# 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**

July 29, 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 July 29, 2021, Corcept Therapeutics Incorporated (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 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 July 29, 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: July 29, 2021

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

**EXHIBIT 99.1**

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

**MENLO PARK, Calif.** (July 29, 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 hormone cortisol, today reported its results for the quarter ended June 30, 2021.

**Financial Results**

- *Revenue of $91.6 million, compared to $88.6 million in second quarter 2020*
- *GAAP diluted net income of $0.21 per share, compared to $0.23 per share in second quarter 2020*
- *Non-GAAP diluted net income of $0.30 per share, compared to $0.32 per share in second quarter 2020*
- *Cash and investments of $471.6 million, compared to $454.8 million at March 31, 2021*
- *Reiterated 2021 revenue guidance of $355 – $385 million*

Second quarter 2021 revenue was $91.6 million, compared to $88.6 million in the second quarter of 2020. First quarter 2021 revenue was $79.4 million. Second quarter 2021 GAAP net income was $26.5 million, compared to $28.3 million in the second 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 second quarter was $38.2 million, compared to $39.7 million in the second quarter of 2020. A reconciliation of GAAP to non-GAAP net income is included below.

Second quarter operating expenses were $59.6 million, compared to $53.3 million in the second quarter of 2020, due to increased employee compensation expenses, commercial spending, spending on clinical trials in Cushing's syndrome and pre-clinical activities.

Cash and investments were $471.6 million at June 30, 2021, compared to $454.8 million at March 31, 2021. The balance at June 30, 2021 reflects the acquisition of $30.8 million of common stock in the second quarter – 1.4 million shares pursuant to the company's stock repurchase program and 0.1 million shares in connection with the net exercise of stock options. Under the repurchase program's current terms, $127.6 million remains available for the purchase of shares.

The company reiterated its 2021 revenue guidance of $355 – $385 million.

"Diminishing COVID-19 public health restrictions and the availability of safe and effective vaccines have allowed our commercial business to resume growing," said Joseph K. Belanoff, MD, Corcept's Chief Executive Officer. "Our second quarter results reflect the fact that physicians are seeing their patients more frequently, which allows them to diagnose and optimally treat those who have Cushing's syndrome. Provided COVID-19 restrictions continue to abate – as we believe they will – we expect growth to continue. Korlym is an excellent treatment for hypercortisolism and there are many eligible patients who have yet to receive it. Our planned successor to Korlym, relacorilant, which is currently in its pivotal trial, promises to be an even better medication."

**Clinical Development**

"We are enthusiastic about the potential of cortisol modulation to help treat many diseases, not just Cushing's syndrome," added Dr. Belanoff. "Our programs in solid tumors, non-alcoholic steatohepatitis (NASH) and antipsychotic-induced weight gain (AIWG) continue to make progress. We are especially excited about our advancing platinum-resistant ovarian cancer program. Based on the statistically significant and clinically meaningful results of our 178-patient, controlled Phase 2 trial, we plan to initiate a pivotal trial in the first quarter of next year."

**Solid Tumors**

- *Phase 3 pivotal trial in patients with platinum-resistant ovarian cancer to start in the first quarter of 2022*
- *Selection of the optimum dose of exicorilant plus enzalutamide in patients with castration-resistant prostate cancer (CRPC) expected later this year*
- *Enrollment continues in 20-patient, open-label, Phase 1b trial of relacorilant plus PD-1 checkpoint inhibitor pembrolizumab in patients with adrenal cancer with cortisol excess*

"We look forward to starting a Phase 3 pivotal trial in women with platinum-resistant ovarian cancer," said Andreas Grauer, MD, Corcept's Chief Medical Officer. "Our Phase 2 results illustrated that women who received relacorilant with nab-paclitaxel experienced improved progression free survival (PFS) without experiencing additional side effects, a welcome finding for women with few good treatment options. We will present detailed results of our Phase 2 trial at the European Society for Medical Oncology (ESMO) meeting in September in a proffered paper oral presentation, with overall survival data expected later in the year. And we continue to evaluate relacorilant as a possible treatment for patients with other glucocorticoid receptor-expressing tumors."

**Metabolic Diseases**

- *Phase 1b dose-finding trial in patients with presumed NASH to start in the fourth quarter of 2021*
- *Enrollment continues in GRATITUDE, a 100-patient 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*

"We plan to begin a Phase 1b, dose-finding trial of miricorilant in patients with presumed NASH in the fourth quarter of this year," said Dr. Grauer. "Patients who received miricorilant in our previous trial experienced exceptionally large and rapid reductions in liver fat accompanied by substantial, but transient, elevations of the liver enzymes ALT and AST. Our hypothesis is that the rapidity and magnitude of miricorilant's fat reducing effect irritated the liver. The objective of our planned study is to identify a dosing regimen that can produce significant reductions in fat without causing liver irritation."

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

**Cushing's Syndrome**

- *Enrollment continues in Phase 3 GRACE trial of relacorilant as a treatment for patients with all etiologies of Cushing's syndrome; NDA submission expected in the second quarter of 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 based on its extremely promising Phase 2 efficacy and safety data, which we recently published in *Frontiers in Endocrinology* (Pivonello 2021)," said Dr. Grauer. "We expect our GRACE trial, which is accruing patients and generating data, to serve as the basis for relacorilant's NDA in Cushing's syndrome. We expect to submit this relacorilant NDA in the second quarter of 2023. The Phase 3 GRADIENT trial will produce valuable data about an etiology of Cushing's syndrome that affects many patients, but has not been subject to rigorous, controlled study."

