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

May 6, 2021
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 or organization)	(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 May 6, 2021, Corcept Therapeutics Incorporated (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2021 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 May 6, 2021
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: May 6, 2021

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

EXHIBIT 99.1

CORCEPT THERAPEUTICS PROVIDES CLINICAL UPDATE AND ANNOUNCES FIRST QUARTER 2021 FINANCIAL RESULTS

- *In a 178-patient, controlled, Phase 2 trial, women with platinum resistant ovarian cancer who received relacorilant plus nab-paclitaxel experienced improved progression free survival (PFS) compared to women who received nab-paclitaxel alone, with comparable safety and tolerability; planning underway for Phase 3 pivotal trial.*
- *In Phase 2 trial, patients with presumed nonalcoholic steatohepatitis (NASH) administered miricorilant experienced large, rapid reductions in liver fat*
- *Revenue of $79.4 million, compared to $93.2 million in first quarter 2020*
- *GAAP diluted net income of $0.18 per share, compared to $0.25 per share in first quarter 2020*
- *Non-GAAP diluted net income of $0.20 per share, compared to $0.34 per share in first quarter 2020*
- *Cash and investments of $454.8 million, compared to $476.9 million at December 31, 2020*
- *Modified 2021 revenue guidance of $355 to $385 million*

MENLO PARK, Calif. (May 6, 2021) – Corcept Therapeutics Incorporated (NASDAQ: CORT), a commercial-stage company engaged in the discovery and development of drugs to treat severe metabolic, oncologic and neuropsychiatric disorders by modulating the effects of the stress hormone cortisol, today reported its results for the quarter ended March 31, 2021.

First quarter 2021 revenue was $79.4 million, compared to $93.2 million in the first quarter of 2020. The decrease in revenue in the first quarter was primarily due to the effects of the COVID-19 pandemic on our business.

First quarter operating expenses were $59.8 million, compared to $55.5 million in the first quarter of 2020, due to increased spending on clinical trials in Cushing's syndrome and metabolic diseases and the formulation and manufacture of the company's proprietary selective cortisol modulators.

First quarter 2021 GAAP net income was $23.5 million, compared to $30.1 million in the first quarter of 2020. Excluding non-cash expenses related to stock-based compensation and the utilization of deferred tax assets, together with related income tax effects, non-GAAP net income in the first quarter was $25.8 million, compared to $41.2 million in the first quarter of 2020. A reconciliation of GAAP to non-GAAP net income is included below.

Cash and investments were $454.8 million at March 31, 2021, compared to $476.9 million at December 31, 2020. The company repurchased 2.1 million shares of its common stock in the first quarter – 1.3 million shares for $33.5 million pursuant to the company's stock repurchase program and 0.8 million shares for $16.4 million in connection with the net exercise of stock options – at a total cost of $50.0 million. Under the stock repurchase program's currently authorized terms, $156.8 million remains available for the purchase of shares.

Corcept modified its 2021 revenue guidance to $355 – $385 million. Corcept anticipates positive cash flow for the foreseeable future.

"The lingering effects of the spike in COVID-19 in the fourth quarter of last year extended further into the first quarter than we anticipated, coloring our commercial results," said Joseph K. Belanoff, MD, Corcept's Chief Executive Officer. "Many physicians are still not able to see their patients often enough to optimally diagnose and treat a complex disease such as Cushing's syndrome. Further, many patients introduced to Korlym during the pandemic have so far not reached their ideal dose, as many physicians are seeing their patients less frequently, particularly in person, and testing them less frequently, slowing optimal titration.

"We expect these effects to diminish as COVID restrictions and fears diminish. The best treatment for Cushing's syndrome involves substantial and frequent engagement between patients and physicians," said Dr. Belanoff. "Our modified 2021 revenue guidance assumes that pandemic-related obstacles will ease substantially in the third

quarter – about two quarters later than we had originally thought. Leading physicians increasingly believe that the number of patients with hypercortisolism is substantially greater than once assumed Korlym is an excellent treatment for hypercortisolism. Relacorilant, if approved, will be even better. We expect significant revenue growth and profits in the years ahead."

