# 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

August 3, 2022 Date of Report (date of earliest event reported)

# **Corcept Therapeutics Incorporated**

## (Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

**000-50679** (Commission File Number) 77-0487658 (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  $\Box$ 

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 August 3, 2022, Corcept Therapeutics Incorporated (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 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 August 3, 2022
- 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: August 3, 2022

By: /s/ Atabak Mokari

Name: Atabak Mokari Title: Chief Financial Officer

#### CORCEPT THERAPEUTICS ANNOUNCES SECOND QUARTER FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

**MENLO PARK, Calif.** (August 3, 2022) – 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 June 30, 2022.

#### **Financial Results**

- Revenue of \$103.4 million, compared to \$91.6 million in second quarter 2021
- Reiterated 2022 revenue guidance of \$400 \$430 million
- Diluted net income per common share of \$0.24, compared to \$0.21 in second quarter 2021
- Cash and investments of \$382.0 million, compared to \$368.1 million at March 31, 2022

Corcept's second quarter 2022 revenue was \$103.4 million, compared to \$91.6 million in the second quarter of 2021. Second quarter operating expenses were \$72.0 million, compared to \$59.6 million in the second quarter of 2021, due to increased clinical trial activity, expenses to support the expansion of our clinical development and commercial teams and legal fees. Net income was \$27.4 million in the second quarter of 2022, compared to \$26.5 million in the second quarter of 2021.

Cash and investments increased \$13.9 million in the second quarter, to \$382.0 million at June 30, 2022.

"Our revenue growth reflects the continued increase in our base of Korlym prescribers," said Joseph K. Belanoff, MD, Corcept's Chief Executive Officer. "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 reiterating our 2022 revenue guidance of \$400 – \$430 million."

#### **Clinical Development**

"Data generated by our clinical development programs have provided increasing evidence of cortisol modulation's potential to treat many serious diseases," added Dr. Belanoff. "Positive results from our Phase 2 trial of selective cortisol modulator relacorilant in women with platinum-resistant ovarian cancer led to the recent initiation of our Phase 3 ROSELLA trial. Later this year, we expect important data from our programs in antipsychotic-induced weight gain and non-alcoholic steatohepatitis."

#### Solid Tumors

- ROSELLA initiated 360-patient pivotal Phase 3 trial of relacorilant plus nab-paclitaxel in patients with recurrent, platinumresistant ovarian cancer
- Enrollment continues in 20-patient, 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 to begin in collaboration with the University of Chicago

"Opening our ROSELLA study is an important step forward," said Bill Guyer, PharmD, Corcept's Chief Development Officer. "The 40,000 women in the United States and Europe with platinum-resistant ovarian cancer have few good treatment options. Our Phase 2 study demonstrated improvements in progression-free survival, duration of response and overall survival without increased side effect burden. Simply replicating these positive results in ROSELLA would be of unprecedented benefit to women with platinum-resistant ovarian cancer, for whom relacorilant plus nab-paclitaxel has the potential to become a new standard."

"We are also pleased to collaborate with investigators at the University of Chicago in initiating a placebo-controlled, Phase 2 trial of relacorilant, combined with enzalutamide, in patients with prostate cancer, pre-prostatectomy," said Dr. Guyer. "There is a large patient population at this stage of disease and we hope to be able to offer them substantial benefit."

#### **Metabolic Diseases**

- Enrollment completed in GRATITUDE and GRATITUDE II two double-blind, placebo-controlled Phase 2 trials of miricorilant to reverse recent and long-standing antipsychotic-induced weight gain (AIWG); data from both trials expected in fourth quarter 2022
- Enrollment continues in Phase 1b dose-finding trial of miricorilant in patients with presumed non-alcoholic steatohepatitis (NASH); data expected in fourth quarter 2022

"Weight gain and other adverse metabolic effects caused by antipsychotic medications reduce the life expectancy of millions of patients. These side effects also dissuade many patients from adhering to their treatment regimen," said Dr. Guyer. "We expect our double-blind, placebo-controlled GRATITUDE and GRATITUDE II trials to build on the positive data from our Phase 1 studies in healthy volunteers."

## **Cushing's Syndrome**

- Enrollment continues 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 second half 2023
- Enrollment continues in Phase 3 GRADIENT trial of relacorilant as a treatment for patients with Cushing's syndrome caused by adrenal adenomas

"We advanced relacorilant to Phase 3 in Cushing's syndrome based on its extremely promising Phase 2 efficacy and safety data. We expect our GRACE trial to serve as the basis for relacorilant's NDA in Cushing's syndrome, which we plan to submit in the second half of 2023," said Dr. Guyer. "The Phase 3 GRADIENT trial will produce valuable data about an etiology of Cushing's syndrome that has not been subject to rigorous, controlled study, but affects many patients."

