
**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): May 07, 2024

CORBUS PHARMACEUTICALS HOLDINGS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-37348
(Commission File Number)

46-4348039
(IRS Employer
Identification No.)

500 River Ridge Drive
Norwood, Massachusetts
(Address of Principal Executive Offices)

02062
(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 2.02 Results of Operations and Financial Condition.

Corbus Pharmaceuticals Holdings, Inc. (the “Company”) issued a press release on May 7, 2024, disclosing financial information and operating metrics for its fiscal quarter ended March 31, 2024 and discussing its business outlook. A copy of the Company’s press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

See “Item 2.02 Results of Operations and Financial Condition” above.

The information in this Current Report on Form 8-K under Items 2.02 and 7.01, including the information contained in Exhibit 99.1, is being furnished to the Securities and Exchange Commission, and shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934 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 or the Securities Exchange Act of 1934, except as shall be expressly set forth by a specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) The following exhibit is furnished with this report:

| Exhibit No. | Description |
|-------------|---|
| 99.1 | Press Release issued by Corbus Pharmaceuticals Holdings, Inc. dated May 7, 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: May 7, 2024

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

Corbus Pharmaceuticals Reports First Quarter 2024 Financial Results and Provides Corporate Update

- Phase 1 data for CRB-701 (SYS6002) to be presented at ASCO Annual Meeting on June 1, 2024
- \$116M of capital raised in Q1 2024 extending cash runway through Q1 2027
- Appointed Dr. Dominic Smethurst as Chief Medical Officer

Norwood, MA, May 7, 2024 (GLOBE NEWSWIRE) - Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) ("Corbus" or the "Company"), a precision oncology company with a diversified portfolio, today provided a corporate update and reported financial results for the quarter ended March 31, 2024.

"During the first quarter of 2024, we continued to make significant progress in advancing our pipeline toward meaningful milestones led by the dosing of the first patient in our U.S. Phase 1 clinical trial of CRB-701, our next-generation antibody drug conjugate targeting expression of Nectin-4," said Yuval Cohen, Ph.D., Chief Executive Officer of Corbus. "The potential of CRB-701 was highlighted at ASCO GU in January 2024. The dose escalation data, presented by our development partner CSPC, demonstrated a differentiated safety and PK profile compared to enfortumab vedotin, as well as an emerging efficacy signal in both bladder and cervical cancer patients who are Nectin-4 positive. We look forward to CSPC's presentation of updated data at the ASCO 2024 Annual Meeting. During the quarter, we also continued to advance CRB-913 for the treatment of obesity and expect to dose the first patient in Q1 2025. We strengthened our balance sheet by raising \$116 million of capital in the quarter and bolstered our management team with the appointment of Dr. Dominic Smethurst as Chief Medical Officer. We look forward to continuing to advance our programs across our pipeline over the course of this year," concluded Dr. Cohen.

Key Corporate and Program Updates:**CRB-701:**

CRB-701 (SYS6002) is a next-generation antibody drug conjugate targeting Nectin-4 that contains a site-specific, cleavable linker and a homogenous drug antibody ratio of 2 using MMAE as the payload. Nectin-4 is a clinically validated, tumor-associated antigen in urothelial cancer.

The first U.S. patient was dosed in the Phase 1 clinical trial of CRB-701-01 in April 2024. The Phase 1 portion of the open label study design (NCT06265727), being conducted in the U.S. and Europe, will evaluate the safety, efficacy and pharmacokinetics ("PK") of CRB-701 in participants with advanced solid tumors associated with high Nectin-4 expression. The Phase 1 trial initiates with dose escalation followed by dose optimization and concludes with dose expansion to determine the recommended Phase 2 dose. The Company expects to present the U.S. dose escalation data by Q1 2025.

Encouraging safety and efficacy data from the Phase 1 dose escalation study in China for patients with Nectin-4 positive tumors was presented in January 2024 by our development partner CSPC at the *2024 American Society of Clinical Oncology Genitourinary Cancers Symposium* ("ASCO GU") as a *Poster Presentation*.

Summary of data presented at ASCO GU:

- Q3W schedule of CRB-701 (SYS6002) demonstrated a 43% ORR and 71% DCR (n=7) at predicted therapeutically relevant doses (≥ 2.7 mgs/kg).
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- All assessable Nectin-4 positive study participants with mUC or cervical cancer treated at or above this dose demonstrated some level of disease control.
- No dose limiting toxicities were observed to date at doses up to 3.6 mg/kg with further escalation at 4.5 mg/kg ongoing.
- No cases of peripheral neuropathy or skin rash have been observed to date.

Updated data from this study will be presented by CSPC as a poster at the ASCO 2024 Annual Meeting on June 1, 2024.

CRB-913:

CRB-913 is a second-generation, highly peripherally restricted CB1 receptor inverse agonist designed to treat obesity. In a diet-induced obesity ("DIO") mouse model, CRB-913, as a monotherapy and in combination with incretin analogues (tirzepatide, semaglutide, or liraglutide), demonstrates a reduction in body weight in DIO mice and improvements were observed in body fat content, leptinemia, insulin resistance, liver triglycerides, liver fat deposits, and liver histology. The Company is currently conducting IND-enabling studies and expects to dose the first patient in the Phase 1 study in Q1 2025.

CRB-601:

CRB-601 is a high affinity and selective anti- $\alpha\text{v}\beta\text{8}$ monoclonal antibody that blocks the activation of TGF β expressed on cancer cells in the tumor microenvironment. In pre-clinical models, CRB-601 demonstrates enhanced anti-tumor activity when combined with anti-PD-1 checkpoint inhibitor therapy compared to either single agent alone.

