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

Date of Report (Date of earliest event reported): December 03, 2024

CORBUS PHARMACEUTICALS HOLDINGS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-37348**	**46-4348039**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
500 River Ridge Drive Norwood, Massachusetts		**02062**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (617) 963-0100

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:

☐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, par value $0.0001 per share	CRBP	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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 7.01 Regulation FD Disclosure.

On December 3, 2024, Corbus Pharmaceuticals Holdings, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (the "FDA") has granted Fast Track designation to CRB-701 for the treatment of relapsed or refractory metastatic cervical cancer. A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Current Report on Form 8-K under Item 7.01, including the information contained in Exhibit 99.1, is being furnished to the Securities and Exchange Commission (the "SEC"), and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by a specific reference in such filing.

Item 8.01 Other Events.

On December 3, 2024, the Company announced that the FDA has granted Fast Track designation to CRB-701 for the treatment of relapsed or refractory metastatic cervical cancer.

CRB-701 is a next-generation antibody drug conjugate targeting Nectin-4 that contains a site-specific, cleavable linker and a precise drug antibody ratio of 2 using MMAE as the payload. The Company recently completed enrollment of the dose escalation part of its bridging Phase 1 clinical trial of CRB-701 that is being conducted in the U.S. and Europe. The three-part Phase 1 trial is evaluating the safety, pharmacokinetics and efficacy of CRB-701 in patients with advanced solid tumors known to be associated with high Nectin-4 expression. The Company expects to report the first data from the dose escalation clinical study in the first quarter of 2025.

Item 9.01 Financial Statements and Exhibits.
(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Corbus Pharmaceuticals Holdings, Inc. dated December 3, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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 thereunto duly authorized.

Corbus Pharmaceuticals Holdings, Inc.

Date: December 3, 2024

By: */s/ Yuval Cohen*
Name: Yuval Cohen
Title: Chief Executive Officer

Exhibit 99.1

FDA Grants Fast Track Designation to CRB-701 for the Treatment of Relapsed or Refractory Metastatic Cervical Cancer

Norwood, MA, December 3, 2024 (GLOBE NEWSWIRE) -- Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) ("Corbus" or the "Company"), an oncology and obesity company with a diversified portfolio, announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to CRB-701 for the treatment of relapsed or refractory metastatic cervical cancer. CRB-701 (SYS6002) is a next-generation antibody drug conjugate (ADC) targeting Nectin-4 that contains a site-specific, cleavable linker and a precise drug antibody ratio of 2 using MMAE as the payload.

The FDA's Fast Track designation is designed to facilitate the development and expedite the review of drugs intended to treat serious conditions that demonstrate the potential to fill an unmet medical need.

Corbus recently completed enrollment of the dose escalation part of its Phase 1 clinical trial of CRB-701 (SYS6002) (NCT06265727) that is being conducted in the U.S. and Europe. The three-part Phase 1 trial is evaluating the safety, pharmacokinetics and efficacy of CRB-701 in patients with advanced solid tumors known to be associated with high Nectin-4 expression. The Company expects to report the first data from the dose escalation clinical study in Q1 2025.

About Corbus
Corbus Pharmaceuticals Holdings, Inc. is an oncology and obesity company with a diversified portfolio and is committed to helping people defeat serious illness by bringing innovative scientific approaches to well-understood biological pathways. Corbus' pipeline includes CRB-701, a next generation antibody drug conjugate that targets the expression of Nectin-4 on cancer cells to release a cytotoxic payload, CRB-601, an anti-integrin monoclonal antibody which blocks the activation of TGFβ expressed on cancer cells, and CRB-913, a highly peripherally restricted CB1 receptor inverse agonist for the treatment of obesity. Corbus is headquartered in Norwood, Massachusetts. For more information on Corbus, visit corbuspharma.com. Connect with us on X, LinkedIn and Facebook.

Forward-Looking Statements
This press release contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's trial results, product development, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors on our operations, clinical development plans and timelines, which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the Securities and Exchange Commission. Prospective investors are

cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

All product names, logos, brands and company names are trademarks or registered trademarks of their respective owners. Their use does not imply affiliation or endorsement by these companies.

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