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

October 30, 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.)

101 Redwood Shores Parkway, Redwood City, CA 94065
(Address of Principal Executive Offices) (Zip Code)

(650) 327-3270
Registrant's telephone number, including area code

149 Commonwealth Drive, Menlo Park, CA 94025
(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 October 30, 2024, Corcept Therapeutics Incorporated (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2024 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 October 30, 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: October 30, 2024

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

EXHIBIT 99.1

CORCEPT THERAPEUTICS ANNOUNCES THIRD QUARTER FINANCIAL RESULTS, POSITIVE RESULTS FROM PHASE 3 GRADIENT TRIAL IN PATIENTS WITH CUSHING'S SYNDROME AND PROVIDES CORPORATE UPDATE

- *Revenue of $182.5 million, a* 48 percent *increase over the same period in 2023*
- *Increase in 2024 revenue guidance to $675 – $700 million, from $640 – $670 million*
- *Net income per common share of $0.41 (diluted), compared to $0.28 in third quarter 2023*
- *Cash and investments of $547.6 million as of September 30, 2024*
- *Results from Phase 3 GRADIENT trial support findings from pivotal Phase 3 GRACE study; new drug application (NDA) of relacorilant to be submitted this quarter*

REDWOOD CITY, Calif., (October 30, 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 ended September 30, 2024.

Financial Results

"In the third quarter, we added more Korlym® prescribers and more patients received Korlym treatment than ever before," said Joseph K. Belanoff, MD, Corcept's Chief Executive Officer. "Physicians are increasingly aware of hypercortisolism's true prevalence and of the poor health outcomes of patients who go untreated. Screening is becoming more common and the number of patients receiving appropriate care continues to increase. For patients and physicians who choose Korlym, our extensive system of support services is critical to optimizing the benefit of our medication."

Corcept's third quarter 2024 revenue was $182.5 million, compared to $123.6 million in the third quarter of 2023. Third quarter operating expenses were $135.9 million, compared to $92.4 million in the third quarter of 2023. Net income was $47.2 million in the third quarter of 2024, compared to $31.4 million in the same period last year.

The company increased its 2024 revenue guidance to $675 – $700 million.

Cash and investments were $547.6 million at September 30, 2024, compared to $492.5 million at June 30, 2024. The balance at September 30, 2024 reflects the acquisition of $23.4 million of common stock (870,000 shares) in the third quarter pursuant to the company's stock repurchase program, net exercise of employee stock options and net vesting of restricted stock grants.

Clinical Development

"Our clinical development programs have positioned us for a transformative fourth quarter," added Dr. Belanoff. "We are on track to submit our NDA for relacorilant as a treatment for patients with hypercortisolism (Cushing's syndrome) by year-end. We also expect to release data from (i) the treatment phase of our CATALYST study in patients with Cushing's syndrome, (ii) ROSELLA, our pivotal study in women with platinum-resistant ovarian cancer, and (iii) DAZALS, our study in patients with amyotrophic lateral sclerosis (ALS) by year-end."

Cushing's Syndrome

- *Relacorilant for Cushing's syndrome – NDA submission expected this quarter*
- *GRACE – Pivotal Phase 3 trial of relacorilant in 152 patients with all etiologies of Cushing's syndrome – primary endpoint achieved in randomized withdrawal phase; open-label phase demonstrated clinically meaningful improvements in a broad range of hypercortisolism signs and symptoms; relacorilant was well-tolerated, with no cases of relacorilant-induced hypokalemia, endometrial hypertrophy or related vaginal bleeding, adrenal insufficiency or QT prolongation*

- *GRADIENT – Supportive trial data for NDA – Patients treated with relacorilant exhibited clinically meaningful improvements in a broad range of hypercortisolism signs and symptoms in randomized, double-blind, placebo-controlled, Phase 3 trial in 137 patients with Cushing's syndrome caused by adrenal gland pathology; relacorilant was well-tolerated, with a safety profile consistent with the GRACE study, including no cases of relacorilant-induced hypokalemia, endometrial hypertrophy or related vaginal bleeding, adrenal insufficiency or QT prolongation*
- *CATALYST – Treatment phase of randomized, double-blind, placebo-controlled study of Korlym in 136 patients with hypercortisolism and difficult-to-control type 2 diabetes; results expected this quarter*

"GRADIENT's positive results in patients with Cushing's syndrome confirm relacorilant's promise as a significant medical advancement for the treatment of this deadly disease. As was true in the GRACE study, patients in GRADIENT who received relacorilant experienced clinically meaningful improvements in a broad range of hypercortisolism signs and symptoms, without suffering some of the serious adverse effects that can arise in patients taking currently approved treatments," said Bill Guyer, PharmD, Corcept's Chief Development Officer. "These data will be a powerful addition to relacorilant's NDA, which we plan to submit by year-end."