### **Amyotrophic Lateral Sclerosis (ALS)**

• DAZALS, a 198-patient, randomized, double-blind, placebo-controlled Phase 2 trial of dazucorilant in patients with ALS, planned to start this quarter

"ALS, commonly known as Lou Gehrig's disease, is a devastating illness with a significant need for better treatment," said Dr. Guyer. "Dazucorilant, a selective cortisol modulator that crosses the blood-brain barrier, showed outstanding promise in animal models of ALS. We plan to initiate a large, controlled Phase 2 trial, which we have named DAZALS, this quarter, at sites in Europe and the United States."

## **Conference Call**

We will hold a conference call on August 3, 2022, 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. The company is conducting clinical trials of its leading cortisol modulators as potential treatments for patients with Cushing's syndrome, ovarian and adrenal cancer, weight gain caused by the use of antipsychotic medications and liver disease. Corcept's drug Korlym<sup>®</sup> 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, those concerning our expectations regarding the course of the COVID-19 pandemic and its effects on our commercial results and clinical activities; the number of eligible patients who have yet to receive Korlym; our continued revenue growth and 2022 revenue guidance; cortisol modulation's potential to treat many serious diseases; development of relacorilant as a treatment for ovarian and prostate cancer, including relacorilant's clinical attributes, regulatory approvals, mandates and oversight, and other requirements; the potential for relacorilant plus nab-paclitaxel to become a standard of care for patients with recurrent platinum-resistant ovarian cancer; the timing and substance of our results in the GRATITUDE trials of miricorilant in patients with antipsychotic-induced weight gain and our Phase 1b trial in patients with NASH; expectations regarding the GRACE trial as the basis for relacorilant's NDA in Cushing's syndrome; our planned trial of dazucorilant in patients with ALS; 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)

_	<b>June 30, 2022</b> (Unaudited)		
Assets			
Cash and investments \$	381,976	\$ 335,812	
Trade receivables, net of allowances	28,164	27,625	
Inventory	17,415	17,950	
Operating lease right-of-use asset	2,264	514	
Deferred tax assets, net	48,491	27,455	
Other assets	18,054	14,400	
Total assets \$	496,364	\$ 423,756	
= Liabilities and Stockholders' Equity			
Accounts payable \$	8,246	\$ 6,908	
Operating lease liabilities	2,264	526	
Other liabilities	43,528	40,516	
Stockholders' equity	442,326	375,806	
Total liabilities and stockholders' equity	496,364	\$ 423,756	

 $^{\left( 1\right) }$  Derived from audited financial statements at that date

## CORCEPT THERAPEUTICS INCORPORATED

## CONDENSED CONSOLIDATED STATEMENTS OF INCOME

## (Unaudited)

(In thousands, except per share data)

	Three Months Ended June 30,			Six Months Ended June 30,				
		2022		2021		2022		2021
Revenues								
Product revenue, net	\$	103,386	\$	91,588	\$	197,074	\$	171,025
Operating expenses								
Cost of sales		1,316		1,384		2,566		2,652
Research and development		32,825		28,232		60,945		57,254
Selling, general and administrative		37,813		30,029		75,362		59,538
Total operating expenses	\$	71,954	\$	59,645	\$	138,873	\$	119,444
Income from operations		31,432		31,943		58,201		51,581
Interest and other income		630		110		710		385
Income before income taxes		32,062		32,053		58,911		51,966
Income tax expense		(4,650)		(5,530)		(8,702)		(1,978)
Net income	\$	27,412	\$	26,523	\$	50,209	\$	49,988
Net income attributable to common stockholders	\$	27,398	\$	26,523	\$	50,196	\$	49,988
Basic net income per common share	\$	0.26	\$	0.23	\$	0.47	\$	0.43
Diluted net income per common share	\$	0.24	\$	0.21	\$	0.44	\$	0.39
Weighted-average shares outstanding used in computing net income per common share								
Basic		106,289		116,294		106,151		116,555
Diluted		115,399		126,680		115,222		128,204

## **CONTACT:**

Corcept Therapeutics Investor Relations <u>ir@corcept.com</u> <u>www.corcept.com</u>