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

September 10, 2025
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

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 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 8.01. Other Events.

On September 10, 2025, Corcept Therapeutics Incorporated (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has accepted the Company's New Drug Application for relacorilant as a treatment for patients with platinum-resistant ovarian cancer. The press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibits No.	Description
99.1	Press Release of Corcept Therapeutics Incorporated, September 10, 2025
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: September 10, 2025

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

Exhibit 99.1

CONTACT:
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FDA Files Corcept's New Drug Application for Relacorilant as a Treatment for Patients with Platinum-Resistant Ovarian Cancer

FDA assigns a Prescription Drug User Fee Act (PDUFA) date of July 11, 2026

REDWOOD CITY, Calif., September 10, 2025 — 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 announced that the U.S. Food and Drug Administration (FDA) has accepted Corcept's New Drug Application (NDA) for relacorilant as a treatment for patients with platinum-resistant ovarian cancer. The FDA has assigned a PDUFA date of July 11, 2026 for the application.

Corcept's NDA is based on positive data from its pivotal Phase 3 ROSELLA and Phase 2 trials. In these trials, patients who received relacorilant plus nab-paclitaxel experienced improved progression-free and overall survival compared to patients who received nab-paclitaxel monotherapy, with no need for biomarker selection. Relacorilant was well-tolerated, consistent with its known safety profile. Importantly, relacorilant conferred its benefit without increasing the safety burden of the patients who received it. The type, frequency and severity of adverse events in the combination arms were similar to those in the nab-paclitaxel monotherapy arms.

"The FDA's acceptance of our NDA brings us closer to offering a much-needed treatment option to patients with this dire disease," said Joseph Belanoff, M.D., Corcept's Chief Executive Officer. "Relacorilant has the potential to redefine how platinum-resistant ovarian cancer is treated."

About Relacorilant

Relacorilant, an oral therapy, is a selective glucocorticoid receptor (GR) antagonist that modulates cortisol activity by binding to the GR but not to the body's other hormone receptors. Corcept is developing relacorilant in ovarian cancer and a variety of other serious disorders, including endogenous hypercortisolism and prostate cancer. Relacorilant is proprietary to Corcept and is protected by composition of matter, method of use and other patents. It has been designated an orphan drug by the FDA and the European Commission (EC) for the treatment of hypercortisolism and by the EC for the treatment of ovarian cancer. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) date of December 30, 2025 for relacorilant as a treatment for patients with hypercortisolism.

About Cortisol's Role in Oncology

Cortisol plays a role in tumor growth through several mechanisms. It helps solid tumors resist chemotherapy by inhibiting cellular apoptosis — the tumor-killing effect chemotherapy is meant to stimulate. In some cancers, cortisol promotes tumor growth by activating oncogenes in the cells to which it binds. Cortisol also suppresses the body's immune response, which weakens its ability to fight all diseases, including cancer.

About Platinum-Resistant Ovarian Cancer

Ovarian cancer is the fifth most common cause of cancer death in women. Patients whose disease returns less than six months after receiving platinum-containing therapy have "platinum-resistant" disease. There are few treatment options for these women. Median overall survival following recurrence is approximately 12 months with single-agent chemotherapy. Approximately 20,000 women with platinum-resistant disease are candidates to start a new therapy each year in the United States, with at least an equal number in Europe.

About Corcept Therapeutics

For over 25 years, Corcept has focused on cortisol modulation and its potential to treat patients with a wide variety of serious disorders, leading to the discovery of more than 1,000 proprietary selective cortisol modulators and glucocorticoid receptor antagonists. 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 endogenous hypercortisolism. 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 and 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 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 statements concerning: relacorilant's potential to receive regulatory approval as a treatment for patients with platinum-resistant ovarian cancer; the timing of FDA review, including the FDA-assigned PDUFA date; and relacorilant's potential to redefine how platinum-resistant ovarian cancer is treated. We disclaim any intention or duty to update forward-looking statements made in this press release.