CORCEPT THERAPEUTICS INC
Form 10-Q
November 06, 2015
Table of Contents

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 September 30, 2015

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 No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes 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
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

On October 30, 2015 there were 108,775,937 shares of common stock outstanding at a par value of $0.001 per share.

Table of Contents

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION	3
ITEM 1. FINANCIAL STATEMENTS	3
CONDENSED BALANCE SHEETS	3
CONDENSED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)	4
CONDENSED STATEMENTS OF CASH FLOWS	5
NOTES TO CONDENSED FINANCIAL STATEMENTS	6
ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	11
ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	15
ITEM 4. CONTROLS AND PROCEDURES	15
PART II. OTHER INFORMATION	16
ITEM 1. LEGAL PROCEEDINGS	16
ITEM 1A. RISK FACTORS	16
ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS	32
ITEM 3. DEFAULTS UPON SENIOR SECURITIES	32
ITEM 4. MINE SAFETY DISCLOSURES	33
ITEM 5. OTHER INFORMATION	33
ITEM 6. EXHIBITS	34
SIGNATURES	35

Table of Contents

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS
CORCEPT THERAPEUTICS INCORPORATED

CONDENSED BALANCE SHEETS

(In thousands, except per share data)

	September 30, 2015 (Unaudited)	December 31, 2014 (See Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 36,450	$ 24,248
Trade receivables	5,945	3,334
Inventory	1,604	1,207
Prepaid expenses and other current assets	1,180	1,441
Total current assets	45,179	30,230
Strategic inventory	2,990	4,090
Property and equipment, net of accumulated depreciation	143	236
Other assets	65	74
Total assets	$ 48,377	$ 34,630
Liabilities and stockholders’ equity		
Current liabilities:		
Accounts payable	$ 1,740	$ 1,886
Accrued clinical expenses	609	336
Other accrued liabilities	2,832	1,876
Long-term obligation - current portion	13,507	9,424
Deferred revenue	79	33
Total current liabilities	18,767	13,555
Long-term obligation, net of current portion	16,133	24,463
Commitments		
Stockholders’ equity:		
Common stock, par value $0.001 per share, 280,000 shares authorized and 108,745 and 101,395 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	109	101
Additional paid-in capital	344,735	320,511

Accumulated deficit	(331,367)	(324,000)
Total stockholders' equity (deficit)	13,477	(3,388)
Total liabilities and stockholders' equity	$ 48,377	$ 34,630

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

Table of Contents

CORCEPT THERAPEUTICS INCORPORATED

CONDENSED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(Unaudited)

(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Product revenue, net	$ 13,261	$ 7,282	$ 35,319	$ 17,537
Operating expenses:				
Cost of sales	256	235	997	624
Research and development	3,612	3,047	11,330	14,583
Selling, general and administrative	9,291	9,103	28,086	26,872
Total operating expenses	13,159	12,385	40,413	42,079
Income (Loss) from operations	102	(5,103)	(5,094)	(24,542)
Interest and other expense	(703)	(903)	(2,273)	(2,946)
Net income (loss) and comprehensive income (loss)	$ (601)	$ (6,006)	$ (7,367)	$ (27,488)
Basic and diluted net income (loss) per share	$ (0.01)	$ (0.06)	$ (0.07)	$ (0.27)
Weighted average shares outstanding used in computing basic and diluted net income (loss) per share	108,461	101,134	106,104	100,880

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

Table of Contents

CORCEPT THERAPEUTICS INCORPORATED

CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Nine Months Ended September, 30,	
	2015	2014
Operating activities		
Net loss	$ (7,367)	$ (27,488)
Adjustments to reconcile net loss to net cash used in operations:		
Stock-based compensation	4,520	3,814
Accretion of interest expense	2,196	2,874
Amortization of debt financing costs	20	23
Depreciation and amortization of property and equipment	127	104
Changes in operating assets and liabilities:		
Trade receivables	(2,611)	(1,318)
Inventory	703	38
Prepaid expenses and other current assets	261	(859)
Other assets	(11)	9
Accounts payable	(146)	(421)
Accrued clinical expenses	273	(3,012)
Other accrued liabilities	956	238
Deferred revenue	46	25
Net cash used in operating activities	(1,033)	(25,973)
Investing activities		
Purchases of property and equipment	(34)	(174)
Cash used in investing activities	(34)	(174)
Financing activities		
Proceeds from issuance of common stock upon exercise of options and warrants, net of issuance costs	19,712	1,338
Payments related to long-term obligation	(6,443)	(3,288)
Net cash provided by (used in) financing activities	13,269	(1,950)
Net increase (decrease) in cash and cash equivalents	12,202	(28,097)

Cash and cash equivalents, at beginning of period	24,248	54,877
Cash and cash equivalents, at end of period	$ 36,450	$ 26,780

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

Table of Contents

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 headquarters are located in Menlo Park, California. We are a pharmaceutical company engaged in the discovery, development and commercialization of medications for the treatment of severe metabolic, oncologic, and psychiatric disorders that are associated with the activity of the hormone cortisol. In 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 have discovered and patented three families of selective cortisol modulators, consisting of more than 300 distinct compounds, and we are developing them to treat a broad range of disorders.

Basis of Presentation

The accompanying unaudited condensed balance sheet as of September 30, 2015 and the condensed statements of comprehensive loss for the three- and nine-month periods ended September 30, 2015 and 2014 and the condensed statements of cash flows for the nine-month periods ended September 30, 2015 and 2014 have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) 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 GAAP for complete financial statements. In the opinion of management, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three- and nine-month periods ended September 30, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015 or any other period. These financial statements and notes should be read in conjunction with the financial statements for the year ended December 31, 2014 included in our Annual Report on Form 10-K. The accompanying balance sheet as of December 31, 2014 has been derived from audited financial statements at that date.

Use of Estimates

The preparation of financial statements in conformity with GAAP 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 revenue recognition, inventory, accrued liabilities, clinical trial accruals, stock-based compensation and the timing of payments with respect to our long-term capped royalty obligation, which determines our interest expense. We base our estimates on relevant experience and on other specific assumptions that we believe are reasonable.

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.

Cash and Cash Equivalents

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 as measured using Level 1 inputs, which approximates cost. As of September 30, 2015 and December 31, 2014, all of our funds were held in checking and money market fund accounts maintained at major U.S. financial institutions.

Inventory

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

Table of Contents

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

Inventory amounts that are not expected to be consumed within 12 months following the balance sheet date are classified as strategic inventory, a noncurrent asset.

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 an FDA approved facility.

