

CORCEPT THERAPEUTICS INC

Form 10-Q

May 04, 2016

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 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
(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 or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one.)

Large Accelerated Filer

Accelerated Filer

Non-accelerated filer

(Do not check if a smaller reporting company)

Smaller Reporting Company

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

On April 29, 2016 there were 109,796,626 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)

	March 31, 2016	December 31, 2015
	(Unaudited)	(See Note 1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 40,744	\$ 40,435
Trade receivables	6,752	6,221
Inventory	1,912	1,682
Prepaid expenses and other current assets	1,106	642
Total current assets	50,514	48,980
Strategic inventory	2,280	2,800
Property and equipment, net of accumulated depreciation	93	98
Other assets	25	24
Total assets	\$ 52,912	\$ 51,902
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,082	\$ 1,325
Accrued clinical expenses	1,094	1,171
Other accrued liabilities	4,527	3,257
Long-term obligation - current portion	16,322	14,965
Deferred revenue	—	158
Total current liabilities	24,025	20,876
Long-term obligation, net of current portion	8,719	12,528
Commitments		
Stockholders' equity:		
Common stock, par value \$0.001 per share, 280,000 shares authorized and 109,671 and 109,642 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	110	110
Additional paid-in capital	350,485	348,796

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Accumulated deficit	(330,427)	(330,408)
Total stockholders' equity (deficit)	20,168	18,498
Total liabilities and stockholders' equity	\$ 52,912	\$ 51,902

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

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CORCEPT THERAPEUTICS INCORPORATED

CONDENSED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

(In thousands, except per share data)

	Three Months Ended March 31,	
	2016	2015
Product revenue, net	\$ 16,061	\$ 10,102
Operating expenses:		
Cost of sales	403	302
Research and development	4,634	4,377
Selling, general and administrative	10,432	9,453
Total operating expenses	15,469	14,132
Income (Loss) from operations	592	(4,030)
Interest and other expense	(611)	(800)
Net loss and comprehensive loss	\$ (19)	\$ (4,830)
Basic and diluted net loss per share	\$ (0.00)	\$ (0.05)
Weighted average shares outstanding used in computing basic and diluted net loss per share	109,661	101,905

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

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CORCEPT THERAPEUTICS INCORPORATED

CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Three Months Ended March, 31,	
	2016	2015
Operating activities		
Net loss	\$ (19)	\$ (4,830)
Adjustments to reconcile net loss to net cash generated from (used in) operations:		
Stock-based compensation	1,613	1,409
Accretion of interest expense	584	762
Amortization of debt financing costs	5	6
Depreciation and amortization of property and equipment	27	40
Changes in operating assets and liabilities:		
Trade receivables	(531)	(967)
Inventory	290	257
Prepaid expenses and other current assets	(464)	819
Other assets	—	(10)
Accounts payable	757	(850)
Accrued clinical expenses	(77)	1,022
Other accrued liabilities	1,270	543
Deferred revenue	(158)	22
Net cash provided by (used in) operating activities	3,297	(1,777)
Investing activities		
Purchases of property and equipment	(22)	(34)
Cash used in investing activities	(22)	(34)
Financing activities		
Proceeds from issuance of common stock upon exercise of options and warrants, net of issuance costs	75	17,381
Payments related to long-term obligation	(3,041)	(1,865)
Net cash provided by (used in) financing activities	(2,966)	15,516
Net increase in cash and cash equivalents	309	13,705

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Cash and cash equivalents, at beginning of period	40,435	24,248
Cash and cash equivalents, at end of period	\$ 40,744	\$ 37,953

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

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CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS

1. Basis of Presentation and Summary of Significant Accounting Policies

Description of Business and Basis of Presentation

Corcept Therapeutics Incorporated was incorporated in the State of Delaware in May 1998, and our headquarters are located in Menlo Park, California. We are a pharmaceutical company engaged in the discovery, development and commercialization of medications for the treatment of severe metabolic, oncologic, and psychiatric disorders that are associated with the activity of the hormone cortisol. In 2012, the United States Food and Drug Administration (FDA) approved Korlym® (mifepristone) 300 mg Tablets as a once-daily oral medication for treatment of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. We have discovered and patented three families of selective cortisol modulators, consisting of more than 300 distinct compounds, and we are developing them to treat a broad range of disorders.

