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 3, 2021
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.

On November 3, 2021, Corcept Therapeutics Incorporated (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2021 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 03, 2021
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 3, 2021

By: /s/ Atabak Mokari
Name: Atakbak Mokari
Title: Chief Financial Officer

EXHIBIT 99.1

CORCEPT THERAPEUTICS ANNOUNCES THIRD QUARTER FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

MENLO PARK, Calif. (November 3, 2021) – Corcept Therapeutics Incorporated (NASDAQ: CORT), a commercial-stage company engaged in the discovery and development of drugs to treat severe metabolic, oncologic and neuropsychiatric disorders by modulating the effects of the hormone cortisol, today reported its results for the quarter ended September 30, 2021.

Financial Results

- *Revenue of $96.1 million, an 11 percent increase from third quarter 2020*
- *GAAP diluted net income of $0.24 per share, compared to $0.17 per share in third quarter 2020*
- *Non-GAAP diluted net income of $0.30 per share, compared to $0.24 per share in third quarter 2020*
- *Cash and investments of $495.2 million, compared to $471.6 million at June 30, 2021*
- *Tightening of 2021 revenue guidance to $365 – $375 million*

“The strong growth of our commercial business in the third quarter reflects the continued easing of COVID-related public health restrictions,” said Joseph K. Belanoff, MD, Corcept’s Chief Executive Officer. “Physicians are seeing their patients more frequently and, as a result, are better able to diagnose and treat patients with Cushing’s syndrome. As pandemic conditions recede, we expect our growth to continue. Korlym is an excellent treatment for Cushing’s syndrome and there are many eligible patients who have yet to receive it.”

Corcept’s third quarter 2021 revenue was $96.1 million, compared to $86.3 million in the third quarter of 2020. Third quarter 2021 GAAP net income was $30.5 million, compared to $21.6 million in the third quarter of 2020. 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 $37.0 million, compared to $30.0 million in the third quarter of 2020. A reconciliation of GAAP to non-GAAP net income is included below.

Corcept narrowed its 2021 revenue guidance to $365 – $375 million. The company’s previous guidance was $355 – $385 million.

Third quarter operating expenses were $59.9 million, compared to $61.6 million in the third quarter of 2020, primarily due to the conclusion of our studies in ovarian and pancreatic cancer, partially offset by increased employee compensation expenses, commercial spending and increased preclinical activities.

Cash and investments of $495.2 million at September 30, 2021 reflects the acquisition in the third quarter of $28.0 million of Corcept common stock – 1.2 million shares pursuant to the company’s stock repurchase program and 0.2 million shares in connection with the exercise of employee stock options. Over the term of the stock repurchase program, which began in November 2020, Corcept acquired 4.3 million shares of common stock at a cost of $98.2 million.

Clinical Development

“Cortisol modulation has the potential to help treat many serious diseases,” said Dr. Belanoff. “Currently, our clinical programs are evaluating treatments for patients with solid tumors, non-alcoholic steatohepatitis (NASH), antipsychotic-induced weight gain (AIWG) and Cushing’s syndrome. We also continue to advance new cortisol modulators to the clinic. Early next year, we plan to start a Phase 2 trial in patients with amyotrophic lateral sclerosis (ALS).”

Solid Tumors

- *Phase 3 trial in patients with recurrent platinum-resistant ovarian cancer to start in the first quarter of 2022; updated overall survival data from the Phase 2 trial expected in the first quarter of 2022*
- *Selection of the optimum dose of exicorilant plus enzalutamide in patients with castration-resistant prostate cancer (CRPC) expected later this year*
- *Enrollment continues in 20-patient, open-label, Phase 1b trial of relacorilant plus PD-1 checkpoint inhibitor pembrolizumab in patients with adrenal cancer with cortisol excess*

“Leading gynecological oncologists have given us extremely positive feedback regarding the statistically significant and clinically meaningful results of our 178-patient, randomized, controlled Phase 2 trial in patients with recurrent platinum-resistant ovarian cancer and our plans to initiate a Phase 3 trial,” said Bill Guyer, PharmD, Corcept’s Chief Development Officer. “We and our investigators are excited to advance relacorilant for the potential treatment of ovarian cancer and plan to meet with the FDA in the coming months to arrive at the best path forward.”

