
**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 09, 2023

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 9, 2023, disclosing financial information and operating metrics for its fiscal quarter ended March 31, 2023 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 9, 2023
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 9, 2023

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

**Corbus Pharmaceuticals Reports First Quarter 2023 Financial Results and
Provides Corporate Update**

- *Company expanded precision oncology pipeline with in-licensing of CRB-701: a clinical-stage Nectin-4 antibody drug conjugate (ADC) from CSPC Pharmaceutical Group*
- *CRB-701 Phase 1 dose escalation study ongoing in patients with advanced solid tumors in China*
- *Presented latest CRB-601 anti-αvβ8 mAb pre-clinical data at American Association of Cancer Research (AACR) 2023 annual meeting with IND submission on track for the second half of 2023*
- *Expanded Board of Directors with appointment of Yong Ben, MD*

Norwood, MA, May 9, 2023 (GLOBE NEWSWIRE) -- Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) ("Corbus" or the "Company"), a precision oncology company, today provided a corporate update and reported financial results for the first quarter of 2023.

"During our first quarter we continued our evolution into a precision oncology company, led by the execution of our exclusive licensing agreement for CRB-701, a next generation Nectin-4 ADC," said Yuval Cohen, Ph.D., Chief Executive Officer of Corbus. "We are excited about the potential of this differentiated clinical stage asset that targets Nectin-4 enriched tumors. We also presented additional pre-clinical data at AACR 2023 annual meeting on CRB-601, demonstrating robust target engagement associated with anti-tumor activity alone and in combination with anti-PD-1. We believe this data reinforces the potential of this new approach in blocking activation of TGFβ locally in the TME. We look forward to advancing both CRB-701 and CRB-601 and potentially delivering on a number of milestones in 2023."

Key Corporate and Program Updates:

• **CRB-701 next generation Nectin-4 ADC:**

o Licensed CRB-701 from CSPC Pharmaceutical Group with exclusive development and commercialization rights in the United States, Canada, the European Union (including the European Free Trade Area), the United Kingdom, and Australia.

o Nectin-4 is a clinically validated tumor associated antigen in urothelial cancer. The Nectin-4 ADC PADCEV® (SeaGen/Astellas) is approved for use in late metastatic urothelial cancer and recently received an expanded label from the Food and Drug Administration based on accelerated approval for use in combination with KEYTRUDA® for patients with locally advanced or metastatic urothelial carcinoma who are ineligible for cisplatin-containing chemotherapy.

o CRB-701 is designed to achieve an improved therapeutic index and will be explored in urothelial cancer, as well as a range of other Nectin-4 expressing solid tumors.

o CRB-701 has key features that support a differentiated profile including site-specific conjugation linker chemistry that results in low payload release in plasma and a novel Fc-enabled antibody with an improved pharmacokinetic profile. Pre-clinical data demonstrates the potential to achieve higher exposures with CRB-701 resulting in an improved therapeutic index.

oClinical development is underway and will focus on Nectin-4 positive tumors, including urothelial cancer. CSPC has commenced a Phase 1 dose escalation study in China for patients with advanced solid tumors. Corbus plans to bridge data from this Phase 1 trial to support a U.S. clinical trial starting in mid-2024.

•**CRB-601 blocking the activation of TGF β**

oCRB-601 is a potent and selective anti- $\alpha\beta 8$ integrin monoclonal antibody designed to block the activation of latent TGF β within the tumor micro-environment (TME). CRB-601 significantly inhibits tumor growth as monotherapy and enhances the efficacy of anti-PD-1 immunotherapy as a combination in checkpoint inhibitor (CPI) sensitive and CPI-resistant tumor models.

oIND submission for CRB-601 is on track for the second half of 2023. The Company expects to enroll the first patient in the Phase 1 study by the end of 2023.

oCorbus presented pre-clinical data at the AACR 2023 annual meeting indicating that CRB-601 exhibited dose dependent tumor growth inhibition (TGI) in the EMT6 tumor model which was significantly augmented in combination with anti-PD1 therapy. These effects were associated with changes in TME immune cell populations with marked increases in infiltrating T cells, NK cells and M1 polarized macrophages. Efficacy correlated with cell surface $\alpha\beta 8$ occupancy by CRB-601. CRB-601 treatment downregulated phosphorylation of SMAD proteins pSMAD2 and pSMAD3, consistent with blockade of the TGF β signaling pathway.

oCorbus hosted the first in the series of virtual “Meet the Expert” events titled “Blocking TGF β with CRB-601—a New Play for an Old Target,” on April 25th. The event featured Jeffrey Clarke, MD (Duke University School of Medicine) and Joan Seoane, PhD (Vall d'Hebron Institute of Oncology) who discussed the challenges and potential opportunities in targeting Transforming Growth Factor β (TGF β) in oncology. A replay of the webinar is available from the events page of the Corbus website here.