Clinical Development Highlights

"Despite having to contend with pandemic-related headwinds," said Dr. Belanoff, "our clinical development efforts, particularly in the United States, gained momentum in the first quarter. Today we announced positive data related to two of our proprietary, selective cortisol modulators as possible treatments for platinum-resistant ovarian cancer and NASH. These are important advances for the potential treatment of these diseases, which have a high unmet need. In addition, we are encouraged that these results provide further clinical validation of our cortisol modulation platform as a treatment for a broad range of diseases. In contrast to the past when sometimes a year would pass between releases of clinical results, we now expect important information to emerge every quarter."

Solid Tumors

- *In a 178-patient, controlled, Phase 2 trial, women with platinum-resistant ovarian cancer who received relacorilant plus nab-paclitaxel experienced improved progression free survival (PFS) compared to women who received nab-paclitaxel alone, with comparable safety and tolerability*[1]
- *Planning underway for a Phase 3 pivotal trial in ovarian cancer*
- *Preliminary results in the first 40 patients enrolled in open-label Phase 3 RELIANT trial of relacorilant plus nab-paclitaxel in patients with metastatic pancreatic cancer expected this quarter*
- *Selection of the optimum dose of exicorilant plus enzalutamide in patients with castration-resistant prostate cancer ("CRPC") expected by third quarter 2021*
- *Enrollment continues in a 20-patient, open-label, Phase 1b trial of relacorilant plus PD-1 checkpoint inhibitor pembrolizumab in patients with adrenal cancer with cortisol excess*

"We are extremely pleased with the results of our trial of relacorilant as a possible treatment for platinum-resistant ovarian cancer," said Andreas Grauer, MD, Corcept's Chief Medical Officer. "Delaying disease progression in these women, without causing additional side effects, is heartening. We are planning a Phase 3 pivotal trial which we hope will replicate these positive data."

Participants in the trial were randomized 1:1:1 to receive either (i) nab-paclitaxel plus a daily dose of relacorilant (100 mg), (ii) nab-paclitaxel plus relacorilant (150mg) given "intermittently" (i.e., the day before, the day after, and the day of each weekly nab-paclitaxel infusion) or (iii) nab-paclitaxel alone.

Women who received the higher dose of relacorilant intermittently exhibited a statistically significant improvement in median progression free survival compared to those who received nab-paclitaxel alone (median PFS: 5.6 months versus 3.8 months, hazard ratio: 0.66; p-value: 0.038). Women who received the lower, daily dose of relacorilant experienced longer progression free survival, but the improvement did not reach statistical significance (5.3 months versus 3.8 months, hazard ratio: 0.83). Full results of the trial, including overall survival, will be available later this year.

"Our trials in other solid tumors continue to progress," added Dr. Grauer. "We expect to have interim data from our RELIANT trial of relacorilant plus nab-paclitaxel in patients with metastatic pancreatic cancer at the end of this quarter. Our trial of relacorilant plus pembrolizumab in patients with adrenal cancer with cortisol excess continues to enroll patients. And by the end of the third quarter, we expect to select an optimal dose of our selective cortisol modulator exicorilant combined with enzalutamide in patients with castration-resistant prostate cancer."

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[1] For more information, see the Investors / Press Releases tab at www.corcept.com.

Metabolic Diseases

- *In Phase 2 trial, patients with presumed NASH administered miricorilant experienced large, rapid reductions in liver fat*[2]
- *Enrollment continues in GRATITUDE, a 100-patient double-blind, placebo-controlled, Phase 2 trial of miricorilant to reverse recent anti-psychotic-induced weight gain ("AIWG")*
- *Enrollment continues in GRATITUDE II, a 150-patient, double-blind, placebo-controlled Phase 2 trial of miricorilant to reverse long-standing AIWG*

"Four of the first five patients who received miricorilant for four weeks in our Phase 2 trial of patients with presumed NASH experienced sharply elevated levels of the liver enzymes ALT and AST, which resolved after miricorilant was withdrawn" said Dr. Grauer. "They also exhibited large reductions in liver fat (see Table 1).

