

**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 **June 30, 2017**

or

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

For the transition period from _____ to _____

Commission File Number:
000-50679

CORCEPT THERAPEUTICS INCORPORATED

(Exact Name of Corporation as Specified in Its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T 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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a small reporting company)	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

On July 28, 2017, there were 113,397,801 shares of common stock outstanding at a par value of \$0.001 per share.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CORCEPT THERAPEUTICS INCORPORATED
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except per share data)

	June 30,	December 31,
	2017	2016
	<u>(Unaudited)</u>	<u>(See Note 1)</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 33,623	\$ 51,536
Short-term marketable securities	32,542	—
Trade receivables, net of allowances	9,504	9,860
Inventory	3,089	2,329
Prepaid expenses and other current assets	2,527	1,964
Total current assets	<u>81,285</u>	<u>65,689</u>
Strategic inventory	3,210	2,835
Property and equipment, net of accumulated depreciation	499	205
Long-term marketable securities	1,494	—
Other assets	49	24
Total assets	<u>\$ 86,537</u>	<u>\$ 68,753</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,082	\$ 2,290
Accrued clinical expenses	1,511	1,467
Other accrued liabilities	12,226	8,953
Long-term obligation - current portion	4,573	14,664
Total current liabilities	<u>20,392</u>	<u>27,374</u>
Commitments		
Stockholders' equity:		
Preferred stock, par value \$0.001 per share, 10,000 shares authorized and no shares outstanding at June 30, 2017 and December 31, 2016	—	—
Common stock, par value \$0.001 per share, 280,000 shares authorized and 113,362 and 112,710 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	113	113
Additional paid-in capital	371,282	363,534
Accumulated other comprehensive loss	(17)	—
Accumulated deficit	<u>(305,233)</u>	<u>(322,268)</u>
Total stockholders' equity	<u>66,145</u>	<u>41,379</u>
Total liabilities and stockholders' equity	<u>\$ 86,537</u>	<u>\$ 68,753</u>

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

CORCEPT THERAPEUTICS INCORPORATED

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(Unaudited)

(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Product revenue, net	\$ 35,559	\$ 19,724	\$ 63,158	\$ 35,785
Operating expenses:				
Cost of sales	775	426	1,421	829
Research and development	7,876	5,672	15,052	10,307
Selling, general and administrative	14,113	12,118	29,150	22,549
Total operating expenses	22,764	18,216	45,623	33,685
Income from operations	12,795	1,508	17,535	2,100
Interest and other expense	(98)	(531)	(323)	(1,142)
Income before income taxes	12,697	977	17,212	958
Provision for income taxes	(50)	—	(177)	—
Net income	\$ 12,647	\$ 977	\$ 17,035	\$ 958
Other comprehensive income (loss):				
Net unrealized loss on available-for-sale investments	(5)	—	(17)	—
Total comprehensive income	\$ 12,642	\$ 977	\$ 17,018	\$ 958
Basic net income per common share	\$ 0.11	\$ 0.01	\$ 0.15	\$ 0.01
Diluted net income per common share	\$ 0.10	\$ 0.01	\$ 0.14	\$ 0.01
Weighted-average shares outstanding used in computing net income per share				
Basic	113,249	110,034	113,059	109,848
Diluted	123,011	115,329	122,171	114,448

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

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

	Six Months Ended June 30,	
	2017	2016
Cash flows from operating activities:		
Net income	\$ 17,035	\$ 958
Adjustments to reconcile net income to net cash generated from operations:		
Stock-based compensation	5,906	3,270
Accretion of interest expense	419	1,107
Amortization of debt financing costs	11	11
Depreciation and amortization of property and equipment	22	51
Changes in operating assets and liabilities:		
Trade receivables	356	(3,080)
Inventory	(1,135)	388
Prepaid expenses and other current assets	(563)	(784)
Other assets	(25)	—
Accounts payable	(216)	756
Accrued clinical expenses	44	(208)
Other accrued liabilities	3,273	2,576
Deferred revenue	—	(158)
Net cash provided by operating activities	<u>25,127</u>	<u>4,887</u>
Cash flows from investing activities:		
Purchases of property and equipment	(308)	(29)
Purchases of marketable securities	(34,053)	—
Cash used in investing activities	<u>(34,361)</u>	<u>(29)</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock upon exercise of options and warrants, net of issuance costs	1,842	2,806
Payments related to long-term obligation	(10,521)	(6,310)
Net cash used in financing activities	<u>(8,679)</u>	<u>(3,504)</u>
Net (decrease) increase in cash and cash equivalents	(17,913)	1,354
Cash and cash equivalents, at beginning of period	51,536	40,435
Cash and cash equivalents, at end of period	<u>\$ 33,623</u>	<u>\$ 41,789</u>

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

NOTES TO UNAUDITED CONDENSED CONSOLIDATED 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 that treat severe metabolic, oncologic, and psychiatric disorders by modulating the effect of the stress 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 structurally distinct series of selective cortisol modulators, consisting of more than 300 compounds. We are developing the lead compounds from these series to treat a broad range of disorders.

Basis of Presentation

The accompanying balance sheet as of June 30, 2017 and the statements of comprehensive income for the three and six months ended June 30, 2017 and 2016 and the statements of cash flows for the six months ended June 30, 2017 and 2016 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 six months ended June 30, 2017 are not necessarily indicative of the results that may be expected for the year ending December 31, 2017 or any other period. These financial statements and notes should be read in conjunction with the financial statements for the year ended December 31, 2016 included in our Annual Report on Form 10-K. The accompanying balance sheet as of December 31, 2016 has been derived from audited financial statements at that date.

Principles of Consolidation

Our financial statements include the financial position and results of Corcept Therapeutics UK Limited, our wholly owned subsidiary. Corcept Therapeutics UK Limited was incorporated in the United Kingdom in March 2017, and to date, there have been no material financial transactions or balances related to this entity.

Use of Estimates

The preparation of financial statements in conformity with U.S. 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, sales returns, inventory, allowances for doubtful accounts, accrued liabilities including our bonus accrual, 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 inputs), 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 inputs), then the lowest priority to unobservable inputs, such as our own data about the assumptions that market participants would use in pricing an asset or liability (Level 3 inputs). Fair value is a market-based measurement and should therefore be based on the assumptions that third-party market participants would use in pricing the asset or liability.

Cash and Cash Equivalents and Marketable Securities

We consider all highly liquid investments purchased with original 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 December 31, 2016, all of our funds were held in checking and money market fund accounts maintained at major U.S. financial institutions.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS, continued

Effective January 2017, we invested a portion of our funds in marketable securities, primarily US Treasury securities, commercial paper and corporate notes. We classify our marketable securities as available-for-sale securities and report them at fair value as “cash equivalents” or “marketable securities” on our balance sheet, with related unrealized gains and losses included in stockholders' equity. Realized gains and losses and permanent declines in value are included in “interest and other income” in our statement of comprehensive income.

Concentration of Credit Risk

We are subject to credit risk from our portfolio of cash, cash equivalents and marketable securities. We limit our investments to U.S. Treasury obligations and high-grade corporate debt with less than a 36-month maturity. We are not exposed to any significant concentration of credit from these investments.

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 in that period.

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. We begin capitalizing costs related to the manufacture of a product candidate when we obtain regulatory approval to begin marketing that product.

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 we recorded as a long-term obligation. In return, we were obligated to make payments to Biopharma totaling \$45.0 million. These payments equal a percentage of (i) our net product sales, including sales from any product containing mifepristone or any of our proprietary selective cortisol modulators (Covered Products) and (ii) cash or cash equivalents received from any licensing transaction or co-promotion arrangement involving Covered Products (together, Korlym Receipts). Once we had paid Biopharma a total of \$45.0 million, no more payments would be due and the obligation would be extinguished. We made our final payment to Biopharma, completely satisfying our obligations under the Financing Agreement, in July 2017.

We recognized a portion of each quarterly payment under the Financing Agreement as interest expense, which we determined 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 was an estimate of the amount we expected to pay Biopharma in the following 12 months. We recorded the balance of the outstanding portion of the obligation, if any, as a long-term liability.

Our estimates of the amount and timing of each quarterly payment to Biopharma were uncertain and subject to change, because they depended on our estimates of future Korlym Receipts, which are difficult to predict. Any changes to our assumed payment stream changed the accretion of interest expense and our split between the current and long-term portions of the obligation, although the total we were obligated to pay Biopharma was fixed at \$45.0 million.

