CORCEPT THERAPEUTICS INC
Form 10-Q
November 03, 2017

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

149 Commonwealth Drive

Menlo Park, CA 94025

(Address of principal executive offices, including zip code)

(650) 327-3270

(Registrant's telephone number, including area code)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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		Accelerated filer
Non-accelerated filer	(Do not check if a small reporting company)	Smaller reporting company
Emerging growth company		

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 October 30, 2017, there were 114,124,161 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)

	September 30, 2017 (Unaudited)	December 31, 2016 (See Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,060	$ 51,536
Short-term marketable securities	44,096	—
Trade receivables, net of allowances	11,872	9,860
Inventory	3,828	2,329
Prepaid expenses and other current assets	3,086	1,964
Total current assets	93,942	65,689
Strategic inventory	1,680	2,835
Property and equipment, net of accumulated depreciation	553	205
Long-term marketable securities	1,508	—
Other assets (Note 5)	12,989	24
Total assets	$ 110,672	$ 68,753
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,226	$ 2,290
Accrued clinical expenses	1,892	1,467
Other accrued liabilities	16,252	8,953
Long-term obligation - current portion	—	14,664
Total current liabilities	24,370	27,374
Commitments and contingencies (Note 5)		
Stockholders’ equity:		
Preferred stock, par value $0.001 per share, 10,000 shares authorized and no shares outstanding at September 30, 2017 and December 31, 2016	—	—
Common stock, par value $0.001 per share, 280,000 shares authorized and 114,082 and 112,710 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	114	113
Additional paid-in capital	377,678	363,534
Accumulated other comprehensive loss	(14)	—
Accumulated deficit	(291,476)	(322,268)
Total stockholders’ equity	86,302	41,379
Total liabilities and stockholders’ equity	$ 110,672	$ 68,753

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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Product revenue, net	$42,763	$21,725	$105,921	$57,509
Operating expenses:				
Cost of sales	976	668	2,397	1,497
Research and development	11,693	7,054	26,745	17,360
Selling, general and administrative	16,471	10,931	45,621	33,480
Total operating expenses	29,140	18,653	74,763	52,337
Income from operations	13,623	3,072	31,158	5,172
Interest and other income (expense)	86	(487)	(237)	(1,629)
Income before income taxes	13,709	2,585	30,921	3,543
Income tax benefit (expense)	48	—	(129)	—
Net income	$13,757	$2,585	$30,792	$3,543
Other comprehensive income (loss):				
Net unrealized gain (loss) on available-for-sale investments	3	—	(14)	—
Total comprehensive income	$13,760	$2,585	$30,778	$3,543
Basic net income per common share	$0.12	$0.02	$0.27	$0.03
Diluted net income per common share	$0.11	$0.02	$0.25	$0.03
Weighted-average shares outstanding used in computing net income per share				
Basic	113,603	110,652	113,242	110,118
Diluted	125,651	116,419	123,417	115,163

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)

	Nine Months Ended September 30,	
	2017	2016
Cash flows from operating activities:		
Net income	$30,792	$3,543
Adjustments to reconcile net income to net cash generated from operations:		
Stock-based compensation	9,529	5,101
Accretion of interest expense	456	1,562
Amortization of debt financing costs	14	16
Depreciation and amortization of property and equipment	58	72
Changes in operating assets and liabilities:		
Trade receivables	(2,012)	(2,015)
Inventory	(344)	(825)
Prepaid expenses and other current assets	(1,122)	(679)
Other assets (Note 5)	(12,965)	—
Accounts payable	3,922	2,984
Accrued clinical expenses	425	604
Other accrued liabilities	7,299	3,617
Deferred revenue	—	(158)
Net cash provided by operating activities	36,052	13,822
Cash flows from investing activities:		
Purchases of property and equipment	(390)	(119)
Purchases of marketable securities	(45,618)	—
Cash used in investing activities	(46,008)	(119)
Cash flows from financing activities:		
Proceeds from issuance of common stock upon exercise of options and warrants, net of issuance costs	4,614	4,073
Payments related to long-term obligation	(15,134)	(10,346)
Net cash used in financing activities	(10,520)	(6,273)
Net (decrease) increase in cash and cash equivalents	(20,476)	7,430
Cash and cash equivalents, at beginning of period	51,536	40,435
Cash and cash equivalents, at end of period	$31,060	$47,865

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

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CORCEPT THERAPEUTICS INCORPORATED

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 500 compounds. We are developing compounds from these series to treat a broad range of disorders.

