

CORCEPT THERAPEUTICS INC

Form 10-Q

November 08, 2012

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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 September 30, 2012

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)

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Delaware
(State or other jurisdiction of

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

incorporation or organization)

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 (§232.405 of this chapter) 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 November 2, 2012 there were 99,814,250 shares of common stock outstanding at a par value of \$0.001 per share.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (Form 10-Q) contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and Section 27A of the Securities Act of 1933, as amended, or the Securities Act. All statements contained in this Form 10-Q other than statements of historical fact are forward-looking statements. When used in this report or elsewhere by management from time to time, the words believe, anticipate, intend, plan, estimate, expect, may, will, should, seeks and similar expressions are forward-looking statements. Such forward-looking statements are based on current expectations, but the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements made in this Quarterly Report on Form 10-Q may include, but are not limited to, statements about:

our ability to manufacture, market and commercialize Korlym (mifepristone) 300mg Tablets;

our ability to realize the benefits of Orphan Drug Designation of Korlym in the United States;

the progress and timing of our research, development and clinical programs and the timing of regulatory activities for mifepristone for the treatment of the psychotic features of psychotic depression;

our estimates of the dates by which we expect to report results of our clinical trials and the anticipated results of these trials;

our ability to achieve marketing approval of Korlym in the European Union (EU) and realize the benefits of Orphan Drug Designation there;

the timing of the market introduction of future product candidates, including any other compound in our families of selective GR-II antagonists;

our ability to manufacture, market, commercialize and achieve market acceptance for our future product candidates, including mifepristone for the treatment of the psychotic features of psychotic depression and any other compound in our families of selective GR-II antagonists;

uncertainties associated with obtaining and enforcing patents;

our estimates for future performance, including revenue and profits; and

our estimates regarding our capital requirements.

Forward-looking statements are not guarantees of future performance and involve risks and uncertainties. Actual events or results may differ materially from those discussed in the forward-looking statements as a result of various factors. For a more detailed discussion of such forward-looking statements and the potential risks and uncertainties that may impact upon their accuracy, see Part II, Item 1A, Risk Factors and the Overview and Liquidity and Capital Resources sections of Part I, Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations included in this Quarterly Report on Form 10-Q. These forward-looking statements reflect our view only as of the date of this report. Except as required by law, we undertake no obligations to update any forward-looking statements. Accordingly, you should also carefully consider the factors set forth in other reports or documents that we file from time to time with the Securities and Exchange Commission (SEC).

Table of Contents**PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****CORCEPT THERAPEUTICS INCORPORATED****CONDENSED BALANCE SHEETS**

(In thousands)

	September 30, 2012 (Unaudited)	December 31, 2011 (See Note 1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 101,628	\$ 39,635
Trade receivables	354	
Inventory	1,837	
Prepaid expenses and other current assets	800	140
Total current assets	104,619	39,775
Strategic inventory	640	
Property and equipment, net of accumulated depreciation	105	26
Other assets	160	32
Total assets	\$ 105,524	\$ 39,833
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,574	\$ 3,611
Accrued clinical expenses	605	644
Accrued compensation	312	238
Other accrued liabilities	786	533
Long-term obligation - current portion	2,250	
Deferred revenue	21	
Total current liabilities	5,548	5,026
Long-term obligation, net of current portion	28,325	
Commitments (Note 5)		
Stockholders' equity:		
Preferred stock		
Common stock	100	84
Additional paid-in capital	307,033	243,281
Accumulated deficit and comprehensive loss	(235,482)	(208,558)
Total stockholders' equity	71,651	34,807
Total liabilities and stockholders' equity	\$ 105,524	\$ 39,833

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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 September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Product sales, net	\$ 1,055	\$	\$ 1,930	\$
Operating expenses:				
Cost of sales	24		72	
Research and development	3,008	3,228	9,218	14,355
Selling, general and administrative	5,694	3,209	18,932	8,049
Total operating expenses	8,726	6,437	28,222	22,404
Loss from operations	(7,671)	(6,437)	(26,292)	(22,404)
Interest and other income		3		3
Interest and other expense	(622)	(1)	(632)	(17)
Net loss and comprehensive loss	\$ (8,293)	\$ (6,435)	\$ (26,924)	\$ (22,418)
Basic and diluted net loss per share	\$ (0.08)	\$ (0.08)	\$ (0.30)	\$ (0.27)
Weighted average shares outstanding used in computing basic and diluted net loss per share	99,082	84,188	90,738	83,000

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)