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 upon receipt we recorded as a long-term obligation. In return, we are obligated to make payments to Biopharma totaling $45.0 million. These payments equal a percentage of (i) our net product sales, which include sales from any product containing mifepristone or any of our proprietary selective GR antagonists (Covered Products) and (ii) cash or cash equivalents received from any licensing transaction or co-promotion arrangement involving Covered Products, including any upfront or milestone payments, if any, (together, Korlym Receipts). Once we have paid Biopharma a total of $45.0 million, no more payments will be due and the obligation will be extinguished.

We recognize a portion of each quarterly payment under the Financing Agreement as interest expense, which we determine by calculating the interest rate to Biopharma implied by the stream of quarterly payments we expect to make. The amount shown on our balance sheet as the current portion is an estimate of the amount we expect to repay Biopharma in the 12 months following September 30, 2015. We record the balance of the outstanding portion of the obligation as a long-term liability.

The amount and timing of our estimated quarterly payments to Biopharma are subject to significant uncertainty and are likely to change. Any changes in our assumed payment stream will change the accretion of interest expense and our split between the current and long-term portions of the obligation, although the total we will pay Biopharma is fixed at $45.0 million.

See Note 3, Long-Term Obligation, for additional information regarding this agreement.

Net Product Revenue

We primarily sell Korlym directly to patients through Dohmen Life Science Services (Dohmen), a specialty pharmacy. Prior authorization and confirmation of coverage by the patients' private or government insurance plan or by a third-party charity, such as the National Organization for Rare Disorders (NORD – discussed below), is a prerequisite for Dohmen to ship Korlym. We recognize revenue upon the delivery of our products to these patients.

We donate cash to NORD, an independent non-profit 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 revenue amounts attributable to our donations to NORD.

We estimate our net product revenue by deducting from our gross product revenue (a) estimated government rebates and chargebacks and (b) allowances for our patient assistance program.

Government Rebates and Chargebacks: We are obligated to provide to government programs, including Medicaid, rebates and chargebacks on our product sales to eligible patients. We deduct the estimated amount of these rebates and chargebacks from our gross product revenue. We estimate rebates and chargebacks by applying the applicable rate to eligible sales reported by a specialty pharmacy.

Allowances for Patient Assistance Program: We provide financial assistance to eligible patients whose insurance policies require them to pay high deductibles and co-payments. We calculate the cost of assistance by applying our program guidelines to the eligible sales in the period.

Research and Development

Research and development expenses consist of direct expenses, such as the cost of clinical trials, pre-clinical studies, the development of second-generation compounds, manufacturing development, preparations for submissions to the FDA or other regulatory agencies, and the related overhead expenses. We 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.

Table of Contents

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

Stock-Based Compensation

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

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.

Recently Issued Accounting Pronouncement

In May 2014, the Financial Accounting Standards Board (FASB) issued a new standard on revenue recognition from contracts with customers. This standard's core principle is that a reporting entity will recognize revenue when it transfers 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. On July 9, 2015, FASB delayed the effective date of this standard by one year. The standard will be effective for us beginning in the first quarter of 2018. Early application is permitted in 2017.

2. Composition of Certain Balance Sheet Items

Inventory

The composition of inventory was as follows:

	September 30, 2015	December 31, 2014
	(in thousands)	
Raw materials	$ 2,849	$ 3,595
Work in progress	9	15
Finished goods	1,736	1,687
Total inventory	4,594	5,297
Less strategic inventory classified as non-current	(2,990)	(4,090)
Total inventory classified as current	$ 1,604	$ 1,207

We have one tablet manufacturer for Korlym — AAI Pharma Services Corp. (AAI). In addition, we have one manufacturer for 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 we require, we may not be able to meet customer demand. In order to mitigate these risks, we purchase and hold as "strategic inventory" additional quantities of API and Korlym tablets that are not expected to be consumed within 12 months following the relevant balance sheet date.

Other Accrued Liabilities

Other accrued liabilities consisted of the following:

	September 30, 2015	December 31, 2014
	(in thousands)	
Government rebates	$ 1,349	$ 275
Accrued compensation	1,007	564
Professional fees	189	330
Commercialization costs	120	556
Legal fees	66	120
Other	101	31
	$ 2,832	$ 1,876

3. 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 make payments to Biopharma calculated as a percentage of our Korlym Receipts. Biopharma's right to receive payments will expire once it has received $45.0 million. Through September 30, 2015, we have paid Biopharma $12.3 million, with an additional payment of $2.8 million made in October 2015.

Table of Contents

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

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

We are obligated to make payments as follows:

- 20 percent of our net product sales of Covered Products, subject to payment caps of $3.75 million each quarter during 2015. There is no quarterly cap on payments 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 will increase to 50 percent and any payment caps will 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) incur indebtedness greater than the sum of our earnings before interest, taxes, depreciation and amortization, and non-cash stock-based compensation, for the four calendar quarters preceding such incurrence and, in each case, fail to cure within the applicable cure period.
- If there is a Corcept change of control transaction or we license 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, will become due.

To secure our obligations in connection with the 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, we may not pay a dividend or other cash distribution unless we will have more than $50.0 million in cash and cash equivalents after we make such payment.

As discussed in Note 1, Basis of Presentation and Summary of Significant Accounting Policies, Long-term Obligation, we recognize a portion of each quarterly payment to Biopharma as interest expense, which we determine by calculating the interest rate to Biopharma implied by the stream of payments we expect to make under the Financing Agreement. We recognize the non-interest portion of each payment as a reduction in our obligation to Biopharma. The current portion of the obligation is the amount we expect to pay, exclusive of interest expense, during the next 12 months.

We recorded interest expense of $698,000 and $2.2 million for the three- and nine-month periods ended September 30, 2015, respectively, $895,000 and $2.9 million for the three- and nine-month periods ended September 30, 2014, respectively, and total accreted interest of $12.0 million for the period from August 2012 through September 30, 2015. The actual amount of each quarterly payment will be based on Korlym Receipts in that quarter and may differ from our estimate. While changes in the timing of Korlym Receipts may affect the recognition of interest expense and the split between the current and long-term portions of the obligation at any balance sheet date, the total we will pay Biopharma is fixed at $45.0 million.

The following table provides a summary of the payment obligations under the Financing Agreement as of September 30, 2015 and December 31, 2014, utilizing the payment assumptions discussed above.

	September 30, 2015	December 31, 2014
	(in thousands)	
Total repayment obligation	$ 45,000	$ 45,000
Less interest to be accreted in future periods	(3,036)	(5,232)
Less payments made	(12,324)	(5,881)
Less current portion	(13,507)	(9,424)
Long-term obligation, net of current portion	$ 16,133	$ 24,463

The estimated fair value of the long-term obligation, as measured using Level 3 inputs, approximates the carrying amounts as presented on the balance sheet as of September 30, 2015 and December 31, 2014. 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 our future product revenue and an estimated cost of capital. Management's estimate of the future product revenue is subject to significant uncertainty because Korlym Receipts are difficult to predict and there is an extended time period associated with the Financing Agreement.

