

**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 9, 2024

COHERUS BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36721
(Commission
File Number)

27-3615821
(IRS Employer
Identification Number)

333 Twin Dolphin Drive, Suite 600
Redwood City, CA 94065
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (650) 649-3530

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, \$0.0001 par value per share	CHRS	The Nasdaq Global 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 Conditions

On May 9, 2024, Coherus BioSciences, Inc. (the “Company”) issued a press release regarding its financial results for the fiscal quarter ended March 31, 2024. The full text of the press release is furnished as Exhibit 99.1 to this Form 8-K.

This information in this Item 2.02 of this Form 8-K and the Exhibit 99.1 attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated May 9, 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, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 9, 2024

COHERUS BIOSCIENCES, INC.

By: /s/ Dennis M. Lanfear

Name: Dennis M. Lanfear

Title: Chief Executive Officer



Coherus BioSciences Reports First Quarter 2024 Financial Results and Provides Business Update

– Net revenue of \$77.1 million in Q1 2024 –

– CRI and ENB Therapeutics development partnership for toripalimab in ovarian cancer –

– New debt and royalty financing replaces \$75 million term loan, with debt maturity of May 2029 –

– Conference call today at 5:00 p.m. Eastern Time –

REDWOOD CITY, Calif., May 9, 2024 -- **Coherus BioSciences, Inc.** (Coherus, Nasdaq: CHRS), today reported financial results for the quarter ended March 31, 2024 and recent business highlights:

RECENT BUSINESS HIGHLIGHTS

UDENYCA® RESULTS and ONBODY™ LAUNCH UPDATE

- UDENYCA net product sales were \$42.7 million in Q1 2024, an increase of 18% compared to \$36.2 million in Q4 2023 and a 63% increase compared to the \$26.2 million in Q1 2023. Total unit demand grew 36% in Q1 2024 compared to Q4 2023 and represented a 108% increase compared to Q1 2023.
- UDENYCA Autoinjector presentation unit demand grew 158% in Q1 2024 compared to Q4 2023.
- UDENYCA ONBODY, a novel and proprietary state-of-the-art delivery system for pegfilgrastim-cbqv, was launched in February 2024. High customer demand and confirmed payer coverage drove early robust uptake.
- Based on data from IQVIA, UDENYCA franchise market share for Q1 2024 was 25%, an increase of 10 market share points in Q1 2024 compared to Q4 2023.

LOQTORZI® LAUNCH UPDATE

- LOQTORZI, the first and only FDA-approved treatment for recurrent, locally advanced or metastatic NPC, commercially launched on January 2, 2024.
- Academic research hospital formulary position achieved on 55% of the 33 NCCN institutions, with the remaining institutional reviews scheduled or in process. Formulary position is expected to be achieved with all NCCN institutions by the end of Q2 2024.
- Payer coverage has been confirmed on >85% of medical benefit lives in health plans including Medicare Fee for Service, Medicare Advantage, and national and regional commercial plans respectively.
- LOQTORZI net sales in Q1 of \$2.0 million, tracking to early launch stage expectations, with patient accrual momentum building.
- Product-specific, permanent J Code has been granted by the Centers for Medicare and Medicaid Services and will take effect July 1, 2024.

NOVEL IMMUNO-ONCOLOGY PIPELINE ADVANCES

- Coherus entered into an agreement with the Cancer Research Institute (CRI) to supply LOQTORZI for a combination study with ENB-003, a first-in-class small molecule inhibitor of endothelin B receptor. Endothelin B receptor is implicated in tumorigenesis and tumor immune suppression for several solid tumors including ovarian cancer. CRI is overseeing the iPROC study.
- Clinical data from the dose escalation stage of the Phase 1 study of CHS-114, a highly selective antibody-dependent cellular cytotoxicity (ADCC)-enhanced anti-CCR8 antibody, will be presented at the 2024 ASCO Annual Meeting in June.

“The strength of our company’s first-quarter performance reflects our ongoing commitment to driving top-line revenues, controlling operating expenses, advancing our pipeline, and improving our capital structure,” said Denny Lanfear, Coherus’ Chairman and Chief Executive Officer. “The progress we reported today aligns with these objectives, consistent with our overarching mission to become a sustainable and growing oncology company improving outcomes for cancer patients.”

FIRST QUARTER 2024 FINANCIAL RESULTS

Net revenue was \$77.1 million during the three months ended March 31, 2024, and included \$42.7 million of net sales of UDENYCA, \$2.0 million of net sales of LOQTORZI, which was launched on January 2, 2024, \$3.9 million of net sales of YUSIMRY®, and \$28.2 million of net sales of CIMERLI®, which was divested to Sandoz on March 1, 2024. Net revenue was \$32.4 million during the three months ended March 31, 2023.