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

Net Product Sales

We primarily sell Korlym directly to patients through a specialty pharmacy, Dohmen Life Science Services (Dohmen). Prior authorization and confirmation of coverage by the patient's private or government insurance plan or by a third-party charity is a prerequisite for selling Korlym to a patient. We recognize revenue upon the delivery of Korlym if (i) there is persuasive evidence that an arrangement exists with the customer, (ii) collectability is reasonably assured and (iii) the sales price is fixed or determinable. Prior authorization or confirmation of coverage by the patient's insurance plan or a supporting charitable foundation is a prerequisite to the

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS, continued

sale of Korlym to a patient. In order to conclude that the price is fixed or determinable, we must be able to (i) calculate gross product revenue from a sale and (ii) reasonably estimate the associated net revenue.

We recognize sales to our specialty distributor (SD) at the time of sale. Sales to the SD were less than one percent of our net revenue in the three and six months ended June 30, 2017.

We donate cash to patient support organizations that help patients with financial need pay for the treatment of Cushing's syndrome. We do not include in revenue payments we receive from these organizations.

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

Rebates and Chargebacks: We contract with Medicaid and other government agencies so that Korlym will be eligible for purchase by, or qualify for partial or full reimbursement from, Medicaid and other government programs. We estimate our rebate and chargeback amounts by applying the discount rates applicable to each government-funded program against our sales to patients covered by such programs.

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 determine the amount of such assistance by applying our program guidelines to all eligible sales in the period.

Sales Returns: We deduct from each period's gross revenue the amount of Korlym we estimate will be returned. When estimating future returns, we analyze quantitative and qualitative information including, but not limited to, historical return rates, the amount of product in the distribution channel, the expiration date of the product, current and projected product demand, the introduction of competing products that may erode demand, and broad economic and industry-wide indicators. If we cannot reasonably estimate product returns with respect to a particular sale, we defer recognition of revenue from that sale until we can make a reasonable estimate.

Research and Development

Research and development expenses consist of direct expenses, such as the cost of discovery research, pre-clinical studies, and clinical trials relating to our portfolio of proprietary, selective cortisol modulators, manufacturing development, preparations for submissions to the FDA or other regulatory agencies and related overhead expenses. We expense nonrefundable payments to third-parties as well as the cost of technologies and materials used in research and development as they are incurred.

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

Segment Reporting

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

Stock-Based Compensation

We account for stock-based compensation related to option grants under the fair value method, based on the value of the award at the grant date using the Black-Scholes option valuation model. We recognize this expense over the requisite service period, net of estimated forfeitures. Employee stock-based compensation expense is calculated based on awards ultimately expected to vest and is reduced for estimated forfeitures. Forfeitures are revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates and an adjustment to stock-based compensation expense will be recognized at that time.

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.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS, continued

Recently Adopted Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-15 (Subtopic 205-40), "Presentation of Financial Statements—Going Concern: Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern" ("ASU 2014-15"). We adopted this standard on January 1, 2017. Because we generated cash in 2015 and 2016 and expect to generate cash in 2017, adoption had no impact on our financial statements.

In July 2015, FASB issued ASU No. 2015-11, Simplifying the Measurement of Inventory (ASU 2015-11), which requires certain inventory to be measured at the lower of cost or net realizable value. We adopted this standard on January 1, 2017 and it did not have a material impact on our financial statements.

In November 2015, FASB issued ASU No. 2015-17 (ASU 2015-17) "Balance Sheet Classification of Deferred Taxes," which requires that deferred tax liabilities and assets be classified as noncurrent. We adopted this standard prospectively on January 1, 2017. Because we have a valuation allowance equal to the full amount of our deferred tax assets, adoption did not have a material impact on our financial statements.

In March 2016, FASB issued ASU No. 2016-09, Compensation - Stock Compensation (Topic 718) "Improvements to Employee Share-Based Payment Accounting" (ASU 2016-09), which simplifies accounting for transactions involving shares awarded to employees as part of their stock-based compensation. It requires companies to record excess tax benefits and deficiencies as income tax expenses or benefits instead of including them in additional paid-in capital. At the start of the year they implement the guidance, companies must adjust retained earnings by an amount equal to any previously unrecognized excess tax expenses or benefits. We adopted this guidance on January 1, 2017, at which time we recognized a \$0.7 million deferred tax asset, with a corresponding increase to our deferred tax valuation allowance. We elected to report cash flows related to excess tax benefits as an operating activity on a prospective basis. We will continue to recognize stock compensation expense with estimated forfeitures. Adoption did not have a material impact on our financial statements.

Recently Issued Accounting Pronouncement Not Yet Adopted

In May 2014, FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers," which changes the way companies recognize revenue. We plan to adopt this update using the modified retrospective approach, with the cumulative effect of adoption being recorded to our retained earnings on January 1, 2018. At present, our only source of revenue is the sale of Korlym. Our evaluation of the contracts governing our sales is in progress. Because our arrangements with customers contain variable consideration, we have focused our analysis on how the update will affect our estimate of transaction prices. We are also reviewing our related policies, procedures and controls and will make appropriate changes to them when we adopt the update. We have not completed our assessment of the adoption on our financial statements.

In February 2016, FASB issued ASU No. 2016-02, "Leases" (ASU 2016-02), which requires the recognition of lease transactions with terms longer than 12 months on the balance sheet as "lease liabilities" and "right-of-use assets." We plan to adopt this new standard prospectively on January 1, 2019 and are evaluating the impact on our financial statements. We expect that adoption will increase our "lease liabilities" and "right-of-use assets" equally.

In August 2016, FASB issued ASU No. 2016-15, "Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments." We plan to adopt this standard on January 1, 2018, and do not expect it to have a material impact on our financial statements.

In May 2017 FASB issued ASU No. 2017-09, Stock Compensation (Topic 718): "Scope of Modification Accounting," which changes the accounting for modifications to the terms and conditions of share-based payment awards. We plan to adopt this standard on January 1, 2018 and do not expect it to have a material impact on our financial statements.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS, continued

2. Composition of Certain Balance Sheet Items*Inventory*

The composition of inventory was as follows:

	June 30, 2017	December 31, 2016
	<i>(in thousands)</i>	
Raw materials	\$ 2,962	\$ 1,848
Work in progress	1,293	1,414
Finished goods	2,044	1,902
Total inventory	6,299	5,164
Less strategic inventory classified as non-current	(3,210)	(2,835)
Total inventory classified as current	<u>\$ 3,089</u>	<u>\$ 2,329</u>

In order to be prepared for potential demand for Korlym and because we rely on single-source manufacturers of both the API for Korlym and Korlym tablets, we have purchased significant inventory of these materials. We classify inventory we do not expect to use within 12 months of the balance sheet date as "Strategic Inventory," a long-term asset.

Other Accrued Liabilities

Other accrued liabilities consisted of the following:

	June 30, 2017	December 31, 2016
	<i>(in thousands)</i>	
Government rebates	\$ 5,556	\$ 3,426
Accrued compensation	5,002	4,702
Commercialization costs	370	308
Legal fees	297	164
Professional fees	521	34
Other	480	319
Total other accrued liabilities	<u>\$ 12,226</u>	<u>\$ 8,953</u>

3. Available-for-Sale Securities and Fair Value Measurements

Our available-for-sale securities included:

	Fair Value Hierarchy Level	Estimated Fair Value	
		June 30, 2017	December 31, 2016
		<i>(in thousands)</i>	
Corporate bonds	Level 2	\$ 16,142	\$ —
Commercial paper	Level 2	14,006	—
U.S. treasury securities	Level 1	6,686	—
Money market funds	Level 1	10,854	31,605
Total Marketable securities		<u>\$ 47,688</u>	<u>\$ 31,605</u>
Classified as:			
Cash equivalents		\$ 13,652	\$ 31,605
Short-term marketable securities		32,542	—
Long-term marketable securities		1,494	—
Total marketable securities		<u>\$ 47,688</u>	<u>\$ 31,605</u>

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS, continued

The estimated fair value of marketable securities is based on quoted market prices for these or similar investments obtained from a commercial pricing service. The fair value of marketable securities classified within Level 2 is based upon inputs that may include benchmark yields, reported trades, broker/dealer quotes and issuer spreads. At June 30, 2017, our accumulated other comprehensive loss on our balance sheets consisted of net unrealized losses on available-for-sale investments of \$17,000 and zero at June 30, 2017 and December 31, 2016, respectively.