Table of Contents

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

We capitalized $140,000 of issuance costs related to the Financing Agreement, which are being amortized over the estimated term of the obligation, based on the assumptions discussed above. At September 30, 2015 and December 31, 2014, the unamortized issuance costs were approximately $42,000 and $58,000, respectively, and are included in other assets on our balance sheets.

4. Stock Option Plans

We have two stock option plans – the 2004 Equity Incentive Plan (the 2004 Plan) and the 2012 Incentive Award Plan (the 2012 Plan) – with stock options outstanding as of September 30, 2015. On February 18, 2015, our Board of Directors authorized an increase of approximately 4.1 million 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, 2014, pursuant to the terms of the 2012 Plan.

During the nine month period ended September 30, 2015, 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 stock-based compensation.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(in thousands)		(in thousands)	
Research and development	$ 196	$ 183	$ 579	$ 514
Selling, general and administrative	1,346	1,027	3,941	3,300
Total stock-based compensation	$ 1,542	$ 1,210	$ 4,520	$ 3,814

5. Capital Stock

In March 2015, we issued approximately 6.2 million shares of our common stock upon the exercise of warrants that had been issued in two private placement transactions, one in 2008 and the other in 2012, at an exercise price of $2.77 and $4.05, respectively. The transactions generated aggregate net proceeds of approximately $17.1 million, after the deduction of issuance costs. Approximately 3.1 million shares of the securities, which generated aggregate gross proceeds of $5.9 million, issued in these transactions were to venture capital funds, trusts and other entities affiliated

with members of our Board of Directors, whom we consider to be our related parties.

6. Net Income (Loss) Per Share

Basic and diluted net income (loss) per share is computed by dividing the net income (loss) by the weighted-average number of common shares outstanding during the period. The computation of net income (loss) per share for each period, including the number of weighted-average shares outstanding, is shown on the condensed statements of comprehensive income (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 income (loss) per common share because all such securities are antidilutive for all periods presented.

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

	September 30,	
	2015	2014
	(in thousands)	
Stock options outstanding	17,033	14,890
Warrants outstanding	—	8,044
Total	17,033	22,934

Table of Contents

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

Forward-Looking Statements

This Management Discussion should be read in conjunction with the financial statements and notes thereto appearing elsewhere in this report. We make statements in this section that are forward-looking within the meaning of the federal securities laws. For a complete discussion of such forward-looking statements and the potential risks and uncertainties that may affect their accuracy, see "Forward-Looking Statements" included in "Risk Factors" in Part I, 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 medications for the treatment of severe metabolic, oncologic and psychiatric disorders that are associated with the activity of the hormone cortisol. Cortisol is widely known as the stress hormone. It is essential for life; there are cortisol receptors in nearly every tissue of the human body. Excess or disordered cortisol activity can cause severe illness.

We develop and commercialize medications that modulate the effect of cortisol. We market Korlym for the treatment of endogenous Cushing's syndrome, the prototypical chronic disease of cortisol excess. We are conducting a Phase 1/2 trial to evaluate whether cortisol modulation improves the efficacy of chemotherapy in women with triple-negative breast cancer, a form of the disease with a poor prognosis. We have also created a large portfolio of next-generation cortisol modulators that may provide treatments for a wide array of serious conditions. We plan to start Phase 2 studies of our lead next-generation compound – CORT125134 – in the treatment of Cushing's syndrome and an oncology indication in the first quarter of 2016.

Korlym for the treatment of Cushing's syndrome

In 2012, the FDA approved Korlym (mifepristone) 300 mg Tablets as a once-daily oral medication 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.

Endogenous Cushing's syndrome is caused by a tumor that produces cortisol or a tumor that produces adrenocorticotropic hormone (ACTH), which in turn stimulates the body to produce cortisol. Cushing's syndrome most commonly affects adults aged 20-50. An estimated 10-15 of every one million people are newly diagnosed with Cushing's syndrome each year, resulting in over 3,000 new patients annually in the United States. An estimated 20,000 patients in the United States have Cushing's syndrome, half of whom are cured by surgery. Cushing's syndrome can affect every organ system in the body and can be lethal if not treated effectively. Korlym modulates the effect of cortisol at the glucocorticoid receptor (GR), one of the two receptors to which cortisol normally binds, thereby diminishing the effects of excess cortisol in these patients.

We have Orphan Drug designation for Korlym for the treatment of Cushing's syndrome. Orphan Drug designation provides seven years of marketing exclusivity for the approved indication from the date of drug approval, tax credits for clinical trial costs, marketing application filing fee waivers and assistance from the FDA in the drug development process.

We promote Korlym using experienced clinical specialists supported by eight medical science liaisons covering 25 territories. We continue to develop and refine our commercialization efforts, including identifying and engaging physicians, increasing the effectiveness of our sales organization, and developing programs to educate and support physicians and patients.

We invest significant amounts to develop Korlym for the treatment of indications other than Cushing's syndrome and to advance our pipeline of next-generation cortisol modulators.

Korlym for the treatment of triple-negative breast cancer

In 2014, we began a Phase 1/2 clinical trial of Korlym in combination with eribulin for the treatment of triple-negative breast cancer, a form of the disease in which the three receptors that fuel most breast cancer growth – estrogen, progesterone and HER-2 – are not present. Because the tumor cells lack these receptors, common treatments such as drugs that target estrogen, progesterone, and HER-2 are ineffective. Approximately 40,000 women in the United States are diagnosed with triple-negative breast cancer each year. Neither a targeted treatment nor an approved standard chemotherapy regimen for relapsed triple-negative breast cancer patients exists. We have completed the dose-finding portion of our Phase 1/2 clinical trial and have begun the efficacy phase, which will enroll 20 patients with relapsed, metastatic, triple-negative breast cancer. These patients will receive one 300 mg Korlym tablet each day, combined with eribulin administered on days one and eight of a 21-day cycle. We expect to have initial efficacy results by the end of 2015.

Table of Contents

Next-generation selective cortisol modulators

We have discovered and patented three families of selective cortisol modulators, consisting of more than 300 distinct compounds, with the goal of identifying treatments for a broad range of disorders. All of these new compounds are potent modulators of cortisol but, unlike Korlym, do not interfere with the activity of progesterone and therefore do not terminate pregnancy. They also do not cause endometrial thickening, a common consequence of progesterone receptor antagonism. Several of our new compounds have demonstrated positive results in animal or in vitro models of one or more of the following diseases: breast, ovarian and prostate cancer, non-alcoholic fatty liver disease, metabolic syndrome, obesity, antipsychotic-induced weight gain, the prevention and reversal of alcohol dependence, amyotrophic lateral sclerosis (ALS), Alzheimer's disease, electroconvulsive shock-induced retrograde amnesia, and stress disorders.

