
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event Reported): August 9, 2018

Corcept Therapeutics Incorporated
(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

000-50679
(Commission File Number)

77-0487658
(I.R.S. Employer Identification Number)

149 Commonwealth Drive, Menlo Park, CA 94025
(Address of Principal Executive Offices) (Zip Code)

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

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). 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.

Item 2.02. Results of Operations and Financial Condition.

Item 7.01. Regulation FD Disclosure.

On August 9, 2018, Corcept Therapeutics Incorporated (“Corcept” or the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 2018 and a corporate update. The press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 2.02 and Item 7.01 and the information contained in the press release attached as Exhibit 99.1 shall not be deemed filed for purposes of Section 18 of the Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information in this Item 2.02 and Item 7.01 and the information contained in the press release attached as Exhibit 99.1 is not incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in the filing unless specifically stated so therein.

Item 8.01. Other Events.

On August 9, 2018, Corcept announced that its Board of Directors approved a program to repurchase up to \$100 million of the Company’s common stock (the “Stock Repurchase Program”). Unless it is terminated or suspended prior to its expiration, the Stock Repurchase Program will remain in effect until June 30, 2019. The timing and amount of any repurchases pursuant to it will be determined based on market conditions, stock price and other factors. The Stock Repurchase Program does not require Corcept to acquire any specific number of shares and it may be modified, suspended or discontinued at any time without notice. Repurchases pursuant to the Stock Repurchase Program may be made through a variety of methods, including open market purchases, privately negotiated transactions, block trades, accelerated share repurchase transactions or any combination of such methods.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

99.1 [Press Release of Corcept Therapeutics Incorporated dated August 9, 2018](#)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Corcept Therapeutics Incorporated

Date: August 9, 2018

By: /s/ G. Charles Robb
G. Charles Robb
Chief Financial Officer

Corcept Therapeutics Announces Second Quarter 2018 Financial Results and Stock Repurchase Program; Provides Clinical Update

MENLO PARK, Calif., Aug. 09, 2018 (GLOBE NEWSWIRE) -- Corcept Therapeutics Incorporated (NASDAQ: CORT), a company engaged in the discovery, development and commercialization of drugs to treat severe metabolic, oncologic and psychiatric disorders by modulating the effects of the stress hormone cortisol, today reported its results for the quarter ended June 30, 2018.

Financial Highlights

- Revenue of \$62.3 million, a 75 percent increase from second quarter 2017
- GAAP net income of \$0.14 per share, compared to \$0.10 per share in second quarter 2017
- Non-GAAP net income of \$0.20 per share, compared to \$0.13 per share in second quarter 2017
- Cash and investments of \$159.9 million, a \$19.6 million increase from first quarter 2018
- 2018 revenue guidance revised to \$250 – 270 million, from \$275 – 300 million
- Company announces \$100 million stock repurchase program

Relacorilant Data

The final 18 patients enrolled in the trial (the “High-Dose” cohort) receive 250 mg/day of relacorilant for four weeks, with dose being increased, as tolerability permits, to 300 mg/day for four weeks, then 350 mg/day for four weeks, then 400 mg/day for four weeks; data are available for the 250 mg/day and 300 mg/day dose levels.

Based on FDA feedback, Corcept has developed response criteria for relacorilant’s Phase 3 trial. Applying these endpoints to the High-Dose cohort at eight weeks of treatment (conclusion of the 300 mg dose level) produces the following results:

- Fifty-eight percent of patients with hyperglycemia achieved improved glucose control, as shown by a (i) 0.5 percent or greater reduction in HbA1c or (ii) 50 mg/dl or greater reduction (or normalization) in 2-hour glucose as measured in the oral glucose tolerance test or (iii) 25 percent or greater decrease in antidiabetic medications
- Fifty-five percent of patients with uncontrolled hypertension achieved a five millimeter or greater drop in either systolic or diastolic blood pressure, as measured by 24-hour ambulatory monitoring
- No evidence of progesterone receptor affinity; no instances of hypokalemia
- Testing of higher doses is ongoing; Phase 3 trial planned to start this year