Metabolic Diseases

- *Initiated Phase 1b dose-finding trial in patients with presumed NASH; results of our Phase 2 study to be presented at the American Association for the Study of Liver Diseases (AASLD) meeting, November 12 - 15*
- *Completion of enrollment in GRATITUDE II, a 150-patient, double-blind, placebo-controlled Phase 2 trial of miricorilant to reverse long-standing AIWG, expected by year-end*
- *Completion of enrollment in GRATITUDE, a 100-patient double-blind, placebo-controlled Phase 2 trial of miricorilant to reverse recent AIWG, expected by mid-2022*

“At the AASLD meeting this month, we will present results from our Phase 2 trial, in which patients with presumed-NASH who received miricorilant experienced exceptionally large and rapid reductions in liver fat, accompanied by substantial, but transient, elevations of the liver enzymes ALT and AST,” said Dr. Guyer. “Our hypothesis is that the rapidity and magnitude of miricorilant’s fat reducing effect irritated the liver. The objective of our Phase 1b study, initiated last month, is to identify a dosing regimen that can produce significant reductions in fat without causing liver irritation.”

Cushing’s Syndrome

- *Enrollment continues in Phase 3 GRACE trial of relacorilant as a treatment for patients with all etiologies of Cushing’s syndrome; new drug application (NDA) submission expected in the second quarter of 2023*
- *Enrollment continues in Phase 3 GRADIENT trial of relacorilant as a treatment for patients with Cushing’s syndrome caused by adrenal adenomas*

“We expect our GRACE trial, which is accruing patients and generating data, to serve as the basis for relacorilant’s NDA in Cushing’s syndrome, and we are on track to make this submission in the second quarter of 2023,” said Dr. Guyer. “The Phase 3 GRADIENT trial will produce valuable data about an etiology of Cushing’s syndrome that affects many patients, but has not been subject to rigorous, controlled study.”

Conference Call

We will hold a conference call on November 3, 2021, at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). To participate, click this link (listen-only mode) or dial 1-833-693-0540 from the United States or 1-661-407-1581 internationally approximately 15 minutes before the start of the call. The passcode will be 5763926. A replay will be available on the Investors / Past Events tab of our website.

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 and can be lethal if not treated effectively. Corcept holds patents covering the composition of relacorilant and the use of cortisol modulators, including Korlym, in the treatment of patients with hypercortisolism.

About Corcept Therapeutics

Corcept is 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 hormone cortisol. Korlym was the first drug approved by the U.S. Food and Drug Administration for patients with Cushing's syndrome. Corcept has discovered a large portfolio of proprietary compounds that selectively modulate the effects of cortisol. The company owns extensive United States and foreign intellectual property covering the composition of its selective cortisol modulators and the use of cortisol modulators 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, basic net income per share and diluted net income per share that exclude the following non-cash expenses – (i) stock-based compensation, (ii) our use of deferred tax assets to offset current tax expense and (iii) 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. 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 based on our current plans and expectations that are subject to risks and uncertainties that might cause our actual results to differ materially from those statements express or imply. These risks and uncertainties include, but are not limited to, our ability to operate our business and achieve our goals and conduct our clinical trials during the COVID-19 pandemic and 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; risks related to the development of our product candidates, including their clinical attributes, regulatory approvals, mandates and oversight, and other requirements; and the scope and protective power of our intellectual property. 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 expectations regarding growth of our business as pandemic conditions recede; eligible patients who have yet to receive Korlym; 2021 revenue guidance; the potential of cortisol modulation to help treat many serious diseases; advancement of new cortisol modulators to the clinic; planned meetings with the Food and Drug Administration (FDA); the clinical attributes of miricorilant and its effects in patients with NASH; expectations regarding the GRACE trial as the basis for relacorilant's NDA in Cushing's syndrome; our clinical development programs; the progress, enrollment, timing, design and results of our clinical trials, including the timing of enrollment, data and dosing selection and the presentation of clinical data; the timing of regulatory submissions; the course of the COVID-19 pandemic and its impact on patients, physicians, medical practice, clinical research activities and our business; and the clinical and commercial

