
**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): August 08, 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

(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 August 8, 2023, disclosing financial information and operating metrics for its fiscal quarter ended June 30, 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 August 8, 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 hereunto duly authorized.

Date: August 8, 2023

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

Corbus Pharmaceuticals Reports Second Quarter 2023 Financial Results and Provides Corporate Update

- CRB-701 Phase 1 trial in China is ahead of schedule with dose escalation completion expected Q4 2023 and U.S. clinical trial start planned for Q1 2024
- Preliminary clinical PK data indicates CRB-701 has a longer half-life and reduced levels of circulating free MMAE relative to published data for PADCEV®
- CRB-601 IND submission is on track for Q4 2023

Norwood, MA, August 8, 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 second quarter of 2023.

"During the second quarter, substantial progress was made advancing CRB-701, our next generation Nectin-4 antibody drug conjugate (ADC), in-licensed earlier this year from CSPC Pharmaceutical Group (CSPC)" said Yuval Cohen, Ph.D., Chief Executive Officer of Corbus. "Following a recent visit to CSPC in China, we're pleased to share that the Phase 1 dose escalation in patients with Nectin-4 enriched solid tumors is proceeding well and is currently ahead of the planned schedule. We now anticipate that the dose escalation portion of this trial in China will be completed in Q4 2023. Accordingly, we are accelerating our own development plans for CRB-701, and now anticipate initiating our U.S. clinical trial in Q1 2024 under the currently active US IND. Preliminary clinical data generated to date demonstrates a differentiated pharmacokinetic profile relative to other Nectin-4 targeting agents."

"Development of our anti-aVb8 mAb CRB-601, is also ongoing and we were pleased to present the latest pre-clinical data for this asset at the AACR 2023 annual meeting in April," continued Dr. Cohen. "The data that was presented builds upon the robust target engagement previously presented 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 plan to submit our Investigational New Drug (IND) application for CRB-601 in Q4 2023 and anticipate initiating our Phase 1 clinical trial in the first half of 2024. We note that key competitive programs from Pfizer and AbbVie have progressed to Phase 2 clinical trials, and we see this as supportive evidence that this class of drugs warrant further clinical exploration. It will be a busy 12 months for us, as we continue our evolution into a precision oncology company, and advance both of our programs into the clinic in the US."

Key Corporate and Program Updates:

•CRB-701 next generation Nectin-4 ADC:

oThe dose exploration of CRB-701 in Nectin-4 positive solid tumors is ahead of schedule. CSPC, our development partner, is enrolling its Phase 1 dose escalation study in China and Corbus now estimates this escalation will be completed by the end of 2023 and plans to initiate an abbreviated Phase 1 in the US in the first quarter of 2024 leveraging the clinical experience from China.

oPreliminary clinical pharmacology data indicates CRB-701 is differentiated from PADCEV® with an increased half-life and reduced levels of circulating free monomethyl auristatin E (MMAE).

oCorbus licensed CRB-701 from CSPC in February 2023 and has exclusive development and commercialization rights in the United States, Canada, the European Union (including the European Free Trade Area), the United Kingdom, and Australia.

oNectin-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.

oCRB-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.

oCRB-701 has key features that support a differentiated profile including a novel Nectin-4 antibody and a site-specific conjugation linker that results in faster ADC internalization, longer half-life, and reduced payload release in plasma. Pre-clinical and dose escalation data demonstrates the potential to achieve higher exposures with CRB-701 resulting in an opportunity to improve the therapeutic index.

•CRB-601 blocking the activation of TGFβ

oCRB-601 is a potent and selective anti-αvβ8 integrin monoclonal antibody (mAb) designed to block the activation of latent TGFβ within the tumor micro-environment (TME). CRB-601 significantly inhibits tumor growth as a monotherapy in murine models and enhances the efficacy of anti-PD-1 immunotherapy as a combination in checkpoint inhibitor (CPI) sensitive and CPI-resistant tumor models.

oCorbus presented pre-clinical data at the American Association of Cancer Research (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-PD-1 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 αvβ8 occupancy by CRB-601. CRB-601 treatment downregulated phosphorylation of SMAD proteins, pSMAD2 and pSMAD3, consistent with blockade of the TGFβ signaling pathway.

oThe IND submission for CRB-601 is anticipated in Q4 2023, and the Company expects to enroll the first patient in its Phase 1 study in the first half of 2024.

oWe note that recent events from other development programs of mAb with a similar mechanism of action including those of Pfizer and AbbVie indicate their advancement into Phase 2 clinical trials.