As of June 30, 2017, all our marketable securities had maturities of less than two years. The weighted-average maturity of our holdings was four months. None of our marketable securities changed from one fair value hierarchy to another during the three and six months ended June 30, 2017.

4. Long-Term Obligation

As discussed in Note 1, *Basis of Presentation and Summary of Significant Accounting Policies, Long-term Obligation*, under the Financing Agreement with Biopharma we made payments to Biopharma calculated as a percentage of our Korlym revenue. Biopharma's right to receive payments expired once it received \$45.0 million. To secure our obligation, we granted Biopharma a security interest in our patents, trademarks, trade names, domain names, copyrights, know-how, books, records and regulatory approvals related to the Covered Products and any proceeds from them. Through June 30, 2017, we paid Biopharma \$40.4 million. We extinguished our obligations under the Financing Agreement in July 2017 with a final payment of \$4.6 million.

We recorded interest expense of \$149,000 and \$419,000 for the three and six months ended June 30, 2017, respectively, and \$523,000 and \$1.1 million for the three and six months ended June 30, 2016, respectively and total accreted interest of \$15.0 million for the period from August 2012 through June 30, 2017.

The following table provides a summary of the payment obligations under the Financing Agreement as of June 30, 2017 and December 31, 2016, utilizing the payment assumptions discussed above:

	June 30, 2017	December 31, 2016
	<i>(in thousands)</i>	
Total repayment obligation	\$ 45,000	\$ 45,000
Less interest in future periods	(37)	(456)
Less unamortized financing costs	(3)	(14)
Less payments made	(40,387)	(29,866)
Less current portion	(4,573)	(14,664)
Long-term obligation, net of current portion	<u>\$ —</u>	<u>\$ —</u>

We capitalized \$140,000 of issuance costs related to the Financing Agreement, which we amortized over the term of the obligation, based on the assumptions discussed above. At June 30, 2017 and December 31, 2016, the unamortized issuance costs were approximately \$3,000 and \$14,000, respectively, and are included in "long-term obligation," netted against debt on our balance sheets.

5. Lease obligations

In February 2016, we extended the lease for our office space through 2019 and added more space. Effective May 1, 2016, we terminated our lease early and replaced it with a new one effective through March 31, 2019. On June 1, 2017, we amended that lease to add more space. Rent expense for the three months ended June 30, 2017 and 2016 was \$256,000 and \$218,000, respectively. Rent expense for the six months ended June 30, 2017 and 2016 was \$507,000 and \$394,000, respectively.

As of June 30, 2017, future minimum lease payments under non-cancelable operating leases were as follows:

	Lease Payments
2017 (remainder)	\$ 528
2018	1,256
2019	314
Thereafter	—
Total	<u>\$ 2,098</u>

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS, continued

6. 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). On February 10, 2017, our Board of Directors authorized an increase in the shares available for grant under the 2012 Plan by 4.5 million shares in the number of shares available for issuance under the 2012 Plan.

During the six months ended June 30, 2017, we issued an aggregate of 652,000 shares of our common stock upon the exercise of stock options.

The following table summarizes our stock-based compensation:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	<i>(in thousands)</i>		<i>(in thousands)</i>	
Research and development	\$ 850	\$ 272	\$ 1,503	\$ 558
Selling, general and administrative	2,355	1,384	4,403	2,712
Total stock-based compensation	<u>\$ 3,205</u>	<u>\$ 1,656</u>	<u>\$ 5,906</u>	<u>\$ 3,270</u>

7. Net Income Per Share

Basic and diluted net income per share is computed by dividing the net income by the weighted-average number of common shares outstanding during the period. The number of dilutive shares of common stock resulting from the potential exercise of stock options was determined using the treasury stock method. The computation of net income per share for each period, including the number of weighted-average shares outstanding, is shown in the statements of comprehensive income.

The following table shows the computation of net income per share for each period:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	<i>(in thousands)</i>		<i>(in thousands)</i>	
Numerator:				
Net income	\$ 12,647	\$ 977	\$ 17,035	\$ 958
Denominator:				
Weighted-average shares used to compute basic net income per share	113,249	110,034	113,059	109,848
Dilutive effect of employee stock options	9,762	5,295	9,112	4,600
Weighted-average shares used to compute diluted net income per share	123,011	115,329	122,171	114,448
Net income per share attributable to common stockholders				
Basic	<u>\$ 0.11</u>	<u>\$ 0.01</u>	<u>\$ 0.15</u>	<u>\$ 0.01</u>
Diluted	<u>\$ 0.10</u>	<u>\$ 0.01</u>	<u>\$ 0.14</u>	<u>\$ 0.01</u>

On a weighted-average basis, 4.1 million and 4.2 million stock options outstanding during the three and six months ended June 30, 2017, respectively; 5.2 million and 5.9 million stock options outstanding during the three and six months ended June 30, 2016, respectively, were excluded from the computation of diluted net income per share because including them would have reduced dilution.

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

	June 30,	
	2017	2016
	<i>(in thousands)</i>	
Stock options outstanding	21,306	18,573

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS, continued

8. Income taxes

Our quarterly income taxes reflect our estimate of the corresponding year's annual effective tax rate. We recorded an income tax expense of \$50,000 and \$177,000 during the three and six months ended June 30, 2017, respectively, compared to no income tax benefit or expense for the three and six months ended June 30, 2016. Income tax expenses increased due primarily to income tax in states where we do not have enough tax credits or net operating loss carryforwards to fully offset our estimated tax liabilities.

We recorded a full valuation allowance against all our net deferred tax assets at both June 30, 2017 and December 31, 2016. We intend to continue maintaining a full valuation allowance on our deferred tax assets until there is sufficient evidence to support the reversal of all or some portion of these allowances. However, there is a reasonable possibility that within the next year sufficient positive evidence may become available to reach a conclusion that a portion of the valuation allowance will no longer be needed. As such, we may release a portion of its valuation allowance against our deferred tax assets within the next 12 months. This release would result in the recognition of certain deferred tax assets and a decrease to income tax expense for the period such release is recorded.

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 II, 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 engaged in the discovery, development and commercialization of drugs that treat severe metabolic, oncologic and psychiatric disorders by modulating the effects of the hormone cortisol. Elevated levels and abnormal release patterns of cortisol are implicated in a broad range of human disorders. Since our inception in 1998, we have been developing mifepristone, a compound that modulates the effects of cortisol by acting as a competitive antagonist at the glucocorticoid receptor (GR). We have also discovered three structurally distinct series of proprietary, selective cortisol modulators, all of which share mifepristone's affinity for GR but, unlike mifepristone, do not bind to the progesterone receptor and so do not cause effects associated with progesterone receptor antagonism. Both pre-clinical and clinical development of the lead compounds from these series are in progress.

In 2012, the United States Food and Drug Administration (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.

We are conducting two clinical trials of our proprietary selective cortisol modulator, CORT125134. One trial is investigating CORT125134 as a treatment for patients with Cushing's syndrome. The second trial is investigating the combination of CORT125134 and nab-paclitaxel (Celgene Corporation's drug, Abraxane®) as a treatment for patients with a variety of solid-tumor cancers. Both trials are enrolling patients.

We expect that two other compounds from our portfolio of selective cortisol modulators, CORT118335 and CORT125281, will enter Phase 1 trials in 2017.

Cushing's Syndrome

Background. Cushing's syndrome is caused by prolonged exposure of the body's tissues to high levels of the stress hormone cortisol. It is relatively uncommon and most often affects adults aged 20 to 50. An estimated 10 to 15 of every one million people are newly diagnosed with this syndrome each year, resulting in approximately 3,000 new patients and an estimated 20,000 patients with Cushing's syndrome in the United States, approximately half of whom are cured by surgery.

Korlym to Treat Patients with Cushing's Syndrome. We have received Orphan Drug designation from the FDA for Korlym for the treatment of patients with endogenous Cushing's syndrome. Drugs that receive Orphan Drug designation receive seven years of marketing exclusivity for the approved indication from the date of drug approval, as well as tax credits for clinical trial costs, marketing application filing fee waivers and assistance from the FDA in the drug development process.