Cost of goods sold (COGS) was \$34.6 million and \$16.9 million during the three months ended March 31, 2024 and 2023, respectively. CIMERLI® COGS included a low to mid 50% royalty on gross profits and UDENYCA® COGS includes a mid-single digit royalty on net sales payable through the first half of 2024. The increase in COGS was primarily driven by higher royalty costs and an increase in product costs from the mix of products sold and the launch of new products.

Research and development (R&D) expense was \$28.5 million and \$34.2 million during the three months ended March 31, 2024 and 2023, respectively. The decrease was primarily due to savings from reduced headcount and lower costs related to biosimilar products, partially offset by increased costs related to moving LOQTORZI production from China to the United States.

Selling, general and administrative (SG&A) expense for the three months ended March 31, 2024 was \$56.5 million compared to \$49.2 million for the same period in 2023. The increase was primarily due to the net \$6.8 million charge in Q1 2024 associated with the full write-off of the outlicense intangible asset and associated release of the CVR liability related to NZV930, obtained in the Surface Oncology acquisition, and higher third-party processing fees from multiple products being commercialized, partially offset by savings from reduced headcount.

Gain on Sale, net for the divestiture of the ophthalmology franchise, which closed during the three months ended March 31, 2024, was \$153.6 million, and reflects total cash proceeds of \$187.8 million, net of assets transferred to Sandoz, assets derecognized, transactions costs of \$7.2 million and other employee transition related expenses.

Net income for the first quarter of 2024 was \$102.9 million, or \$0.83 per share on a diluted basis, compared to a net loss of \$75.7 million, or \$(0.96) per share on a diluted basis for the same period in 2023.

Non-GAAP net loss for the first quarter of 2024 was \$35.8 million, or \$(0.32) per share on a diluted basis, compared to non-GAAP net loss of \$59.5 million, or \$(0.75) per share on a diluted basis for the same period in 2023. See “Non-GAAP Financial Measures” below for a discussion on how Coherus calculates non-GAAP net loss and a reconciliation to the most directly comparable GAAP measures.

Cash, cash equivalents and investments in marketable securities were \$259.8 million as of March 31, 2024, compared to \$117.7 million as of December 31, 2023. Proceeds from the divestiture of our ophthalmology franchise received in March 2024 were used to pay down \$175.0 million of the total \$250.0 in principal on Coherus’ 2027 Term Loans in April 2024.

2024 R&D and SG&A Expense Guidance

Coherus projects combined R&D and SG&A expenses for 2024 to be in the range of \$250 to \$265 million. This guidance includes approximately \$40 million of stock-based compensation expense and excludes the effects of acquisitions, collaborations, investments, divestitures including expenses incurred on behalf of and reimbursed by Sandoz to satisfy Coherus’ obligations under the Transition Services Agreement (TSA), restructuring, the exercise of rights or options related to collaboration programs, and any other transactions or circumstances not yet identified or quantified. This guidance is subject to a number of risks and uncertainties. See Forward-Looking Statements described in the section below.

Conference Call Information

When: Thursday, May 9, 2024, starting at 5:00 p.m. Eastern Daylight Time

To access the conference call:

Dial: (800) 715-9871 (toll-free USA and Canada); (646) 307-1963 (international)

Webcast: <https://edge.media-server.com/mmc/p/jqq7phbt/>

An archived webcast will be available on the “Investors” section of the Coherus website at <https://investors.coherus.com/events-presentations>.

About Coherus BioSciences

Coherus is a commercial-stage biopharmaceutical company focused on the research, development and commercialization of innovative immunotherapies to treat cancer. Coherus is developing an innovative immuno-oncology pipeline that is expected to be synergistic with its proven commercial capabilities in oncology.

Coherus’ immuno-oncology pipeline includes multiple antibody immunotherapy candidates focused on enhancing the innate and adaptive immune responses to enable a robust immunologic response and enhance outcomes for patients with cancer. Casdozokitug is a novel anti-IL-27 antibody currently being evaluated in two ongoing clinical studies: a Phase 1/2 study in advanced solid tumors and a Phase 2 study in hepatocellular carcinoma. CHS-114 is a highly selective, competitively positioned, ADCC-enhanced anti-CCR8 antibody currently in a Phase 1 study as a monotherapy in patients with advanced solid tumors. CHS-1000 is a preclinical candidate targeting immune-suppressive mechanisms via the novel pathway ILT4 with a response from the FDA on our IND filing expected in the second quarter of 2024.

Coherus markets LOQTORZI® (toripalimab-tpzi), a novel next-generation PD-1 inhibitor, UDENYCA® (pegfilgrastim-cbqv), a biosimilar of Neulasta®, and YUSIMRY® (adalimumab-aqvh), a biosimilar of Humira®.

Neulasta® is a registered trademark of Amgen, Inc.

Humira® is a registered trademark of AbbVie Inc.

Forward-Looking Statements

Except for the historical information contained herein, the matters set forth in this press release are forward-looking statements within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding Coherus’ ability to identify synergies between its I-O pipeline and its commercial operations; Coherus’ expected timing for an FDA response to its IND for CHS-1000; Coherus’ future projections for R&D expense and SG&A expense; and Coherus’ expectations about revenues and long term growth.