Oncologic and Metabolic Disorders

- Placebo-controlled, Phase 2 trial of relacorilant plus Abraxane[®] (nab-paclitaxel) in metastatic ovarian cancer planned to start by year-end
- Results expected by year-end in study of relacorilant plus Abraxane in patients with metastatic pancreatic cancer
- Dosing continues in Phase 1/2 trial of CORT125281 plus Xtandi[®] (enzalutamide) in patients with metastatic castration-resistant prostate cancer
- Planning underway for placebo-controlled, Phase 2 trials of CORT118335 in patients with antipsychotic-induced weight gain and non-alcoholic steatohepatitis (“NASH”); both trials planned to start by year-end

Financial Results

Corcept reported quarterly revenue of \$62.3 million, compared to \$35.6 million in the second quarter of 2017. Second quarter GAAP net income was \$18.2 million, compared to \$12.6 million in the same period last year. Excluding non-cash expenses related to stock-based compensation, utilization of deferred tax assets, accreted interest on the company’s retired royalty financing obligation and related income tax effects, non-GAAP net income in the second quarter was \$25.4 million, compared to \$16.0 million in the second quarter of 2017. (A reconciliation of GAAP to non-GAAP net income is set forth below.) The company reduced its 2018 guidance to \$250 – 270 million.

Second quarter operating expenses were \$41.7 million, compared to \$22.8 million in the second quarter of 2017, primarily due to increased spending to advance relacorilant, CORT118335 and CORT125281 and costs from increased sales volume.

Cash and investments were \$159.9 million at June 30, 2018, an increase of \$19.6 million from first quarter 2018.

The company announced a program to repurchase up to \$100 million of its common stock, which it intends to fund using cash and investments. Details of the program are provided below.

“Our Cushing’s syndrome franchise continues its significant growth, driven by physicians’ increasing realization that hypercortisolism is a serious disorder and that cortisol modulation is the best medical therapy for many patients,” said Joseph K. Belanoff, MD, Corcept’s Chief Executive Officer. “We are confident this shift in medical practice will continue.”

Relacorilant’s Phase 2 Trial

“Interim data from our Phase 2 trial’s High-Dose cohort showed that relacorilant provided clinically meaningful benefit without the two off-target effects – progesterone receptor affinity and increased cortisol levels – that cause Korlym[®]’s most common and serious adverse events – termination of pregnancy, endometrial thickening, vaginal bleeding and low potassium (hypokalemia),” said Robert S. Fishman, MD, Corcept’s Chief Medical Officer.

“That relacorilant did not cause hypokalemia in these patients is surprising – and important,” he added. “Forty-four percent of the patients in Korlym’s pivotal trial experienced hypokalemia, which can be life-threatening. It is one of the most common adverse events in patients taking Korlym today.

“Interim efficacy data have also been impressive. Based on our planned Phase 3 endpoints, 58 percent of the patients with hyperglycemia achieved improved glucose control. Applying the same endpoints, this figure was 48 percent at the comparable time in Korlym’s pivotal trial (“SEISMIC”) and 23 percent at the conclusion of treatment in the Low-Dose cohort. (See Figure 1) For patients with hypertension, 55 percent responded in the High-Dose cohort, compared to 44 percent in SEISMIC and 45 percent of the Low-Dose cohort. (See Figure 2)

“Relacorilant was well-tolerated,” he concluded. “We observed one serious adverse event, a pilonidal abscess, which resolved without discontinuing relacorilant. One patient discontinued due to musculoskeletal pain and fatigue – a relatively common adverse event seen as cortisol modulation decreases cortisol activity.”

Oncology

“At ASCO’s annual meeting this May, we reported positive data from the dose-finding portion of our Phase 1/2 study of relacorilant plus Abraxane to treat patients with solid tumors,” added Dr. Fishman. “At the minimum therapeutic dose, four of nine patients with metastatic pancreatic cancer and four of seven patients with metastatic ovarian cancer demonstrated durable disease control. These results are especially notable in patients with such dire disease, all of whom had progressed on one or more prior taxane-based treatments. Recently, another patient with pancreatic cancer has achieved a partial response.

“These results justify significantly expanding our oncology program. By year-end, we plan to open a placebo-controlled, Phase 2 trial of relacorilant plus Abraxane in metastatic ovarian cancer. We also expect to have enough data by year-end in patients with metastatic pancreatic cancer to determine if a definitive trial is warranted.”