The Phase 1 clinical trial of one of our next-generation selective cortisol modulators - CORT125134 - demonstrated that the compound is well-tolerated and potently modulates activity at the glucocorticoid receptor, a necessity in treating Cushing's syndrome and potentially treating a variety of other metabolic illnesses. When administered in conjunction with chemotherapeutic agents, CORT125134 also slows tumor growth significantly in mouse models of triple-negative breast cancer and castration-resistant prostate cancer and in in-vitro models of ovarian cancer, with in-vivo studies currently pending. We expect to advance this compound to Phase 2 clinical trials for both Cushing's syndrome and an oncology indication in the first quarter of 2016.

We have other next-generation cortisol modulators in pre-clinical development and plan to advance the most promising of them to the clinic in 2016.

Financing update

We have supported our operations primarily with proceeds from public and private sales of our equity securities and funds from our Biopharma Financing Agreement. Since 2012, revenues from the sale of Korlym have substantially increased and are now our primary source of funds that support our operations. Based on the anticipated increase in revenues from Korlym and our current development plans, which include funding our Cushing's syndrome commercial operations, completing our Phase 1/2 study of Korlym for the treatment of triple-negative breast cancer and (if that study produces positive results) conducting a Phase 3 study, advancing CORT125134 to Phase 2 studies in both Cushing syndrome and an oncology indication, and advancing to the clinic at least one more of our next generation compounds, we expect to reach cash-flow breakeven without needing to raise additional funds. However, we may choose to raise additional funds to finance our strategic priorities.

As of September 30, 2015, we had an accumulated deficit of $331.4 million. We have historically incurred operating losses due to the cost of our research and development activities, including clinical trial activities for Korlym and our next generation selective cortisol modulators, 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 commercialization of Korlym, offset by our net product revenue. We may incur further losses as we continue our discovery and clinical development programs, apply for regulatory approvals,

develop or acquire medications in other therapeutic areas, and expand our sales, marketing and administrative capabilities.

Results of Operations

Net Product Revenue – Net product revenue is gross product revenue from sales to our customers less deductions including (1) estimated government rebates and chargebacks and (2) estimated allowance for our patient assistance program.

Net product revenue was $13.3 million and $35.3 million for the three- and nine-month periods ended September 30, 2015, respectively, as compared to $7.3 million and $17.5 million, respectively, in the corresponding periods in 2014. The increase in net product revenue for both the three- and nine-month periods in 2015 was driven by the increase in our sales volume and price increases.

Cost of sales – Cost of sales includes the cost of API, tableting and packaging, indirect personnel and overhead costs, and the cost of stability testing and distribution.

Cost of sales was $256,000 and $997,000 for the three- and nine-month periods ended September 30, 2015, respectively, as compared to $235,000 and $624,000, respectively, in the corresponding periods in 2014. The increase in cost of sales was driven primarily by the increase in our product sales. For both the three- and nine-month periods in 2015 and 2014, our cost of sales was between two and four percent of our net product revenue.

Research and development expenses – Research and development expenses include the cost of (1) personnel engaged in development activities, including stock-based compensation, (2) discovery research and pre-clinical studies, (3) clinical trials, including trial preparation, enrollment, site monitoring and data management and analysis expenses, (4) regulatory activities, (5) manufacturing development, including the development and activities to qualify a tablet manufacturing site, (6) acquisition of clinical trial materials and material used in registration and validation batches included in regulatory submissions prior to product approval and (7) the preparation and prosecution of the regulatory submissions related to Korlym and our other product candidates.

Table of Contents

Research and development expenses increased approximately 18.5 percent to $3.6 million for the three-month period ended September 30, 2015 from $3.0 million for the comparable period in 2014. Research and development expenses decreased approximately 22.3 percent to $11.3 million for the nine-month period ended September 30, 2015 from $14.6 million for the comparable period in 2014. The change in costs between the periods was due to the discontinuation of our Phase 3 psychotic depression clinical trial in May 2014 offset by increased spending on development of our new compounds.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
Project	2015	2014	2015	2014
	(in thousands)		(in thousands)	
Development programs:				
Oncology	$ 915	$ 491	$ 2,329	$ 1,704
Cushing's syndrome	151	644	467	1,788
Psychotic depression	68	555	282	5,772
Selective cortisol modulators	1,137	847	5,566	3,601
Unallocated activities, including discovery supportive studies and manufacturing, regulatory and pre-clinical activities	1,145	327	2,107	1,204
Stock-based compensation	196	183	579	514
Total research and development expense	$ 3,612	$ 3,047	$ 11,330	$ 14,583

We expect our research and development expenditures in the remainder of 2015 and beyond to increase as we advance our clinical trials and discoveries.

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 cortisol modulators will depend on the success of our efforts and any difficulties that we may encounter. The development of all of our product candidates is subject to extensive governmental regulation. These factors make it difficult to predict the timing and cost of the further development and approval of our product candidates.

Selling, general and administrative expenses – Selling, general and administrative expenses include (1) the cost of personnel, consultancy, and contractors engaged in administrative and commercialization activities, including stock-based compensation, (2) expenses of third-party vendors used in our commercial activities related to Korlym, including sales, marketing and promotion, market research, 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.

Selling, general and administrative expenses for the three-month period ended September 30, 2015 increased 2.1 percent to $9.3 million from $9.1 million for the comparable period in 2014. Selling, general and administrative expenses for the nine-month period ended September 30, 2015 increased 4.5 percent to $28.1 million from $26.9 million for the comparable period in 2014. The increases were driven primarily by increased staffing and consultancy costs.

Selling, general and administrative expenses included stock-based compensation expense of $1.4 million and $3.9 million for the three- and nine-month periods ended September 30, 2015, respectively, as compared to $1.0 million and $3.3 million, respectively, for the corresponding periods in 2014.

Our selling, general and administrative expenses may increase in 2016 and beyond as our commercial business grows.

Interest and other expense – Interest and other expense for the three- and nine-month periods ended September 30, 2015 was $703,000 and $2.3 million, respectively, as compared to $903,000 and $2.9 million, respectively, for the comparable periods in 2014. These amounts consisted primarily of interest expense related to our Biopharma financing agreement for all periods presented. Interest expense for the remainder of 2015 and future years related to this obligation will decrease from the levels of 2014 as the outstanding balance of the obligation is reduced by the quarterly payments.