Patient	Miricorilant (per day)	Days on Drug	% Liver Fat at Baseline	% Liver Fat at Follow up	Days Between Last Dose and Follow-up	Relative Reduction in % Liver Fat
Patient 1	900 mg	30	17.6	6.1	19	-65.3%
Patient 2	900 mg	31	27.8	17.1	64	-38.5%
Patient 3	900 mg	44	28.3	15.0	16	-47.0%
Patient 4	600 mg	34	12.6	3.3	21	-73.8%

Table 1: Reduction in liver fat content measured by magnetic resonance imaging proton density fat fraction (MRI-PDFF)

"The improvement in liver fat in these patients was greater and occurred much more rapidly than we had expected. We powered our trial with a planned enrollment of 120 patients to detect a 30 percent reduction in liver fat after twelve weeks' dosing," said Dr. Grauer. "These results are especially notable given that they were measured many days after miricorilant was stopped. We are gathering more information, consulting with experts in liver disease and formulating our plans to advance miricorilant in NASH."

"In the meantime, our Phase 2 trials evaluating miricorilant as treatment for patients with AIWG – GRATITUDE and GRATITUDE II – continue to add patients," added Dr. Grauer. "We expect to complete enrollment in GRATITUDE II by year-end and GRATITUDE in mid-2022."

Cushing's Syndrome

- *Enrollment continues in Phase 3 GRACE trial of relacorilant as a treatment for patients with any etiology of Cushing's syndrome at sites in the United States, Canada, Europe and Israel; NDA submission expected by second quarter 2023*
- *Enrollment continues in Phase 3 GRADIENT trial of relacorilant as a treatment for patients with Cushing's syndrome of adrenal origin at sites in the United States, Europe and Israel*

"Relacorilant's Phase 2 efficacy and safety data were extremely promising. We expect GRACE to serve as the basis for our NDA in Cushing's syndrome. GRACE is accruing patients and generating data and we have observed an improved enrollment rate at our sites in the United States over the last few months. While the pandemic continues to suppress enrollment in GRACE and GRADIENT, particularly in Europe, where the pace of recovery from COVID has lagged, we remain on track for NDA submission by the second quarter of 2023," said Dr. Grauer. "GRADIENT will produce valuable data about the role of cortisol modulation in an etiology of Cushing's syndrome that has not previously been subject to a rigorous, controlled study."

Conference Call

[2] For more information, see the Investors / Press Releases tab at www.corcept.com.

We will hold a conference call on May 6, 2021, at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). To participate, click this link (listen-only mode) or dial 1-888-204-4368 from the United States or 1-313-209-4906 internationally approximately 15 minutes before the start of the call. The passcode will be 8720277. A replay will be available on the Investors / Past Events tab of our website.

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 in the body and can be lethal if not treated effectively. Corcept holds patents covering the composition of relacorilant and the use of cortisol modulators, including Korlym, in the treatment of patients with hypercortisolism.

About Corcept Therapeutics

Corcept is a commercial-stage company engaged in the discovery and development of drugs to treat severe metabolic, oncologic and psychiatric disorders by modulating the effects of the hormone cortisol. Korlym was the first drug approved by the U.S. Food and Drug Administration for patients with Cushing's syndrome. Corcept has discovered a large portfolio of proprietary compounds that selectively modulate the effects of cortisol. The company owns extensive United States and foreign intellectual property covering the composition of its selective cortisol modulators and the use of cortisol modulators to treat a variety of serious disorders.

GAAP Measures of Net Income

To supplement our financial results presented on a GAAP basis, we use non-GAAP measures of net income, basic net income per share and diluted net income per share that exclude the following non-cash expenses – (i) stock-based compensation, (ii) our use of deferred tax assets to offset current tax expense and (iii) related income tax effects. We believe these non-GAAP measures help investors evaluate our financial performance and potential future results. Our non-GAAP measures may be different from, and not directly comparable to, those used by other companies. They are not a substitute for comparable GAAP measures and should not be considered in isolation. Investors should read our non-GAAP presentation in conjunction with our financial statements prepared in accordance with GAAP.

