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 28, 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 February 28, 2023, Corcept Therapeutics Incorporated (the "Company") issued a press release announcing its financial results for the quarter ended December 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 February 28, 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: February 28, 2023

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

EXHIBIT 99.1

CORCEPT THERAPEUTICS ANNOUNCES FOURTH QUARTER AND FULL-YEAR 2022 AUDITED FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

MENLO PARK, Calif. (February 28, 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 and year ended December 31, 2022.

Financial Results

- *Fourth quarter revenue of $103.1 million, compared to $98.8 million in fourth quarter 2021*
- *2022 revenue of $401.9 million, compared to $366.0 million in 2021*
- *2023 revenue guidance of $430 – $450 million*
- *Fourth quarter diluted net income per common share of $0.14, compared to $0.26 in fourth quarter 2021*
- *2022 diluted net income per common share of $0.87, compared to $0.89 in 2021*
- *Cash and investments of $436.6 million, compared to $335.8 million at December 31, 2021*

Corcept's fourth quarter 2022 revenue was $103.1 million, compared to $98.8 million in the fourth quarter of 2021. Revenue for the full year was $401.9 million, compared to $366.0 million in 2021. The company expects 2023 revenue of $430 – $450 million.

Net income was $16.6 million in the fourth quarter of 2022, compared to $32.1 million in the fourth quarter of 2021. For the full year, it was $101.4 million compared to $112.5 million in 2021.

Cash and investments of $436.6 million at December 31, 2022 compared to $335.8 million at December 31, 2021.

"We remain extremely optimistic about the growth potential of our Cushing's syndrome business. 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 screening and treatment of these patients. We are providing 2023 revenue guidance of $430 – $450 million," said Joseph K. Belanoff, MD, Corcept's Chief Executive Officer.

Clinical Development

"We significantly advanced our clinical development programs, with three of our proprietary selective cortisol modulators – relacorilant, dazucorilant and miricorilant – now in the clinic," added Dr. Belanoff. "We expect to make further progress in the next twelve months with submission of the NDA for relacorilant in Cushing's syndrome, enrollment of our confirmatory Phase 3 trial of relacorilant in platinum-resistant ovarian cancer and Phase 2 trial of dazucorilant in ALS, and advancement to Phase 2 of miricorilant as a potential treatment for NASH."

Cushing's Syndrome

- *Enrollment to close in the coming weeks 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 first quarter of 2024*
- *Enrollment continues in Phase 3 GRADIENT trial of relacorilant as a treatment for patients with Cushing's syndrome caused by adrenal adenomas*
- *CATALYST – 1,000-patient randomized, double-blind, placebo-controlled Phase 4 trial to examine the prevalence of hypercortisolism in patients with difficult to control type 2 diabetes and treat the patients determined to have hypercortisolism with Korlym – to begin this quarter*

“We are pleased to announce that we believe that we have enough patients in screening in our GRACE trial to complete enrollment in the coming weeks. We expect GRACE to serve as the basis for relacorilant’s NDA in Cushing’s syndrome, which we plan to submit in the first quarter of 2024,” said Bill Guyer, PharmD, Corcept’s Chief Development Officer. “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.”

“Our randomized, double-blind, placebo-controlled, Phase 4 CATALYST study will examine the prevalence of hypercortisolism in patients with difficult to control type 2 diabetes and treat the patients determined to have hypercortisolism with Korlym. Planned enrollment is 1,000 patients, which we expect to complete by the end of this year. The most prominent diabetologists in the country helped design and are participating in this study. We expect CATALYST to produce data that will improve the screening and treatment of these patients,” added Dr. Guyer.

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 extremely excited to advance relacorilant in platinum-resistant ovarian cancer. The 40,000 women in the United States and Europe with this disease do not have good treatment options and relacorilant plus nab-paclitaxel has the potential to become a new standard of care,” 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*

“The 55,000 patients in the United States and Europe with ALS have an urgent need for better treatment. Dazucorilant showed great promise in animal models of ALS – improving motor performance and reducing neuroinflammation and muscular atrophy. We are conducting this important 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,” said Dr. Guyer.

Non-alcoholic Steatohepatitis (NASH)

- *Screening closed in Phase 1b dose-finding trial of miricorilant in patients with presumed NASH – data expected by mid-year*

“Miricorilant, an oral medication, 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 reduces 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 2 trial later this year.”

Conference Call

We will hold a conference call on February 28, 2023, at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). To access the conference call, please dial 877-407-8029 from the United States or +1-201-689-8029 internationally. 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. The company is conducting clinical trials of its leading cortisol modulators as potential treatments for patients with Cushing's syndrome, ovarian, prostate and adrenal cancer, ALS 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 timing and expectations of our CATALYST trial to improve the screening and treatment of patients with Cushing's syndrome; the potential for relacorilant plus nab-paclitaxel to become a standard of care for patients with recurrent platinum-resistant ovarian cancer; 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)

	December 31, 2022[1]	December 31, 2021[1]
Assets		
Cash and investments	$ 436,619	$ 335,812
Trade receivables, net of allowances	31,057	27,625
Insurance recovery receivable related to Melucci litigation	14,000	—
Inventory	17,031	17,950
Operating lease right-of-use asset	1,143	514
Deferred tax assets, net	61,465	27,455
Other assets	22,115	14,400
Total assets	$ 583,430	$ 423,756
Liabilities and Stockholders' Equity		
Accounts payable	$ 11,976	$ 6,908
Accrued settlement related to Melucci litigation	14,000	—
Operating lease liabilities	1,143	526
Other liabilities	54,469	40,516
Stockholders' equity	501,842	375,806
Total liabilities and stockholders' equity	$ 583,430	$ 423,756

[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 December 31,		Year Ended December 31,	
	2022	**2021**	**2022**	**2021**
Revenues				
Product revenue, net	$ 103,056	$ 98,822	$ 401,858	$ 365,978
Operating expenses				
Cost of sales	1,480	1,354	5,385	5,281
Research and development	36,754	28,519	130,991	113,864
Selling, general and administrative	42,323	32,285	152,848	122,356
Settlement expense related to Melucci litigation	14,000	—	14,000	—
Insurance recovery related to Melucci litigation	(14,000)	—	(14,000)	—
Total operating expenses	80,557	62,158	289,224	241,501
Income from operations	22,499	36,664	112,634	124,477
Interest and other income	1,777	72	3,557	529
Income before income taxes	24,276	36,736	116,191	125,006
Income tax expense	(7,675)	(4,683)	(14,773)	(12,494)
Net income	$ 16,601	$ 32,053	$ 101,418	$ 112,512
Net income attributable to common stockholders	$ 16,553	$ 32,053	$ 101,288	$ 112,512
Basic net income per common share	$ 0.15	$ 0.28	$ 0.95	$ 0.97
Diluted net income per common share	$ 0.14	$ 0.26	$ 0.87	$ 0.89
Weighted-average shares outstanding used in computing net income per common share				
Basic	107,700	113,741	106,787	115,653
Diluted	116,328	122,432	115,966	125,963

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