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

February 15, 2022
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 February 15, 2022, Corcept Therapeutics Incorporated (the "Company") issued a press release announcing its financial results for the quarter ended December 31, 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 February 15, 2022
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: February 15, 2022

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

EXHIBIT 99.1

CORCEPT THERAPEUTICS ANNOUNCES FOURTH QUARTER AND FULL-YEAR 2021 AUDITED FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

MENLO PARK, Calif. (February 15, 2022) – Corcept Therapeutics Incorporated (NASDAQ: CORT), a commercial stage company engaged in the discovery, development and sale 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 and year ended December 31, 2021.

Financial Results

- *Fourth quarter revenue of $98.8 million, compared to $85.7 million in fourth quarter 2020*
- *2021 revenue of $366.0 million, compared to $353.9 million in 2020*
- *2022 revenue guidance of $400 – $430 million*
- *Fourth quarter GAAP net income of $32.1 million, compared to $26.0 million in fourth quarter 2020*
- *2021 GAAP net income of $112.5 million, compared to $106.0 million in 2020*
- *Purchase of ten million shares of Corcept common stock for $207.5 million in fourth quarter 2021*
- *Cash and investments of $335.8 million*

“Korlym is an excellent treatment for Cushing’s syndrome and there are many eligible patients who have yet to receive it. As pandemic restrictions and fears recede, as they already have in certain locations, we expect our growth to continue and are providing 2022 revenue guidance of $400 – $430 million,” said Joseph K. Belanoff, MD, Corcept’s Chief Executive Officer.

Corcept’s fourth quarter 2021 revenue was $98.8 million, compared to $85.7 million in the fourth quarter of 2020. 2021 revenue was $366.0 million, compared to $353.9 million in 2020. The company expects 2022 revenue of $400 – $430 million.

GAAP net income was $32.1 million in the fourth quarter of 2021, compared to $26.0 million in the fourth quarter of 2020. For the full year, it was $112.5 million in 2021, compared to $106.0 million in 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 fourth quarter was $42.6 million, compared to $34.7 million in the fourth quarter of 2020. For the full-year, non-GAAP net income was $149.5 million, compared to $145.6 million in 2020. A reconciliation of GAAP to non-GAAP net income is included below.

Cash and investments of $335.8 million at December 31, 2021 reflects the purchase of ten million shares of Corcept common stock for $207.5 million in the fourth quarter 2021.

Clinical Development

“In addition to successfully managing challenges posed by the pandemic for our commercial business, we significantly advanced our clinical development programs in 2021,” said Dr. Belanoff. “Cortisol modulation has the potential to treat many serious diseases. Data generated by our ovarian cancer and non-alcoholic steatohepatitis (NASH) programs last year provided evidence of cortisol modulation’s broad application. In 2022, we will see important results from many of our ongoing clinical programs. We also continue to advance new cortisol modulators to the clinic. Of particular note, we plan to start a Phase 2 trial in patients with amyotrophic lateral sclerosis (ALS) in the second quarter.”

Solid Tumors

- *Updated overall survival data from Phase 2 trial in patients with recurrent platinum-resistant ovarian cancer expected in first quarter 2022; Phase 3 trial planned to start second quarter 2022*
- *Selection of the optimum dose of exicorilant or relacorilant plus enzalutamide in patients with castration-resistant prostate cancer (CRPC) expected in second quarter 2022*
- *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*

“Our 178-patient, randomized, controlled Phase 2 trial of relacorilant in patients with recurrent platinum-resistant ovarian cancer met its objective of improving progression free survival, *without* increased side effect burden,” 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 based on these statistically significant and clinically meaningful results. We expect the trial’s updated overall survival data later this quarter and plan to meet with the FDA in the coming months to define the best path forward.”

Metabolic Diseases

- *Enrollment completed in GRATITUDE II, a 150-patient, double-blind, placebo-controlled Phase 2 trial of miricorilant to reverse long-standing antipsychotic-induced weight gain (AIWG); data expected in fourth quarter 2022*
- *Completion of enrollment in GRATITUDE, a double-blind, placebo-controlled Phase 2 trial of miricorilant to reverse recent AIWG, expected by mid-2022; data expected in fourth quarter 2022*
- *Enrollment continues in Phase 1b dose-finding trial of miricorilant in patients with presumed NASH*

“We are pleased to have fully-enrolled GRATITUDE II and to be nearing completion of enrollment in GRATITUDE. AIWG is a serious metabolic disorder suffered by millions of patients in the United States, with few treatment options,” said Dr. Guyer. “We initiated these double-blind, placebo-controlled, Phase 2 trials to build on the positive data from our studies of both miricorilant and mifepristone in healthy volunteers. We look forward to the data readout from both trials, which we expect in the fourth quarter.”

“We and our investigators are very excited by the unprecedented rapidity and magnitude of liver fat reduction experienced by patients taking miricorilant in our previous NASH study,” added Dr. Guyer. “The goal of our Phase 1b dose-finding study is to identify a dosing regimen that significantly reduces fat without causing excessive 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 second quarter 2023*
- *Enrollment continues in Phase 3 GRADIENT trial of relacorilant as a treatment for patients with Cushing’s syndrome caused by adrenal adenomas*

“Our Phase 3 GRACE and GRADIENT trials continue to accrue patients and generate data. We expect GRACE 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. “GRADIENT is on track to 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 February 15, 2022, 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. A replay will be available through February 22, 2022 at 1-855-859-2056 from the United States and 1-404-537-3406 internationally. The passcode will be 1861918. A replay will also 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 directed to the composition of relacorilant and the use of cortisol modulators, including Korlym, in the treatment of patients with hypercortisolism.