Non-GAAP Financial Measures

We prepare our condensed financial statements and footnotes thereto, which are included in Part I, Item 1 of this Quarterly Report on Form 10-Q, in accordance with GAAP. To supplement our financial results presented on a GAAP basis, we use non-GAAP measures of net loss and net loss per share that exclude non-cash expenses related to stock-based compensation expense and the accretion of interest expense under our capped royalty financing transaction. We use these non-GAAP measures to manage our business and believe

Table of Contents

that they 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 measures of net loss and net loss per share we use may be different from, and not directly comparable to, similarly titled measures used by other companies.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(in thousands, except for per share data)			
GAAP net income (loss)	$ (601)	$ (6,006)	$ (7,367)	$ (27,488)
Non-cash expenses:				
Stock-based compensation	1,542	1,210	4,520	3,814
Accretion of interest expense related to long-term obligation	698	895	2,196	2,874
Non-GAAP net income (loss), as adjusted for non-cash expenses	$ 1,639	$ (3,901)	$ (651)	$ (20,800)
GAAP basic and diluted net income (loss) per share	$ (0.01)	$ (0.06)	$ (0.07)	$ (0.27)
Non-GAAP basic and diluted net income (loss) per share, as adjusted for non-cash expenses	$ 0.02	$ (0.04)	$ (0.01)	$ (0.21)
Shares used in computing basic and diluted net income (loss) per share	108,461	101,134	106,104	100,880

Table of Contents

Liquidity and Capital Resources

At September 30, 2015, we had cash and cash equivalents of $36.5 million, compared to $24.2 million at December 31, 2014. We received $17.2 million from warrant exercises by accredited investors, including certain related parties in March 2015. Net cash used in operating activities for the nine-month periods ended September 30, 2015 and 2014 was $1.0 million and $26.0 million, respectively. We used cash in each period primarily for the commercialization of Korlym and for research and development activities. In addition, we made payments under the Biopharma Financing Agreement of $6.4 million and $3.3 million during the nine-month periods ended September 30, 2015 and 2014, respectively.

We are required to make aggregate payments under the Biopharma Financing Agreement of $45.0 million, with $12.3 million paid through September 30, 2015 and an additional payment of $2.8 million made in October 2015. Future individual payment amounts will be variable.

We expect net cash used during the remainder of 2015 and future periods will be significantly lower than in the corresponding periods of 2014 as cash generated from the sales of Korlym will increase and offset our expenditures related to the commercialization of Korlym, the continuation of our Phase 1/2 trial of Korlym for triple-negative breast cancer, development of our selective cortisol modulators and payments under our Biopharma Financing Agreement.

Based on our current plans, we expect that we will reach cash-flow breakeven without needing to raise additional funds. However, we may choose to raise additional funds to finance our strategic priorities. We cannot be certain that additional funding will be available on acceptable terms or at all. Further, any additional equity financing may be dilutive to stockholders, and any debt financing, if available, may involve restrictive covenants. If we obtain funds through collaborations with others, these arrangements may be on unfavorable terms or may require us to relinquish certain rights to our technologies or product candidates that we would otherwise seek to develop on our own.

Contractual Obligations and Commercial Commitments

Our contractual payment obligations and purchase commitments as of December 31, 2014 are disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014, and have not changed materially during the nine-months ended September 30, 2015.

Off-Balance Sheet Arrangements

None.

Critical Accounting Policies and Estimates

Our financial statements have been prepared in accordance with GAAP. 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, 2014. During the nine months ended September 30, 2015, we did not make any significant changes to our critical accounting policies and estimates.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risks as of December 31, 2014 are disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014, and have not changed materially during the nine-months ended September 30, 2015.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures. Our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of our disclosure controls and procedures, as defined under Rules 13a-15(e) and 15d-15(e) of the Exchange Act as of September 30, 2015. 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.

Table of Contents

Changes in internal control over financial reporting. There were no changes in our internal control over financial reporting during the quarter ended September 30, 2015, 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.

Risks Related to the Commercialization of Korlym

We depend heavily on the success of Korlym. If we are unable to increase revenue 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 revenue and achieve profitability will be solely dependent on the successful commercialization of Korlym. Many factors could hamper our efforts to commercialize Korlym, including:

- an inability to generate sufficient revenue due to low product usage or inadequate insurance coverage and reimbursement;
- competition from Novartis's Signifor and from other companies with greater financial and marketing resources than ours;
- an inability to manufacture Korlym or the active ingredient in Korlym in commercial quantities and at an acceptable cost;
- political concerns relating to other uses of mifepristone, 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.

There are inherent difficulties in predicting the sales volumes of Korlym. Failure to meet revenue expectations of investors could cause our stock price to decline.

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

Physicians will prescribe Korlym only if they determine, based on experience, clinical data, side effect profiles and other factors, that it is preferable to other treatments, 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.

Table of Contents

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

- the rate of adoption of Korlym by physicians and patients;
- 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;
- the competition from alternative treatment methods;
- the product labeling required by the FDA for Korlym; and
- negative publicity concerning Korlym, RU-486, Mifeprex® or mifepristone.

The failure of Korlym to achieve commercial success would prevent us from generating sufficient revenue.

The Orphan Drug designation for Korlym may not prevent competition from companies that develop mifepristone or other compounds for the treatment of Cushing's syndrome. These companies may have significantly more resources than we do. Competition from them could limit our revenue from the commercialization of Korlym for the treatment of Cushing's syndrome or other indications.

Although we have received Orphan Drug designation in the United States and the European Union (EU), we cannot be assured that we will recognize the potential benefits of these designations. Even after an orphan drug is approved for its orphan indication, the FDA or European Medicines Agency (EMA) can subsequently approve a different drug for the same condition if it concludes that the later drug is safer, more effective or makes a major contribution to patient care. In addition, the FDA or EMA may, during the orphan drug exclusivity period, approve the same drug for a different indication or different drug for the same indication. Upon expiration of the orphan drug exclusivity period, we may be subject to competition from manufacturers offering a generic form of Korlym at a lower price, in which case our business could be harmed.

Notwithstanding Korlym's Orphan Drug designation in the United States and the EU, Novartis received approval in both jurisdictions in 2012 to market its somatostatin analogue Signifor for adult patients with Cushing's disease (a subset of Cushing's syndrome that afflicts approximately 70 percent of all Cushing's syndrome patients) for whom pituitary surgery is not an option or has not been curative. Novartis also announced that is undertaking an investigational study of an experimental compound to determine whether it can safely reduce the level of urinary free cortisol in patients with Cushing's disease and to examine the compound's safety and efficacy. Novartis has substantially more resources and experience than we do and may provide significant competition.

We are aware that Laboratoire HRA Pharma (HRA) 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 aware that Strongbridge

Biopharma plc (Strongbridge) has received Orphan Drug designation in the United States and the EU for the use of levoketoconazole to treat Cushing's syndrome. Strongbridge has begun a Phase 3 clinical trial in Europe and the United States for this indication. We are also aware that Exelgyn Laboratories, which operates as a subsidiary of Medi Challenge (Pty) Ltd., received Orphan Drug designation for mifepristone to treat Cushing's syndrome in the EU, but it has stated that it has not yet conducted any clinical trials.

