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 3, 2023
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)	(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 3, 2023, Corcept Therapeutics Incorporated (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2023 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 3, 2023
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 3, 2023

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 3, 2023) – Corcept Therapeutics Incorporated (NASDAQ: CORT), a commercial-stage company engaged in the discovery and development of medications to treat severe endocrine, oncologic, metabolic and neurological disorders by modulating the effects of the hormone cortisol, today reported its results for the quarter ended March 31, 2023.

Financial Results

- *Revenue of $105.7 million, compared to $93.7 million in first quarter 2022*
- *Raised 2023 revenue guidance to $435 – $455 million, from $430 – $450 million*
- *Net income per common share of $0.14 (diluted), compared to $0.20 in first quarter 2022*
- *Cash and investments of $465.1 million as of March 31, 2023*
- *Purchase of 6.6 million shares of Corcept common stock for $145.4 million in April 2023*

Corcept's first quarter 2023 revenue was $105.7 million, compared to $93.7 million in the first quarter of 2022. First quarter operating expenses were $90.8 million, compared to $66.9 million in the first quarter of 2022, due to increased spending on clinical trials and sales and marketing activities and to support the expansion of our clinical development and commercial teams. Net income was $15.9 million in the first quarter of 2023 compared to $22.8 million in the same period last year.

Cash and investments were $465.1 million at March 31, 2023 compared to $436.6 million at December 31, 2022. In April 2023, Corcept purchased 6.6 million shares of its common stock for $145.4 million.

"Korlym is an excellent treatment for patients with Cushing's syndrome and there are many eligible patients who have yet to receive it. We are making substantial investments to improve the ability of physicians to identify and treat patients with hypercortisolism, most notably our recently established CATALYST study, and are optimistic about the growth of our Cushing's syndrome business. We are raising our 2023 revenue guidance to $435 - $455 million," said Joseph K. Belanoff, MD, Corcept's Chief Executive Officer.

Clinical Development

"In the next twelve months we expect data from our GRACE, GRADIENT and NASH Phase 1b studies, submission of the NDA for relacorilant in Cushing's syndrome, completion of enrollment of our CATALYST, ROSELLA and DAZALS studies and initiation of a Phase 2b trial of miricorilant in patients with NASH," added Dr. Belanoff.

Cushing's Syndrome

- *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 first half of 2024*
- *Enrollment continues in Phase 3 GRADIENT trial of relacorilant as a treatment for patients with Cushing's syndrome caused by adrenal adenomas*
- *Enrollment continues in CATALYST – 1,000-patient Phase 4 trial examining the prevalence of hypercortisolism in patients with difficult to control type 2 diabetes; patients with hypercortisolism may enter a randomized, double-blind, placebo-controlled study of Korlym*

Our GRACE trial will serve as the basis for relacorilant's NDA in Cushing's syndrome, which we plan to submit in the first half of 2024. We are pleased to share that we have identified all the patients necessary to complete this study and expect to complete enrollment in the coming weeks. Our Phase 3 GRADIENT trial will produce

valuable data about an etiology of Cushing's syndrome that affects many patients but has not been rigorously examined in a controlled study.

"Independent studies conducted over the last fifteen years have found that the prevalence of hypercortisolism in patients with type 2 diabetes is substantially higher than in the general population. The most prominent diabetologists in the United States helped us design and are participating in our CATALYST trial, which will be the largest study of its kind and is now enrolling patients. CATALYST identifies patients whose diabetes is caused by hypercortisolism and offers them a placebo-controlled study where Korlym is the active treatment. We expect to complete enrollment by the end of this year," said Bill Guyer, PharmD, Corcept's Chief Development Officer.

Oncology

- *Enrollment continues in ROSELLA – 360-patient pivotal Phase 3 trial of relacorilant plus nab-paclitaxel in patients with recurrent, platinum-resistant ovarian cancer*
- *Enrollment continues in open-label, Phase 1b trial of relacorilant plus pembrolizumab in patients with adrenal cancer with cortisol excess*
- *Randomized, placebo-controlled Phase 2 trial of relacorilant plus enzalutamide in patients with prostate cancer expected to begin by mid-year in collaboration with the University of Chicago*

"We and our investigators are excited to advance relacorilant in platinum-resistant ovarian cancer. Relacorilant plus nab-paclitaxel has the potential to become a new standard of care for the treatment of patients with this dire disease. We are on track to complete enrollment in ROSELLA by the end of this year," said Dr. Guyer.