**Conference Call**

We will hold a conference call on July 29, 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 from the United States or 1-661-407-1581

internationally approximately 15 minutes before the start of the call. The passcode will be 1482035. 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 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 in women with platinum-resistant ovarian cancer and continued evaluation of relacorilant as a possible treatment for patients with other glucocorticoid receptor-expressing tumors; the clinical attributes of miricorilant and its effects in patients with NASH and plans to initiate a Phase 1b trial in NASH; 2021 revenue guidance; our expectations regarding growth of our business; 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)

| | June 30, 2021 | December 31, 2020 |
|---|---|---|
| | (Unaudited) | (See Note 1) |
| **Assets** | | |
| Cash and investments | $ 471,639 | $ 476,892 |
| Trade receivables, net of allowances | 27,620 | 26,198 |
| Inventory | 19,403 | 21,157 |
| Operating lease right-of-use asset | 1,524 | 2,509 |
| Deferred tax assets, net | 33,741 | 31,603 |
| Other assets | 14,553 | 13,372 |
| **Total assets** | $ 568,480 | $ 571,731 |
| **Liabilities and Stockholders' Equity** | | |
| Accounts payable | $ 9,216 | $ 10,554 |
| Operating lease liabilities | 1,559 | 2,551 |
| Other liabilities | 35,030 | 35,288 |
| Stockholders' equity | 522,675 | 523,338 |
| **Total liabilities and stockholders' equity** | $ 568,480 | $ 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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2021** | **2020** | **2021** | **2020** |
| **Revenues** | | | | |
| Product revenue, net | $ 91,588 | $ 88,565 | $ 171,025 | $ 18 |
| **Operating expenses** | | | | |
| Cost of sales | 1,384 | 1,234 | 2,652 | |
| Research and development | 28,232 | 26,497 | 57,254 | 5 |
| Selling, general and administrative | 30,029 | 25,572 | 59,538 | 5 |
| **Total operating expenses** | $ 59,645 | $ 53,303 | $ 119,444 | $ 10 |
| Income from operations | 31,943 | 35,262 | 51,581 | 7 |
| Interest and other income | 110 | 1,010 | 385 | |
| Income before income taxes | 32,053 | 36,272 | 51,966 | 7 |
| Income tax expense | (5,530) | (7,945) | (1,978) | (1 |
| **Net income** | $ 26,523 | $ 28,327 | $ 49,988 | $ 5 |
| Other comprehensive income: | | | | |
| Net unrealized (loss) gain on available-for-sale investments, net of tax impact of $16, $(170), 77 and (190), respectively | (50) | 545 | (242) | |
| Foreign currency translation gain (loss), net of tax | 16 | (15) | 42 | |
| **Total comprehensive income** | $ 26,489 | $ 28,857 | $ 49,788 | $ 5 |
| **Basic net income per share** | $ 0.23 | $ 0.25 | $ 0.43 | $ |
| **Diluted net income per share** | $ 0.21 | $ 0.23 | $ 0.39 | $ |
| **Shares used in computing basic net income per common share** | 116,294 | 115,006 | 116,555 | 11 |
| **Shares used in computing diluted net income per common share** | 126,680 | 123,234 | 128,204 | 12 |

**CORCEPT THERAPEUTICS INCORPORATED**

**RECONCILIATION OF GAAP TO NON-GAAP NET INCOME**

(Unaudited)

(In thousands, except per share data)

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2021** | **2020** | **2021** | **2020** |
| **GAAP net income** | $ 26,523 | $ 28,327 | $ 49,988 | $ 58,392 |
| **Non-cash expenses (benefits)** | | | | |
| Stock-based compensation | | | | |
| Cost of sales | 16 | 15 | 26 | 38 |
| Research and development | 3,825 | 2,794 | 7,330 | 5,399 |
| Selling, general and administrative | 7,227 | 5,680 | 13,813 | 10,970 |
| **Total stock-based compensation** | 11,068 | 8,489 | 21,169 | 16,407 |
| Deferred income taxes | 3,299 | 4,922 | (2,061) | 10,017 |
| Income tax effect of non-GAAP adjustments [(1)] | (2,656) | (2,037) | (5,081) | (3,938) |
| **Non-GAAP net income, adjusted for non-cash expenses** | $ 38,234 | $ 39,701 | $ 64,015 | $ 80,878 |
| **GAAP basic net income per share** | $ 0.23 | $ 0.25 | $ 0.43 | $ 0.51 |
| **GAAP diluted net income per share** | $ 0.21 | $ 0.23 | $ 0.39 | $ 0.48 |
| **Non-GAAP basic net income per share, adjusted for non-cash expenses per share** | $ 0.33 | $ 0.35 | $ 0.55 | $ 0.70 |
| **Non-GAAP diluted net income per share, adjusted for non-cash expenses per share** | $ 0.30 | $ 0.32 | $ 0.50 | $ 0.66 |
| **Shares used in computing basic net income per common share** | 116,294 | 115,006 | 116,555 | 114,790 |
| **Shares used in computing diluted net income per common share** | 126,680 | 123,234 | 128,204 | 122,756 |

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

**CONTACT:**
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