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

November 7, 2019
Date of Report (date of earliest event reported)

Corcept Therapeutics Incorporated

(Exact name of registrant as specified in its charter)

Delaware	**000-50679**	**77-0487658**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

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 (see General Instruction A.2. below):

☐ 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	CORT	The Nasdaq Stock Market

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

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.

O n November 7, 2019, Corcept Therapeutics Incorporated (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2019 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 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibits No.	Description
99.1	Press Release of Corcept Therapeutics Incorporated, dated November 7, 2019.
104.1	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document.

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: November 7, 2019

By: /s/ G. Charles Robb

Name: G. Charles Robb

Title: Chief Financial Officer and Secretary

EXHIBIT 99.1

Corcept Therapeutics Announces Third Quarter 2019 Financial Results and Provides Corporate Update

MENLO PARK, Calif. (November 7, 2019) - Corcept Therapeutics Incorporated (NASDAQ: CORT), a commercial-stage company engaged in the discovery and development 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 September 30, 2019.

Financial Highlights

- *Revenue of $81.5 million, a 26 percent increase from third quarter 2018*
- *GAAP diluted net income of $0.22 per share, compared to $0.14 per share in third quarter 2018*
- *Non-GAAP diluted net income of $0.31 per share, compared to $0.22 per share in third quarter 2018*
- *Cash and investments of $266.9 million, compared to $225.7 million in second quarter 2019*
- *2019 revenue guidance narrowed to $300 - $315 million*

Corcept reported quarterly revenue of $81.5 million in the third quarter, compared to $64.4 million in the third quarter of 2018. Third quarter GAAP net income was $26.3 million, compared to $17.7 million in the same period last year. Excluding non-cash expenses related to stock-based compensation and the utilization of deferred tax assets, together with related income tax effects, non-GAAP net income in the third quarter was $37.8 million, compared to $27.9 million in the third quarter of 2018. A reconciliation of GAAP to non-GAAP net income is included below.

The company narrowed 2019 revenue guidance to $300 - $315 million. Guidance had previously been $285 - $315 million.

Third quarter operating expenses were $48.5 million, compared to $41.5 million in the third quarter of 2018, primarily due to increased spending to recruit and compensate additional personnel and discover and develop new selective cortisol modulators, as well as increased legal expense. Cash and investments were $266.9 million at September 30, 2019, an increase of $41.2 million from June 30, 2019.

“Our Cushing’s syndrome business had an excellent quarter,” said Joseph K. Belanoff, MD, Corcept’s Chief Executive Officer. “We expect the number of patients receiving Korlym and physicians prescribing the medication to continue to increase. To reach more doctors, we are expanding our sales force. We expect the clinical specialists we are hiring now to begin contributing to our results next year.

“I am also pleased to announce an important advance in our program to treat serious metabolic disorders. In a double-blind, placebo-controlled trial in healthy subjects, our selective cortisol modulator miricorilant significantly reduced the weight gain caused by the commonly prescribed antipsychotic medication olanzapine (Eli Lily’s drug, Zyprexa®). We have already initiated one of two planned Phase 2 trials to further test miricorilant’s activity in this indication.”

Cushing’s Syndrome

- *European sites begin dosing patients in Phase 3 trial (“GRACE”) of relacorilant to treat patients with Cushing’s syndrome*
- *Double-blind, placebo-controlled, Phase 3 trial of relacorilant in patients whose Cushing’s syndrome is caused by adrenal adenomas to start in the first quarter of next year*

“As of today, 42 of 62 planned sites are recruiting patients for GRACE,” said Andreas Grauer, MD, Corcept’s Chief Medical Officer. “We expect to open an additional 13 sites by the end of the year. The activation pace of ex-US sites, which we expect will provide the majority of enrollments, has refined our estimate of the trial’s completion date. Our plan is to submit our NDA in the fourth quarter of 2021.

We spent substantial time in Europe in the past quarter helping clinical site activation and speaking to investigators. Most important, our investigators are highly enthusiastic about GRACE[1], because of relacorilant’s positive Phase 2 efficacy and side effect profile.”

Patients in relacorilant's Phase 2 trial exhibited meaningful improvements in glucose control and hypertension - two of Cushing's syndrome's most common and pernicious symptoms. The trial also met a wide range of secondary endpoints, including weight loss, liver function, coagulopathy, insulin resistance, cognitive function, mood and quality of life. These results were achieved without relacorilant causing Korlym's significant off-target effects - vaginal bleeding, endometrial thickening and low potassium[2].

