

CORCEPT THERAPEUTICS INC

Form 10-Q

November 02, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2016

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number:

000-50679

CORCEPT THERAPEUTICS INCORPORATED

(Exact Name of Corporation as Specified in Its Charter)

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

149 Commonwealth Drive

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Menlo Park, CA 94025

(Address of principal executive offices, including zip code)

(650) 327-3270

(Registrant's telephone number, including area code)

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

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

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

Large Accelerated Filer

Accelerated Filer

(Do not  
check if a  
smaller  
reporting

Non-accelerated filer

company) Smaller Reporting Company

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

On October 28, 2016, there were 111,031,762 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 BALANCE SHEETS

(In thousands, except per share data)

	September 30, 2016 (Unaudited)	December 31, 2015 (See Note 1)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 47,865	\$ 40,435
Trade receivables	8,236	6,221
Inventory	2,327	1,682
Prepaid expenses and other current assets	1,353	642
Total current assets	59,781	48,980
Strategic inventory	2,980	2,800
Property and equipment, net of accumulated depreciation	145	98
Other assets	24	24
Total assets	\$ 62,930	\$ 51,902
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 4,309	\$ 1,325
Accrued clinical expenses	1,775	1,171
Other accrued liabilities	6,874	3,257
Long-term obligation - current portion	18,725	14,965
Deferred revenue	—	158
Total current liabilities	31,683	20,876
Long-term obligation, net of current portion	—	12,528
Commitments		
Stockholders' equity:		
Common stock, par value \$0.001 per share, 280,000 shares authorized and 110,881		
and 109,642 shares issued and outstanding at September 30, 2016 and December 31,		
2015		
respectively	111	110
Additional paid-in capital	358,001	348,796
Accumulated deficit	(326,865 )	(330,408 )
Total stockholders' equity	31,247	18,498
Total liabilities and stockholders' equity	\$ 62,930	\$ 51,902

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



## CORCEPT THERAPEUTICS INCORPORATED

## CONDENSED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(Unaudited)

(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Product revenue, net	\$21,725	\$13,261	\$57,509	\$35,319
Operating expenses:				
Cost of sales	668	256	1,497	997
Research and development	7,054	3,612	17,360	11,330
Selling, general and administrative	10,931	9,291	33,480	28,086
Total operating expenses	18,653	13,159	52,337	40,413
Income (Loss) from operations	3,072	102	5,172	(5,094 )
Interest and other expense	(487 )	(703 )	(1,629 )	(2,273 )
Net income (loss) and comprehensive income				
(loss)	\$2,585	\$(601 )	\$3,543	\$(7,367 )
Basic and diluted net income (loss) per common				
share	\$0.02	\$(0.01 )	\$0.03	\$(0.07 )
Weighted average shares outstanding used in				
computing net income (loss) per share				
Basic	110,652	108,461	110,118	106,104
Diluted	116,419	108,461	115,163	106,104

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

## CORCEPT THERAPEUTICS INCORPORATED

## CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities:		
Net income (loss)	\$3,543	\$(7,367)
Adjustments to reconcile net income (loss) to net cash generated from (used in)		
operations:		
Stock-based compensation	5,101	4,520
Accretion of interest expense	1,562	2,196
Amortization of debt financing costs	16	20
Depreciation and amortization of property and equipment	72	127
Changes in operating assets and liabilities:		
Trade receivables	(2,015)	(2,611)
Inventory	(825)	703
Prepaid expenses and other current assets	(679)	261
Other assets	—	(11)
Accounts payable	2,984	(146)
Accrued clinical expenses	604	273
Other accrued liabilities	3,617	956
Deferred revenue	(158)	46
Net cash provided by (used in) operating activities	13,822	(1,033)
Cash flows from investing activities:		
Purchases of property and equipment	(119)	(34)
Cash used in investing activities	(119)	(34)
Cash flows from financing activities:		
Proceeds from issuance of common stock upon exercise of options and warrants, net		
of issuance costs	4,073	19,712
Payments related to long-term obligation	(10,346)	(6,443)
Net cash provided by (used in) financing activities	(6,273)	13,269
Net increase in cash and cash equivalents	7,430	12,202
Cash and cash equivalents, at beginning of period	40,435	24,248
Cash and cash equivalents, at end of period	\$47,865	\$36,450

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





CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS

1. Basis of Presentation and Summary of Significant Accounting Policies

Description of Business and Basis of Presentation

Corcept Therapeutics Incorporated was incorporated in the State of Delaware in May 1998, and our 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, and we are developing them to treat a broad range of disorders.

