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, 2024
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 LLC

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, 2024, Corcept Therapeutics Incorporated (the "Company") issued a press release announcing its financial results for the quarter ended December 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 February 15, 2024
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, 2024

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

EXHIBIT 99.1

CORCEPT THERAPEUTICS ANNOUNCES FOURTH QUARTER FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

MENLO PARK, Calif., (February 15, 2024) – Corcept Therapeutics Incorporated (NASDAQ: CORT), a commercial-stage company engaged in the discovery and development of medications to treat severe endocrinologic, oncologic, metabolic and neurologic disorders by modulating the effects of the hormone cortisol, today reported its results for the quarter and year ended December 31, 2023.

Financial Results

- *Fourth quarter revenue of $135.4 million, a 31 percent increase over the same period in 2022*
- *Full year 2023 revenue of $482.4 million, a 20 percent increase over 2022*
- *Reiterated 2024 revenue guidance of $600 – $630 million*
- *Fourth quarter net income of $31.4 million, compared to $16.6 million in fourth quarter 2022*
- *2023 net income of $106.1 million, compared to $101.4 million in 2022*
- *Cash and investments of $425.4 million as of December 31, 2023*

"The medical field is increasingly recognizing that Cushing's syndrome is much more prevalent than was previously assumed. Our strong 2023 commercial results reflect that physicians are more regularly screening for hypercortisolism. The results demonstrate our ability to support these physicians as they manage this complex disease. We are confident these trends will continue and are reiterating our 2024 revenue guidance of $600 – $630 million," said Joseph K. Belanoff, MD, Corcept's Chief Executive Officer.

Corcept's fourth quarter 2023 revenue was $135.4 million, compared to $103.1 million in the fourth quarter of 2022. Revenue for the full year was $482.4 million, compared to $401.9 million in 2022.

Diluted net income per common share was $0.28 in the fourth quarter of 2023, compared to $0.14 in the fourth quarter of 2022. For the full year, it was $0.94 compared to $0.87 in 2022.

Cash and investments were $425.4 million at December 31, 2023 compared to $436.6 million at December 31, 2022. In 2023, Corcept paid $154.5 million to purchase its common stock in connection with the April 2023 tender offer, the exercise of employee stock options and vesting of restricted stock grants.

Clinical Development

"Our clinical development programs are advancing rapidly and will reach important milestones this year. We are on-track to submit our NDA for relacorilant in Cushing's syndrome and will report data from our trials in Cushing's syndrome (GRACE, GRADIENT and CATALYST), ovarian cancer (ROSELLA) and ALS (DAZALS)," added Dr. Belanoff.

Cushing's Syndrome

- *GRACE – Phase 3 trial of relacorilant as a treatment for patients with all etiologies of Cushing's syndrome – results from open label and randomized withdrawal phases expected in the second quarter*
- *Relacorilant New Drug Application (NDA) – NDA submission for Cushing's syndrome expected in the second quarter*
- *GRADIENT – Phase 3 trial of relacorilant in patients with Cushing's syndrome caused by adrenal adenomas – enrollment continues; results expected in the second half of this year*
- *CATALYST – 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 – enrollment continues; preliminary prevalence phase results: 24%*

prevalence rate in the first 700 patients enrolled; final results from prevalence and treatment phases expected by year-end

"We are on-track to submit our relacorilant NDA in the second quarter. Relacorilant has demonstrated tremendous promise as a treatment for patients with Cushing's syndrome and we are eager to make it more broadly available," said Bill Guyer, PharmD, Corcept's Chief Development Officer.

"Our CATALYST trial is the largest study ever conducted to establish the prevalence of hypercortisolism in patients with difficult-to-control diabetes. We expect CATALYST's findings to greatly stimulate physicians' efforts to screen for hypercortisolism in patients with difficult-to-control diabetes and to treat them when hypercortisolism is found. Almost all of these patients currently go undiagnosed. We believe that CATALYST will be a landmark study and look forward to presenting the final results from the prevalence phase at the American Diabetes Association's 84th Scientific Sessions in June," added Dr. Guyer.

Oncology

- *ROSELLA – Pivotal Phase 3 trial of relacorilant plus nab-paclitaxel in patients with platinum-resistant ovarian cancer – enrollment continues; results expected by year-end*
- *Open-label, Phase 1b trial of relacorilant plus pembrolizumab in patients with adrenal cancer with cortisol excess - enrollment completed; results expected by mid-year*
- *Randomized, placebo-controlled, Phase 2 trial of relacorilant plus enzalutamide in patients with prostate cancer in collaboration with the University of Chicago - enrollment continues*

"If our ROSELLA trial replicates the results of our Phase 2 trial in patients with platinum-resistant ovarian cancer (results published in *The Journal of Clinical Oncology,* June 2023), it will constitute a major medical advance and could establish the combination of relacorilant and nab-paclitaxel as a new standard of care for women with this devastating disease. We expect data from ROSELLA by the end of this year," said Dr. Guyer.