We first made Korlym available to patients on a commercial basis in April 2012. We sell Korlym using experienced sales representatives, who target U.S. endocrinologists who care for a large portion of the patients with Cushing's syndrome. We also reach patients directly through web-based initiatives and interactions with patient groups. Because a large percentage of the people who suffer from Cushing's syndrome remain undiagnosed or are inadequately treated, we have developed and continue to refine and expand programs to educate the medical community and patients about diagnosis of this syndrome and to increase awareness regarding the role of cortisol modulators to treat the disease. In addition, we have a field-based force of medical science liaisons.

We use a specialty pharmacy and a specialty distributor to distribute Korlym and provide logistical support. We have retained a vendor to help patients with the reimbursement process and to administer our financial assistance programs for uninsured or under-insured patients. We donate money to independent charitable foundations. These organizations, along with our own programs, help us ensure that no patient with Cushing's syndrome is denied access to Korlym for financial reasons.

CORT125134 to Treat Patients with Cushing's Syndrome. We are enrolling patients in a Phase 2 trial of our proprietary, selective cortisol modulator, CORT125134, to treat patients with Cushing's syndrome. CORT125134 shares Korlym's affinity for GR. Data from the compound's Phase 1 trial showed that it can prevent the effects of the steroid prednisone, a commonly-used GR agonist, on serum osteocalcin, white blood cell counts, glucose metabolism and expression of the FKBP5 gene – a marker of GR activation. Modulating the effect of prednisone is important because it is a strong surrogate for modulation of cortisol – the essential quality of an effective treatment for patients with Cushing's syndrome. Unlike Korlym, CORT125134 has no affinity for the progesterone receptor.

We are developing a CLIA-validated assay to measure FKBP5 gene expression that we believe will enable physicians to more easily identify new patients with hypercortisolism and better treat patients already in their care.

Oncology

Background. A range of tumor-types express GR and are potential targets for cortisol modulation therapy, among them triple-negative breast, ovarian, castration-resistant prostate, cervical, and pancreatic cancers, as well as sarcoma and melanoma.

Korlym to Treat Patients with Solid-Tumor Cancers. In December 2016, we announced the results of our Phase 1/2 trial of Korlym in combination with eribulin (Eisai Inc.'s drug, Halaven®) to treat patients with metastatic triple-negative breast cancer. The trial studied 21 patients with GR positive tumors, one with GR negative tumors and one with tumors whose GR status was not known. As determined using the Response Evaluation Criteria in Solid Tumors (RECIST), efficacy results were as follows: four patients exhibited a partial response, defined as a 30 percent or greater reduction in tumor size; eight had stable disease; and 11 had progressive disease. Six patients achieved progression-free survival (PFS) longer than the upper bound of the 95% confidence interval for PFS (15 weeks) in patients receiving Halaven® monotherapy in a comparable population (Aogi et al., *Annals of Oncology* 23: 1441-1448, 2012). Median PFS in the trial was 11.1 weeks – compared to 7.2 weeks in the Halaven monotherapy study reported by Aogi. We believe that the addition of Korlym to chemotherapy warrants further study. University of Chicago investigators are leading a 64-patient double-blind, placebo-controlled, multi-center trial of Korlym combined with Abraxane to treat patients with triple-negative breast cancer.

CORT125134 to Treat Patients with Solid-Tumor Cancers. We are conducting a Phase 1/2 trial of Abraxane in combination with CORT125134 to treat any solid-tumor cancer suitable for treatment with Abraxane. Once we identify a recommended dose of this combination, we will open 20-patient cohorts to test the combination's efficacy in one or more solid-tumor cancers. Our likely initial targets will be pancreatic, triple-negative breast and ovarian cancer. Other possible indications include cervical cancer and sarcoma. We may choose to evaluate CORT125134 in combination with other cancer therapies, including immunotherapy, to treat solid tumors.

Our Other Selective Cortisol Modulators

CORT125134 is the lead compound in our portfolio of proprietary selective cortisol modulators, which consists of three structurally distinct series. All of these compounds, like Korlym, potentially block GR but do not block the progesterone, estrogen or androgen receptors. In addition to our findings with CORT125134, several of our new compounds have demonstrated positive results in animal or in vitro models of cortisol modulation. We are advancing the most promising of these compounds towards the clinic and expect to begin clinical trials of CORT118335 and CORT125281 in 2017. CORT118335 is a potential medication for fatty-liver disease, anti-psychotic-induced weight gain and other metabolic disorders. CORT125281 is a candidate for the treatment of castration-resistant prostate cancer and other indications.

The United States Patent & Trademark Office (USPTO) and the European Patent Office (EPO) have issued to us composition of matter patents related to our selective cortisol modulators. We own nine U.S. composition of matter patents, and have one U.S. composition of matter patent application pending. We own 21 U.S. method of use patents and have exclusively licensed seven issued U.S. method of use patents. We have seven U.S. method of use patent applications pending covering the use of mifepristone or our next-generation selective cortisol modulators. In addition, we have been issued foreign method of use patents and composition of matter patents around the world. We have applied, and will continue to apply, for patents covering our product candidates as we deem appropriate. We have filed, and will continue to file, where we deem 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: three issued U.S. patents for the use of cortisol modulators in the treatment of triple-negative breast cancer, one issued U.S. patent covering the use of cortisol modulators to treat castration-resistant prostate cancer, and a second U.S. patent application covering the treatment of prostate cancer.

Results of Operations

Net Product Revenue – Net product revenue is gross product revenue from sales to our customers less deductions for estimated government rebates and chargebacks.

Net product revenue was \$35.6 million and \$63.2 million for the three and six months ended June 30, 2017, respectively, as compared to \$19.7 million and \$35.8 million in the corresponding periods in 2016. These increases were driven by the increase in our sales volume and price increases.

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

Cost of sales was \$775,000 and \$1.4 million for the three and six months ended June 30, 2017, respectively, as compared to \$426,000 and \$829,000 for the corresponding periods in 2016. For each of the three and six months ended June 30, 2017, cost of sales was 2.2 percent of net product revenue, compared to 2.2 percent and 2.3 percent in the corresponding periods of 2016. Cost of sales slightly declined as a percentage of net product revenue for the three and six months ended June 30, 2017 due to reduced manufacturing costs and increases in the price of Korlym. Cost of sales increased for the three and six months ended June 30, 2017 due to greater sales volumes.

Research and development expenses – Research and development expenses include the cost of (1) retaining and compensating development personnel, (2) clinical trials, (3) discovery research and pre-clinical studies, (4) drug product for use in clinical trials and to support regulatory submissions, (5) the development of drug formulations and manufacturing processes and (6) regulatory activities.

Research and development expenses increased 38.9 percent to \$7.9 million for the three months ended June 30, 2017 compared to \$5.7 million for the three months ended June 30, 2016. Research and development expenses increased 46.0 percent to \$15.1 million for the six months ended June 30, 2017 from \$10.3 million for the comparable period in 2016. These increases were due primarily to the advancement of CORT125134 and the hiring of additional clinical development employees.

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

Project	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	<i>(in thousands)</i>		<i>(in thousands)</i>	
Development programs:				
Oncology	\$ 1,238	\$ 1,309	\$ 2,579	\$ 2,498
Cushing's syndrome	1,933	906	3,384	1,605
Psychotic depression	—	1	—	1
Pre-clinical selective cortisol modulators	2,747	1,800	5,400	3,584
Unallocated activities, including pre-clinical, manufacturing and regulatory activities	1,108	1,384	2,186	2,061
Stock-based compensation	850	272	1,503	558
Total research and development expense	<u>\$ 7,876</u>	<u>\$ 5,672</u>	<u>\$ 15,052</u>	<u>\$ 10,307</u>

Research and development expenses in 2017 and thereafter will depend on the outcomes of our pre-clinical and clinical trials and our development plans. We expect research and development spending for the rest of 2017 to be higher than it was in the corresponding period of 2016 as we advance our research and development programs.

Many factors affect the cost and timing of pre-clinical and clinical programs, including inconclusive results, slow patient enrollment, adverse side effects, unforeseen difficulties in the formulation or manufacture of study drugs and their real or perceived lack of efficacy or safety. Clinical development is also subject to extensive government regulation. These factors make it difficult to predict the timing and cost of development activities.

Selling, general and administrative expenses – Selling, general and administrative expenses include (1) compensation of employees, consultants and contractors engaged in commercial and administrative activities, (2) the cost of vendors that support commercial activities and (3) legal and accounting fees.