Basis of Presentation

The accompanying unaudited condensed balance sheet as of September 30, 2016 and the condensed statements of comprehensive income (loss) for the three and nine months ended September 30, 2016 and 2015 and the condensed statements of cash flows for the nine months ended September 30, 2016 and 2015 have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016 or any other period. These financial statements and notes should be read in conjunction with the financial statements for the year ended December 31, 2015 included in our Annual Report on Form 10-K. The accompanying balance sheet as of December 31, 2015 has been derived from audited financial statements at that date.

Use of Estimates

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

We evaluate our estimates and assumptions on an ongoing basis, including those related to revenue recognition, inventory, accrued liabilities 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 input), then to quoted prices in non-active markets or in active

markets for similar assets or liabilities, inputs other than quoted prices that are observable for the asset or liability, and inputs that are not directly observable, but that are corroborated by observable market data for the asset or liability (Level 2 input), then the lowest priority to unobservable inputs, for example, our own data about the assumptions that market participants would use in pricing an asset or liability (Level 3 input). Fair value is a market-based measurement, not an entity-specific measurement, and a fair value measurement should therefore be based on the assumptions that market participants would use in pricing the asset or liability.

#### Cash and Cash Equivalents

We consider all highly liquid investments purchased with maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents are carried at fair value as measured using Level 1 inputs, which approximates cost. As of September 30, 2016 and December 31, 2015, all of our funds were held in checking and money market fund accounts maintained at major U.S. financial institutions.

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

Inventory

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

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

We recognize a portion of each quarterly payment under the Financing Agreement as interest expense, which we determine by calculating the interest rate to Biopharma implied by the stream of quarterly payments we expect to make. The amount shown on our balance sheet as the current portion is an estimate of the amount we expect to repay Biopharma in the 12 months following September 30, 2016. We record the balance of the outstanding portion of the obligation, if any, as a long-term liability.

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

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

Net Product Sales

We primarily sell Korlym directly to patients through Dohmen Life Science Services (Dohmen), a specialty pharmacy. Prior authorization and confirmation of coverage by the patients' private or government insurance plan or by a third-party charity is a prerequisite for Dohmen to ship Korlym to a patient. We recognize revenue upon the delivery of Korlym to these patients.

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

Effective January 1, 2016, we recognize sales to our specialty distributor (SD) at the time of sale to the SD. Before that date, we did not recognize these sales until the SD had in turn sold to its customers. Sales to the SD were less than two percent of our revenue in each of the three and nine months ended September 30, 2016.

We donate cash to the National Organization for Rare Disorders ("NORD"), an independent non-profit organization that helps patients with financial need pay for the treatment of Cushing's syndrome. We do not include in revenue payments we receive from NORD.

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

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 calculate the cost of assistance by applying our program guidelines to the eligible sales in the period.

#### Research and Development

Research and development expenses consist of direct expenses, such as the cost of 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.

#### 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 and we recognize expense over the requisite service period, net of estimated forfeitures.

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.

#### Recently Issued Accounting Pronouncement

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09, “Revenue from Contracts with Customers.” The standard states that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In August 2015, the FASB issued ASU No. 2015-14, “Revenue from Contracts with Customers: Deferral of the Effective Date,” which deferred the effective date of ASU No. 2014-09. ASU No. 2014-09 will now be effective for the Company beginning January 1, 2018 and can be

adopted on a full retrospective basis or on a modified retrospective basis. Early application is permitted in 2017. In March 2016, the FASB issued ASU No. 2016-08, "Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations," which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU No. 2016-10, "Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing," which clarifies certain aspects of identifying performance obligations and licensing implementation guidance. In May 2016, the FASB issued ASU No. 2016-12, "Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients," related to disclosures of remaining performance obligations, as well as other amendments to guidance on collectability, non-cash consideration and the presentation of sales and other similar taxes collected from customers. We are evaluating the impact of the adoption of these standards on our Condensed Consolidated Financial Statements.

