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

May 5, 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 May 5, 2022, Corcept Therapeutics Incorporated (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2022 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 May 5, 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: May 5, 2022

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

EXHIBIT 99.1

CORCEPT THERAPEUTICS ANNOUNCES FIRST QUARTER FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

MENLO PARK, Calif. (May 5, 2022) – Corcept Therapeutics Incorporated (NASDAQ: CORT), a commercial-stage company engaged in the discovery and development of medications to treat severe endocrine, metabolic, oncologic and neurological disorders by modulating the effects of the hormone cortisol, today reported its results for the quarter ended March 31, 2022.

Financial Results

- *Revenue of $93.7 million, compared to $79.4 million in first quarter 2021*
- *Reiterated 2022 revenue guidance of $400 – $430 million*
- *Diluted net income per share of $0.20, compared to $0.18 in first quarter 2021*
- *Cash and investments of $368.1 million, compared to $335.8 million at December 31, 2021*

"As pandemic restrictions and fears recede, we expect our growth to continue and are reiterating our 2022 revenue guidance of $400 – $430 million," said Joseph K. Belanoff, MD, Corcept's Chief Executive Officer. "Korlym is an excellent treatment for patients with Cushing's syndrome and there are many eligible patients who have yet to receive it."

Corcept's first quarter 2022 revenue was $93.7 million, compared to $79.4 million in the first quarter of 2021. First quarter operating expenses were $66.9 million, compared to $59.8 million in the first quarter of 2021, due to increased expenses to support the expansion of our clinical development and commercial teams and legal fees. Diluted net income per share was $0.20 in the first quarter of 2022, compared to $0.18 in the first quarter of 2021.

Cash and investments increased $32.3 million in the first quarter, to $368.1 million at March 31, 2022.

Clinical Development

"Corcept was founded on the premise that cortisol modulation has the potential to help treat many serious diseases," said Dr. Belanoff. "Our clinical development programs have produced increasing amounts of evidence validating this hypothesis and our programs in castration-resistant prostate cancer, antipsychotic-induced weight gain and non-alcoholic steatohepatitis will produce important data this year. We are especially excited about our advancing platinum-resistant ovarian cancer program. Based on the statistically significant and clinically meaningful results of our large, controlled Phase 2 study, we will soon initiate a pivotal trial."

Solid Tumors

- *Phase 3 trial in patients with recurrent platinum-resistant ovarian cancer planned to start this quarter; Oral presentation of Phase 2 trial results at the American Society of Clinical Oncology (ASCO) annual meeting on June 6 in Chicago*
- *Selection of the optimum dose of exicorilant or relacorilant plus enzalutamide in patients with castration-resistant prostate cancer (CRPC) expected this quarter*
- *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*

"We are excited to start our Phase 3 trial of relacorilant in patients with recurrent platinum-resistant ovarian cancer," said Bill Guyer, PharmD, Corcept's Chief Development Officer. "Our goal is to replicate the positive findings of our 178-patient Phase 2 trial, in which women who received relacorilant in addition to nab-paclitaxel exhibited meaningful improvements in progression-free survival, duration of response and overall survival, *without* increased side effects, when compared to women who received nab-paclitaxel alone. The 20,000 women

in the United States and an equal number in Europe with platinum-resistant ovarian cancer have few good treatment options. If our Phase 3 trial is successful, relacorilant plus nab-paclitaxel could become the new standard of care for these patients. We plan to meet with the FDA in June regarding our proposed path forward."

Metabolic Diseases

- *Enrollment completed in GRATITUDE and GRATITUDE II – two double-blind, placebo-controlled Phase 2 trials of miricorilant to reverse recent and long-standing antipsychotic-induced weight gain (AIWG); data from both trials expected in fourth quarter 2022*
- *Enrollment continues in Phase 1b dose-finding trial of miricorilant in patients with presumed NASH*

"We look forward to the results of GRATITUDE and GRATITUDE II," said Dr. Guyer. "Weight gain and other metabolic adverse effects caused by antipsychotic medications pose serious risks to the health of millions of patients, who have few treatment options. We initiated these double-blind, placebo-controlled trials to build on the positive data from our studies of both miricorilant and mifepristone in healthy volunteers."

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 now expected in second half 2023*
- *Enrollment continues in Phase 3 GRADIENT trial of relacorilant as a treatment for patients with Cushing's syndrome caused by adrenal adenomas*

"We advanced relacorilant to Phase 3 in Cushing's syndrome based on its extremely promising Phase 2 efficacy and safety data. 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. The timing for the completion of this trial has been impacted by the pandemic, as clinical trial sites have experienced challenges in recruiting and managing patients. We are currently planning to submit this relacorilant NDA in the second half of 2023," said Dr. Guyer. "The Phase 3 GRADIENT trial will produce valuable data about an etiology of Cushing's syndrome that has not been subject to rigorous, controlled study, but affects many patients."

Conference Call

We will hold a conference call on May 5, 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 May 12, 2022 at 1-855-859-2056 from the United States and 1-404-537-3406 internationally. The passcode will be 6942208. 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, adrenal and prostate cancer, weight gain caused by the use of antipsychotic medications and liver disease. Corcept's drug Korlym® was the first medication approved by the U.S. Food and Drug Administration for the treatment of patients with Cushing's syndrome.

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; the number of eligible patients who have yet to receive Korlym; our continued growth and 2022 revenue guidance; cortisol modulation's potential to treat many serious diseases; 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, including the pace of enrollment, study design, dose selection and the accrual and attributes of clinical data; and the timing of regulatory submissions. 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)

	March 31, 2022	December 31, 2021[1]
	(Unaudited)	
Assets		
Cash and investments	$ 368,093	$ 335,812
Trade receivables, net of allowances	27,178	27,625
Inventory	18,177	17,950
Operating lease right-of-use asset	2,816	514
Deferred tax assets, net	37,713	27,455
Other assets	14,146	14,400
Total assets	$ 468,123	$ 423,756
Liabilities and Stockholders' Equity		
Accounts payable	$ 9,269	$ 6,908
Operating lease liabilities	2,816	526
Other liabilities	48,227	40,516
Stockholders' equity	407,811	375,806
Total liabilities and stockholders' equity	$ 468,123	$ 423,756

[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 March 31,	
	2022	**2021**
Revenues		
Product revenue, net	$ 93,688	$ 79,437
Operating expenses		
Cost of sales	1,250	1,268
Research and development	28,120	29,022
Selling, general and administrative	37,549	29,509
Total operating expenses	$ 66,919	$ 59,799
Income from operations	26,769	19,638
Interest and other income	80	275
Income before income taxes	26,849	19,913
Income tax (expense) benefit	(4,052)	3,552
Net income	$ 22,797	$ 23,465
Other comprehensive income:		
Unrealized loss on available-for-sale investments, net of tax effect of $323 and $61, respectively	(1,019)	(192)
Foreign currency translation (loss) gain, net of tax	(105)	26
Total comprehensive income	$ 21,673	$ 23,299
Basic net income per share	$ 0.22	$ 0.20
Diluted net income per share	$ 0.20	$ 0.18
Shares used in computing basic net income per common share	106,012	116,818
Shares used in computing diluted net income per common share	115,037	129,668

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