The pivotal Phase 3 GRACE trial is the basis for relacorilant's NDA in Cushing's syndrome and met its primary endpoint. Patients in GRACE's initial, open-label phase exhibited clinically meaningful and statistically significant improvements in hypertension, hyperglycemia and other symptoms experienced by patients with Cushing's syndrome. In the randomized withdrawal phase, GRACE met its primary endpoint and demonstrated that patients who remained on relacorilant maintained these improvements while those who received placebo saw a significant worsening in their signs and symptoms of hypercortisolism. Consistent with its known safety profile, relacorilant was well-tolerated in both phases of GRACE.

As part of relacorilant's NDA in Cushing's syndrome, the 22-week Phase 3 GRADIENT study supports the GRACE trial by providing further evidence of relacorilant's efficacy and safety profile. Patients treated with relacorilant in the GRADIENT study exhibited clinically meaningful and statistically significant improvements in hypertension, hyperglycemia, weight and body composition compared to baseline, while patients who received placebo did not. The trial's primary endpoint was the improvement in systolic blood pressure (SBP) compared to placebo with hyperglycemia, weight and body composition as secondary endpoints.

Patients who entered GRADIENT with hypertension and received relacorilant exhibited clinically meaningful and statistically significant improvements in mean SBP at 22 weeks (reduction of 6.6 mm Hg; p-value: 0.012), compared to baseline. Patients who received placebo did not (reduction of 2.1 mm Hg; p-value: ns), compared to baseline. The comparison between those who received relacorilant and placebo was not statistically significant. During the study, 5 patients who received placebo compared to 1 patient who received relacorilant required rescue therapy with anti-hypertension medications. To ensure accuracy, hypertension was measured by 24-hour ambulatory blood pressure monitoring.

GRADIENT patients with hyperglycemia who received relacorilant experienced clinically meaningful and statistically significant improvements at 22 weeks in glucose metabolism, including fasting glucose (placebo-adjusted reduction of 22.2 mg/dL; p-value: 0.002), area under the curve of the oral glucose tolerance test (placebo-adjusted reduction of 2.6 h*mmol/L; p-value: 0.046) and hemoglobin A1c (placebo-adjusted reduction of 0.3 percent; p-value: 0.019), compared to those who received placebo.

Patients in GRADIENT who received relacorilant experienced clinically meaningful and statistically significant improvements at 22 weeks in body weight (placebo-adjusted reduction of 3.9 kg; p-value: 0.0001) and both visceral adipose fat mass and volume (p-values: 0.018 and 0.016, respectively), compared to those who received placebo.

Relacorilant was well tolerated in GRADIENT, with side effects consistent with those seen in its Phase 2 and GRACE trials. Across all of these studies, the most common adverse events were mild-to-moderate nausea, edema, pain in extremities and back, and fatigue – all symptoms associated with the "cortisol withdrawal" many patients experience following surgery or start of medical therapy for Cushing's syndrome. Importantly, there were

no relacorilant-induced instances of hypokalemia, relacorilant-induced endometrial hypertrophy or related vaginal bleeding, adrenal insufficiency or QT prolongation.

Complete results from the GRADIENT trial will be presented at a medical conference next year.

“We are also looking forward to results from the treatment phase of our CATALYST study by year-end,” continued Dr. Guyer. “CATALYST is the largest and most rigorous study ever conducted of hypercortisolism in patients with difficult-to-control diabetes. CATALYST’s prevalence results confirm there are many more patients with Cushing’s syndrome than was previously assumed and the trial is poised to be a landmark study in the identification and treatment of patients with hypercortisolism. We are confident it will lead to better health outcomes for many patients who are struggling today.”

Oncology

- *ROSELLA – Enrollment completed in pivotal Phase 3 trial of relacorilant plus nab-paclitaxel in 381 patients with platinum-resistant ovarian cancer; results expected this quarter*
- *Early-stage prostate cancer – Enrollment continues in randomized, placebo-controlled, Phase 2 trial of relacorilant plus enzalutamide in patients with early-stage prostate cancer, conducted in collaboration with the University of Chicago*

“Relacorilant has the potential to become the standard of care for patients with platinum-resistant ovarian cancer. If ROSELLA replicates the positive results of our large, controlled, Phase 2 study, it will constitute a major medical advance and serve as the basis for relacorilant’s next NDA. We expect progression-free survival data, ROSELLA’s primary endpoint, by the end of this year,” said Dr. Guyer.