Basis of Presentation

We have prepared the September 30, 2017 balance sheet and the statements of comprehensive income and cash flows 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. 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, 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 December 31, 2016 balance sheet 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 reevaluate our estimates and assumptions each quarter, including those related to revenue recognition, sales returns, inventory, allowances for doubtful accounts and accrued liabilities, including our bonus accrual, clinical trial accruals and stock-based compensation.

Fair Value Measurements

We value financial instruments using the assumptions we believe third-party market participants would adopt when valuing such instruments. Our methodology uses a "fair value hierarchy" that gives the highest priority to quoted prices in active markets for identical instruments (called "Level 1 inputs"). If no Level 1 inputs are available, we consider (i) quoted prices in non-active markets for identical instruments; (ii) active markets for similar instruments; (iii) inputs other than quoted prices for the instrument; and (iv) inputs that are not directly observable, but that are corroborated by observable data ("Level 2 inputs"). In the absence of Level 2 inputs, we rely on unobservable inputs, such as our own data about the assumptions market participants would use in pricing the instrument ("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.

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS, continued

Effective January 2017, we invested a portion of our funds in marketable securities, primarily U.S. 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 inventory 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 equaled 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 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 expected to make. In each period, the amount shown on our balance sheet as the current portion was our estimate of the amount we expected to pay Biopharma in the following 12 months. We recorded the rest of the outstanding portion of the obligation, if any, as a long-term liability.

We made our final payment to Biopharma, completely satisfying our obligations under the Financing Agreement, in July 2017.

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. 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. 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. 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 provide Korlym at no cost to patients without insurance who do not qualify for charitable support.

Through August 9, 2017 our exclusive specialty pharmacy was Dohmen Life Science Services ("Dohmen"). On August 10, 2017, Optime Care, Inc. ("Optime") became our exclusive specialty pharmacy.

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS, continued

We also sell Korlym to a specialty distributor ("SD"), which we recognize at the time the SD receives the Korlym. SD sales were less than two percent of our net revenue in the three and nine months ended September 30, 2017.

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

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

Rebates and Chargebacks: Korlym is eligible for purchase by or qualifies for partial or full reimbursement from Medicaid and other government programs. We estimate any government rebate 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: It is our policy that no patient be denied Korlym due to inability to pay. 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 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 and 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, make 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 vesting period, net of estimated forfeitures. If actual forfeitures differ from our estimates, we adjust stock-based compensation expense accordingly.

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 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”. 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.

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS, continued

In July 2015, FASB issued ASU No. 2015-11, Simplifying the Measurement of Inventory, 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 "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,” which simplifies accounting for transactions involving shares awarded to employees. 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 in which 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, which was offset by a corresponding increase to our deferred tax valuation allowance, resulting in no change to our balance sheet. We elected to report on a prospective basis cash flows related to excess tax benefits as an operating activity and to continue to recognize stock compensation expense net of estimated forfeitures. Adoption of this standard did not have a material impact on our financial statements.

Recently Issued Accounting Pronouncements 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. We have completed our evaluation of the contracts governing our sales process and are reviewing our related disclosures, policies and controls, which we will change as required when we adopt the standard. Because our arrangements with customers contain variable consideration, we have focused our analysis on how the new standard will affect our estimate of transaction prices, which we believe the update will not change materially. We do not believe adoption will have a material impact on our financial statements.

In February 2016, FASB issued ASU No. 2016-02, “Leases”, 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. 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.

2. Composition of Certain Balance Sheet Items

Inventory

The composition of inventory was as follows:

	September 30, 2017	December 31, 2016
	(in thousands)	
Raw materials	$1,122	$ 1,848
Work in progress	1,934	1,414
Finished goods	2,452	1,902
Total inventory	5,508	5,164
Less strategic inventory classified as non-current	(1,680)	(2,835)
Total inventory classified as current	$3,828	$ 2,329

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS, continued

In order to be prepared for potential demand for Korlym and because we rely on single-source manufacturers of both the active pharmaceutical ingredient ("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:

	September 30, 2017	December 31, 2016
	(in thousands)	
Government rebates	$6,955	$ 3,426
Accrued compensation	7,886	4,702
Commercialization costs	415	308
Legal fees	342	164
Professional fees	247	34
Other		