In August 2014, the FASB issued 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"), which provides guidance about management's responsibility to evaluate whether or not there is substantial doubt about the Company's ability to continue as a going concern and to provide related footnote disclosure. ASU 2014-15 is effective for fiscal years, and interim periods within those fiscal years, ending after December 15, 2016. Early application is permitted. The adoption of this standard had no impact on our Condensed Consolidated Financial Statements.

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

In April 2015, the FASB issued ASU No. 2015-03, Simplifying the Presentation of Debt Issuance Costs (ASU 2015-03), which requires an entity to present such costs in the balance sheet as a direct deduction from the related debt liability rather than as an asset. Amortization of the costs will continue to be reported as interest expense. ASU 2015-03 is effective for fiscal years beginning after December 15, 2015 and interim periods within those fiscal years, with early adoption permitted. The new guidance will be applied retrospectively to each prior period presented. The Company retrospectively adopted ASU 2015-03 as of January 1, 2016, resulting in a \$35,000 decrease to long-term assets and long-term debt as of December 31, 2015 on its consolidated balance sheets. The adoption of this standard had no impact on our Condensed Statement of Comprehensive Income (Loss).

In July 2015, the FASB issued ASU No. 2015-11, Simplifying the Measurement of Inventory (ASU 2015-11), which simplifies the measurement of inventory by requiring certain inventory to be measured at the lower of cost or net realizable value. The amendments in this ASU are effective for fiscal years beginning after December 15, 2016 and for interim periods therein, with early adoption permitted. We do not expect adoption of this standard to have an impact on our Condensed Consolidated Financial Statements.

In November 2015, the FASB issued ASU No. 2015-17 (ASU 2015-17) "Balance Sheet Classification of Deferred Taxes." ASU 2015-17 requires that deferred tax liabilities and assets be classified as noncurrent on the balance sheet. Previous guidance required deferred tax liabilities and assets to be separated into current and noncurrent amounts on the balance sheet. The guidance will become effective for us beginning in the first quarter of 2017 and may be applied either prospectively or retrospectively. Early adoption is permitted. At the time of adoption, we will reclassify current deferred tax amounts on our Consolidated Balance Sheets as noncurrent. As we have a full valuation allowance against its deferred tax assets for all periods presented, the adoption is not expected to have a material impact on our Condensed Consolidated Financial Statements.

In February 2016, the FASB issued ASU No. 2016-02, "Leases" (ASU 2016-02), which increases transparency and comparability among organizations by recognizing all lease transactions (with terms in excess of 12 months) on the balance sheet as a lease liability and a right-of-use asset (as defined). ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with earlier application permitted. Upon adoption, the lessee will apply the new standard retrospectively to all periods presented or retrospectively using a cumulative effect adjustment in the year of adoption. We are evaluating the impact of the adoption of this standard on our Condensed Consolidated Financial Statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation - Stock Compensation (Topic 718) "Improvements to Employee Share-Based Payment Accounting" (ASU 2016-09), which is intended to simplify several aspects of the accounting for share-based payment award transactions. The guidance will be effective for the fiscal year beginning after December 15, 2016, including interim periods within that year. We are evaluating the impact of the adoption of this standard on our Condensed Consolidated Financial Statements.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): "Classification of Certain Cash Receipts and Cash Payments," which addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice. The guidance will be effective for the fiscal year beginning after December 15, 2017, including interim periods within that year. We do not expect adoption of this standard to have an impact on our Condensed Consolidated Financial Statements.

