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): November 07, 2023

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 2.02 Results of Operations and Financial Condition.

Corbus Pharmaceuticals Holdings, Inc. (the "Company") issued a press release on November 7, 2023, disclosing financial information and operating metrics for its fiscal quarter ended September 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 November 7, 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: November 7, 2023

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

Exhibit 99.1

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

•Data from dose escalation study for CRB-701, a Nectin-4 ADC to treat solid tumors, on track for release in early 2024 along with start of U.S./EU Study

•IND Submission for CRB-601, an αvβ8 *Monoclonal Antibody to treat solid tumors, on track for Q4 2023*

•Pre-clinical data for CRB-913, a peripherally restricted CB1 inverse agonist, published in Obesity and presented at Obesity Week

Norwood, MA, November 7, 2023 (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 third quarter of 2023.

"The third quarter was a productive period for Corbus as data was presented for each of our three programs at relevant scientific conferences" said Yuval Cohen, Ph.D., Chief Executive Officer of Corbus. "We are looking forward to our partners at CSPC sharing the first clinical experience with CRB-701 (SYS6002), a next generation Nectin-4 targeting ADC, in early 2024. This novel ADC comprising of a differentiated monoclonal antibody, proprietary site-specific conjugation cleavable linker, and an MMAE as a payload is designed to provide a stable ADC with significantly less free-circulating MMAE. Pre-clinical data has demonstrated marked differentiation from PADCEV and was presented for the first time at the AACR triple meeting held in October. We also presented two data sets related to CRB-601, our latent TGFb blocking mAb targeting the integrin avb8, at the Society for Immunotherapy of Cancer meeting held in San Diego last week. Finally, we presented the first ever comprehensive data on CRB-913, our highly peripherally restricted cannabinoid type-1 receptor (CB1) inverse agonist. We demonstrated that this orthogonal mechanism of action is active both as a monotherapy and is additive to drugs that target the incretin pathway such as liraglutide, semaglutide, and tirzepatide. Unlike incretin analogs, CRB-913 did not result in loss of lean muscle mass. The data was presented at *Obesity Week* and coincided with the release of a related manuscript in *Obesity* the journal" concluded Dr. Cohen.

Key Corporate and Program Updates:

- ***CRB-701 next generation Nectin-4 ADC***
  - The Phase 1 clinical trial with CRB-701 targeting Nectin-4 positive solid tumors is recruiting dose level 6 and is ongoing in China. Early clinical experience will be shared in Q1 2024, which will coincide with the initiation of a U.S./EU trial by Corbus. CRB-701 is designed to achieve an improved therapeutic index relative to PADCEV® (SeaGen/Astellas) and will be explored in urothelial cancer and other solid tumors.

- Nectin-4 is a clinically validated, tumor-associated antigen in urothelial cancer. The Nectin-4 ADC PADCEV® 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.

- The first data characterizing the pre-clinical validation of CRB-701 was presented at the *2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics*.

    - The poster, *Development of CRB-701 (SYS6002): A novel site-specific Nectin-4 targeting ADC*, provided an overview of the pre-clinical development and validation of the differentiating features of CRB-701, including site specific conjugation chemistry, a stable linker that leads to low payload release, and a novel Nectin-4 targeting monoclonal antibody with improved speed of internalization.

    - The pre-clinical safety profile supports dosing at higher ADC exposures relative to enfortumab vedotin (PADCEV®).

- The potential of CRB-701 was further highlighted in a *"Meet the Expert"* webinar hosted by Corbus that featured several notable oncology experts: Daniel P. Petrylak, MD (Genitourinary, Yale School of Medicine), Ari Rosenberg, MD (Head and Neck, University of Chicago), Alexander Spira, MD, PhD, FACP (NSCLC, Virginia Cancer Specialists), and Paraic Kenny, PhD (Breast cancer, Translational Expert, Kabara Cancer Research Institute).

•*CRB-601 Anti-* αvβ8 mAb blocking the activation of TGFβ expressed on cancer cells

- Corbus presented two posters at the *38th Annual Meeting of the Society for Immunotherapy of Cancer (SITC)* held on November 1 - 5, 2023.

    - *CRB-601, an integrin αvβ8 blocking antibody entering Phase I: pre-clinical and translational biomarkers for indication selection* - which demonstrates anti-tumor activity, immunological changes, and biomarkers of response in mouse models. Results demonstrate the importance of protein detection of the integrin avb8 in selecting disease indications and that in both MC38 and EMT6 models tumor growth inhibition correlated with immune cell penetration into the tumor microenvironment.

    - *CRB-601, a selective integrin αvβ8-blocking antibody, prevents TGFβ activation, promotes immune cell remodeling, and exhibits potent antitumor activity* – which assessed tumor growth inhibition of CRB-601+/- anti PD-1 in three tumor models, MC38, EMT6, and 4T1. Results showed CRB-601 advances immunotherapeutic strategies by antagonizing integrin αvβ8 and enhancing the efficacy of immune checkpoint inhibitors in vivo. This combination reveals the potential of such synergistic strategies in strengthening anti-tumor immunological responses, thereby emphasizing the promise of this combinatorial approach in advancing the domain of immunotherapy.

- The IND submission for CRB-601 is on track for the fourth quarter of 2023.