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

The commercial success of our product depends on whether third-party coverage and reimbursement is available. 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 Korlym. Our near-term dependence on the commercial success of Korlym makes us particularly susceptible to cost containment efforts. Accordingly, even though Korlym has been approved for commercial sale, unless government and other third-party payors continue to provide adequate and timely coverage and reimbursement, physicians may not prescribe it and patients may not purchase it. In addition, meaningful delays in insurance coverage for individual patients may increase our costs and reduce our revenues.

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 Korlym or the exclusion from reimbursement programs.

Table of Contents

The Patient Protection and Affordable Care Act (PPACA), which was passed in 2010 included 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; and
- an increase in the number of entities eligible for discounts under the Public Health Service pharmaceutical pricing program.

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

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, due to subsequent legislative amendments to the statute, 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, which 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 next-generation selective cortisol modulators.

To achieve commercial success for any approved product, we must either develop internal sales and marketing capabilities 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. Any delay or failure to develop or maintain the ability to market and sell Korlym would adversely affect the commercialization of the product and 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 expansion of our research and development efforts will strain our administrative, operational and management resources. Growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. To date, we have relied on a small management team, including a number of part-time contributors. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to manage growth effectively.

Table of Contents

To that end, we must be able to:

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

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

Public perception of mifepristone may limit our ability to sell Korlym.

The active ingredient in Korlym, mifepristone, 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 no manufacturing capabilities and we currently depend on third parties, both of which are single-source suppliers, to manufacture the active ingredient and the tablets for Korlym. 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 have no manufacturing capabilities and depend solely on single-source third-parties to manufacture Korlym. We depend on PCAS, a third-party manufacturer, to supply all of the API in Korlym. We depend on AAI, another third-party manufacturer, to produce all of our Korlym tablets. We have entered into long-term agreements with these manufacturers. However, if either of them is unable or unwilling to meet our future requirements, 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.

The facilities used by our contract manufacturers to manufacture our product must be approved by the FDA. 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 (cGMPs). If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict requirements of the FDA or others, they will not be able to 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, we may need to find alternative manufacturing facilities, which would significantly hamper 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 acquiring additional supplies of Korlym.

If we or others identify previously unknown, serious side effects of Korlym or mifepristone, we may be required to perform lengthy additional clinical trials, change the labeling of Korlym or withdraw it from the market.

The FDA's approval of Korlym required 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. The data from this study are currently being analyzed. It also requires us to study drug utilization to better characterize the reporting rates of adverse events associated with the long-term use of Korlym. If we or others identify previously unknown, serious side effects of Korlym or mifepristone:

- regulatory authorities may withdraw their approvals;

Table of Contents

- 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 Korlym or could increase the costs and expenses of commercializing and marketing Korlym.

We may not have adequate insurance to cover our exposure to product liability claims.

We may be subject to product liability or other claims based on allegations that the use of our product 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 strict precautions to ensure that the medicine is not administered to pregnant women. The failure to observe these precautions could result in significant product liability claims.

We have only limited product liability insurance coverage, with limits that we believe to be customary for a company marketing a single 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 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 we were successfully sued for 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 and report on the interactions between Korlym and ketoconazole, a medication which is approved as an anti-fungal agent which is sometimes used "off-label" to treat patients with Cushing's syndrome. It also requires us to conduct a drug utilization study to better characterize the reporting rates of adverse events associated with the long-term use of Korlym.

We are subject to ongoing obligations and continued regulatory review by the FDA and other regulatory authorities in the United States and other countries with respect to the research, testing, manufacturing, labeling, distribution, adverse event reporting, storage, selling, advertising, promotion, recordkeeping and marketing of products. These requirements include submissions of safety and other post-marketing information and reports, annual updates on manufacturing activities and continued compliance with cGMPs, and current good clinical practices (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, untitled letters, 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 New Drug Applications (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

Table of Contents

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.

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

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 market Korlym for treatment of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery and provide promotional materials and training programs to physicians regarding the use of Korlym for this indication. Although we believe our marketing materials and training programs for physicians do not constitute "off-label" promotion of Korlym, the FDA may disagree. If the FDA determines that our promotional materials, training or other activities by our employees or agents constitute "off-label" promotion of Korlym, it could request that we modify our training or promotional materials or other activities or subject us to regulatory enforcement actions, including the issuance of an untitled letter, 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, with, manufacturers required to submit reports detailing these financial arrangements by the 90th day of each calendar year;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 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

Table of Contents

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.

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.

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. For example, our headquarters are located in the San Francisco Bay Area, which is earthquake-prone, and our specialty pharmacy and warehouses are located in areas that are subject to severe weather conditions. 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.

Risks Related to the Development of Korlym and Our Next-Generation Cortisol Modulators

Clinical drug development is lengthy and expensive and has an uncertain outcome. 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, despite having generated positive Phase 2 clinical trial results, we discontinued our Phase 3 clinical trial of mifepristone for the treatment of psychotic depression 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 1/2 clinical trial of Korlym in combination with chemotherapy to treat triple-negative breast cancer is too small to demonstrate definitively the safety or efficacy of mifepristone for that indication. Even if the trial generates positive results, those results would have to be confirmed in at least one substantially larger, more expensive, and lengthier trial if we are to have sufficient basis for seeking regulatory approval.

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

- delays obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with contract research organizations (CROs), and clinical trial sites;
- obtaining institutional review board (IRB), approval at each site;
- slower than anticipated patient enrollment;

Table of Contents

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 where such trials are being conducted, the Data Safety Monitoring Board for such trial, or the FDA or other regulatory authorities. Such authorities may impose 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 other product candidates, including Korlym for the treatment of triple-negative breast cancer or any other indication.

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 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 prescribed protocol, and the applicable legal, regulatory and scientific standards. 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 Korlym for the treatment of triple-negative breast cancer or other development programs.

We have agreements with the CRO and consultants conducting and managing our Phase 1/2 trial of Korlym for the treatment of triple-negative breast cancer and Phase 1 trial of our selective cortisol modulator, CORT125134, to supervise and monitor clinical site performance and to perform investigator supervision, data collection and analysis for these trials. 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 these 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, Korlym for the treatment of triple-negative breast cancer, or CORT125134 or any of our other next-generation selective cortisol modulators.

Table of Contents

We may be unable to obtain and maintain regulatory approvals for our future product candidates, including Korlym for the treatment of triple-negative breast cancer.