## 2. Composition of Certain Balance Sheet Items

## Inventory

The composition of inventory was as follows:

	September 30, 2016	December 31, 2015
	(in thousands)	
Raw materials	\$2,866	\$ 2,141
Work in progress	3	3
Finished goods	2,438	2,338
Total inventory	5,307	4,482
Less strategic inventory classified as non-current	(2,980)	(2,800 )
Total inventory classified as current	\$2,327	\$ 1,682



## CORCEPT THERAPEUTICS INCORPORATED

## NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

We have one manufacturer for mifepristone, the active pharmaceutical ingredient (API) in Korlym — Produits Chimiques Auxiliaires et de Synthèse SA (PCAS) — and one tablet manufacturer for Korlym — Alcami Corporation (formerly known as AAI Pharma Services Corp.). If either of these companies is unable to manufacture API or Korlym tablets in the quantities and time frames we require, we may not be able to meet customer demand. In order to mitigate these risks, we purchase and hold as “Strategic Inventory” additional quantities of API and Korlym tablets that we do not expect to consume within 12 months following the relevant balance sheet date.

## Other Accrued Liabilities

Other accrued liabilities consisted of the following:

	September 30, 2016	December 31, 2015
	(in thousands)	
Government rebates	\$2,787	\$ 1,663
Accrued compensation	3,380	1,103
Commercialization costs	89	111
Legal fees	140	69
Professional fees	146	220
Other	332	91
Total other accrued liabilities	\$6,874	\$ 3,257

## 3. Long-Term Obligation

As discussed in Note 1, Basis of Presentation and Summary of Significant Accounting Policies, Long-term Obligation, under the Financing Agreement with Biopharma we make payments to Biopharma calculated as a percentage of our Korlym Receipts. Biopharma’s right to receive payments will expire once it has received \$45.0 million. Through September 30, 2016, we have paid Biopharma \$25.4 million, with an additional payment of \$4.4 million made in October 2016. We expect to fully repay this obligation in 2017.

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

We are obligated to make payments as follows:

- 20 percent of our net sales of Covered Products.
- 20 percent of payments received for upfront, milestone or other contingent fees under co-promotion and out-license agreements for Covered Products.
-

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

If there is a Corcept change of control transaction or we license Korlym to a third-party for promotion and sale in the United States, the entire \$45.0 million, less any amounts already paid, will become due.

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

## CORCEPT THERAPEUTICS INCORPORATED

## NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

As discussed in Note 1, Basis of Presentation and Summary of Significant Accounting Policies, Long-term Obligation, we recognize a portion of each quarterly payment to Biopharma as interest expense, which we determine by calculating the interest rate to Biopharma implied by the stream of payments we expect to make under the Financing Agreement. We recognize the non-interest portion of each payment as a reduction in our obligation to Biopharma. The current portion of the obligation is the amount we expect to pay, exclusive of interest expense, during the next 12 months. The actual amount of each quarterly payment will be based on Korlym Receipts in that quarter and may differ from our estimate. Management's estimate of the future product revenue is subject to uncertainty because Korlym Receipts are difficult to predict. While changes in the timing of Korlym Receipts may affect the recognition of interest expense and the split between the current and long-term portions of the obligation at any balance sheet date, the total we will pay Biopharma is fixed at \$45.0 million.

We recorded interest expense of \$455,000 and \$1.6 million for the three and nine months ended September 30, 2016, respectively, and \$698,000 and \$2.2 million for the three and nine months ended September 30, 2015, respectively, and total accreted interest of \$14.2 million for the period from August 2012 through September 30, 2016.

The following table provides a summary of the payment obligations under the Financing Agreement as of September 30, 2016 and December 31, 2015, utilizing the payment assumptions discussed above.

	September 30, 2016	December 31, 2015
	(in thousands)	
Total repayment obligation	\$45,000	\$ 45,000
Less interest in future periods	(822 )	(2,385 )
Less unamortized financing costs	(19 )	(35 )
Less payments made	(25,434 )	(15,087 )
Less current portion	(18,725 )	(14,965 )
Long-term obligation, net of current portion	\$—	\$ 12,528

We capitalized \$140,000 of issuance costs related to the Financing Agreement, which are being amortized over the estimated term of the obligation, based on the assumptions discussed above. At September 30, 2016 and December 31, 2015, the unamortized issuance costs were approximately \$19,000 and \$35,000, respectively, and are included in long-term obligation, netted against debt on our balance sheets, pursuant to ASU 2015-03.