In addition to GRACE, Corcept plans to start a Phase 3, double-blind, placebo-controlled trial of relacorilant in patients whose Cushing's syndrome is caused by an adrenal adenoma - a population that has not been rigorously studied. Patients with adrenal Cushing's syndrome typically experience a slower onset of symptoms, but their ultimate health outcomes are poor. Corcept expects to enroll 130 patients at sites in the United States and Europe in the study. Most of the planned investigators and sites are also participating in GRACE.

[1]For more about GRACE, go to cushingresearch.com.
[2]For more data, see our poster from the 2019 American Association of Clinical Endocrinologists' 28th Annual Congress, available at the Investors/Events tab of our website.

Metabolic Disease

- *Positive top-line results from double-blind, placebo-controlled, Phase 1b trial of miricorilant to reduce antipsychotic-induced weight gain*
- *Recruiting underway in double-blind, placebo-controlled, Phase 2 trial of miricorilant to reverse recent antipsychotic-induced weight gain*

"Our program to develop miricorilant as a treatment for metabolic disorders is off to an excellent start," said Dr. Grauer. "Antipsychotic medications such as olanzapine are essential to the health of millions of patients, but the weight gain and other metabolic side effects they cause are life-threatening and often lead patients to discontinue treatment. At the first dose level tested in our Phase 1b trial, healthy subjects given olanzapine plus miricorilant gained less weight than subjects receiving olanzapine plus placebo (*see* Figure 1). In addition, markers of liver damage that often rise temporarily at the start of olanzapine therapy increased less sharply in subjects receiving miricorilant, suggesting that miricorilant may have protective effects in the liver (*see* Figure 2). Five subjects in the olanzapine alone group were unable to complete the study due to elevated liver enzymes, while one patient in the miricorilant group experienced this problem.

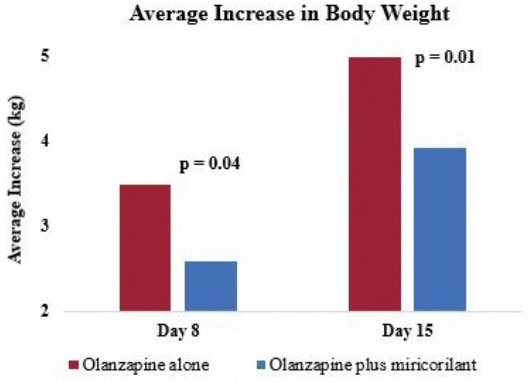

Figure 1. Increase in body weight

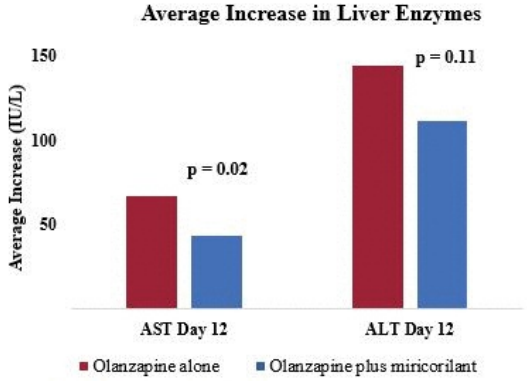

Figure 2. Increase in liver enzymes

The Phase 1b trial's first part enrolled 66 healthy subjects, each of whom received olanzapine (10 mg) and either miricorilant (600 mg) or placebo daily. The trial's duration was two weeks. The second part of the trial, which is planned to start in December, will test a higher dose of miricorilant (900 mg) in 30 healthy subjects. The study's full results will be presented at a scientific meeting in 2020.

“These preliminary results are especially encouraging given the short duration of treatment and the low dose of miricorilant. They are consistent with the effects we had previously seen in animal studies. Our plan is to confirm these findings and explore the full breadth of miricorilant’s activity,” said Dr. Grauer.

In addition to the second part of its Phase 1b trial, Corcept plans to conduct two double-blind, placebo-controlled Phase 2 trials of miricorilant for the treatment of patients with antipsychotic-induced weight gain. The first trial, which is underway, will test miricorilant’s activity in reversing recent weight gain. It is expected to enroll 100 patients with schizophrenia at 20 sites in the United States. Patients will continue to receive their established antipsychotic medication and will have either miricorilant or placebo added to their regimen for 12 weeks. A second Phase 2 trial is planned to start next year. It will enroll patients with long-standing weight gain. A third Phase 2 trial, testing miricorilant’s activity in preventing antipsychotic-induced weight gain, is under consideration.