Selling, general and administrative expenses for the three months ended June 30, 2017 increased 16.5 percent, to \$14.1 million, from \$12.1 million for the comparable period of 2016. This increase was primarily due to the growth of our sales organization. Selling, general and administrative expenses for the six months ended June 30, 2017 increased 29.3 percent, to \$29.2 million, from \$22.5 million for the comparable period in 2016.

We expect our selling, general and administrative expenses to be higher in the remainder of 2017 than in the corresponding period of 2016 due to the increased scope of our commercial activities. Selling, general and administrative activities for the rest of 2017 and future years will depend on the cost of our commercial and clinical development efforts.

Interest and other expense – Interest and other expense for the three and six months ended June 30, 2017 was \$98,000 and \$323,000, respectively, compared to \$531,000 and \$1.1 million for the corresponding periods in 2016. In all periods, these amounts

primarily consisted of interest expense related to the Biopharma Financing Agreement. Interest expense for the remainder of 2017 will decrease following the retirement of the Financing Agreement in July 2017.

Provision for income taxes – Our provision for income taxes for the three and six months ended June 30, 2017 was \$50,000 and \$177,000, respectively, which reflects primarily income taxes in states where we have no net operating loss carryforwards. We had no provision for income taxes for the corresponding period in 2016.

Non-GAAP Financial Measures

We prepare our financial statements and footnotes in accordance with GAAP. To supplement our financial results presented on a GAAP basis, we use non-GAAP measures of net income and net income per share that exclude non-cash expenses related to stock-based compensation expense and the accretion of interest expense under the Financing Agreement. We use these non-GAAP measures to manage our business and believe 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 income and net income per share we use may be different from, and not directly comparable to, similarly titled measures used by other companies.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	<i>(in thousands, except for per share data)</i>			
GAAP net income	\$ 12,647	\$ 977	\$ 17,035	\$ 958
Non-cash expenses:				
Stock-based compensation	3,205	1,656	5,906	3,270
Accretion of interest expense related to long-term obligation	149	523	419	1,107
Non-GAAP net income, as adjusted for non-cash expenses	<u>\$ 16,001</u>	<u>\$ 3,156</u>	<u>\$ 23,360</u>	<u>\$ 5,335</u>
Basic net income per share	<u>\$ 0.11</u>	<u>\$ 0.01</u>	<u>\$ 0.15</u>	<u>\$ 0.01</u>
Diluted net income per share	<u>\$ 0.10</u>	<u>\$ 0.01</u>	<u>\$ 0.14</u>	<u>\$ 0.01</u>
Non-GAAP basic net income per share, as adjusted for non-cash expenses	<u>\$ 0.14</u>	<u>\$ 0.03</u>	<u>\$ 0.21</u>	<u>\$ 0.05</u>
Non-GAAP diluted net income per share, as adjusted for non-cash expenses	<u>\$ 0.13</u>	<u>\$ 0.03</u>	<u>\$ 0.19</u>	<u>\$ 0.05</u>
Weighted-average shares outstanding shares used in computing net income per share				
Basic	<u>113,249</u>	<u>110,034</u>	<u>113,059</u>	<u>109,848</u>
Diluted	<u>123,011</u>	<u>115,329</u>	<u>122,171</u>	<u>114,448</u>

Liquidity and Capital Resources

Until 2016, we incurred net operating losses each year since inception. At June 30, 2017, we had an accumulated deficit of \$305.2 million. Since 2012, we have relied on revenues from the sale of Korlym and proceeds from the sale of common stock and from the Financing Agreement to fund our operations.

Based on our current plans, which include funding our Cushing's syndrome commercial operations, conducting Phase 2 trials of CORT125134 in both Cushing's syndrome and solid tumor cancers and advancing to the clinic CORT125281 and CORT118335, we expect to fund our operations without needing to raise additional funds. We may choose to raise additional funds to finance our strategic priorities. Additional equity financing may be dilutive to stockholders. Debt financing, if available, may involve restrictive covenants. If we obtain funds through collaborations with other companies, these arrangements may be on unfavorable terms or may require us to relinquish rights to our technologies or product candidates that we would otherwise keep.

At June 30, 2017, we had cash, cash equivalents and marketable securities of \$67.7 million, consisting of cash and cash equivalents of \$33.6 million and marketable securities of \$34.1 million, compared to \$51.5 million of cash and cash equivalents at

December 31, 2016. Net cash provided by operating activities for the six months ended June 30, 2017 was \$25.1 million, due to higher sales volumes and a price increase, compared to \$4.9 million for the six months ended June 30, 2016. Net cash used in investing activities for the six months ended June 30, 2017 was \$34.4 million, primarily due to purchases of marketable securities, while net cash used in investing activities for the six months ended June 30, 2016 was \$29,000. Net cash provided by stock option exercises was \$1.8 million for the six months ended June 30, 2017, compared to \$2.8 million for the comparable period of 2016. We made payments under the Financing Agreement of \$10.5 million and \$6.3 million during the six months ended June 30, 2017 and 2016, respectively.

We were required to make payments totaling \$45.0 million under the Financing Agreement. We paid a total of \$40.4 million through June 30, 2017 and a final payment of \$4.6 million in July 2017. No further payments under the Financing Agreement are due.

The cash in our checking account and our marketable securities could be affected if the financial institution holding them were to fail or be subject to adverse conditions in the financial markets. We have never experienced a loss or lack of access to cash.

Contractual Obligations and Commercial Commitments

Our contractual payment obligations and purchase commitments as of December 31, 2016 are disclosed in our Annual Report on Form 10-K for the year ended December 31, 2016, and have not changed materially during the six months ended June 30, 2017.

Off-Balance Sheet Arrangements

None.

Critical Accounting Policies and Estimates

We have prepared our financial statements in accordance with GAAP, which requires us to make estimates regarding our assets, liabilities and expenses. We base our estimates on our experience and on assumptions we believe to be reasonable. Actual results may differ if our assumptions are incorrect or the conditions in which we do business change. Our critical accounting policies and estimates are discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016. During six months ended June 30, 2017, 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 June 30, 2017 are disclosed in our Annual Report on Form 10-K for the year ended December 31, 2016. They have not changed materially during the six months ended June 30, 2017.

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, evaluated our disclosure controls and procedures, as defined under Rules 13a-15(e) and 15d-15(e) of the Exchange Act as of June 30, 2017. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures provide a reasonable level of assurance that the information required to be disclosed in this Quarterly Report on Form 10-Q was (1) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and Form 10-Q and (2) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met.

Changes in internal control over financial reporting. There were no changes in our internal control over financial reporting during the quarter ended June 30, 2017 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 involved from time to time in various legal proceedings arising in the ordinary course of business. Although the outcome of any pending matters, and the amount, if any, of our ultimate liability and any other forms of remedies with respect to these matters, cannot be determined or predicted with certainty, we do not believe that the ultimate outcome of these matters will have a material adverse effect on our business, financial position or results of operations.

ITEM 1A. RISK FACTORS

Investing in our common stock involves significant risks. Before doing so, 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. The risks and uncertainties described below are those that we believe may materially affect us. Of course, there may be others of which we are unaware or incorrectly deem immaterial which become important and harm our business. If any of these risks or uncertainties 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 part or all of your investment.

Risks Related to the Commercialization of Korlym

Failure to generate sufficient revenue from the sale of Korlym® would harm our financial results and would likely cause our stock price to decline.

For the foreseeable future, our ability to generate revenue and fund our commercial operations and development programs will be solely dependent on sales of Korlym. Physicians will prescribe Korlym only if they determine 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 Korlym, even with clinical trial results that show it is a compelling treatment.

Many factors could hamper our efforts to generate Korlym revenue, including:

- the preference of some physicians for familiar, long-standing off-label treatments for Cushing's syndrome or for Novartis' drug, Signifor, for the treatment of Cushing's disease, a subset of patients with Cushing's syndrome;
- competition from non-medical treatment methods, such as surgery and radiation therapy;
- negative publicity and political concerns about Korlym, RU-486, Mifeprex® or mifepristone;
- the availability of private and government insurance coverage; and
- rapid technological change that makes Korlym obsolete.

Failure to generate sufficient Korlym revenue would prevent us from fully funding our planned commercial and clinical activities and would likely cause our stock price to decline.

The Orphan Drug designation for Korlym may not prevent competition from companies that develop 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, we cannot be assured that we will realize the potential benefits of the designation. Even after a drug is approved for its orphan indication, the FDA 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. 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.