#### 4. Lease obligations

In July 2015, we exercised our option to extend the lease for our office space through December 2016. We subsequently amended the lease agreement in February 2016 to extend the lease through 2019 and to add additional space. In March 2016, we early terminated the lease and replaced it with a new lease effective May 1, 2016 through

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March 31, 2019. Rent expense for the three months ended September 30, 2016 and 2015 was \$246,000 and \$158,000, respectively. Rent expense for the nine months ended September 30, 2016 and 2015 was \$639,000 and \$474,000, respectively.

As of September 30, 2016, future minimum lease payments under non-cancelable operating leases were as follows:

	Lease Payments
2016 (remainder)	\$ 200
2017	937
2018	1,115
2019	279
Thereafter	—
Total	\$ 2,531

## CORCEPT THERAPEUTICS INCORPORATED

## NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

## 5. Stock Option Plans

We have two stock option plans – the 2004 Equity Incentive Plan (the 2004 Plan) and the 2012 Incentive Award Plan (the 2012 Plan) with stock options outstanding as of September 30, 2016. On February 26, 2016, our Board of Directors authorized an increase of approximately 4.4 million shares in the number of shares available for issuance under the 2012 Plan, which was 4% of the shares of our common stock outstanding as of December 31, 2015, pursuant to the terms of the 2012 Plan.

During the nine months ended September 30, 2016, we issued an aggregate of 1,239,000 shares of our common stock upon the exercise of stock options.

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

	Three Months Ended September 30, 2016 2015 (in thousands)		Nine Months Ended September 30, 2016 2015 (in thousands)	
Research and development	\$321	\$196	\$879	\$579
Selling, general and administrative	1,510	1,346	4,222	3,941
Total stock-based compensation	\$1,831	\$1,542	\$5,101	\$4,520

## 6. Net Income (Loss) Per Share

Basic net income (loss) per share is computed using net income by the weighted-average number of common shares outstanding for the period. Diluted net income (loss) per share is computed by dividing the net income (loss) by the weighted-average number of common shares outstanding for the period plus potential outstanding common shares for the period. Potential outstanding common stock includes stock options, but only to the extent that their inclusion is dilutive.

The following table shows the computation of net income (loss) per share for each period, including the number of weighted-average shares outstanding.

	Three Months Ended September 30, 2016 2015 (in thousands)		Nine Months Ended September 30, 2016 2015 (in thousands)	
Numerator:				

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Net income (loss)	\$2,585	\$(601 )	\$3,543	\$(7,367 )
<b>Denominator:</b>				
Weighted-average shares used to compute basic net income				
(loss) per share	110,652	108,461	110,118	106,104
Dilutive effect of employee stock options	5,767	—	5,045	—
Weighted-average shares used to compute diluted net income				
(loss) per share	116,419	108,461	115,163	106,104
<b>Net income (loss) per share attributable to common stockholders</b>				
Basic and diluted	\$0.02	\$(0.01 )	\$0.03	\$(0.07 )

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

	September 30,	
	2016	2015
	(in thousands)	
Stock options outstanding	18,570	17,033

## 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

Corcept is 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<sup>®</sup> (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 a Phase 1/2 trial of mifepristone in combination with the chemotherapy drug eribulin (Halaven<sup>®</sup>) to treat patients with metastatic, triple-negative breast cancer – a form of solid-tumor cancer with a particularly poor prognosis. Enrollment in this trial is complete. We expect to release top-line results of this trial in the fourth quarter of 2016.

We are conducting two clinical trials of our proprietary selective cortisol modulator, CORT125134. One trial is investigating CORT125134 as a potential treatment for patients with Cushing’s syndrome. The second trial is investigating the combination of CORT125134 and anti-cancer agents as a treatment for patients with a variety of solid-tumor cancers. Both trials are currently enrolling patients.

We are advancing other compounds from our portfolio of selective cortisol modulators towards the clinic and expect to begin clinical trials of two or more of them 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 prevalence of 20,000 patients with Cushing’s syndrome in the United States.