Financial Results for Quarter Ended June 30, 2023:

The Company reported a net loss of approximately \$8.8 million, or a net loss per diluted share of \$2.05, for the three months ended June 30, 2023, compared to a net loss of approximately \$13.2 million, or a net loss per diluted share of \$3.18, for the same period in 2022.

Operating expenses decreased by \$4.1 million to approximately \$8.2 million for the three months ended June 30, 2023, compared to \$12.3 million in the comparable period in the prior year. The decrease was primarily attributable to a litigation settlement payment of \$5.0 million in 2022 and reduction in general and administrative expenses in the current period offset by increases in product development expenses for CRB-701 and CRB-601.

As of June 30, 2023, the company has \$36.6 million of cash, cash equivalents 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 Balance Sheets (Unaudited)

	<u>June 30, 2023</u>	<u>December 31, 2022</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 8,349,346	\$ 17,002,715
Investments	28,216,560	42,194,296
Restricted cash	192,475	192,475
Prepaid expenses and other current assets	1,515,616	791,616
Total current assets	<u>38,273,997</u>	<u>60,181,102</u>
Restricted cash	477,425	477,425
Property and equipment, net	1,273,602	1,613,815
Operating lease right of use assets	3,486,416	3,884,252
Other assets	211,943	155,346
Total assets	<u>\$ 43,723,383</u>	<u>\$ 66,311,940</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Notes payable	\$ 51,157	\$ 353,323
Accounts payable	1,505,734	2,173,963
Accrued expenses	6,418,803	5,999,252
Derivative liability	36,868	36,868
Operating lease liabilities, current	1,357,240	1,280,863
Current portion of long-term debt	7,016,096	2,795,669
Total current liabilities	<u>16,385,898</u>	<u>12,639,938</u>
Long-term debt, net of debt discount	11,319,365	15,984,426
License agreement payable, noncurrent	2,500,000	—
Other long-term liabilities	22,205	22,205
Operating lease liabilities, noncurrent	3,975,329	4,675,354
Total liabilities	<u>34,202,797</u>	<u>33,321,923</u>
Stockholders' equity		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized, no shares issued and outstanding at June 30, 2023 and December 31, 2022	—	—
Common stock, \$0.0001 par value; 300,000,000 shares authorized, 4,422,741 and 4,171,297 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	442	417
Additional paid-in capital	428,153,252	425,196,359
Accumulated deficit	(418,609,320)	(392,080,667)
Accumulated other comprehensive loss	(23,788)	(126,092)
Total stockholders' equity	<u>9,520,586</u>	<u>32,990,017</u>
Total liabilities and stockholders' equity	<u>\$ 43,723,383</u>	<u>\$ 66,311,940</u>

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 4,248,705	\$ 2,499,642	\$ 17,637,048	\$ 5,785,878
General and administrative	3,940,286	4,840,368	7,848,968	10,071,291
Litigation Settlement	—	5,000,000	—	5,000,000
Total operating expenses	<u>8,188,991</u>	<u>12,340,010</u>	<u>25,486,016</u>	<u>20,857,169</u>
Operating loss	(8,188,991)	(12,340,010)	(25,486,016)	(20,857,169)
Other expense, net:				
Other income (expense), net	182,657	(208,683)	412,164	(402,034)
Interest expense, net	(775,586)	(490,339)	(1,453,608)	(949,248)
Foreign currency exchange loss, net	(1,921)	(209,856)	(1,193)	(477,679)
Other expense, net	<u>(594,850)</u>	<u>(908,878)</u>	<u>(1,042,637)</u>	<u>(1,828,961)</u>
Net loss	<u>\$ (8,783,841)</u>	<u>\$ (13,248,888)</u>	<u>\$ (26,528,653)</u>	<u>\$ (22,686,130)</u>
Net loss per share, basic and diluted	<u>\$ (2.05)</u>	<u>\$ (3.18)</u>	<u>\$ (6.27)</u>	<u>\$ (5.44)</u>
Weighted average number of common shares outstanding, basic and diluted				
	<u>4,277,701</u>	<u>4,170,464</u>	<u>4,229,894</u>	<u>4,170,255</u>
Comprehensive loss:				
Net loss	\$ (8,783,841)	\$ (13,248,888)	\$ (26,528,653)	\$ (22,686,130)
Other comprehensive income (loss):				
Change in unrealized gain (loss) on marketable debt securities	44,681	50,373	102,304	(56,875)
Total other comprehensive income (loss)	44,681	50,373	102,304	(56,875)
Total comprehensive loss	<u>\$ (8,739,160)</u>	<u>\$ (13,198,515)</u>	<u>\$ (26,426,349)</u>	<u>\$ (22,743,005)</u>