Addition to the Board:

•Dr. Yong Ben joined the Corbus Board of Directors on March 1, 2023. Dr. Ben is an oncology researcher and pharma industry executive, with multiple drug approvals to his credit. He was formerly the Chief Medical Officer of BeiGene, Ltd. and BioAtla, Inc., and led the clinical development of the Immuno-Oncology portfolio for AstraZeneca PLC. This appointment augments our Board with his extensive oncology experience both in the United States and China.

Financial Results for Quarter Ended March 31, 2023:

The Company reported a net loss of approximately \$17.7 million, or a net loss per diluted share of \$4.24, for the three months ended March 31, 2023, compared to a net loss of approximately \$9.4 million, or a net loss per diluted share of \$2.26, for the same period in 2022.

Operating expenses increased by \$8.8 million to approximately \$17.3 million for the three months ended March 31, 2023, compared to \$8.5 million in the comparable period in the prior year. The increase was primarily attributable to the upfront payment of \$7.5 million associated with the CSPC License Agreement, \$1.2 million associated with the achievement of a development milestone under the USCF License

Agreement, and higher drug manufacturing costs offset by reductions in general and administrative expenses associated with legal costs, stock-based compensation expense, and insurance policies.

As of March 31, 2023, the company has \$44.2 million of cash and investments on hand which is expected to fund operations through the second quarter of 2024, based on the current planned expenditures.

About Corbus

Corbus Pharmaceuticals Holdings, Inc. (the "Company" or "Corbus") is a precision oncology company committed to helping people defeat serious illness by bringing innovative scientific approaches to well understood biological pathways. Corbus' internal development pipeline includes CRB-701, a next generation antibody drug conjugate (ADC) that targets the expression of Nectin-4 on cancer cells to release a cytotoxic payload and CRB-601, an anti-integrin monoclonal antibody which blocks the activation of TGF β expressed on cancer cells. 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 restructuring, 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.

INVESTOR CONTACT:

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---tables to follow---

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

	For the Three Months Ended March 31,	
	2023	2022
Operating expenses:		
Research and development	13,388,343	3,286,236
General and administrative	3,908,682	5,230,923
Total operating expenses	17,297,025	8,517,159
Operating loss	(17,297,025)	(8,517,159)
Other income (expense), net:		
Other income (expense), net	229,507	(193,351)
Interest income (expense), net	(678,022)	(458,909)
Foreign currency exchange gain (loss), net	728	(267,823)
Other income (expense), net	(447,787)	(920,083)
Net loss	\$ (17,744,812)	\$ (9,437,242)
Net loss per share, basic and diluted	\$ (4.24)	\$ (2.26)
Weighted average number of common shares outstanding, basic and diluted	4,181,556	4,170,043
Comprehensive loss:		
Net loss	\$ (17,744,812)	\$ (9,437,242)
Other comprehensive income (loss):		
Change in unrealized gain (loss) on marketable debt securities	57,623	(107,248)
Total other comprehensive income (loss)	57,623	(107,248)
Total comprehensive loss	\$ (17,687,189)	\$ (9,544,490)

Corbus Pharmaceuticals Holdings, Inc.
Condensed Consolidated Balance Sheets

	March 31, 2023 (Unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 7,324,437	\$ 17,002,715
Investments	36,902,563	42,194,296
Restricted cash	192,475	192,475
Prepaid expenses and other current assets	1,445,524	791,616
Total current assets	45,864,999	60,181,102
Restricted cash	477,425	477,425
Property and equipment, net	1,431,945	1,613,815
Operating lease right of use assets	3,688,468	3,884,252
Other assets	182,436	155,346
Total assets	<u>\$ 51,645,273</u>	<u>\$ 66,311,940</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Notes payable	\$ 203,258	\$ 353,323
Accounts payable	1,322,990	2,173,963
Accrued expenses	6,468,302	5,999,252
Derivative liability	36,868	36,868
Operating lease liabilities, current	1,318,671	1,280,863
Current portion of long-term debt	5,008,858	2,795,669
Total current liabilities	14,358,947	12,639,938
Long-term debt, net of debt discount	13,972,360	15,984,426
Other long-term liabilities	2,522,205	22,205
Operating lease liabilities, noncurrent	4,332,809	4,675,354
Total liabilities	35,186,321	33,321,923
Stockholders' equity		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized, no shares issued and outstanding at March 31, 2023 and December 31, 2022.	—	—
Common stock, \$0.0001 par value; 300,000,000 shares authorized, 4,215,133 and 4,171,297 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	422	417
Additional paid-in capital	426,352,478	425,196,359
Accumulated deficit	(409,825,479)	(392,080,667)
Accumulated other comprehensive loss	(68,469)	(126,092)
Total stockholders' equity	16,458,952	32,990,017
Total liabilities and stockholders' equity	<u>\$ 51,645,273</u>	<u>\$ 66,311,940</u>