Symptoms vary, but most people with Cushing’s syndrome have one or more of the following manifestations: high blood sugar, diabetes, high blood pressure, upper body obesity, rounded face, increased fat around the neck, thinning

arms and legs, severe fatigue and weak muscles. Irritability, anxiety, cognitive disturbances and depression are also common. Cushing's syndrome can affect every organ system in the body and can be lethal if not treated effectively. The preferred treatment for Cushing's syndrome patients is surgery, which, if successful, can cure the disease. In approximately half of the patients, surgery is not successful, either because the tumor cannot be removed completely or the disease returns.

**Korlym to Treat Patients with Cushing's Syndrome.** We received Orphan Drug designation from the FDA in 2007 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 the approximately 1,500 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 Cushing's syndrome patient is denied access to Korlym for financial reasons.

**Development of CORT125134 to Treat Patients with Cushing's Syndrome.** In the second quarter of 2016, we began 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 potently modulate the effects of the steroid prednisone, a commonly-used GR agonist, on serum osteocalcin, white blood cell counts, glucose metabolism and expression of the protein FKBP5 – a genetic marker of GR activation. Modulating the effect of prednisone is important, because it is a strong surrogate for Korlym's modulation of cortisol – the essential quality of an effective treatment for patients with Cushing's syndrome. Phase 1 pharmacokinetic data indicate that CORT125134 is suitable for once-daily oral dosing.

## Oncology

**Background.** There is substantial in vitro, in vivo and clinical evidence that cortisol's binding to GR allows certain solid-tumor cancers to resist treatment. In some cancers, such as triple-negative breast cancer, cortisol activity at GR promotes tumor growth. After binding to GR, cortisol stimulates genes that retard cellular apoptosis. Cortisol also suppresses the body's immune response. Suppression of the body's immune response is often beneficial, as it lessens the frequency of autoimmune diseases. However, activating, not suppressing, the body's immune system is beneficial in fighting certain cancers. When a patient undergoes chemotherapy that is intended to promote apoptosis in tumor cells, cortisol's anti-apoptotic effect is counterproductive. Our expectation is that adding a cortisol modulator to a patient's treatment regimen will also help the patient's own immune system combat the disease.

Our research has shown that a range of tumor-types express GR and are potential targets for cortisol modulation therapy, among them triple-negative breast, ovarian, prostate, cervical, and pancreatic cancers, as well as sarcoma and melanoma.

**Development of Korlym to Treat Patients with Solid-Tumor Cancers.** In January 2014, we began a Phase 1/2 trial of Korlym in combination with eribulin to treat metastatic triple-negative breast cancer. ("Eribulin" is the generic name of Eisai Inc.'s drug Halaven.) Approximately 40,000 women are diagnosed with this type of cancer each year. There is no FDA-approved treatment and neither a targeted treatment nor a preferred standard chemotherapy regimen for metastatic triple-negative breast cancer patients exists. Our research indicates that more than 75 percent of the tumors in patients with this disease express GR and so may respond to therapy that includes a cortisol modulator. We completed enrollment in the efficacy phase of this Phase 1/2 trial in the second quarter of 2016.

Investigators at the University of Chicago have initiated a double-blind, placebo-controlled, multicenter Phase 2 study of Korlym in combination with nab-paclitaxel (Celgene's drug, Abraxan®) to treat 64 patients with advanced, GR-positive triple-negative breast cancer. University of Chicago investigators are also leading a randomized, controlled multicenter Phase 2 study of Korlym combined with the androgen deprivation agent enzalutamide (Medivation's drug, Xtand®) versus enzalutamide monotherapy to treat 84 patients with metastatic, castration-resistant prostate cancer. The investigators' hypothesis is that adding cortisol modulation to androgen deprivation therapy will better suppress tumor growth. We are providing Korlym for both trials.

We have licensed patents from the University of Chicago covering the use of cortisol modulators in combination with anti-cancer agents to treat triple-negative breast cancer and with androgen deprivation agents to treat castration-resistant prostate cancer.