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. Failure can occur at any stage. In order to receive approval from the FDA for a 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. These 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 harm our business and our financial condition.

Future governmental action or changes in FDA 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 Korlym 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 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."

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. Although we have received Orphan Drug designation in the EU, we are not currently seeking to obtain any foreign approvals.

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.

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, 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.

Table of Contents

Korlym 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 Korlym 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 Korlym for Cushing's syndrome are at an early stage. If we fail to identify and develop additional uses for cortisol modulators, we may be unable to market additional products.

To develop additional sources of revenue, we believe that we must identify and develop product candidates or new therapeutic uses for mifepristone. We own or have exclusively licensed issued U.S. patents covering the use of cortisol modulators to treat triple-negative breast cancer, 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, combination steroid and glucocorticoid receptor antagonist therapy, migraine headaches, neurological damage in premature infants, psychotic depression, as well as to increase the therapeutic response to electroconvulsive therapy, and optimize mifepristone levels in plasma serum of patients suffering from mental disorders. We own or have exclusively licensed three additional pending U.S. method of use patent applications covering the use of cortisol modulators to treat castration-resistant prostate cancer, muscular dystrophy, and ALS. We also own a pending patent application for optimizing mifepristone absorption for the treatment of patients suffering from mental disorders. We own seven U.S. composition of matter patents covering specific cortisol modulators, with one additional application pending. We have also filed patent applications in the major international markets.

The use of cortisol modulators may not be effective to treat these or any other indications. Moreover, we could discover that the use of cortisol modulators in these patient populations has unacceptable side effects or is otherwise not safe. Due to the potential for lack of efficacy and side effects inherent in 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.

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 new compounds to the clinic, 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 Cushing's syndrome and, potentially, triple-negative breast cancer. For example, we do not intend to develop mifepristone for mitigation of the weight gain associated with the use of Zyprexa, Risperdal or other atypical antipsychotics, even though we have reported positive results in the proof of concept studies. We may pursue other cortisol modulators 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 their development. 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, marketing considerations, 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 cortisol modulators, 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 managerial, scientific, sales, marketing, and financial personnel, and attracting and retaining additional highly qualified personnel in these areas. We depend substantially on the principal members of our management and scientific staff. We do not have agreements with any of our executive officers that provide for their continued employment with us or employment insurance covering any of our key personnel. Any officer or employee can terminate his or her relationship with us at any time and work for one of our competitors. The loss of these key individuals could result in competitive harm because we could experience delays in our product research, development and commercialization efforts without their expertise.

Table of Contents

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.

A break-down or breach of our information technology systems could subject us to liability or interrupt the operation of our business.

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 Korlym for the treatment of triple-negative breast cancer or other indications or for the development and commercialization of our proprietary, selective cortisol modulators. 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 Korlym for the treatment of triple-negative breast cancer and of our proprietary, selective cortisol modulators in various indications. We may also raise additional funds for other research and development activities, including clinical trials, and working capital and for other general corporate purposes, or to acquire or invest in businesses, products and technologies that are complementary to our own.

Factors affecting our liquidity include the following:

- the pace at which physicians adopt Korlym as a treatment;
- the willingness of insurance companies and the government payors to provide coverage for Korlym;
- the costs and timing of site selection and enrollment of our clinical trials;
- the results of our research efforts and clinical trials;
- the timing and outcome of our Phase 1/2 clinical trial of Korlym for the treatment of triple-negative breast cancer and further clinical development related to this indication;
- the outcome of our planned Phase 2 clinical trials of CORT125134 and further clinical development of that compound;
- changes in our research and development plans for our other proprietary, selective cortisol modulators;
- the need to perform additional clinical trials and other supportive studies;
- actual or anticipated fluctuations in our operating results and changes in our growth rates, and
- developments or disputes concerning patents or proprietary rights, including announcements of claims of infringement, interference or litigation against us or our licensors.

Consequently we may need additional funds. In addition, we may choose to raise additional capital due to favorable 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. 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

Table of Contents

financing could cause further dilution. 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 we may incur losses in the future.

We have financed our operations and internal growth primarily through private placements of preferred and common stock, the public sale of common stock, our financing agreement with Biopharma and revenue from the sale of Korlym. We have incurred losses in each year since our inception in 1998. As of September 30, 2015, we had an accumulated deficit of $331.4 million. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for mifepristone and our next generation cortisol modulators, 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 commercialization of Korlym, offset by our net product revenue. We may continue to incur net losses as we continue our mifepristone and new compounds discovery and clinical development programs, apply for regulatory approvals, acquire and/or develop treatments in other therapeutic areas, expand sales and marketing capabilities and our operations.

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 cortisol modulators 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 Korlym 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. 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 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 cortisol modulators 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 arise, we may attempt to acquire other technologies or product candidates that are complementary to our operating plan. We currently have no commitments, agreements or plans for any acquisitions. Acquiring rights to another 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 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 cortisol modulators, subject to certain quarterly caps, as well as an un-capped 20 percent of any upfront, milestone or other

Table of Contents

contingent payments we receive with respect to Covered Products, until such payments to Biopharma total $45.0 million, at which point the obligation will extinguished.

Pursuant to this agreement, we may not: (i) incur indebtedness greater than the sum of earnings before interest, taxes, depreciation and amortization, including such items as non-cash stock-based compensation, for the four calendar quarters preceding such incurrence, which we refer to as the Indebtedness Covenant; (ii) pay a dividend or other cash distribution, unless we have cash and cash equivalents in excess of $50.0 million after such payment; (iii) amend or restate our certificate of incorporation or bylaws unless such amendments or restatements do not affect Biopharma's interests under the transaction; and (iv) encumber any of the collateral securing our performance under the agreement.

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

Upon a Corcept change of control transaction, as defined in the agreement, Biopharma will be automatically entitled to receive any amounts not previously paid, up to our maximum repayment obligation of $45.0 million. As defined in the agreement, "Change of Control" includes, among other things, (i) a greater than 50 percent change in the ownership of Corcept, (ii) certain changes in Board composition of Corcept and (iii) the licensing of Korlym to a third party for sale in the United States.

To secure our obligations under the agreement, we granted Biopharma a security interest in our rights in patents, trademarks, trade names, domain names, copyrights, know-how and regulatory approvals related to the Covered Products, all books and records relating to the foregoing and all proceeds of the foregoing, which we refer to as the Collateral. If we (i) fail to deliver a royalty payment when due and do not remedy that failure within 30 days, (ii) fail to maintain a first-priority perfected security interest in the Collateral in the United States and do not remedy that failure within five business days of receiving notice of such failure or (iii) become subject to an event of bankruptcy, then Biopharma may attempt to recover up to $45.0 million (after deducting any payments we have already made).