Basis of Presentation

The accompanying unaudited condensed balance sheet as of March 31, 2016 and the condensed statements of comprehensive loss for the three-month periods ended March 31, 2016 and 2015 and the condensed statements of cash flows for the three-month periods ended March 31, 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-month period ended March 31, 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, 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 March 31, 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.

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).

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NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

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

We expense the manufacturing costs for product candidates incurred prior to regulatory approval as research and development expense as we incur them. When regulatory approval of a product is obtained, we begin capitalizing manufacturing costs related to the approved product into inventory, provided such product is produced by an FDA approved facility.

Long-term Obligation

In August 2012, we entered into a Purchase and Sale Agreement (Financing Agreement) with Biopharma Secured Debt Fund II Sub, S.à r.l (Biopharma), a private limited liability company organized under the laws of Luxembourg. Under the terms of the Financing Agreement, we received \$30.0 million from Biopharma, which upon receipt we recorded as a long-term obligation. In return, we are obligated to make payments to Biopharma totaling \$45.0 million. These payments equal a percentage of (i) our net product sales, which include sales from any product containing mifepristone or any of our proprietary selective GR antagonists (Covered Products) and (ii) cash or cash equivalents received from any licensing transaction or co-promotion arrangement involving Covered Products, including any upfront or milestone payments, if any, (together, Korlym Receipts). Once we have paid Biopharma a total of \$45.0 million, no more payments will be due and the obligation will be extinguished.

We recognize a portion of each quarterly payment under the Financing Agreement as interest expense, which we determine by calculating the interest rate to Biopharma implied by the stream of quarterly payments we expect to make. The amount shown on our balance sheet as the current portion is an estimate of the amount we expect to repay Biopharma in the 12 months following March 31, 2016. We record the balance of the outstanding portion of the obligation 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, such as the National Organization for Rare Disorders (NORD – discussed below), is a prerequisite for Dohmen to ship Korlym. We recognize revenue upon the delivery of our products to these patients.

We 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 product to a patient. In order to conclude that the price is fixed or determinable, we must be able to (i) calculate gross product revenues from the sales to our customers and (ii) reasonably estimate net product revenues.

Effective January 1, 2016, we recognize sales to our specialty distributor (SD) at the time of sale to the SD. Before, 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 the first quarter.

We donate cash to 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.

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

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.

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NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

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

Research and Development

Research and development expenses consist of direct expenses, such as the cost of clinical trials, pre-clinical studies, discovery research 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 clinical trials, research and preclinical activities on estimates of work completed under service agreements, milestones achieved, patient enrollment and past experience with similar contracts. Our estimates of work completed and associated cost accruals include our assessments of information from third-party contract research organizations and the overall status of clinical trial and other development and administrative activities.

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. For service-based awards, we recognize expense over the requisite service period.

We recognize the expense of options granted to non-employees based on the fair-value based measurement of the option grants at the time of vesting.

Recently Issued Accounting Pronouncement

In May 2014, the Financial Accounting Standards Board (FASB) issued a new standard on revenue recognition from contracts with customers. This standard's core principle is that a reporting entity will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. On July 9, 2015, FASB delayed the effective date of this standard by one year. The standard will be effective for us beginning in the first quarter of 2018. Early application is permitted in 2017. Entities have the option of using either a full retrospective or a modified retrospective approach to adopt this new guidance. We are evaluating the impact of the adoption of this standard on our consolidated financial statements.

In April 2015, the FASB issued Accounting Standards Update (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 in the first quarter of 2016. As a result,

the Company reclassified the financing costs from long term assets to long term debt by \$30,000 and \$35,000 as of March 31, 2016 and December 31, 2015, respectively, on its consolidated balance sheets.