CORT125134 to Treat Patients with Solid-Tumor Cancers. We are conducting an open-label Phase 1/2 trial of CORT125134 in combination with anti-cancer agents to treat a range of solid-tumor cancers. The trial's initial phase is studying the combination of nab-paclitaxel and CORT125134 to treat any solid-tumor cancer suitable for treatment with nab-paclitaxel (Celgene's drug, Abraxan®). Once we identify a recommended dose of the CORT125134/nab-paclitaxel combination, we plan to open one or more expansion cohorts, each containing 20 patients, to test the combination's efficacy in one or more of the solid-tumor cancers studied in the dose-finding phase. Possible target indications include triple-negative breast cancer, castration-resistant prostate cancer, ovarian cancer, pancreatic cancer and cervical cancer. We may choose to open additional dose-finding cohorts to study CORT125134 in combination with different companion therapeutic agents, including immunotherapy, to treat other solid-tumor cancers.

#### Our Proprietary, 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, potently 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 various indications, including but not limited to the prevention and reversal of alcohol dependence; Alzheimer's disease; post-traumatic stress disorder; electroconvulsive-induced retrograde amnesia; amyotrophic lateral sclerosis (ALS or Lou Gehrig's Disease); muscular dystrophy; prevention of glucocorticoid-induced neurological damage in premature infants; anti-

psychotic-induced weight gain; fatty liver disease; metabolic syndrome; obesity; and breast, ovarian and prostate cancer (in combination with an anti-cancer agent). We are advancing the most promising of these compounds towards the clinic and expect to begin clinical trials of two or more of them in 2017.

The United States Patent & Trademark Office (USPTO) and the European Patent Office (EPO) have issued to us composition of matter patents related to these compounds. In addition, we own or have exclusively-licensed patents for the use of all cortisol modulators (including Korlym) in a broad range of disorders.

#### Financing update

Before Korlym generated revenue, we supported our operations primarily with proceeds from public and private sales of our equity securities and funds from our Biopharma Financing Agreement. Revenues from the sale of Korlym have substantially increased since the medication's approval in 2012 and now fully support our operations. Based on the anticipated increase in revenues from Korlym and our current development plans, which include funding our Cushing's syndrome commercial operations, completing our Phase 1/2 study of Korlym for the treatment of triple-negative breast cancer and (if that study produces positive results) conducting a Phase 3 study, conducting two clinical trials of CORT125134, one in Cushing syndrome and another in solid tumor cancers, and advancing to the clinic at least two more of our next generation compounds, we expect to remain cash-flow breakeven without needing to raise additional funds. However, we may choose to raise additional funds to finance strategic priorities.

As of September 30, 2016, we had an accumulated deficit of \$326.9 million. We have historically incurred operating losses due to the cost of our research and development activities, including clinical trial activities for Korlym and our selective cortisol modulators, discovery research, non-clinical activities such as toxicology and carcinogenicity studies, manufacturing and regulatory activities, as well as selling, general and administrative expenses, including expenses related to the commercialization of Korlym, offset by our net product revenue. We may incur further losses as we continue our discovery and clinical development programs, apply for regulatory approvals, develop or acquire medications in other therapeutic areas, and expand our sales, marketing and administrative capabilities.

#### Results of Operations

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

Net product revenue was \$21.7 million and \$57.5 million for the three and nine months ended September 30, 2016, respectively, as compared to \$13.3 million and \$35.3 million in the corresponding periods in 2015. This increase was primarily driven by the increase in our sales volume and price increases.

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

Cost of sales was \$668,000 and \$1.5 million for the three and nine months ended September 30, 2016, respectively, as compared to \$256,000 and \$997,000 in the corresponding periods in 2015. Cost of sales increased for the three and nine months ended September 30, 2016 due to greater sales volumes. For the three months and nine months ended September 30, 2016, cost of sales was 3.1 percent and 2.6 percent, respectively, of our net product revenue, as compared to 1.9 percent and 2.8 percent in the corresponding periods in 2015. The increase in cost of sales in the third quarter of 2016 as a percentage of net product revenue was due to a one-time expenditure at one of our manufacturers.

**Research and development expenses** – Research and development expenses include the cost of (1) personnel engaged in development activities, including stock-based compensation, (2) clinical trials, including trial preparation, enrollment,

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

Research and development expenses increased approximately 95.3 percent to \$7.1 million for the three months ended September 30, 2016 from \$3.6 million for the comparable period in 2015. Research and development expenses increased approximately 53.2 percent to \$17.4 million for the nine months ended September 30, 2016 from \$11.3 million for the comparable period in 2015. The increase in expenses was due primarily to increased spending on the advancement of CORT125134, which entered clinical trials in patients in the second quarter of 2016, as well as increased compensation expense due to our hiring of additional clinical employees.