Amyotrophic Lateral Sclerosis (ALS)

- *DAZALS – Enrollment completed in randomized, double-blind, placebo-controlled, Phase 2 trial of dazucorilant in 249 patients with ALS; results expected this quarter*

“ALS is a dire disease, with few good treatment options. Our selective cortisol modulator dazucorilant showed great promise in an animal model of ALS, improving motor performance and reducing neuroinflammation and muscular atrophy. We expect data regarding DAZALS’s primary endpoint – improvement in patients’ ALS Functional Rating Scale-Revised (ALSFRS-R) score – by the end of this year. We hope DAZALS will lead to a much-needed advance for patients with ALS,” said Dr. Guyer.

Metabolic Dysfunction-Associated Steatohepatitis (MASH)

- *MONARCH – Enrollment continues in randomized, double-blind, placebo-controlled, Phase 2b trial of miricorilant in 120 patients with biopsy-confirmed MASH and in 75 patients with presumed MASH*

“In our Phase 1b study, miricorilant reduced liver fat very rapidly, improved liver health and key metabolic and lipid measures, and was well-tolerated. We look forward to building on these promising results in our MONARCH study,” said Dr. Guyer. “Miricorilant has the potential to greatly benefit the millions of patients with MASH.”

Conference Call

We will hold a conference call on October 30, 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 Corcept.com.

About Corcept Therapeutics

For over 25 years, Corcept's focus on cortisol modulation and its potential to treat patients with a wide variety of serious disorders has led to the discovery of more than 1,000 proprietary selective cortisol modulators. Corcept is conducting advanced clinical trials in patients with hypercortisolism, solid tumors, ALS and liver disease. 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 Redwood City, 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, risks related to the sale and reimbursement of Korlym and our ability to operate our business successfully in a competitive and closely regulated market; risks related to the study and development of Korlym, relacorilant, dazucorilant, miricorilant and our other product candidates, including their clinical attributes and applicable regulatory approvals, mandates, oversight and other government requirements; general litigation risks; 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: trends in medical practice, including trends regarding the identification and treatment of patients with hypercortisolism; our revenue growth and 2024 revenue guidance; the development of relacorilant as a treatment for patients with Cushing's syndrome and solid tumors, dazucorilant as a treatment for patients with ALS, miricorilant as a treatment for patients with MASH; the timing and outcome of relacorilant's NDA in Cushing's syndrome; the timing of and expectations regarding our CATALYST, ROSELLA, DAZALS and MONARCH trials and the possibility of relacorilant, dazucorilant and miricorilant being approved for the treatment of any disorder; and the accrual and attributes of our clinical data and the timing and content of our 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)

	September 30, 2024	December 31, 2023[1]
	(Unaudited)	
Assets		
Cash and investments	$ 547,646	$ 425,397
Trade receivables, net of allowances	59,717	41,123
Insurance recovery receivable related to Melucci litigation	—	14,000
Inventory	15,814	15,974
Operating lease right-of-use asset	5,503	120
Deferred tax assets, net	126,799	90,605
Other assets	28,778	34,298
Total assets	$ 784,257	$ 621,517
Liabilities and Stockholders' Equity		
Accounts payable	$ 18,584	$ 17,396
Accrued settlement related to Melucci litigation	—	14,000
Operating lease liabilities	6,791	151
Other liabilities	120,047	83,265
Stockholders' equity	638,835	506,705
Total liabilities and stockholders' equity	$ 784,257	$ 621,517

[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,	
	2024	**2023**	**2024**	**2023**
Revenues				
Product revenue, net	$ 182,546	$ 123,601	$ 493,150	$ 346,970
Operating expenses				
Cost of sales	2,867	1,645	7,926	4,604
Research and development	59,336	45,517	176,587	129,646
Selling, general and administrative	73,745	45,262	196,948	137,107
Total operating expenses	135,948	92,424	381,461	271,357
Income from operations	46,598	31,177	111,689	75,613
Interest and other income	6,345	5,208	17,844	12,135
Income before income taxes	52,943	36,385	129,533	87,748
Income tax expense	(5,730)	(5,007)	(19,070)	(12,963)
Net income	$ 47,213	$ 31,378	$ 110,463	$ 74,785
Net income attributable to common stockholders	$ 46,690	$ 31,172	$ 109,344	$ 74,353
Basic net income per common share	$ 0.45	$ 0.31	$ 1.06	$ 0.72
Diluted net income per common share	$ 0.41	$ 0.28	$ 0.98	$ 0.66
Weighted-average shares outstanding used in computing net income per common share				
Basic	103,371	102,014	103,094	103,933
Diluted	113,723	111,099	111,571	112,054

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