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 8, 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 February 8, 2021, Corcept Therapeutics Incorporated (the "Company") issued a press release announcing its preliminary fourth quarter and selected financial results for the period ended December 31, 2020 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 8, 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: February 8, 2021

By: /s/ Charles Robb
Name: Charles Robb
Title: Chief Financial Officer and Secretary

EXHIBIT 99.1

CORCEPT THERAPEUTICS ANNOUNCES FOURTH QUARTER, FULL-YEAR 2020 PRELIMINARY SELECTED FINANCIAL RESULTS AND 2021 REVENUE GUIDANCE; PROVIDES CORPORATE UPDATE

Financial Highlights, 2021 Revenue Guidance and Legal Update

- *Preliminary 2020 revenue $353.9 million, compared to $306.5 million in 2019*
- *Preliminary fourth quarter revenue $85.7 million, compared to $87.9 million in fourth quarter 2019*
- *2021 revenue guidance $375 - 405 million*
- *Preliminary 2020 fully diluted GAAP net income $0.85 per share, compared to $0.77 per share in 2019*
- *Preliminary fourth quarter fully diluted GAAP net income $0.20 per share, compared to $0.24 per share in fourth quarter 2019*
- *Preliminary cash and investments at December 31, 2020 of $476.9 million, an increase of $161.6 million from December 31, 2019*
- *Patent Trial and Appeals Board affirms validity of all claims in Corcept's U.S. Patent No. 10,195,214 (patent term: 2037)*

MENLO PARK, Calif. (February 8, 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 preliminary fourth quarter revenue of $85.7 million, compared to $87.9 million in the fourth quarter of 2019. Preliminary 2020 revenue was $353.9 million compared to $306.5 million in 2019. The company expects 2021 revenue of $375 – 405 million.

Cash and investments increased by $32.7 million in the fourth quarter to $476.9 million. At December 31, 2019, cash and investments totaled $315.3 million. The company spent $9.7 million in the fourth quarter repurchasing 458,769 shares of common stock pursuant to its stock repurchase program. Under the currently authorized terms of that program, $190.3 million remains available for the repurchase of shares.

These results are prior to completion of the company's annual independent audit and are subject to adjustment.

"Corcept's performance during the COVID-19 pandemic demonstrates the durability of our business," said Joseph K. Belanoff, MD, Corcept's Chief Executive Officer. "Confronted with unprecedented obstacles, we generated significantly more revenue, more income and more cash than we did in 2019. Having won an important legal victory in our dispute with Teva Pharmaceuticals, we look with confidence to the future. As the pandemic is contained, we expect our commercial growth to resume and have provided 2021 revenue guidance of $375 – 405 million.

"The pandemic's impact on our clinical activities has been variable. Trials in acutely life-threatening indications, such as advanced ovarian and pancreatic cancer, recruited briskly. Studies of illnesses with a slower course of disease, such as Cushing's syndrome, castration-resistant prostate cancer ("CRPC"), anti-psychotic-induced weight gain ("AIWG") and non-alcoholic steatohepititus ("NASH") have proceeded more slowly.

"Despite these challenges, our development team made important advances. They maintained our existing trials, although the pandemic significantly slowed enrollment in many of them. They also started new trials that greatly broadened the scope of our clinical program. In 2020, we initiated trials in Cushing's syndrome of adrenal origin, metastatic pancreatic cancer, advanced adrenocortical cancer, AIWG and NASH. We also laid the groundwork for further expansion by advancing promising compounds from our portfolio of selective cortisol modulators towards the clinic."

Cushing's Syndrome

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

"While our Phase 3 GRACE and GRADIENT trials in patients with Cushing's syndrome continue to accrue patients and generate valuable data, pandemic-related public health measures, which in many places became even more restrictive in the fourth quarter, continue to slow the pace of enrollment," said Andreas Grauer, MD, Corcept's Chief Medical Officer. "As vaccination campaigns falter – especially in Europe, where many of our most productive clinical sites are located – the retarding effects of the pandemic remain in place. Ultimately, relacorilant's NDA submission date will depend on the duration and severity of pandemic-related restrictions, which cannot be known with certainty. The delay may be as long as one year, to the second quarter of 2023.

"These delays are especially frustrating because relacorilant's Phase 2 data were extremely promising. Our team of clinical investigators are enthusiastic. We are confident enrollments will accelerate once conditions improve."