About Corcept Therapeutics

Corcept has discovered a large portfolio of proprietary compounds that selectively modulate the effects of cortisol and owns extensive United States and foreign intellectual property covering both their composition and their use to treat a variety of serious disorders. The company is conducting clinical trials of its leading cortisol modulators as potential treatments for patients with Cushing's syndrome, ovarian cancer, castration-resistant prostate cancer, weight gain caused by the use of antipsychotic medications and liver disease. Korlym® was the first drug approved by the U.S. Food and Drug Administration for the treatment of patients with Cushing's syndrome.

GAAP Measures of Net Income

To supplement our financial results presented on a GAAP basis, we use a non-GAAP measure 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) the use of deferred tax assets to offset current tax expense and (iii) related income tax effects. We believe this non-GAAP measure helps investors evaluate our financial performance and potential future results. Our non-GAAP measure may be different from, and not directly comparable to, those used by other companies. It is 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 such statements express or imply. These risks and uncertainties include, but are not limited to, our ability to operate our business, conduct our clinical trials and achieve our other goals during the COVID-19 pandemic and generate sufficient revenue to fund our activities; the availability of competing treatments for hypercortisolism, including generic versions of Korlym; our ability to obtain acceptable prices and adequate insurance coverage and reimbursement for Korlym; risks related to the development of our product candidates, including their clinical attributes, regulatory approvals, mandates, oversight and other requirements; the timing, cost and outcome of legal disputes and investigations; 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 the course of the COVID-19 pandemic and its effects on our commercial results and clinical activities as pandemic restrictions and fears intensify or recede; the number of eligible patients who have yet to receive Korlym; our 2022 revenue guidance; cortisol modulation's potential to treat many serious diseases; the advancement of our new cortisol modulators to the clinic; planned meetings with the Food and Drug Administration (FDA);

expectations regarding the GRACE trial as the basis for relacorilant's NDA in Cushing's syndrome; our clinical development programs generally, including the pace of enrollment, study design, dose selection and the accrual and attributes of clinical data; the timing of regulatory submissions; 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)

	December 31, 2021	December 31, 2020[1]
Assets		
Cash and investments	$ 335,812	$ 476,892
Trade receivables, net of allowances	27,625	26,198
Inventory	17,950	21,157
Operating lease right-of-use asset	514	2,509
Deferred tax assets, net	27,455	31,603
Other assets	14,400	13,372
Total assets	$ 423,756	$ 571,731
Liabilities and Stockholders' Equity		
Accounts payable	$ 6,908	$ 10,554
Operating lease liabilities	526	2,551
Other liabilities	40,516	35,288
Stockholders' equity	375,806	523,338
Total liabilities and stockholders' equity	$ 423,756	$ 571,731

[1] *Derived from audited financial statements at that date*

CORCEPT THERAPEUTICS INCORPORATED

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(In thousands, except per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2021	**2020**	**2021**	**2020**
Revenues				
Product revenue, net	$ 98,822	$ 85,735	$ 365,978	$ 353,874
Operating expenses				
Cost of sales	1,354	1,254	5,281	5,582
Research and development	28,519	28,275	113,864	114,764
Selling, general and administrative	32,285	25,696	122,356	105,326
Total operating expenses	$ 62,158	$ 55,225	$ 241,501	$ 225,672
Income from operations	36,664	30,510	124,477	128,202
Interest and other income	72	297	529	3,400
Income before income taxes	36,736	30,807	125,006	131,602
Income tax expense	(4,683)	(4,813)	(12,494)	(25,591)
Net income	$ 32,053	$ 25,994	$ 112,512	$ 106,011
Other comprehensive income:				
Net unrealized loss on available-for-sale investments, net of tax impact of $113, $96, $198 and $15, respectively	(356)	(309)	(621)	(50)
Foreign currency translation gain (loss), net of tax	14	147	(21)	204
Total comprehensive income	$ 31,711	$ 25,832	$ 111,870	$ 106,165
Basic net income per share	$ 0.28	$ 0.22	$ 0.97	$ 0.92
Diluted net income per share	$ 0.26	$ 0.20	$ 0.89	$ 0.85
Shares used in computing basic net income per common share	113,741	116,320	115,653	115,412
Shares used in computing diluted net income per common share	122,432	127,423	125,963	124,194

CORCEPT THERAPEUTICS INCORPORATED

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021	**2020**	**2021**	**2020**
GAAP net income	$ 32,053	$ 25,994	$ 112,512	$ 106,011
Non-cash expenses (benefits)				
Stock-based compensation				
Cost of sales	21	15	59	66
Research and development	3,342	2,865	14,106	11,222
Selling, general and administrative	7,447	5,550	28,766	22,251
Total stock-based compensation	10,810	8,430	42,931	33,539
Deferred income taxes	2,299	2,311	4,346	14,089
Income tax effect of non-GAAP adjustments [1]	(2,594)	(2,023)	(10,303)	(8,049)
Non-GAAP net income, adjusted for non-cash expenses	$ 42,568	$ 34,712	$ 149,486	$ 145,590
GAAP basic net income per share	$ 0.28	$ 0.22	$ 0.97	$ 0.92
GAAP diluted net income per share	$ 0.26	$ 0.20	$ 0.89	$ 0.85
Non-GAAP basic net income per share, adjusted for non-cash expenses per share	$ 0.37	$ 0.30	$ 1.29	$ 1.26
Non-GAAP diluted net income per share, adjusted for non-cash expenses per share	$ 0.35	$ 0.27	$ 1.19	$ 1.17
Shares used in computing basic net income per common share	113,741	116,320	115,653	115,412
Shares used in computing diluted net income per common share	122,432	127,423	125,963	124,194

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

CONTACT:
Corcept Therapeutics
Investor Relations
ir@corcept.com
www.corcept.com