Next year, Corcept also plans to start a double-blind, placebo-controlled, Phase 2 trial of miricorilant as a treatment for patients with non-alcoholic steatohepatitis (NASH), a serious liver disorder that afflicts millions of people.

Solid Tumor

- *European Commission designates relacorilant orphan drug for treatment of pancreatic cancer*
- *Phase 3 trial of relacorilant plus nab-paclitaxel in patients with metastatic pancreatic cancer to start upon completion of consultations with the U.S. Food and Drug Administration (FDA)*

“We are pleased the European Commission (EC) has joined the FDA in designating relacorilant an orphan drug for the treatment of pancreatic cancer,” said Dr. Grauer. “The EC based its decision on the European Medicines Agency’s finding that relacorilant has the potential to significantly benefit patients.

“We presented the clinical data reviewed by the EMA at last year’s ASCO meeting and it was indeed promising,” said Dr. Grauer. “Seven of 25 patients with metastatic pancreatic cancer treated with relacorilant plus nab-paclitaxel (Celgene’s drug, Abraxane®) achieved durable disease control, meaning their tumors either shrank or ceased growing for 16 weeks or longer. Tumor response in two patients lasted more than 50 weeks[3]. All of these patients’ tumors had progressed during multiple lines of prior therapy, including treatments with nab-paclitaxel or another taxane. That any of them responded is remarkable. We have sought FDA guidance as to the optimum development path in pancreatic cancer and plan to start a Phase 3 trial promptly upon the conclusion of our discussions.”

Corcept’s 180-patient, placebo-controlled Phase 2 trial of relacorilant plus nab-paclitaxel in ovarian cancer continues to enroll patients at sites in the United States and the European Union. Dosing also continues in the company’s Phase 1/2 study of exicorilant plus enzalutamide in patients with castration-resistant prostate cancer.

[3]For more data, see our ASCO poster at the Investors/Past Events tab of our website.

Conference Call

We will hold a conference call on November 7, 2019, at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). To participate, dial 1-877-260-1479 from the United States or 1-334-323-0522 internationally approximately ten minutes before the start of the call (passcode 8532239). A replay will be available through November 21, 2019 at 1-888-203-1112 in the United States and 1-719-457-0820 internationally (passcode 8532239).

Hypercortisolism

Hypercortisolism, often referred to as Cushing’s syndrome, is caused by excessive activity of the 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 diagnosed each year. Symptoms vary, but most patients 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. Hypercortisolism can affect every organ system in the body and can be lethal if not treated effectively.

About Corcept Therapeutics Incorporated

Corcept's approved product, Korlym®, was the first treatment approved by the U.S. Food and Drug Administration for patients with Cushing's syndrome. Corcept has discovered a large portfolio of proprietary compounds, including relacorilant, exicorilant and miricorilant, that selectively modulate the effects of cortisol but not progesterone. Corcept owns extensive United States and foreign intellectual property covering the composition of its selective cortisol modulators and the use of cortisol modulators, including mifepristone, to treat a variety of serious disorders.

GAAP Measures of Net Income

To supplement our financial results presented on a GAAP basis, we use non-GAAP measures of net income, non-GAAP basic net income per share and non-GAAP diluted net income per share that exclude the following non-cash expenses - stock-based compensation, our use of deferred tax assets to offset current tax expense, and related income tax effects. We believe these non-GAAP measures help investors evaluate our financial performance and potential future results. Our non-GAAP measures may be different from, and not directly comparable to, those used by other companies. They are not a substitute for comparable GAAP measures and should not be considered in isolation. Rather, investors should read our non-GAAP presentation in conjunction with our financial statements prepared in accordance with GAAP.