Conference Call

Corcept will hold a conference call August 9, 2018, at 5:00 pm Eastern Time (2:00 pm Pacific Time). To participate, dial 1-888-394-8218 from the United States or 1-323-794-2588 internationally ten minutes before the start of the call (passcode: 6703650). A replay will be available through August 23, 2018 at 888-203-1112 from the United States and 719-457-0820 internationally (passcode: 6703650).

About Corcept Therapeutics Incorporated

Corcept is a pharmaceutical company engaged in the discovery, development and commercialization of drugs that treat severe metabolic, oncologic and psychiatric disorders by modulating the effects of cortisol. Korlym is our first FDA-approved medication. We have a large portfolio of proprietary compounds that modulate the effects of cortisol but not progesterone. We own extensive United States and foreign intellectual property covering the use of cortisol modulators, including mifepristone, in the treatment of a wide variety of serious disorders, including Cushing’s syndrome. We also hold composition of matter patents covering its selective cortisol modulators.

About Hypercortisolism

Hypercortisolism, often referred to as Cushing’s syndrome, is caused by excessive activity of the stress hormone cortisol. Endogenous Cushing’s syndrome is an orphan disease that most often affects adults aged 20-50. In the United States, an estimated 20,000 patients have Cushing’s syndrome, with about 3,000 new patients being diagnosed each year. Symptoms vary, but most people experience 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. Our first approved product, Korlym, inhibits the effects of excess cortisol by modulating activity at the glucocorticoid receptor, one of the two receptors to which cortisol binds. Korlym was the first FDA-approved treatment for patients with Cushing’s syndrome and the FDA has designated it as an Orphan Drug for that indication.

About Corcept’s Stock Repurchase Program

Our Board of Directors has approved a program authorizing the repurchase of up to \$100 million of the company’s common stock through June 30, 2019. Purchases under this program may be made in the open market, in privately negotiated transactions or otherwise. The timing and amount of any repurchases will be determined based on market conditions, stock price and other factors. The program does not require the company to repurchase any specific number of shares of its common stock and may be modified, suspended or discontinued at any time without notice.

Non-GAAP Measures of Net Income

To supplement Corcept's financial results presented on a GAAP basis, we use non-GAAP measures of net income that include the following non-cash items – stock-based compensation, utilization of deferred tax assets to offset a portion of our income tax liability, accreted interest on our now-retired royalty financing obligation and related income tax effects. We believe these non-GAAP measures 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 the company's financial statements prepared in accordance with GAAP. The non-GAAP measures of net income we use may be different from, and not directly comparable to, similarly titled measures used by other companies.

Forward-Looking Statements

Statements and quotations in this press release, other than statements of historical fact, are forward-looking statements based on our plans and expectations and are subject to risks and uncertainties that might cause actual results to differ materially from those such statements express or imply. These risks and uncertainties include, but are not limited to, our ability to generate sufficient revenue to fund our commercial operations and development programs, the protections afforded by Korlym's Orphan Drug designation and our intellectual property, the availability of competing treatments, including generic versions of Korlym, our ability to obtain acceptable prices or adequate insurance coverage and reimbursement for Korlym, and scientific, regulatory, management and financial risks related to the development of our product candidates for any indication. These and other risks are set forth in our SEC filings, available at our website and the SEC's website. In this press release, forward-looking statements include those concerning our 2018 revenue guidance and expected growth in 2019 and beyond; our stock repurchase program and its intended funding sources; physician awareness of hypercortisolism and selection of Korlym as the best medical therapy for many patients and continued shift in medical practice; the clinical attributes of relacorilant based on interim data; data from the dose-finding portion of our Phase 1/2 study of relacorilant plus Abraxane[®] as justification for significantly expanding our oncology program; and the progress and results of our development programs, including our current and planned clinical trials of relacorilant, CORT125281 and CORT118335. We disclaim any intention or duty to update forward-looking statements made in this press release.

Abraxane[®] is a registered trademark of Celgene Corporation.

Xtandi[®] is a registered trademark of Astellas Pharma Inc.