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 are evaluating the impact of the adoption of this standard on our consolidated financial statements.

In November 2015, the FASB issued ASU 2015-17, Balance Sheet Classification of Deferred Taxes (ASU 2015-17), requiring all deferred tax assets and liabilities, along with any related valuation allowance, to be classified as noncurrent on the balance sheet. The amendments in this ASU are effective for fiscal years beginning after December 15, 2016 and for interim periods therein. We are evaluating the impact of the adoption of this standard on our 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 consolidated financial statements.

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NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

In March 2016, the FASB issued ASU No. 2016-09, Stock Compensation (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 consolidated financial statements.

2. Composition of Certain Balance Sheet Items

Inventory

The composition of inventory was as follows:

	March 31, 2016	December 31, 2015
	(in thousands)	
Raw materials	\$ 2,162	\$ 2,141
Work in progress	6	3
Finished goods	2,024	2,338
Total inventory	4,192	4,482
Less strategic inventory classified as non-current	(2,280)	(2,800)
Total inventory classified as current	\$ 1,912	\$ 1,682

We have one tablet manufacturer for Korlym — AAI Pharma Services Corp. (AAI). In addition, we have one manufacturer for mifepristone, the active pharmaceutical ingredient (API), in Korlym — Produits Chimiques Auxiliaires et de Synthèse SA (PCAS). If either of these companies is unable to manufacture API or Korlym tablets in the quantities and time 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:

March	December
31,	31,
2016	2015

(in thousands)

Government rebates	\$ 2,186	\$ 1,663
Accrued compensation	1,550	1,103
Commercialization costs	240	111
Legal fees	218	69
Professional fees	207	220
Other	126	91
	\$ 4,527	\$ 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 March 31, 2016, we have paid Biopharma \$18.1 million, with an additional payment of \$3.3 million made in April 2016.

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

We are obligated to make payments as follows:

- 20 percent of our net product sales of Covered Products.
- 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 and any payment caps will lapse if we
 - (i) fail to provide Biopharma with certain information regarding our promotion and sales of Covered Products,
 - (ii) do not devote a

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CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

commercially reasonable amount of resources to the promotion and marketing of the Covered Products or (iii) incur indebtedness greater than the sum of our earnings before interest, taxes, depreciation and amortization, and non-cash stock-based compensation, for the four calendar quarters preceding such incurrence and, in each case, fail to cure within the applicable cure period.

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

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

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

We recorded interest expense of \$584,000 for the three-month period ended March 31, 2016, and \$762,000 for the three-month period ended March 31, 2015, and total accreted interest of \$13.2 million for the period from August 2012 through March 31, 2016. The actual amount of each quarterly payment will be based on Korlym Receipts in that quarter and may differ from our estimate. While changes in the timing of Korlym Receipts may affect the recognition of interest expense and the split between the current and long-term portions of the obligation at any balance sheet date, the total we will pay Biopharma is fixed at \$45.0 million.

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

	March 31, 2016	December 31, 2015
	(in thousands)	
Total repayment obligation	\$ 45,000	\$ 45,000

Less interest to be accreted in future periods	(1,801)	(2,385)
Less unamortized financing costs	(30)	(35)
Less payments made	(18,128)	(15,087)
Less current portion	(16,322)	(14,965)
Long-term obligation, net of current portion	\$ 8,719	\$ 12,528

The estimated fair value of the long-term obligation, as measured using Level 3 inputs, approximates the carrying amounts as presented on the balance sheet as of March 31, 2016 and December 31, 2015. The estimated fair value was calculated using the income method of valuation. The key assumptions required for the calculation were an estimate of the amount and timing of our future product revenue and an estimated cost of capital. Management's estimate of the future product revenue is subject to significant uncertainty because Korlym Receipts are difficult to predict and there is an extended time period associated with the Financing Agreement.

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

4. 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 March 31, 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.

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CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

During the three-month period ended March 31, 2016, we issued an aggregate of 29,000 shares of our common stock upon the exercise of stock options.

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