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

Project	Three Months Ended		Nine Months Ended	
	September 30, 2016	September 30, 2015	September 30, 2016	September 30, 2015
	(in thousands)		(in thousands)	
<b>Development programs:</b>				
Oncology	\$1,127	\$915	\$3,625	\$2,329
Cushing's syndrome	891	151	2,496	467
Psychotic depression	—	68	—	282
Pre-clinical selective cortisol modulators	3,904	1,137	7,487	5,566
Unallocated activities, including pre-clinical, manufacturing and regulatory activities	811	1,145	2,873	2,107
Stock-based compensation	321	196	879	579
Total research and development expense	\$7,054	\$3,612	\$17,360	\$11,330

We expect our research and development expenditures in the remainder of 2016 and beyond to increase as we conduct additional pre-clinical and clinical trials, advance our current clinical trials, and perform additional discovery research.

Many factors can affect the cost and timing of our pre-clinical and clinical programs, including inconclusive results, slow patient enrollment, adverse side effects, insufficient supplies of medicine, unforeseen difficulties in the formulation or manufacture of the study drug, and real or perceived lack of effectiveness or safety of the drug being investigated. The development of our product candidates is subject to extensive governmental regulation. These factors make it difficult to predict the timing and cost of the further development and approval of our product candidates.

Selling, general and administrative expenses – Selling, general and administrative expenses include (1) the cost of employees, consultants, and independent contractors engaged in administrative and commercial activities, including their stock-based compensation; (2) expenses of third-party vendors used in our commercial activities, including sales, marketing and promotion; market research, reimbursement support services, pharmacovigilance, distribution of marketing materials and other logistical needs; (3) medical educational grants and donations; and (4) legal, accounting and other professional fees.

Selling, general and administrative expenses for the three months ended September 30, 2016 increased 17.7 percent to \$10.9 million, from \$9.3 million for the comparable period in 2015. Selling, general and administrative expenses for the nine months ended September 30, 2016 increased 19.2 percent to \$33.5 million from \$28.1 million for the comparable period in 2015. The increases were driven primarily by increased compensation expense due to additional hiring, Fiscal 2016 bonus expense, and commissions related to increased sales. Stock-based compensation expense was \$1.5 million and \$4.2 million for the three and nine months ended September 30, 2016, respectively, compared to \$1.4 million and \$3.9 million for the corresponding periods in 2015. Our selling, general and administrative expenses are likely to increase in the remainder of 2016 and beyond as our commercial business grows.

Interest and other expense – Interest and other expense for the three and nine months ended September 30, 2016 was \$487,000 and \$1.6 million, respectively, as compared to \$703,000 and \$2.3 million for the comparable period in 2015.

These amounts consisted of interest expense related to our Biopharma financing agreement for all periods presented. Interest expense for the remainder of 2016 and future years related to this obligation will decrease as our quarterly payments reduce the obligation's outstanding balance. We expect to fully repay the underlying obligation in 2017.

## Non-GAAP Financial Measures

We prepare our condensed financial statements and footnotes thereto, which are included in Part I, Item 1 of this Quarterly Report on Form 10-Q, in accordance with GAAP. To supplement our financial results presented on a GAAP basis, we use non-GAAP measures of net income (loss) and net income (loss) per share that exclude non-cash expenses related to stock-based compensation expense and the accretion of interest expense under our capped royalty financing transaction. We use these non-GAAP measures to manage our business and believe 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 (loss) and net income (loss) per share we use may be different from, and not directly comparable to, similarly titled measures used by other companies.

	Three Months Ended September 30, 2016		Nine Months Ended September 30, 2015	
	2016	2015	2016	2015
	(in thousands, except for per share data)			
GAAP net income (loss)	\$2,585	\$(601 )	\$3,543	\$(7,367)
Non-cash expenses:				
Stock-based compensation	1,831	1,542	5,101	4,520