CORCEPT THERAPEUTICS INCORPORATED
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	June 30,	December 31,
	2018	2017⁽¹⁾
	(Unaudited)	
ASSETS		
Cash and investments	\$ 159,945	\$ 104,025
Trade receivables, net of allowances	28,704	15,300
Inventory	10,447	8,376
Other receivable	—	12,896
Deferred tax assets	71,102	76,703
Other assets	4,184	3,237
Total assets	\$ 274,382	\$ 220,537
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable	\$ 6,365	\$ 8,579
Other liabilities	24,508	20,990
Stockholders' equity	243,509	190,968
Total liabilities and stockholders' equity	\$ 274,382	\$ 220,537

⁽¹⁾Derived from audited financial statements at that date

CORCEPT THERAPEUTICS INCORPORATED
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

(Unaudited)

Three

Six Months Ended

	Months Ended June 30,		June 30,	
	2018	2017	2018	2017
Revenues:				
Product sales, net	\$ 62,312	35,559	\$ 119,971	63,158
Operating expenses:				
Cost of sales	1,154	775	2,328	1,421
Research and development	20,543	7,876	37,593	15,052
Selling, general and administrative	19,981	14,113	38,421	29,150
Total operating expenses	\$ 41,678	\$ 22,764	\$ 78,342	\$ 45,623
Income from operations	20,634	12,795	41,629	17,535
Interest and other income (expense)	562	(98)	856	(323)
Income before income taxes	21,196	12,697	42,485	17,212
Income tax expense	(3,000)	(50)	(6,830)	(177)
Net income	\$ 18,196	\$ 12,647	\$ 35,655	\$ 17,035
Other comprehensive income:				
Net unrealized gain (loss) on available-for-sale securities, net of tax impact of \$(7), \$0, \$41 and \$0, respectively	25	(5)	(127)	(17)
Total comprehensive income	\$ 18,221	\$ 12,642	\$ 35,528	\$ 17,018
Basic net income per common share	\$ 0.16	\$ 0.11	\$ 0.31	\$ 0.15
Diluted net income per common share	\$ 0.14	\$ 0.10	\$ 0.28	\$ 0.14
Shares used to compute basic net income per share	115,492	113,249	115,189	113,059
Shares used to compute diluted net income per share	127,515	123,011	127,610	122,171

CORCEPT THERAPEUTICS INCORPORATED
RECONCILIATION OF GAAP TO NON-GAAP NET INCOME
(in thousands, except per share amounts)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
GAAP net income	\$ 18,196	\$ 12,647	\$ 35,655	\$ 17,035
Non-cash expenses (benefits):				
Stock-based compensation				
Research and development	1,963	850	3,427	1,503
Selling, general and administrative	4,054	2,355	7,544	4,403
Total stock-based compensation	6,017	3,205	10,971	5,906
Accretion of interest expense related to debt obligation	—	149	—	419
Deferred tax assets	2,474	—	5,643	—
Income tax effect of non-GAAP adjustments ⁽¹⁾	(1,264)	—	(2,304)	—
Non-GAAP net income, as adjusted for non-cash expenses	\$ 25,423	\$ 16,001	\$ 49,965	\$ 23,360
GAAP basic net income per share	\$ 0.16	\$ 0.11	\$ 0.31	\$ 0.15
GAAP diluted net income per share	\$ 0.14	\$ 0.10	\$ 0.28	\$ 0.14

Non-GAAP basic net income per share, as adjusted for non-cash expenses	<u>\$ 0.22</u>	<u>\$ 0.14</u>	<u>\$ 0.43</u>	<u>\$ 0.21</u>
Non-GAAP diluted net income per share, as adjusted for non-cash expenses	<u>\$ 0.20</u>	<u>\$ 0.13</u>	<u>\$ 0.39</u>	<u>\$ 0.19</u>
Shares used to compute basic net income per share	<u>115,492</u>	<u>113,249</u>	<u>115,189</u>	<u>113,059</u>
Shares used to compute diluted net income per share	<u>127,515</u>	<u>123,011</u>	<u>127,610</u>	<u>122,171</u>

⁽¹⁾Calculated by applying the statutory tax rate to the pre-tax, non-discrete, non-GAAP adjustments.

CONTACT:
Charles Robb
Chief Financial Officer
Corcept Therapeutics
650-688-8783
crobb@corcept.com
www.corcept.com

Photos accompanying this announcement are available at

<http://www.globenewswire.com/NewsRoom/AttachmentNg/06e45b60-50ce-4fdf-8748-1ce8dbd93b05>

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