In 2012 Novartis received approval in both the United States and the European Union (EU) to market its somatostatin analogue Signifor for adult patients with Cushing's disease (a subset of Cushing's syndrome that accounts for approximately 70 percent of all patients with Cushing's syndrome) for whom pituitary surgery is not an option or has not been curative. In addition, Novartis has received Orphan Drug designation in the United States for the use of the experimental compound osilodrostat to treat Cushing's disease and in the EU to treat Cushing's syndrome. Novartis has begun a Phase 2 clinical trial in Japan investigating the use of this compound to treat Cushing's syndrome due to causes other than Cushing's disease and a Phase 3 clinical trial in the EU investigating its use to treat Cushing's disease. Novartis has substantially more resources and experience than we do and may provide significant competition.

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 began and terminated a Phase 2 clinical trial in Europe and the United States for this indication. 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. 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 has stated that it has not yet conducted any clinical trials.

If we cannot continue to obtain acceptable prices or adequate insurance coverage and reimbursement for Korlym, we will be unable to generate significant revenues.

The commercial success of Korlym depends on whether insurance coverage and reimbursement is available. Government payors, including Medicare, Medicaid and the Veterans Administration, as well as commercial health maintenance organizations and other third-party payors, are increasingly attempting to contain healthcare costs by limiting reimbursement of new medicines. As a result, they may not cover or provide adequate payment for Korlym. Our dependence on the commercial success of Korlym makes us particularly susceptible to cost containment efforts. 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 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.

The Patient Protection and Affordable Care Act (PPACA), which was passed in 2010, substantially changed the way health care is financed by both governmental and private insurers and significantly impacts the U.S. pharmaceutical industry. The PPACA, among other things, expanded Medicaid program eligibility and access to commercial health insurance coverage, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and promoted a new Medicare Part D coverage gap discount program. The PPACA also appropriated additional funding to comparative clinical effectiveness research, although it remains unclear how the research will impact current Medicare coverage and reimbursement or how new information will influence other third-party payor policies.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the PPACA, and we expect there will be additional challenges and amendments to the PPACA in the future, particularly in light of the new presidential administration and U.S. Congress. In addition, Congress could consider subsequent legislation to replace repealed elements of the PPACA. On January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. At this time, the full effect that the PPACA, the Executive Order and any subsequent legislation would have on our business remains unclear. Any new limitations on, changes to, or uncertainty with respect to the ability of individuals to enroll in governmental reimbursement programs or other third-party payor insurance plans could impact demand for Korlym, which in turn could affect our ability to successfully develop and commercialize our products.

Other legislative and regulatory changes have been proposed and adopted in the United States since the PPACA was enacted. These changes included an aggregate reduction in Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013 and will remain in effect through 2025 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. On February 1, 2016, the Centers for Medicare & Medicaid Services, or CMS, published a final rule that revised certain requirements involved in our calculation of prices we report in connection with our participation in government reimbursement programs so that Korlym will be eligible for purchase by, or qualify for partial or full reimbursement from, Medicaid and other government programs. The extent to which this rule may alter our reported prices and estimated rebates and chargebacks under government programs remains unclear.

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.

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 or pharmacy capabilities and depend on third-party vendors to manufacture Korlym and dispense it to patients. We also depend on third-party suppliers to manufacture the API and capsules for CORT125134, CORT118335 and CORT125281. If these third-parties are unable or unwilling to continue to manufacture our drug products or dispense Korlym for us and we are unable to identify qualified replacement vendors and transfer our business to them in a timely manner or if these third-parties fail to comply with FDA or other applicable regulations or their agreements with us or otherwise fail to meet our requirements, our business will be harmed.

PCAS, a third-party manufacturer, supplies all of the API in Korlym. Alcami, another third-party manufacturer, produces all of our Korlym tablets. Dohmen Life Science Services (Dohmen), a specialty pharmacy, dispenses all Korlym we sell directly to patients. We have entered into agreements with these vendors that automatically renew. We rely on other third-parties to manufacture the API and capsules of our selective cortisol modulators, including CORT125134, CORT118335 and CORT125281. If any of these vendors is unable or unwilling to meet our requirements, we may not be able to manufacture or dispense our product in a timely manner. Our arrangements with these manufacturers are terminable by them, subject to notice provisions. Any third-party manufacturer or specialty pharmacy we engage will be subject to regulation by the FDA and other governmental authorities. We do not control these vendors' processes or operations and cannot assure that they will meet applicable regulatory requirements or their contractual obligations to us. Identifying replacements for these vendors and transitioning our business to them would be complex and expensive. Failure to do so in a timely manner would harm our business.

The facilities used by our vendors to manufacture our product and product candidates must be approved by the FDA. We do not control the manufacturing activities 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 Korlym or our product candidates on a timely basis in the quantities that we require or fail to maintain manufacturing capabilities that meet FDA standards, we may exhaust our Korlym inventory and not be able to generate revenue or our clinical development programs may be delayed.

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 Korlym or one of our product candidates has caused adverse effects. Such a claim may damage our reputation by raising questions about Korlym or any of our product candidates' safety and could prevent or interfere 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 product liability insurance with coverage limits we believe to be appropriate for a company marketing a single pharmaceutical product and developing others. However, this insurance may become 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 sued successfully, our liability could exceed our assets.

We are subject to ongoing and continued regulatory review. If we are unable to maintain regulatory approval of Korlym for the treatment of patients with Cushing’s syndrome, 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.

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 information reporting. If we violate any of the FDA’s restrictions or other marketing requirements, the FDA could withdraw its approval.

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, 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 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. Indeed, we cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA’s ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications.

For example, on January 30, 2017, President Trump issued an Executive Order directing all executive agencies, including the FDA, that, for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the “two-for-one” provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the “two-for-one” provisions may apply not only to agency regulations, but also to significant agency guidance documents. In addition, on February 24, 2017, President Trump issued an executive order directing each affected agency to designate an agency official as a “Regulatory Reform Officer” and establish a “Regulatory Reform Task Force” to implement the two-for-one provisions and other previously issued executive orders relating to the review of federal regulations; however, it is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA’s ability to exercise its regulatory authority. If these executive actions impose restrictions on FDA’s ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. Similarly, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may place at risk the FDA marketing approval for Korlym and any other marketing approval that we may obtain, which would adversely affect our business, prospects and ability to 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. 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, including, without limitation, the False Claims Act, 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 Civil Monetary Penalties law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary’s decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- 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, including the federal Physician Payment Sunshine Act, 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. Manufacturers are 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
- 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. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under such laws, it is possible that some of our business activities, including our relationships with physicians and other healthcare providers, some of whom recommend, purchase and/or prescribe our products, and the manner in which we promote our products, could be subject to challenge under one or more of such laws. We are also exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, distributors, and CROs may engage in fraudulent or other illegal activity. While we have policies and procedures in place prohibiting such activity, it is not always possible to identify and deter misconduct by our employees and other third-parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or

losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

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.

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

We store sensitive data on our computer networks and on the networks of third-party vendors, including intellectual property and confidential information relating to our business and employees. Despite the implementation of security measures, our internal computer systems and those of our vendors are subject to the risk of cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. In addition, system failures could cause the loss of valuable clinical trial data or otherwise disrupt our clinical and commercial activities and be expensive and time-consuming to remedy. If a disruption or security breach resulted in the inappropriate disclosure of confidential or proprietary information, we could incur liability and our research, development and commercialization efforts could be delayed or otherwise harmed.

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 our Product Candidates

Clinical drug development is lengthy, expensive and may produce negative study results. Results of earlier studies and trials may not be predictive of future trial results.

Clinical development is a long, expensive and uncertain process. Data obtained from clinical trials is susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The results from early clinical trials may not be predictive of results 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 produced positive results in preclinical studies and initial clinical trials. Many companies have suffered significant setbacks in advanced clinical trials due to lack of efficacy or the adverse safety profile of their medication candidate.

Our current clinical trials are too small to support marketing approvals for the compounds being studied. Even if these trials generate positive results, those results would have to be confirmed in one or more substantially larger, more expensive and lengthier trials before we could seek regulatory approvals.