In January 2024, the FDA cleared the IND for CRB-601 and the Company expects to initiate a Phase 1 study of CRB-601 in the summer of 2024.

\$116M of Capital Raised in Q1 2024

Immediately following the ASCO GU data, the Company completed a public offering raising \$94.5 million of gross proceeds combined with an additional \$21.1 million from ATM sales. The \$116 million of additional capital extends the Company's cash runway through Q1 2027.

Dr. Dominic Smethurst Appointed as Chief Medical Officer

In February 2024, the Company appointed Dr. Dominic Smethurst, MA MRCP, as the Company's Chief Medical Officer ("CMO"). He has over twenty years of experience working with pharmaceutical and biotechnology companies and most recently served as the CMO of Bicycle Therapeutics.

Financial Results for Quarter Ended March 31, 2024:

The Company reported a net loss of approximately \$6.9 million, or a net loss per diluted share of \$0.83, for the three months ended March 31, 2024, compared to a net loss of approximately \$17.7 million, or a net loss per diluted share of \$4.24, for the same period in 2023.

Operating expenses decreased by \$7.7 million to approximately \$9.6 million for the three months ended March 31, 2024, compared to \$17.3 million in the comparable period in the prior year. The decrease was primarily attributable to the upfront licensing fee of \$7.5 million due to CSPC for licensing of CRB-701 recorded during the first quarter of 2023. In Q1 2024, the Company received \$2.5 million refundable tax credit from a foreign tax authority that was recorded in Other Income, net.

As of March 31, 2024, the Company had \$120.1 million of cash, cash equivalents and investments on hand, which is expected to fund operations through Q1 2027, based on the current planned expenditures.

About Corbus

Corbus Pharmaceuticals Holdings, Inc. is a precision oncology 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 Twitter, 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.

INVESTOR CONTACTS:

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Managing Director

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--tables to follow--

Corbus Pharmaceuticals Holdings, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss

| | For the Three Months Ended March 31, | |
|---|---|-------------------------|
| | 2024 | 2023 |
| Operating expenses: | | |
| Research and development | \$ 5,761,494 | \$ 13,388,343 |
| General and administrative | 3,861,251 | 3,908,682 |
| Total operating expenses | <u>9,622,745</u> | <u>17,297,025</u> |
| Operating loss | (9,622,745) | (17,297,025) |
| Other income (expense), net: | | |
| Other income, net | 2,909,097 | 229,507 |
| Interest expense, net | (177,015) | (678,022) |
| Change in fair value of derivative liability | 28,568 | — |
| Foreign currency transaction (loss) gain, net | (36,676) | 728 |
| Other income (expense), net | <u>2,723,974</u> | <u>(447,787)</u> |
| Net loss | <u>\$ (6,898,771)</u> | <u>\$ (17,744,812)</u> |
| Net loss per share, basic and diluted | <u>\$ (0.83)</u> | <u>\$ (4.24)</u> |
| Weighted average number of common shares outstanding, basic and diluted | <u>8,310,508</u> | <u>4,181,556</u> |
| Comprehensive loss: | | |
| Net loss | \$ (6,898,771) | \$ (17,744,812) |
| Other comprehensive (loss) income : | | |
| Change in unrealized (loss) gain on marketable debt securities | (326,949) | 57,623 |
| Total other comprehensive (loss) income | <u>(326,949)</u> | <u>57,623</u> |
| Total comprehensive loss | <u>\$ (7,225,720)</u> | <u>\$ (17,687,189)</u> |

Corbus Pharmaceuticals Holdings, Inc.
Consolidated Balance Sheets

| | March 31, 2024 (Unaudited) | December 31, 2023 |
|---|-------------------------------|-------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 14,103,120 | \$ 13,723,681 |
| Investments | 106,000,091 | 7,182,325 |
| Restricted cash | 284,950 | 192,475 |
| Prepaid expenses and other current assets | 1,308,336 | 2,447,549 |
| Total current assets | 121,696,497 | 23,546,030 |
| Restricted cash | 384,950 | 477,425 |
| Property and equipment, net | 821,526 | 973,214 |
| Operating lease right-of-use assets | 2,841,189 | 3,062,920 |
| Other assets | — | 212,804 |
| Total assets | \$ 125,744,162 | \$ 28,272,393 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Notes payable | \$ 189,818 | \$ 300,664 |
| Accounts payable | 2,081,812 | 3,178,516 |
| Accrued expenses | 9,398,225 | 11,030,506 |
| Derivative liability | 10,882 | 39,450 |
| Operating lease liabilities, current | 1,477,669 | 1,436,723 |
| Current portion of long-term debt | 12,764,915 | 15,908,214 |
| Total current liabilities | 25,923,321 | 31,894,073 |
| Other long-term liabilities | — | 44,411 |
| Operating lease liabilities, noncurrent | 2,855,140 | 3,238,631 |
| Total liabilities | 28,778,461 | 35,177,115 |
| Stockholders' equity | | |
| Preferred stock, \$0.0001 par value; 10,000,000 shares authorized, no shares issued and outstanding at March 31, 2024 and December 31, 2023 | — | — |
| Common stock, \$0.0001 par value; 300,000,000 shares authorized, 10,507,237 and 4,423,683 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively | 1,050 | 442 |
| Additional paid-in capital | 540,875,910 | 429,780,375 |
| Accumulated deficit | (443,582,754) | (436,683,983) |
| Accumulated other comprehensive loss | (328,505) | (1,556) |
| Total stockholders' equity (deficit) | 96,965,701 | (6,904,722) |
| Total liabilities and stockholders' equity | \$ 125,744,162 | \$ 28,272,393 |

