $ 1,226 | $ 1,265 | $ 2,603 | $ 2,575 |

**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.

| | June 30, | |
|---|---|---|
| | 2014 | 2013 |
| | *(in thousands)* | |
| Stock options outstanding | 14,618 | 14,494 |
| Warrants outstanding | 8,044 | 8,904 |
| Total | 22,662 | 23,398 |

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

**Forward-Looking Statements**

*This Management Discussion should be read in conjunction with the financial statements and notes thereto appearing elsewhere in this report. We make statements in this section that are forward-looking 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 as a once-daily oral medication for treatment of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing s syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. We made the drug available to patients in the United States in April 2012.

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

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

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

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

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

We have Orphan Drug designations for Korlym from the FDA for the approved indication and from the European Commission for the treatment of endogenous Cushing s syndrome. Orphan Drug designation in the United States is a special status granted by the FDA to encourage the development of treatments for diseases or conditions that affect fewer than 200,000 patients in the United States. Drugs that receive Orphan Drug designation obtain seven years of marketing exclusivity for the approved indication from the date of drug approval, as well as tax credits for clinical trial costs, marketing application filing fee waivers and assistance from

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

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

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

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

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

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

*General*

Our activities to date have included:

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

intellectual property prosecution and expansion.

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.

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As of June 30, 2014, we had an accumulated deficit of $314.1 million. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for mifepristone, discovery research, non-clinical activities such as toxicology and carcinogenicity studies, manufacturing and regulatory activities, as well as selling, general and administrative expenses, including expenses related to the commercial launch of Korlym. We may continue to incur net losses as we continue our mifepristone and selective GR-II antagonist discovery and clinical development programs, apply for regulatory approvals, acquire and / or develop treatments in other therapeutic areas, establish sales and marketing capabilities and expand our operations.

Our business is subject to significant risks, including the risks inherent in our research and development efforts, the results of our mifepristone and other clinical trials, uncertainties associated with securing financing, uncertainties associated with obtaining and enforcing patents, our investment in manufacturing set-up, the management of our supply chain, the lengthy and expensive regulatory approval process and competition from other products. Our ability to successfully generate revenues in the foreseeable future is dependent upon our ability, alone or with others, to finance our operations and develop, obtain regulatory approval for, manufacture and market our products.

**Results of Operations**

*Net Product Sales* Net product sales includes product revenue resulting from sales to our customers, reduced by (1) trade allowances, such as discounts for prompt payment and distributor fees, (2) estimated government rebates and chargebacks, (3) reserves for expected product returns and 4) estimated costs of our patient assistance program. We made Korlym available commercially in the United States in April 2012.

For the three- and six-month periods ended June 30, 2014, we recorded net product sales of $5.9 million and $10.3 million, respectively, as compared to $1.9 million and $3.6 million in the respective periods in 2013. To calculate net product sales, we deducted from gross sales estimates of prompt-pay discounts (which we ceased to incur with respect to our specialty pharmacy customer beginning in the third quarter of 2013), distribution service fees, rebates and chargebacks owed to government payors and patient assistance program costs, which amounts are not material for any of the periods presented.

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

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

Cost of sales was $215,000 and $389,000 for the three- and six-month periods ended June 30, 2014, respectively, which equaled 3.7 percent and 3.8 percent of net product sales for each of the respective periods. Cost of sales was $23,000 and $43,000 for the three- and six-month periods ended June 30, 2013, respectively, which equaled 1.2 percent of net product sales for each of the respective periods. Direct product cost for tablets sold during the three- and six-month periods ended June 30, 2014 represented approximately 2.9 percent and 3.1 percent of net product sales, respectively, as compared to less than 1 percent of net product sales for each of the three- and six-month periods ended June 30, 2013. The remainder of the cost of sales during each period related to stability testing and distribution costs. Product sold during the three- and six-month periods ended June 30, 2014, included the cost to manufacture the Korlym tablets and indirect personnel and other overhead costs but did not include the cost of the active pharmaceutical ingredient (API) as that had been expensed prior to FDA approval of Korlym. Product sold during the three- and six-month periods ended June 30, 2013, did not include either the cost to manufacture the Korlym tablets or the API costs as these tablets had been fully manufactured prior to FDA approval.