Amyotrophic Lateral Sclerosis (ALS)

- *DAZALS – Randomized, double-blind, placebo-controlled, Phase 2 trial of dazucorilant in patients with ALS – enrollment continues; results expected by year-end*

"ALS is a lethal illness with an urgent need for better treatment. Dazucorilant showed great promise in animal models of ALS – improving motor performance and reducing neuroinflammation and muscular atrophy. Our DAZALS study is investigating dazucorilant's potential to significantly improve the lives of patients with ALS. We expect data by the end of this year," said Dr. Guyer.

Non-alcoholic Steatohepatitis (NASH)

- *MONARCH – Randomized, double-blind, placebo-controlled, Phase 2b trial of miricorilant in patients with biopsy-confirmed NASH – enrollment continues*

"Miricorilant has the potential to greatly benefit the millions of patients with NASH. Our Phase 1b study demonstrated that miricorilant effectively reduces liver fat, improves liver health and key metabolic and lipid measures and is well-tolerated. We look forward to building on these promising results in our MONARCH study," said Dr. Guyer.

Conference Call

We will hold a conference call on February 15, 2024, 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.

About Corcept Therapeutics

For over 25 years, Corcept's focus on cortisol modulation and its potential to treat patients across a wide variety of serious disorders has led to the discovery of more than 1,000 proprietary selective cortisol modulators. Corcept's advanced clinical trials are being conducted in patients with hypercortisolism, solid tumors, ALS and NASH. In February 2012, the company introduced Korlym®, the first medication approved by the U.S. Food and Drug Administration for the treatment of patients with Cushing's syndrome. Corcept is headquartered in Menlo Park, California. For more information, visit www.corcept.com.

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; 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 relacorilant, dazucorilant, miricorilant and our other 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: our continued revenue growth and 2024 revenue guidance; the rates of screening and treatment of hypercortisolism; 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; the design, timing and expectations regarding our GRACE trial; the timing and outcome of relacorilant's NDA in Cushing's syndrome; the design, timing and expectations regarding our GRADIENT trial; the design, timing and expectations regarding our CATALYST trial; the timing and expectations of our ROSELLA trial and the potential for relacorilant plus nab-paclitaxel to become a standard of care; the timing and expectations of our DAZALS trial of dazucorilant in patients with ALS; the timing and substance of our MONARCH trial in patients with NASH, and the pace of enrollment, study design and timelines, and the accrual and attributes of clinical data, as well as the timing of regulatory submissions with respect to all of our development activities. 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, 2023	December 31, 2022[1]
	(Unaudited)	
Assets		
Cash and investments	$ 425,397	$ 436,619
Trade receivables, net of allowances	41,123	31,057
Insurance recovery receivable related to Melucci litigation	14,000	14,000
Inventory	15,974	17,031
Operating lease right-of-use asset	120	1,143
Deferred tax assets, net	90,605	61,465
Other assets	34,298	22,115
Total assets	$ 621,517	$ 583,430
Liabilities and Stockholders' Equity		
Accounts payable	$ 17,396	$ 11,976
Accrued settlement related to Melucci litigation	14,000	14,000
Operating lease liabilities	151	1,143
Other liabilities	83,265	54,469
Stockholders' equity	506,705	501,842
Total liabilities and stockholders' equity	$ 621,517	$ 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 December 31,		Year Ended December 31,	
	2023	**2022**	**2023**	**2022**
Revenues				
Product revenue, net	$ 135,405	$ 103,056	$ 482,375	$ 401,858
Operating expenses				
Cost of sales	1,876	1,480	6,481	5,385
Research and development	54,707	36,754	184,353	130,991
Selling, general and administrative	47,152	42,323	184,259	152,848
Settlement expense related to Melucci litigation	—	14,000	—	14,000
Insurance recovery related to Melucci litigation	—	(14,000)	—	(14,000)
Total operating expenses	103,735	80,557	375,093	289,224
Income from operations	31,670	22,499	107,282	112,634
Interest and other income	5,139	1,777	17,275	3,557
Income before income taxes	36,809	24,276	124,557	116,191
Income tax expense	(5,454)	(7,675)	(18,417)	(14,773)
Net income	$ 31,355	$ 16,601	$ 106,140	$ 101,418
Net income attributable to common stockholders	$ 31,138	$ 16,553	$ 105,496	$ 101,288
Basic net income per common share	$ 0.30	$ 0.15	$ 1.02	$ 0.95
Diluted net income per common share	$ 0.28	$ 0.14	$ 0.94	$ 0.87
Weighted-average shares outstanding used in computing net income per common share				
Basic	102,455	107,700	103,560	106,787
Diluted	110,886	116,328	111,742	115,966

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