Forward-Looking Statements

Statements in this press release, other than statements of historical fact, are forward-looking statements, which are based on our current 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 availability of competing treatments, including generic versions of Korlym; our ability to obtain acceptable prices or adequate insurance coverage and reimbursement for Korlym; and risks related to the development of our product candidates, including regulatory approvals, mandates, oversight and other requirements. These and other risks are set forth in our SEC filings, which are available at our website and the SEC's website. In this press release, forward-looking statements include those concerning our 2019 revenue guidance; expected growth in the number of patients receiving Korlym and physicians writing Korlym prescriptions; the planned expansion of our sales force and the productivity of these newly-hired clinical specialists; the progress, enrollment, timing, design and results of our development programs, including the GRACE trial, our Phase 3 trial in patients with adrenal Cushing's syndrome, and our other clinical trials; discussions with and planned submissions to regulatory authorities; the clinical and commercial attributes of relacorilant, exicorilant and miricorilant; and the scope and protective power of our intellectual property. We disclaim any intention or duty to update forward-looking statements made in this press release.

CORCEPT THERAPEUTICS INCORPORATED

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except per share data)

	September 30, 2019	December 31, 2018 [1]
	(Unaudited)	
ASSETS		
Cash and investments	$ 266,895	$ 206,760
Trade receivables, net of allowances	22,405	17,588
Inventory	17,001	16,242
Operating lease right-of-use asset	742	—
Deferred tax assets, net	50,804	62,659
Other assets	9,175	8,445
Total assets	$ 367,022	$ 311,694
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable	$ 5,937	$ 8,266
Operating lease liability	770	—
Other liabilities	25,939	27,546
Stockholders' equity	334,376	275,882
Total liabilities and stockholders’ equity	$ 367,022	$ 311,694

[1] Derived from audited financial statements at that date

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,	
	2019	**2018**	**2019**	**2018**
Revenues:				
Product revenue, net	$ 81,505	$ 64,445	$ 218,591	$ 184,416
Operating expenses:				
Cost of sales	1,451	1,308	4,068	3,636
Research and development	22,805	18,860	64,705	56,453
Selling, general and administrative	24,245	21,308	73,228	59,729
Total operating expenses	48,501	41,476	142,001	119,818
Income from operations	33,004	22,969	76,590	64,598
Interest and other income	1,348	759	3,626	1,615
Income before income taxes	34,352	23,728	80,216	66,213
Income tax expense	(8,012)	(5,981)	(15,416)	(12,811)
Net income	$ 26,340	$ 17,747	$ 64,800	$ 53,402
Other comprehensive income (loss):				
Net unrealized income (loss) on available-for-sale investments, net of tax impact of $1, $(16), $(123) and $25, respectively	(2)	50	389	(77)
Foreign currency translation loss, net of tax	(5)	—	(5)	—
Total comprehensive income	$ 26,333	$ 17,797	$ 65,184	$ 53,325
Basic net income per share	$ 0.23	$ 0.15	$ 0.57	$ 0.46
Diluted net income per share	$ 0.22	$ 0.14	$ 0.53	$ 0.42
Shares used in computing basic net income per common share	113,875	115,798	114,349	115,394
Shares used in computing diluted net income per common share	121,762	126,159	122,478	127,167

CORCEPT THERAPEUTICS INCORPORATED

RECONCILIATION OF GAAP TO NON-GAAP NET INCOME
(Unaudited)
(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
GAAP net income	$ 26,340	$ 17,747	$ 64,800	$ 53,402
Non-cash expenses (benefits):				
Stock-based compensation				
Cost of sales	22	—	105	—
Research and development	2,350	1,961	6,834	5,388
Selling, general and administrative	4,899	4,549	14,764	12,093
Total stock-based compensation	7,271	6,510	21,703	17,481
Deferred income taxes	5,897	4,960	11,731	10,603
Income tax effect of non-GAAP adjustments [(1)]	(1,745)	(1,367)	(5,209)	(3,671)
Non-GAAP net income, as adjusted for non-cash expenses	$ 37,763	$ 27,850	$ 93,025	$ 77,815
GAAP basic net income per share	$ 0.23	$ 0.15	$ 0.57	$ 0.46
GAAP diluted net income per share	$ 0.22	$ 0.14	$ 0.53	$ 0.42
Non-GAAP basic net income per share, as adjusted for non-cash expenses	$ 0.33	$ 0.24	$ 0.81	$ 0.67
Non-GAAP diluted net income per share, as adjusted for non-cash expenses	$ 0.31	$ 0.22	$ 0.76	$ 0.61
Shares used in computing basic net income per share	113,875	115,798	114,349	115,394
Shares used in computing diluted net income per share	121,762	126,159	122,478	127,167

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

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