Amyotrophic Lateral Sclerosis (ALS)

- *Enrollment continues in DAZALS – 198-patient, randomized, double-blind, placebo-controlled Phase 2 trial of dazucorilant in patients with ALS*

"ALS, commonly known as Lou Gehrig's disease, is a devastating illness with an urgent need for better treatment. We are conducting our DAZALS study in collaboration with TRICALS, the leading ALS academic consortium in Europe, to investigate dazucorilant's potential to significantly improve the lives of patients with ALS. We are on track to complete enrollment in DAZALS by early 2024," said Dr. Guyer.

Non-alcoholic Steatohepatitis (NASH)

- *Enrollment completed in Phase 1b dose-finding trial of miricorilant in patients with presumed NASH – data expected by mid-year; Phase 2b trial to begin in the fourth quarter*

"Miricorilant, a potent, oral, selective cortisol modulator with targeted activity in the liver, continues to demonstrate great promise as a treatment for NASH. Our Phase 1b study has identified a range of doses, all substantially lower than our originally tested doses, that significantly reduce liver fat without causing excessive liver irritation," said Dr. Guyer. "We expect to share results from this study by mid-year and plan to start a Phase 2b trial in the fourth quarter of this year."

Conference Call

We will hold a conference call on May 3, 2023, at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). Participants must register in advance of the conference call by clicking here. Upon registering, each participant will receive a dial-in number and a unique access PIN. Each access PIN will accommodate one caller. Additionally, a listen-only webcast will be available by clicking here. A replay of the call will be available on the Investors / Events tab of www.corcept.com.

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. Clinical trials are being conducted with the company's leading selective cortisol modulators as potential treatments for patients with serious disorders – Cushing's syndrome, ovarian, prostate and adrenal cancer, ALS, post-traumatic stress disorder 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, among others: our continued revenue growth and 2023 revenue guidance; the number of eligible patients who have yet to receive Korlym; cortisol modulation's potential to treat many serious diseases; development of relacorilant as a treatment for Cushing's syndrome and ovarian, adrenal and prostate cancer, including relacorilant's clinical attributes, regulatory approvals, mandates, oversight and other requirements; expectations regarding the GRACE trial as the basis for relacorilant's NDA in Cushing's syndrome; the design, timing and expectations regarding our CATALYST trial; the timing and expectations of our ROSELLA trial of relacorilant plus nab-paclitaxel in patients with recurrent platinum-resistant ovarian cancer and the potential for relacorilant plus nab-paclitaxel to become a standard of care for these patients; the timing and expectations of our DAZALS trial of dazucorilant in patients with ALS; the timing and substance of our Phase 1b trial and planned Phase 2 trial in patients with NASH; our other pre-clinical and clinical development programs, including the pace of enrollment, study design and timelines, 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, 2023	December 31, 2022[1]
	(Unaudited)	
Assets		
Cash and investments	$ 465,057	$ 436,619
Trade receivables, net of allowances	32,557	31,057
Insurance recovery receivable related to Melucci litigation	14,000	14,000
Inventory	16,565	17,031
Operating lease right-of-use asset	575	1,143
Deferred tax assets, net	67,999	61,465
Other assets	21,095	22,115
Total assets	$ 617,848	$ 583,430
Liabilities and Stockholders' Equity		
Accounts payable	$ 11,216	$ 11,976
Accrued settlement related to Melucci litigation	14,000	14,000
Operating lease liabilities	575	1,143
Other liabilities	62,473	54,469
Stockholders' equity	529,584	501,842
Total liabilities and stockholders' equity	$ 617,848	$ 583,430

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

CORCEPT THERAPEUTICS INCORPORATED

CONDENSED CONSOLIDATED STATEMENTS OF INCOME

(In thousands, except per share data)

	Three Months Ended March 31,	
	2023	**2022**
Revenues		
Product revenue, net	$ 105,654	$ 93,688
Operating expenses		
Cost of sales	1,386	1,250
Research and development	40,851	28,120
Selling, general and administrative	48,564	37,549
Total operating expenses	90,801	66,919
Income from operations	14,853	26,769
Interest and other income	3,581	80
Income before income taxes	18,434	26,849
Income tax expense	(2,555)	(4,052)
Net income	$ 15,879	$ 22,797
Net income attributable to common stockholders	$ 15,807	$ 22,797
Basic net income per common share	$ 0.15	$ 0.22
Diluted net income per common share	$ 0.14	$ 0.20
Weighted-average shares outstanding used in computing net income per common share		
Basic	107,885	106,012
Diluted	115,425	115,037

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