The commencement and completion of clinical trials may be delayed by many factors beyond our control, including:

- delays obtaining regulatory approval to start a trial;
- obtaining acceptable terms with Clinical Research Organizations (“CROs”) and clinical trial sites;
- obtaining institutional review board (IRB) approval at each site;
- slower than anticipated patient enrollment;
- negative or inconclusive results;
- patient noncompliance with the clinical trial protocol;
- lack of effectiveness or safety observed during the clinical trials;
- negative inspections of our clinical or manufacturing operations by the FDA or other regulatory authorities; and

We could encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the clinical trial sites where these trials are being conducted, the trial's data safety monitoring board, or the FDA or other regulatory authorities. These authorities may suspend or terminate a trial for many reasons, including failure to conduct the trial in accordance with regulatory requirements or our

clinical protocols, negative findings in an inspection by the FDA or other authorities of our clinical trial operations or clinical trial sites, unforeseen safety issues, failure to demonstrate a benefit from using a product candidate, or changes in government regulations.

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 planned. Also, additional trials or studies that we decide are necessary or desirable may delay or prevent the completion of our development programs or increase their cost. Even if we are able to conduct all of the clinical trials and supportive studies that we consider appropriate, we may not receive regulatory approval to market our product candidates.

We depend on third-parties to conduct and manage many of our clinical trials and to perform related data collection and analysis. Failure of these third-parties to successfully carry out their contractual duties or meet expected timelines may prevent or delay regulatory approval for the commercialization of 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. We cannot assure you that upon inspection by a 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 drug 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 effectiveness of those sites. If our clinical investigators and clinical sites fail to enroll a sufficient number of patients or fail to enroll them on schedule, we may be unable to complete our trials as planned, which could delay or prevent us from completing the clinical development of our product candidates.

We have agreements with the CROs and consultants helping to conduct our clinical trials. We may not be able to maintain relationships with these or other CROs and consultants, or with the clinical investigators and clinical sites conducting our trials. If any of our agreements with these third-parties terminate, we may not be able to enter into alternative arrangements on commercially reasonable terms, or at all. If the third-parties on which we rely do not carry out their contractual duties or fail to meet expected deadlines or if the quality or accuracy of the data they obtain is compromised, our clinical trials may be extended, delayed or terminated and we may be unable to obtain regulatory approval for, or successfully commercialize, any of our product candidates.

We may be unable to obtain and maintain regulatory approvals for our product candidates.

We are not permitted to market or promote any products before we receive regulatory approval from the FDA or comparable foreign regulatory authorities. Although we have received FDA approval to market Korlym, we may be unable to maintain such approval. We may not receive regulatory approval for any of our product candidates. Obtaining regulatory approval of a new drug is uncertain, lengthy and expensive. 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 FDA regulations known as "cGMPs." cGMPs include requirements related to production processes, quality control and assurance, and recordkeeping. 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 product sales, and 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, 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.

Failure to obtain regulatory approval in foreign jurisdictions would prevent us from commercializing our product candidates abroad.

We may seek to commercialize our products in international markets on our own or with the help of partners. 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. 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. Although we have received Orphan Drug designation in the EU of Korlym to treat patients with Cushing's syndrome, we are not currently seeking any foreign approvals.

We face competition from companies with financial, technical and marketing resources substantially greater than our own.

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, specialized pharmaceutical firms, universities and public and private research institutions. These competitors, may develop and commercialize medications that are superior to and more cost-effective than ours. We expect competition to intensify as technical advances are made.

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 drug development, obtaining regulatory approvals, manufacturing and commercializing products. They may succeed in developing drugs that are superior to our product candidates, which could render our product candidates obsolete or non-competitive.

Our efforts to discover, develop and commercialize product candidates beyond Korlym for the treatment of patients with Cushing's syndrome are at an early stage and we may fail to successfully commercialize any of them.

To develop additional sources of revenue, we must identify and develop new product candidates or new therapeutic uses for Korlym. Cortisol modulators may not be effective to treat any additional indications. Moreover, we could discover that the use of cortisol modulators has unacceptable side effects or is otherwise not safe. Due to the potential for lack of efficacy and side effects inherent in novel compounds and in new uses for existing medications, we are developing multiple compounds, which will increase our rate of spending, with no assurance that we will be successful in developing drugs that are safe and effective.

We may enter into collaboration arrangements with respect to one or more of our product candidates. Such an arrangement would make us dependent on a collaborative partner for the success of the product candidates covered by the arrangement. Any future collaborative partner may fail to successfully develop or commercialize a product candidate.

We only have significant clinical and commercial experience with mifepristone, the active ingredient in Korlym, and we may determine that mifepristone is not desirable for uses other than for the treatment of patients with Cushing's syndrome. The compounds developed pursuant to our early discovery, preclinical and clinical research programs may fail to become viable product candidates regardless of the resources we dedicate to their development. Even if product candidates are identified, we may abandon further development efforts after expending significant expense and time due to financial constraints, concerns over safety or efficacy, 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.

We will need to increase the size of our organization and we may experience difficulties in managing growth.

The development of our research and development efforts will be constrained by our existing administrative, operational and management resources. Growth will impose significant added responsibilities on members of management, including the need to identify, recruit and retain additional employees. To date, we have relied on a small management team. Our future financial performance and our ability to compete effectively will depend on our ability to manage growth effectively.

To that end, we must:

- manage our sales and marketing efforts, clinical trials, research and development activities and supply chain effectively;
- hire additional management, clinical development, administrative and sales and marketing personnel; and
- develop our administrative, accounting and management information systems and controls.

Our failure to accomplish any of these tasks could harm our business.

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 cause delays in our product research, development and commercialization efforts.

We face intense competition for qualified personnel. Although we believe we have been successful in attracting and retaining qualified personnel, our success may not continue. The inability to attract and retain these personnel could harm our commercial business or delay the discovery, development and commercialization of our product candidates.

Rapid technological change could make our product and product candidates obsolete.

Pharmaceutical technologies advance rapidly. Our future will depend on our ability to maintain a competitive position with respect to these technologies. Korlym and other products we develop may become obsolete or uneconomical before we recover any of the cost of their development. Rapid technological change could make Korlym and our product candidates obsolete, which could harm our business.

Risks Related to Our Capital Needs and Financial Results

We may need additional capital to develop and commercialize Korlym for additional indications or our selective cortisol modulators for any indication. Additional capital may not be available on favorable terms, or at all, which could adversely affect our business.

Our Korlym revenues may be insufficient to fully fund development of our proprietary selective cortisol modulators for any indication or for additional indications for Korlym. We may need to raise funds to support our research and development activities, including clinical trials, for working capital or for other general corporate purposes, or to acquire or invest in businesses, products and technologies.

Factors affecting our ability to generate funds from the sale of Korlym include:

- 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 outcome of clinical trials of Korlym and our other product candidates and the further clinical development of those compounds;
- changes in our research and development plans for Korlym and our other product candidates; and
- disputes concerning patents or proprietary rights, including announcements of claims of infringement, interference or litigation against us or our licensors.

We may also choose to raise additional capital due to 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 additional equity 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 or our product candidates. 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 substantial losses and may incur more.

We finance our operations through revenue from the sale of Korlym. Before 2016, we incurred substantial losses and relied on the public sale of common stock, our Financing Agreement and private placements of preferred and common stock to fund our activities. We may incur additional losses.

Global economic conditions could adversely affect our liquidity and financial condition.

Turbulence in the global financial markets and economies may cause lenders and institutional investors to stop providing credit to businesses such as ours, or to greatly increase its cost, which could adversely affect our liquidity and financial condition.

If our commercial activities do not generate enough cash to fully fund the operation of our business and we are unable to borrow funds or raise 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, 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 products 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 development of our existing business. We may fail to realize the anticipated benefits of any acquired potential product or technology. Acquisitions could dilute our stockholders' ownership interest 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.

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 or Korlym for a new indication.

Patents in the pharmaceutical industry are highly uncertain, involve complex legal and factual questions and are the subject of much litigation. Our product candidates may give rise to claims that our patents are invalid or that we infringe on the rights of others. If it is determined that our product candidates infringe others' patent rights, we may be required to obtain licenses to those rights. If we fail to obtain licenses when necessary, we may have to delay commercializing our product candidates while we attempt to design around the infringed patent. We could fail and may be unable to commercialize our product candidates. If we become involved in intellectual property litigation, we are likely to incur considerable costs. We do not believe that we infringe any patents or other proprietary rights. We are not obligated to pay royalties relating to the use of intellectual property except to Stanford University and the University of Chicago.