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Although the cost of manufacturing Korlym reflected in our cost of sales through June 30, 2014, does not reflect the full cost of production because we have previously expensed the majority of the raw materials, labor and overhead costs incurred to produce the product sold during these periods, we do not expect that the inclusion of these previously expensed cost components in future periods will materially increase our cost of sales, because we expect that the added costs will be offset by production efficiencies. In addition, as the amount and timing of stability testing varies from period to period as determined by FDA regulations and our production schedule and is not a fixed percentage of our sales volumes, our cost of sales of Korlym as a percentage of net product sales may fluctuate from period to period.

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

Research and development expenses decreased 5.3 percent to $4.3 million for the three-month period ended June 30, 2014 from $4.5 million for the comparable period in 2013. For the six-month period ended June 30, 2014, research and development expenses increased 32.0 percent to $11.5 million from $8.7 million for the comparable period in 2013.

During the three-month period ended June 30, 2014, as compared to the corresponding period in 2013, there was an increase of $229,000 in staffing and consultancy costs. During the six-month period ended June 30, 2014, as compared to the corresponding period in 2013, there was an increase of $1.5 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 $651,000 in staffing and consulting costs in the first half of 2014 as compared to the same period in 2013. The increase in costs between years was 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 and increased activities in our oncology study.

Clinical trial costs reflected net increases of $108,000 and $1.8 million during the three- and six-month periods ended June 30, 2014, respectively, as compared to the respective periods in 2013. During the three- and six-month periods ended June 30, 2014 as compared to 2013, there were increases of $134,000 and $1.5 million, respectively, related to our Phase 3 study with mifepristone for the treatment of psychotic depression study and $206,000 and $760,000, respectively, related to our oncology study. During the three- and six-month periods ended June 30, 2014, as compared to the respective periods in 2013, there were decreases of $232,000 and $486,000, respectively, in clinical trial activities related to other clinical trials as work on these studies was completed.

In addition, there were decreases in spending of $420,000 and $73,000 during the three- and six-month periods ended June 30, 2014, respectively, as compared to the respective periods in 2013, related to the development of new compounds, and decreases in spending of $182,000 and $383,000 in the respective periods related to development of other products.

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

| Project | Three Months Ended June 30, 2014 | Three Months Ended June 30, 2013 | Six Months Ended June 30, 2014 | Six Months Ended June 30, 2013 |
|---|---|---|---|---|
| | *(in thousands)* | | *(in thousands)* | |
| Development programs: | | | | |
| Psychotic Depression | $ 1,862 | $ 1,697 | $ 5,257 | $ 3,204 |
| Cushing s syndrome | 502 | 765 | 1,144 | 1,303 |
| Cancer | 404 | | 1,171 | |
| Selective GR-II antagonists | 875 | 1,385 | 2,732 | 2,848 |
| Unallocated activities, including NDA supportive studies and manufacturing, regulatory and pre-clinical activities | 440 | 487 | 902 | 1,088 |
| Stock-based compensation | 169 | 157 | 331 | 305 |
| Total research and development expense | $ 4,252 | $ 4,491 | $ 11,537 | $ 8,748 |

We expect research and development expenditures during the remainder of 2014 to be less than they were in 2013, as reductions in our spending on psychotic depression are only partially offset by increases in spending on our development programs for oncology and 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 June 30, 2014, selling, general and administrative expenses decreased 2.4 percent to $8.0 million from $8.2 million for the comparable period in 2013. For the six-month period ended June 30, 2014, selling, general and administrative expenses increased 7.4 percent to $17.8 million from $16.5 million for the comparable period in 2013.

During the three-month period ended June 30, 2014, as compared to the corresponding period in 2013, there was an increase of $364,000 in staffing and consultancy costs. During the six-month period ended June 30, 2014, as compared to the corresponding period in 2013, staffing and consultancy costs increased by $3.0 million, primarily due to the payment of $2.5 million in bonuses awarded in February 2014. These increases were offset by decreases in other professional services related to commercial activities of $635,000 and $1.4 million in the respective comparable periods.

Selling, general and administrative expenses included stock-based compensation expense related to option grants to individuals performing these functions of $1.1 million and $2.3 million during the three- and six-month periods ended June 30, 2014, respectively, which amounts were the same in the respective periods of 2013.

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. See also, Liquidity and Capital Resources.

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*Interest and other expense* Interest and other expense for the three- and six-month periods ended June 30, 2014 was $971,000 and $2.0 million, respectively, as compared to $1.1 million and $2.3 million for the respective periods in 2013. Costs in this category consisted primarily of interest expense related to our Biopharma financing agreement for all periods presented. Interest expense for the 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 June 30,** |
|---|---|