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

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

Risks Relating to Our Intellectual Property

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

Our success depends in part on our ability to obtain and maintain adequate patent protection for the use of Korlym for the treatment of triple-negative breast cancer and other potential uses of cortisol modulators. If we do not adequately protect our intellectual property, competitors may be able to use our intellectual property and erode our competitive advantage.

We own 18 issued U.S. method of use patents and have exclusively licensed five issued U.S. method of use patents. We have five U.S. method of use patent applications pending for our next generation selective cortisol modulators. We also own seven composition of matter patents. We have applied, and will continue to apply, for patents covering our product candidates as we deem appropriate. We have 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 cortisol modulators, including mifepristone, in the treatment of psychotic depression, cocaine-induced psychosis and early dementia, including early Alzheimer’s disease. We have also exclusively licensed from the University of Chicago one issued U.S. patent for the use of cortisol modulators in the treatment of triple-negative breast cancer, along with a continuation application, and a second patent family with applications in the US and Europe having claims directed to the use of cortisol modulators to treat castration-resistant prostate cancer.

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

Table of Contents

noncompliant with our obligations under our agreements, we may lose the right to commercialize mifepristone for the treatment of psychotic depression, cocaine-induced psychosis, early dementia, triple-negative breast cancer and castration-resistant prostate 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 psychotic depression, cocaine-induced psychosis or early dementia. If the University of Chicago were to terminate our licenses, we may not be able to commercialize cortisol modulators for the treatment of triple-negative breast cancer or castration-resistant prostate cancer.

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

Our presently pending and future patent applications may not issue as patents, and any patent issued to us may be challenged, invalidated, held unenforceable or circumvented. For example, the arguments presented by Akzo Nobel could be raised in the United States either before the U.S. Patent and Trademark Office or in a court of law. Furthermore, the claims in patents which we own or have licensed, or which we may license 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 successfully asserted an infringement claim against us, we could be forced to pay damages and be 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.

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

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.

The mifepristone patents that we own cover its use, not its composition, which may make it more difficult for us to prove patent infringement if physicians prescribe another manufacturer's mifepristone or if patients acquire mifepristone from other sources, such as the internet or underground market.

We own or have exclusively licensed issued U.S. patents covering the methods of using cortisol modulators to treat a variety of disorders, including triple-negative breast cancer. A method of use patent covers only a specified use of a particular compound, not a compound's composition. Because our patents do not cover the composition of mifepristone, we cannot prevent others from commercializing mifepristone in indications such as triple-negative breast cancer or those set forth in 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.

Table of Contents

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 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 October 30, 2015, our average daily trading volume was approximately 291,329 shares and the intra-day sales prices per share of our common stock on The NASDAQ Stock Market ranged from $2.69 to $7.67. As of October 30, 2015, our officers, directors and principal stockholders controlled 26 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 insurance coverage and reimbursement;
- actual or anticipated timing and results of our clinical trials;
- changes in financial estimates or recommendations by securities analysts or failure of our financial performance to meet the guidance we have provided to the public;
- purchases or sales of our common stock by us, our officers, directors or our stockholders;
- distributions in-kind of our common stock by our venture capital or private equity stockholders, which will increase the supply of our common stock and could decrease its price;
- our cash and short-term investment position;
- 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;
- 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; and

success of additional financing efforts.

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.

Table of Contents

Our stock price may decline if our financial performance does not meet the guidance that we provided to the public, estimates published by research analysts or other investor expectations.

We have provided guidance as to our expected 2015 net product revenue. Our guidance is only an estimate of what management believes is realizable as of the date of the release of such guidance. Our actual results may vary from our guidance and the variations may be material.

There are a number of reasons why we might fail to meet our financial guidance or other expectations about our business, including, but not limited to, the risks and uncertainties described in this report and in our other public filings and public statements. In particular, there are inherent difficulties in predicting the amount of Korlym that will be sold. For example, the rate of physician adoption of Korlym is uncertain. Research analysts who cover our business have put forth a range of revenue estimates, based on their own analyses. We believe research analysts will consider the guidance we have provided as one factor in determining their own annual revenue estimates. Estimating our net revenue for future periods is difficult and you should rely on our guidance and the estimates of research analysts at your own discretion. If, in the future, our operating or financial results for a particular period do not meet our guidance, analyst estimates or the expectations of investors, or if we reduce our guidance for future periods, our stock price may decline.

Research analysts may not continue to provide or initiate coverage of our common stock or may issue negative reports.

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, distributions in-kind of our common stock by our venture capital or private equity stockholders, 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.

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

As of October 30, 2015, our officers, directors and principal stockholders control 26 percent of our common stock. As a result, these stockholders, acting together, will be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders and may prevent or delay a change in control. This significant concentration of share ownership may adversely affect the trading price of our common stock because investors often perceive disadvantages to owning stock in companies with controlling stockholders.

Changes in laws and regulations may significantly increase our costs, which could 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.

Table of Contents

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

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.

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 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.

Table of Contents

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

Table of Contents

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation, as amended (incorporated by reference to Exhibit 3.1 to the registrant's Quarterly Report on Form 10-Q filed on August 9, 2012).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed on September 27, 2007).
10.1†	Consulting Agreement with Anne M. LeDoux, dated July 1, 2015
10.2†	Employment offer letter to Robert S. Fishman dated September 16, 2015
10.3†	Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and Robert S. Fishman, dated September 28, 2015
31.1	Rule 13a-14(a)/15d-14(a) Certifications of Joseph K. Belanoff, M.D., Chief Executive Officer of the registrant.
31.2	Rule 13a-14(a)/15d-14(a) Certifications of G. Charles Robb, Chief Financial Officer of the registrant.
32.1	18 U.S.C. Section 1350 Certifications of Joseph K. Belanoff, M.D., Chief Executive Officer of the registrant.
32.2	18 U.S.C. Section 1350 Certifications of G. Charles Robb, Chief Financial Officer of the registrant.
101	The following materials from the registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, formatted in Extensible Business Reporting Language (XBRL): (i) unaudited Condensed Balance Sheets at September 30, 2015 and December 31, 2014, (ii) unaudited Condensed Statements of Comprehensive Loss for the three- and nine-month periods ended September 30, 2015 and 2014, (iii) unaudited Condensed Statements of Cash Flows for the three-and nine-month periods ended September 30, 2015 and 2014, and (iv) Notes to Condensed Financial Statements.

† Management contract or compensatory plan or arrangement

Table of Contents

SIGNATURES

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

CORCEPT THERAPEUTICS INCORPORATED

Date: November 5, 2015 /s/ Joseph K. Belanoff
Joseph K. Belanoff, M.D.

Chief Executive Officer

Date: November 5, 2015 /s/ G. Charles Robb
G. Charles Robb
Chief Financial Officer

Table of Contents

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