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

We bear the costs of prosecuting, protecting and defending the patents we licensed from Stanford and the University of Chicago. To maintain the exclusive license to these patents, we must make milestone and royalty payments to both universities. If we do not comply with our obligations under our licenses, we may lose the right to commercialize cortisol modulators, including mifepristone, for the treatment of psychotic depression, cocaine-induced psychosis, early dementia, triple-negative breast cancer and 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. 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. Our patent claims may not be sufficiently broad to prevent third-parties from producing competing products. The laws of foreign countries in which we may someday compete may not protect our intellectual property to the same extent as the laws of the United States. If we fail to obtain adequate patent protection in other countries for our proprietary technology, our competitors in these countries may produce in these countries competing products based on our technology, which would impair our ability to succeed.

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 infringement. A third-party could require us to obtain a license to use their intellectual property, which we may not be able to do on commercially acceptable terms, or at all. If we become involved in litigation, it could consume a substantial portion of our resources and of management's time. Regardless of the merit of a particular claim, defending a lawsuit is expensive and diverts management's attention from productive business.

Our ability to compete 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 proprietary information. These measures may not provide adequate protection, in which case third-parties could use our proprietary information to diminish our ability to compete. In addition, employees, consultants and others may breach their agreements with us regarding our proprietary information and we may not have adequate remedies for the breach.

The mifepristone patents that we own or license cover the use of mifepristone, not its composition, which may make it more difficult for us to prevent 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 use of cortisol modulators to treat a variety of disorders, including triple-negative breast cancer and castration-resistant prostate cancer. A method of use patent covers only a particular use of a compound, not its composition. Because our patents do not cover the composition of mifepristone, we cannot prevent others from commercializing mifepristone to treat disorders not covered by our method of use patents. The availability of mifepristone for these disorders may enable patients to obtain mifepristone for indications covered by our patents. Although any such "off-label" use would violate our patents, effectively monitoring compliance and enforcing our rights may be difficult and costly. Patients may be able to purchase mifepristone through the internet or underground market. Mifepristone is sold in the United States by Danco Laboratories for the termination of early pregnancy. Although distribution is limited to a single dose provided in the physician's office and covered by other restrictions, we cannot be certain that patients with Cushing's syndrome will not be able to obtain mifepristone from this source or others, should another company receive approval to market mifepristone for another indication.

Risks Related to Our Stock

The market price of our common stock has been and is likely to continue to be subject to wide fluctuations in price in response to various factors, many of which are beyond our control. Opportunities for the sale of shares at any given time may be limited.

We cannot assure that an active trading market for our common stock will exist at any particular 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 July 28, 2017, our average daily trading volume was approximately 743,194 shares and the intra-day sales prices per share of our common stock on The NASDAQ Capital Market ranged from \$5.24 to \$13.25. As of July 28, 2017, our officers, directors and principal stockholders controlled 14 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:

- actual or anticipated variations in our quarterly operating results;
- changes in financial analyst estimates or estimates or recommendations by securities analysts or failure of our financial performance to meet the guidance we have provided to the public;
- actual or anticipated timing and results of our clinical trials;
- sales or distributions in-kind of our common stock by our venture capital or private equity stockholders, which would increase the supply of our common stock and could decrease its price;
- purchases or sales of our common stock by us, our officers, directors or our stockholders;
- trading volume of our common stock;
- actual or anticipated regulatory approvals of our product candidates or of competing products;
- new products or services introduced or announced by us or our competitors;
- our cash and short-term investment position;
- changes in laws or regulations applicable to our product candidates or our competitors' products;
- changes in the expected or actual timing of our competitors' potential development programs;
- announcements of technological innovations by us, our collaborators or our competitors;
- conditions or trends in the biotechnology and pharmaceutical industries;
- changes in the market valuations of similar companies;
- general market and economic conditions;
- 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;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborators or capital commitments; and
- additional financing activities.

All stock markets, 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 these companies. This volatility may significantly reduce the market price of our common stock, regardless of our operating performance. Securities class-action litigation is often instituted against companies following periods of stock market volatility. If instituted against us, such litigation could result in substantial costs and diversion of management's attention.

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 2017 revenue. Our guidance is only an estimate of what management believes is realizable as of the date of the release of such guidance and our actual results may vary materially.

Reasons why we might fail to meet our financial guidance or other investor expectations include, without limitation, the risks and uncertainties described in this report and in our other public filings and public statements. 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 have published a range of revenue estimates, based on their own analyses. The guidance we provided is one factor analysts consider when determining their own estimates. Readers of this report should rely on our guidance and the estimates of research analysts at their own discretion.

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

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 could decline rapidly and significantly. 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.

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 distributions in-kind of our common stock by our venture capital or private equity stockholders, the exercise of stock options by employees, or equity financing by us, the supply of our common stock will increase, which could decrease the share 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, could significantly influence corporate actions.

As of July 28, 2017, our officers and directors control 14 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 statutes and regulations concerning the development, approval, and marketing of medications, 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 Capital 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. 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.

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.

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 the effectiveness of, and provide a management report with respect to, our internal controls over financial reporting. It 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 management's required assessment and report as to the adequacy of our internal control over financial reporting in 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, 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, which could have a material adverse effect on our business, financial position and results of operations and could cause the price 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 our Board of Directors appoints. 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 would be willing to pay for shares of our common stock and result in the market price being lower than it would be without these provisions.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS**Exhibit
Number****Description of Document**

- | | |
|------|--|
| 3.1 | Amended and Restated Certificate of Incorporation, as amended (incorporated by reference to Exhibit 3.1 to the registrant's Quarterly Report on Form 10-Q filed on August 9, 2012). |
| 3.2 | Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed on February 13, 2017). |
| 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 June 30, 2017, formatted in Extensible Business Reporting Language (XBRL): (i) Unaudited Condensed Consolidated Balance Sheets at June 30, 2017 and December 31, 2016, (ii) Unaudited Condensed Consolidated Statements of Comprehensive Income for the three and six month periods ended June 30, 2017 and 2016, (iii) Unaudited Condensed Consolidated Statements of Cash Flows for the six month periods ended June 30, 2017 and 2016, and (iv) Notes to Unaudited Condensed Consolidated Financial Statements. |

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: August 1, 2017

/s/ Joseph K. Belanoff

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

Date: August 1, 2017

/s/ G. Charles Robb

G. Charles Robb
Chief Financial Officer

Exhibit Number	Description of Document
3.1	<u>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).</u>
3.2	<u>Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed on February 13, 2017).</u>
31.1	<u>Rule 13a-14(a)/15d-14(a) Certifications of Joseph K. Belanoff, M.D., Chief Executive Officer of the registrant.</u>
31.2	<u>Rule 13a-14(a)/15d-14(a) Certifications of G. Charles Robb, Chief Financial Officer of the registrant.</u>
32.1	<u>18 U.S.C. Section 1350 Certifications of Joseph K. Belanoff, M.D., Chief Executive Officer of the registrant.</u>
32.2	<u>18 U.S.C. Section 1350 Certifications of G. Charles Robb, Chief Financial Officer of the registrant.</u>
101	The following materials from the registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, formatted in Extensible Business Reporting Language (XBRL): (i) Unaudited Condensed Consolidated Balance Sheets at June 30, 2017 and December 31, 2016, (ii) Unaudited Condensed Consolidated Statements of Comprehensive Income for the three and six month periods ended June 30, 2017 and 2016, (iii) Unaudited Condensed Consolidated Statements of Cash Flows for the six month periods ended June 30, 2017 and 2016, and (iv) Notes to Unaudited Condensed Consolidated Financial Statements.

CERTIFICATION

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

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2017 of Corcept Therapeutics Incorporated;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Joseph K. Belanoff

Joseph K. Belanoff, M.D.
Chief Executive Officer and President
August 1, 2017

CERTIFICATION

I, G. Charles Robb, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2017 of Corcept Therapeutics Incorporated;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ G. Charles Robb

G. Charles Robb
Chief Financial Officer and Secretary
August 1, 2017

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

In connection with the Quarterly Report of Corcept Therapeutics Incorporated (the "Company") on Form 10-Q for the period ended June 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joseph K. Belanoff, M.D., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

/s/ Joseph K. Belanoff

Joseph K. Belanoff, M.D.
Chief Executive Officer and President
August 1, 2017

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

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

In connection with the Quarterly Report of Corcept Therapeutics Incorporated (the "Company") on Form 10-Q for the period ended June 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, G. Charles Robb, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

/s/ G. Charles Robb

G. Charles Robb
Chief Financial Officer and Secretary
August 1, 2017

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