•CRB-913 a highly peripherally restricted CB1 inverse agonist for the treatment of obesity

- A pre-clinical study was selected for an *oral presentation* and as a *late breaking poster* at the 2023 Obesity Week Conference held on October 14-17, 2023. In addition, the study was just *published* in the November edition of *Obesity*, the scientific journal of The Obesity Society.

    - In this study, CRB-913, a highly peripherally restricted cannabinoid type-1 receptor (CB1) inverse agonist for the treatment of obesity, was evaluated as monotherapy and in combination with incretin analogs (tirzepatide, semaglutide, or liraglutide) in a diet induced-obesity (DIO) mouse model. CRB-913 demonstrated enhanced plasma exposure and a markedly reduced concentration in the brain compared to the first generation CB1 inverse agonist rimonabant. CRB-913 monotherapy yielded dose-dependent decrease in body weight in DIO mice that was further decreased in combination with tirzepatide, semaglutide, or liraglutide. Concomitantly, improvements were observed in body fat content, leptinemia, insulin resistance, liver triglycerides, liver fat deposits, and liver histology. All changes were statistically significant. Importantly, CRB-913 did not induce loss of lean muscle mass, a harmful phenomenon associated with incretin analogs.

    - The authors of the publication concluded that CRB-913, in combination with incretin analogs, could potentially deliver meaningful improvements in obesity and related conditions.

Financial Results for Quarter Ended September 30, 2023:

The Company reported a net loss of approximately $10.1 million, or a net loss per diluted share of $2.27, for the three months ended September 30, 2023, compared to a net loss of approximately $8.8 million, or a net loss per diluted share of $2.11, for the same period in 2022.

Operating expenses increased by $1.3 million to approximately $9.5 million for the three months ended September 30, 2023, compared to $8.2 million in the comparable period in the prior year. The increase was primarily attributable to manufacturing costs to support the Phase 1 clinical trial material for CRB-601 offset by a reduction in general and administrative compensation expenses. As of September 30, 2023, the company has $28.7 million of cash, cash equivalents and investments on hand.

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 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 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)

	September 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,248,806	$ 17,002,715
Investments	17,484,437	42,194,296
Restricted cash	192,475	192,475
Prepaid expenses and other current assets	2,280,255	791,616
Total current assets	31,205,973	60,181,102
Restricted cash	477,425	477,425
Property and equipment, net	1,120,793	1,613,815
Operating lease right of use assets	3,277,943	3,884,252
Other assets	201,271	155,346
Total assets	$ 36,283,405	$ 66,311,940
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Notes payable	$ —	$ 353,323
Accounts payable	4,713,532	2,173,963
Accrued expenses	7,545,781	5,999,252
Derivative liability	36,868	36,868
Operating lease liabilities, current	1,396,585	1,280,863
Current portion of long-term debt	17,849,562	2,795,669
Total current liabilities	31,542,328	12,639,938
Long-term debt, net of debt discount	—	15,984,426
License agreement payable, noncurrent	775,000	—
Other long-term liabilities	44,410	22,205
Operating lease liabilities, noncurrent	3,610,651	4,675,354
Total liabilities	35,972,389	33,321,923
Stockholders' equity		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized, no shares issued and outstanding at September 30, 2023 and December 31, 2022.	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized, 4,423,683 and 4,171,297 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	442	417
Additional paid-in capital	428,981,198	425,196,359
Accumulated deficit	(428,662,589)	(392,080,667)
Accumulated other comprehensive loss	(8,035)	(126,092)
Total stockholders' equity	311,016	32,990,017
Total liabilities and stockholders' equity	$ 36,283,405	$ 66,311,940

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 6,550,496	$ 4,108,190	$ 24,187,544	$ 9,894,068
General and administrative	2,937,442	4,073,266	10,786,410	14,144,557
Litigation settlement	—	—	—	5,000,000
Total operating expenses	9,487,938	8,181,456	34,973,954	29,038,625
Operating loss	(9,487,938)	(8,181,456)	(34,973,954)	(29,038,625)
Other expense, net:				
Other income (expense), net	217,545	77,712	629,709	(324,322)
Interest expense, net	(763,356)	(541,889)	(2,216,964)	(1,491,137)
Foreign currency exchange loss, net	(19,520)	(136,087)	(20,713)	(613,766)
Other expense, net	(565,331)	(600,264)	(1,607,968)	(2,429,225)
Net loss	$ (10,053,269)	$ (8,781,720)	$ (36,581,922)	$ (31,467,850)
Net loss per share, basic and diluted	$ (2.27)	$ (2.11)	$ (8.52)	$ (7.55)
Weighted average number of common shares outstanding, basic and diluted	4,423,617	4,170,881	4,295,178	4,170,466
Comprehensive loss:				
Net loss	$ (10,053,269)	$ (8,781,720)	$ (36,581,922)	$ (31,467,850)
Other comprehensive income (loss):				
Change in unrealized gain (loss) on marketable debt securities	15,753	(87,554)	118,057	(144,429)
Total other comprehensive income (loss)	15,753	(87,554)	118,057	(144,429)
Total comprehensive loss	$ (10,037,516)	$ (8,869,274)	$ (36,463,865)	$ (31,612,279)