Solid Tumors

- *Preliminary results in 178-patient, controlled, Phase 2 trial of relacorilant plus nab-paclitaxel in patients with metastatic ovarian cancer expected in first half 2021*
- *Preliminary results in first 40 patients enrolled in open-label Phase 3 RELIANT trial of relacorilant plus nab-paclitaxel in patients with metastatic pancreatic cancer expected in first half 2021*
- *Selection of optimum dose of exicorilant plus enzalutamide in patients with castration-resistant prostate cancer ("CRPC") expected by third quarter 2021*
- *Patient selection underway in 20-patient, open-label, Phase 1b trial of relacorilant plus PD-1 checkpoint inhibitor pembrolizumab in patients with adrenal cancer with cortisol excess*

"Our trials in patients with metastatic ovarian and pancreatic cancer are on track to generate preliminary data in the first half of 2021, as planned," said Dr. Grauer. "These trials are evaluating whether relacorilant can enhance the efficacy of nab-paclitaxel by reducing cortisol's suppression of apoptosis in patients with advanced disease, many of whom have experienced progression on prior rounds of taxane-based therapies. It would be wonderful to be able to offer a therapy that benefits them.

"The dose-finding trial of our selective cortisol modulator exicorilant with enzalutamide as a treatment for CRPC continues to enroll patients," said Dr. Grauer, "although the pandemic has slowed its pace, pushing selection of an optimum dose to the second or third quarter of this year, depending on how quickly pandemic condtions improve. Our hypothesis, which is well-supported by pre-clinical data, is that combining an androgen receptor antagonist like enzalutamide with a cortisol modulator will block an important tumor escape route.

"Last year, we initiated a Phase 1b trial in patients with adrenal cancer with cortisol excess," said Dr. Grauer. "This study will evaluate whether adding relacorilant to pembrolizumab therapy will reduce cortisol-activated immune suppression sufficiently to help pembrolizumab achieve its intended tumor-killing effect, while relacorilant treats the Cushing's syndrome caused by excess cortisol activity."

Metabolic Diseases

- *Enrollment underway in double-blind, placebo-controlled Phase 2 trial of miricorilant in patients with NASH*

- *Enrollment continues in GRATITUDE, a double-blind, placebo-controlled, Phase 2 trial of miricorilant to reverse recent AIWG*
- *Enrollment continues in GRATITUDE II, a 150-patient, double-blind, placebo-controlled Phase 2 trial of miricorilant to reverse long-standing AIWG*

“In the fourth quarter, we initiated a double-blind, placebo-controlled Phase 2 trial of miricorilant as a potential treatment for NASH, a serious liver disorder that affects millions of people,” said Dr. Grauer. “We plan to enroll 120 patients, who will receive either 900 mg miricorilant, 600 mg miricorilant or placebo for twelve weeks. The primary endpoint will be reduction in liver fat content, as measured by MRI. Our pre-clinical data suggest miricorilant may be a potent treatment for NASH. We hope to demonstrate similarly encouraging results in patients.

“Our Phase 2 trials in AIWG – GRATITUDE and GRATITUDE II – continue to enroll patients, although the pandemic has slowed the pace,” added Dr. Grauer. “AIWG reduces the quality of life and shortens the life expectancy of millions of patients. Results from the Phase 1b trial we completed last year suggest that miricorilant may benefit them. In that study, healthy volunteers given miricorilant plus olanzapine gained less weight and had lower triglycerides and less sharply elevated liver enzymes than those who received olanzapine plus placebo after only two weeks of dosing. These results build on those we achieved in similar trials using mifepristone (*see* Gross et al, Advances in Therapy (2009); Gross et al, Obesity (2010). Miricorilant, like mifepristone, modulates cortisol activity. Unlike mifepristone, miricorilant does not affect progesterone activity.”

Conference Call

We will hold a conference call on February 8, 2021, at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). To participate, click this link (listen-only mode) or dial 1-833-693-0540 (United States) or 1-661-407-1581 (international) approximately ten minutes before the start of the call. The conference ID number is 9289307. 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.

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.

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, the completion of our financial closing procedures and any adjustments that may result from the completion of the annual independent audit of our consolidated financial statements; 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 our preliminary fourth quarter and full year 2020 financial results; 2021 revenue guidance; our clinical development programs; the progress, enrollment, timing, design and results of our clinical trials; the course of the COVID-19 pandemic and its impact on patients, physicians, medical practice and clinical research activities; 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.

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