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 statements express or imply. These risks and uncertainties include, but are not limited to, our ability to operate our business and achieve our goals and conduct our clinical trials during the COVID-19 pandemic and to generate sufficient revenue to fund our commercial operations and development programs; the availability of competing treatments, including generic versions of Korlym; our ability to obtain acceptable prices or adequate insurance coverage and reimbursement for Korlym; risks related to the development of our product candidates, including their clinical attributes, regulatory approvals, mandates and oversight, and other requirements; 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 the clinical attributes of relacorilant and its effects in patients with ovarian cancer, plans to initiate a phase 3 trial and potential to treat other solid tumors; the clinical attributes of miricorilant and its effects in patients with NASH and the requirements to resume the Phase 2 trial in NASH; 2021 revenue guidance; our clinical development programs; the progress, enrollment, timing, design and results of our clinical trials, including the timing of enrollment, data and dosing selection; the timing of regulatory

submissions; the course of the COVID-19 pandemic and its impact on patients, physicians, medical practice, clinical research activities and our business; and the clinical and commercial attributes of Korlym, relacorilant, exicorilant and miricorilant. 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, except per share data)

	March 31, 2021	December 31, 2020
	(Unaudited)	(See Note 1)
Assets		
Cash and investments	$ 454,793	$ 476,892
Trade receivables, net of allowances	22,200	26,198
Inventory	20,332	21,157
Operating lease right-of-use asset	2,020	2,509
Deferred tax assets, net	37,025	31,603
Other assets	16,028	13,372
Total assets	$ 552,398	$ 571,731
Liabilities and Stockholders' Equity		
Accounts payable	$ 6,969	$ 10,554
Operating lease liabilities	2,067	2,551
Other liabilities	32,560	35,288
Stockholders' equity	510,802	523,338
Total liabilities and stockholders' equity	$ 552,398	$ 571,731

(1) Derived from audited financial statements at that date

CORCEPT THERAPEUTICS INCORPORATED

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Unaudited)
(In thousands, except per share data)

	Three Months Ended March 31,	
	2021	**2020**
Revenues		
Product revenue, net	$ 79,437	$ 9
Operating expenses		
Cost of sales	1,268	
Research and development	29,022	2
Selling, general and administrative	29,509	2
Total operating expenses	$ 59,799	$ 5
Income from operations	19,638	3
Interest and other income	275	
Income before income taxes	19,913	3
Income tax benefit (expense)	3,552	(
Net income	$ 23,465	$ 3
Other comprehensive income:		
Net unrealized (loss) gain on available-for-sale investments, net of tax impact of $61, $(20), respectively	(192)	
Foreign currency translation gain (loss), net of tax	26	
Total comprehensive income	$ 23,299	$ 3
Basic net income per share	$ 0.20	$
Diluted net income per share	$ 0.18	$
Shares used in computing basic net income per common share	116,818	11
Shares used in computing diluted net income per common share	129,668	12

CORCEPT THERAPEUTICS INCORPORATED

RECONCILIATION OF GAAP TO NON-GAAP NET INCOME
(Unaudited)
(In thousands, except per share data)

	Three Months Ended March 31,	
	2021	**2020**
GAAP net income	$ 23,465	$ 30,065
Non-cash expenses (benefits)		
Stock-based compensation		
Cost of sales	10	23
Research and development	3,505	2,605
Selling, general and administrative	6,586	5,290
Total stock-based compensation	10,101	7,918
Deferred income taxes	(5,360)	5,095
Income tax effect of non-GAAP adjustments [(1)]	(2,424)	(1,900)
Non-GAAP net income, adjusted for non-cash expenses	$ 25,782	$ 41,178
GAAP basic net income per share	$ 0.20	$ 0.26
GAAP diluted net income per share	$ 0.18	$ 0.25
Non-GAAP basic net income per share, adjusted for non-cash expenses per share	$ 0.22	$ 0.36
Non-GAAP diluted net income per share, adjusted for non-cash expenses per share	$ 0.20	$ 0.34
Shares used in computing basic net income per common share	116,818	114,575
Shares used in computing diluted net income per common share	129,668	122,226

[(1)] Calculated by applying the statutory tax rate to the pre-tax, non-discrete, non-GAAP adjustments.

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