	Nine Months Ended September 30,	
	2012	2011
Operating activities		
Net loss	\$ (26,924)	\$ (22,418)
Adjustments to reconcile net loss to net cash used in operations:		
Non-cash expense related to stock options	4,264	2,403
Accretion of interest expense	575	
Depreciation and amortization	23	1
Changes in operating assets and liabilities:		
Trade receivables	(354)	
Inventory	(2,477)	
Prepaid expenses and other current assets	(660)	(9)
Other assets	3	64
Accounts payable	(2,037)	249
Accrued clinical expenses	(39)	(60)
Deferred revenue	21	
Other liabilities	327	(1,336)
Net cash used in operating activities	(27,278)	(21,106)
Investing activities		
Purchases of property and equipment	(93)	
Net cash used in investing activities	(93)	
Financing activities		
Proceeds from issuance of common stock and warrants, including collection of notes receivable, net of issuance costs	59,504	42,437
Proceeds from issuance of long-term obligation, net of issuance costs	29,860	
Net cash provided by financing activities	89,364	42,437
Net increase in cash and cash equivalents	61,993	21,331
Cash and cash equivalents, at beginning of period	39,635	24,578
Cash and cash equivalents, at end of period	\$ 101,628	\$ 45,909

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. Summary of Significant Accounting Policies

Description of Business and Basis of Presentation

Corcept Therapeutics Incorporated was incorporated in the state of Delaware on May 13, 1998, and our facilities are located in Menlo Park, California. Corcept is a pharmaceutical company engaged in the discovery, development and commercialization of drugs for the treatment of severe metabolic and psychiatric disorders. Since our inception in May 1998, we have been developing our lead product, Korlym®. Mifepristone, the active ingredient in Korlym, is a potent glucocorticoid receptor II (GR-II) antagonist, which means that it blocks the effects of cortisol throughout the body. On February 17, 2012, the United States Food and Drug Administration (FDA) approved Korlym (mifepristone) 300 mg Tablets in the United States 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 released Korlym for sale on April 10, 2012. We also have a clinical program for the use of mifepristone, the active ingredient in Korlym, for the treatment of the psychotic features of psychotic depression. We are currently conducting a phase 3 study for this indication. In addition, we have discovered three series of novel selective glucocorticoid receptor II (GR-II) antagonists. Unless otherwise stated, all references in these financial statements to we, us, our, Corcept, the Company, our company and similar designations refer to Corcept Therapeutics Incorporated.

We were considered to be in the development stage prior to the second quarter of 2012 when we recorded significant revenue from our planned principal operations following commercialization of Korlym.

The accompanying unaudited balance sheet as of September 30, 2012, statements of comprehensive loss for the three- and nine-month periods ended September 30, 2012 and 2011, and statements of cash flows for the nine-month periods ended September 30, 2012 and 2011 have been prepared in accordance with U.S. generally accepted accounting principles 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 U.S. generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three- and nine-month periods ended September 30, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012 or any other period. These financial statements and notes should be read in conjunction with the financial statements for the year ended December 31, 2011 included in our Annual Report on Form 10-K. The accompanying balance sheet as of December 31, 2011 has been derived from audited financial statements at that date.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to use assumptions and make estimates to form judgments about the carrying value of assets and liabilities reported in the financial statements and accompanying notes, the value of which we cannot readily determine from other sources. Actual results could differ materially from those estimates.

We evaluate our estimates and assumptions on an ongoing basis, including those related to our discounts for prompt payment of sales invoices, chargebacks and rebates, patient assistance, potential product returns, excess/obsolete inventories, allowances for doubtful accounts, accruals of clinical and preclinical expenses, contingent liabilities, and the magnitude and timing of payments with respect to our long-term capped royalty obligation, which determine its effective interest rate. We base our estimates on relevant experience and on other specific assumptions that we believe are reasonable.

We update these assumptions and estimates as new information becomes available. Any changes in estimates are recorded in the period of the change.

Cash and Cash Equivalents

We invest our excess cash in bank deposits, money market accounts, corporate debt securities, and obligations of the U.S. government and U.S. government sponsored entities. 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, which approximates cost and, as of September 30, 2012 and

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December 31, 2011, all of our funds were invested in cash and cash equivalents that consist of a money market fund maintained at a major U.S. financial institution.

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CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONDENSED FINANCIAL STATEMENTS, continued

Credit Risks and Concentrations

We have a concentration of credit risk related to our cash and cash equivalents. We are exposed to credit risk in the event of default by the financial institutions holding these funds to the extent of the amount recorded on our balance sheet. We mitigate this risk by investing in a money market fund that invests primarily in short-term U.S. Treasury notes and bills. For the nine-month periods ended September 30, 2012 and 2011, we experienced no loss or lack of access to cash and cash equivalents in our operating or investment accounts.

Beginning with the commercialization of Korlym in April 2012, we are also exposed to credit risk in regard to our trade receivables. We have only two customers – one specialty pharmacy and one specialty distributor, which are subsidiaries of the same corporate parent. We extend credit to these customers based on their individual creditworthiness and that of their shared parent organization. We monitor our exposure and will record a reserve against uncollectible trade receivables as necessary.

We carry a concentration of risk regarding the manufacture of our product. As of September 30, 2012, we had one manufacturer of Korlym tablets, which has indicated that it will temporarily suspend commercial production in the fourth quarter of 2012 while it relocates to, and seeks regulatory approval to begin operation of, a new facility. On