attributes of Korlym, relacorilant, exicorilant and miricorilant. 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, 2021	December 31, 2020
	(Unaudited)	(See Note 1)
Assets		
Cash and investments	$ 495,176	$ 476,892
Trade receivables, net of allowances	26,508	26,198
Inventory	18,653	21,157
Operating lease right-of-use asset	1,022	2,509
Deferred tax assets, net	29,641	31,603
Other assets	14,399	13,372
Total assets	$ 585,399	$ 571,731
Liabilities and Stockholders' Equity		
Accounts payable	$ 6,558	$ 10,554
Operating lease liabilities	1,046	2,551
Other liabilities	37,566	35,288
Stockholders' equity	540,229	523,338
Total liabilities and stockholders' equity	$ 585,399	$ 571,731

(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,	
	2021	**2020**	**2021**	**2020**
Revenues				
Product revenue, net	$ 96,131	$ 86,327	$ 267,156	$ 26
Operating expenses				
Cost of sales	1,275	1,216	3,927	
Research and development	28,091	33,869	85,345	8
Selling, general and administrative	30,533	26,523	90,071	7
Total operating expenses	$ 59,899	$ 61,608	$ 179,343	$ 17
Income from operations	36,232	24,719	87,813	9
Interest and other income	72	622	457	
Income before income taxes	36,304	25,341	88,270	10
Income tax expense	(5,833)	(3,716)	(7,811)	(2
Net income	$ 30,471	$ 21,625	$ 80,459	$ 8
Other comprehensive income:				
Net unrealized (loss) gain on available-for-sale investments, net of tax impact of $8, $109, 85 and (81), respectively	(23)	(347)	(265)	
Foreign currency translation (loss) gain, net of tax	(77)	84	(35)	
Total comprehensive income	$ 30,371	$ 21,362	$ 80,159	$ 8
Basic net income per share	$ 0.26	$ 0.19	$ 0.69	$
Diluted net income per share	$ 0.24	$ 0.17	$ 0.63	$
Shares used in computing basic net income per common share	115,791	115,734	116,297	11
Shares used in computing diluted net income per common share	125,136	124,464	127,173	12

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,	
	2021	**2020**	**2021**	**2020**
GAAP net income	$ 30,471	$ 21,625	$ 80,459	$ 80,017
Non-cash expenses (benefits)				
Stock-based compensation				
Cost of sales	12	13	38	51
Research and development	3,434	2,958	10,764	8,357
Selling, general and administrative	7,506	5,731	21,319	16,701
Total stock-based compensation	10,952	8,702	32,121	25,109
Deferred income taxes	(1,822)	1,761	2,047	11,778
Income tax effect of non-GAAP adjustments [(1)]	(2,628)	(2,088)	(7,709)	(6,026)
Non-GAAP net income, adjusted for non-cash expenses	$ 36,973	$ 30,000	$ 106,918	$ 110,878
GAAP basic net income per share	$ 0.26	$ 0.19	$ 0.69	$ 0.70
GAAP diluted net income per share	$ 0.24	$ 0.17	$ 0.63	$ 0.65
Non-GAAP basic net income per share, adjusted for non-cash expenses per share	$ 0.32	$ 0.26	$ 0.92	$ 0.96
Non-GAAP diluted net income per share, adjusted for non-cash expenses per share	$ 0.30	$ 0.24	$ 0.84	$ 0.90
Shares used in computing basic net income per common share	115,791	115,734	116,297	115,107
Shares used in computing diluted net income per common share	125,136	124,464	127,173	123,337

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

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