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

November 1, 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 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 November 1, 2023, Corcept Therapeutics Incorporated (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 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 November 1, 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: November 1, 2023

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

EXHIBIT 99.1

CORCEPT THERAPEUTICS ANNOUNCES THIRD QUARTER FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

MENLO PARK, Calif., (November 1, 2023) – Corcept Therapeutics Incorporated (NASDAQ: CORT), a commercial-stage company engaged in the discovery and development of medications to treat severe endocrine, oncology, metabolism and neurology disorders by modulating the effects of the hormone cortisol, today reported results for the quarter ended September 30, 2023.

Financial Results

- *Revenue of $123.6 million, a 22 percent increase from third quarter 2022*
- *Increase in 2023 revenue guidance to $470 – $480 million, from $455 – $470 million*
- *Net income per common share of $0.28 (diluted), compared to $0.30 in third quarter 2022*
- *Cash and investments of $414.8 million as of September 30, 2023*

"Our strong results in the third quarter reflect returns on our substantial investment in helping physicians to better recognize and treat hypercortisolism. As screening for hypercortisolism (Cushing's syndrome) becomes more common, the number of patients receiving medical therapy grows. We are confident this trend will continue. 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 raising our 2023 revenue guidance again, to $470 - $480 million," said Joseph K. Belanoff, MD, Corcept's Chief Executive Officer.

Corcept's third quarter 2023 revenue was $123.6 million, compared to $101.7 million in the third quarter of 2022. Third quarter operating expenses were $92.4 million, compared to $69.8 million in the third quarter of 2022, due to increased clinical trial activity and expenses to support the expansion of our clinical development and commercial teams. Net income was $31.4 million in the third quarter of 2023 compared to $34.6 million in the same period last year.

Cash and investments were $414.8 million at September 30, 2023 compared to $363.3 million at the end of the prior quarter.

Clinical Development

"We are also very excited by the potential of our clinical development programs, with important milestones approaching. In 2024, we expect to report data from our trials in Cushing's syndrome (the GRACE, GRADIENT and CATALYST studies), ovarian cancer (ROSELLA) and ALS (DAZALS). We also plan to submit an NDA for relacorilant in Cushing's syndrome and to complete enrollment of our Phase 2b MONARCH study in patients with NASH," added Dr. Belanoff.

Cushing's Syndrome

- *GRACE – Phase 3 trial of relacorilant as a treatment for patients with all etiologies of Cushing's syndrome – enrollment completed; new drug application (NDA) submission expected in the second quarter of 2024*
- *GRADIENT – Phase 3 trial of relacorilant as a treatment for patients with Cushing's syndrome caused by adrenal adenomas – continues enrollment; results expected in mid-2024*
- *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 – continues enrollment; prevalence phase results expected in first quarter of 2024 and full results by year-end 2024*

“Relacorilant has tremendous promise as a treatment for patients with Cushing’s syndrome and we are eager to make it available,” said Bill Guyer, PharmD, Corcept’s Chief Development Officer.

“Additionally, our CATALYST trial has the potential to serve as a landmark study to guide physician’s understanding of Cushing’s syndrome. CATALYST 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 enhance physicians’ ability to diagnose and treat the many patients with Cushing’s syndrome whose condition now frequently goes undiagnosed. We expect data from the prevalence phase of the CATALYST study by early next year.”

Oncology

- *ROSELLA – 360-patient pivotal Phase 3 trial of relacorilant plus nab-paclitaxel in patients with recurrent, platinum-resistant ovarian cancer – continues enrollment; results expected by year-end 2024*
- *Open-label, Phase 1b trial of relacorilant plus pembrolizumab in patients with adrenal cancer with cortisol excess – continues enrollment; results expected in early 2024*
- *Randomized, placebo-controlled, Phase 2 trial of relacorilant plus enzalutamide in patients with prostate cancer – initiated in collaboration with the University of Chicago*

“Our Phase 2 trial demonstrated the potential of relacorilant combined with nab-paclitaxel to become a new standard of care for the treatment of patients with platinum-resistant ovarian cancer. The results were published in June in *The Journal of Clinical Oncology*. Our pivotal ROSELLA trial aims to replicate those results. We expect data by the end of next year,” said Dr. Guyer.

Amyotrophic Lateral Sclerosis (ALS)

- *DAZALS – 198-patient, randomized, double-blind, placebo-controlled, Phase 2 trial of dazucorilant in patients with ALS – continues enrollment; results expected by year-end 2024*

“ALS, also known as Lou Gehrig’s disease, is a devastating illness with an urgent need for better treatment. We are conducting our DAZALS study at sites in Europe and the United States to investigate dazucorilant’s potential to significantly improve the lives of patients with ALS. We expect data from this study by the end of next year,” said Dr. Guyer.

Non-alcoholic Steatohepatitis (NASH)

- *MONARCH – 150-patient, randomized, double-blind, placebo-controlled, Phase 2b trial of miricorilant in patients with biopsy-confirmed NASH – initiated in October 2023*

“We intend MONARCH to build on the promising results of our Phase 1b study, which demonstrated that miricorilant effectively reduces liver fat, improves liver health and key metabolic and lipid measures and is well-tolerated. Miricorilant has the potential to greatly benefit the millions of patients with NASH. We look forward to sharing our Phase 1b results and more details about MONARCH at a medical conference this fall,” said Dr. Guyer.

Conference Call

We will hold a conference call on November 1, 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.

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 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 2023 revenue guidance; 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; expectations regarding the GRACE trial; the timing and outcome of relacorilant's NDA in Cushing's syndrome; 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)

	September 30, 2023	December 31, 2022[1]
	(Unaudited)	
Assets		
Cash and investments	$ 414,846	$ 436,619
Trade receivables, net of allowances	34,626	31,057
Insurance recovery receivable related to Melucci litigation	14,000	14,000
Inventory	16,265	17,031
Operating lease right-of-use asset	178	1,143
Deferred tax assets, net	87,102	61,465
Other assets	27,005	22,115
Total assets	$ 594,022	$ 583,430
Liabilities and Stockholders' Equity		
Accounts payable	$ 16,710	$ 11,976
Accrued settlement related to Melucci litigation	14,000	14,000
Operating lease liabilities	225	1,143
Other liabilities	101,408	54,469
Stockholders' equity	461,679	501,842
Total liabilities and stockholders' equity	$ 594,022	$ 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 September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenues				
Product revenue, net	$ 123,601	$ 101,728	$ 346,970	$ 298,802
Operating expenses				
Cost of sales	1,645	1,339	4,604	3,905
Research and development	45,517	33,292	129,646	94,237
Selling, general and administrative	45,262	35,163	137,107	110,525
Total operating expenses	92,424	69,794	271,357	208,667
Income from operations	31,177	31,934	75,613	90,135
Interest and other income	5,208	1,070	12,135	1,780
Income before income taxes	36,385	33,004	87,748	91,915
Income tax (expense) benefit	(5,007)	1,604	(12,963)	(7,098)
Net income	$ 31,378	$ 34,608	$ 74,785	$ 84,817
Net income attributable to common stockholders	$ 31,172	$ 34,550	$ 74,353	$ 84,755
Basic net income per common share	$ 0.31	$ 0.32	$ 0.72	$ 0.80
Diluted net income per common share	$ 0.28	$ 0.30	$ 0.66	$ 0.73
Weighted-average shares outstanding used in computing net income per common share				
Basic	102,014	107,125	103,933	106,479
Diluted	111,099	116,620	112,054	115,818

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