Such forward-looking statements involve substantial risks and uncertainties that could cause Coherus’ actual results, performance or achievements to differ significantly from any future results, performance or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the risks and uncertainties inherent in the clinical drug development process; risks related to Coherus’ existing and potential collaboration partners; risks of Coherus’ competitive position; the risks and uncertainties of the regulatory approval process, including the speed of regulatory review and the timing of Coherus’ regulatory filings; the risk of FDA review issues; the risks of competition; the risk that Coherus is unable to complete commercial transactions and other matters that could affect the availability or commercial potential of Coherus’ products and product candidates; and the risks and uncertainties of possible litigation. All forward-looking statements contained in this press release speak only as of the date of this press release. Coherus undertakes no obligation to update or revise any forward-looking statements. For a further description of the significant risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Coherus’ business in general, see Coherus’ quarterly filing on Form 10-Q for the fiscal quarter ended March 31, 2024 filed with the Securities and Exchange Commission on or about the date of this press release, including the section therein captioned “Risk Factors” and in other documents Coherus files with the Securities and Exchange Commission. Coherus’ results for the fiscal quarter ended March 31, 2024 are not necessarily indicative of its operating results for any future periods.

UDENYCA®, UDENYCA® ONBODY™, YUSIMRY® and LOQTORZI®, whether or not appearing in large print or with the trademark symbol, are trademarks of Coherus, its affiliates, related companies or its licensors or joint venture partners unless otherwise noted. Trademarks and trade names of other companies appearing in this press release are, to the knowledge of Coherus, the property of their respective owners.

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Coherus BioSciences, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended March 31,	
	2024	2023
Net revenue	\$ 77,063	\$ 32,436
Costs and expenses:		
Cost of goods sold	34,586	16,874
Research and development	28,470	34,154
Selling, general and administrative	56,532	49,153
Total costs and expenses	119,588	100,181
Loss from operations	(42,525)	(67,745)
Interest expense	(11,116)	(9,712)
Gain on Sale Transaction, net	153,647	—
Other income (expense), net	2,869	1,728
Income (loss) before income taxes	102,875	(75,729)
Income tax provision	—	—
Net income (loss)	\$ 102,875	\$ (75,729)
Net income (loss) per share:		
Basic	\$ 0.91	\$ (0.96)
Diluted	\$ 0.83	\$ (0.96)
Weighted-average number of shares used in computing net income (loss) per share:		
Basic	112,749,306	79,268,853
Diluted	125,529,971	79,268,853

Coherus BioSciences, Inc.
Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	March 31, 2024	December 31, 2023
Assets		
Cash and cash equivalents	\$ 259,775	\$ 102,891
Investments in marketable securities	—	14,857
Trade receivables, net	251,951	260,522
TSA receivables, net	32,194	—
Inventory	127,623	130,100
Intangible assets, net	57,104	71,673
Other assets	34,898	49,561
Total assets	\$ 763,545	\$ 629,604
Liabilities and Stockholders' Deficit		
Accrued rebates, fees and reserve	\$ 155,775	\$ 169,645
TSA payables and other accrued liabilities	30,770	—
Term loans	247,452	246,481
Convertible notes	227,220	226,888
Other liabilities	184,172	180,015
Total stockholders' deficit	(81,844)	(193,425)
Total liabilities and stockholders' deficit	\$ 763,545	\$ 629,604

Coherus BioSciences, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	Three Months Ended	
	March 31,	
	2024	2023
Cash, cash equivalents and restricted cash at beginning of the period	\$ 103,343	\$ 63,987
Net cash used in operating activities	(46,766)	(68,732)
Proceeds from maturities of investments in marketable securities	6,200	17,500
Proceeds from sale of investments in marketable securities	8,688	—
Cash received from Sale Transaction	187,823	—
Other investing activities, net	52	26
Net cash provided by investing activities	202,763	17,526
Proceeds from issuance of common stock under ATM Offering, net of issuance costs	1,507	6,835
Proceeds from issuance of common stock upon exercise of stock options	291	103
Taxes paid related to net share settlement	(745)	(2,781)
Other financing activities	(166)	(353)
Net cash provided by financing activities	887	3,804
Net increase (decrease) in cash, cash equivalents and restricted cash	156,884	(47,402)
Cash, cash equivalents and restricted cash at end of the period	\$ 260,227	\$ 16,585
Reconciliation of cash, cash equivalents, and restricted cash		
Cash and cash equivalents	\$ 259,775	\$ 16,145
Restricted cash balance	452	440
Cash, cash equivalents and restricted cash	\$ 260,227	\$ 16,585

Non-GAAP Financial Measures

To supplement the financial results presented in accordance with GAAP, Coherus has also included in this press release non-GAAP net loss, and the related per share measures, which exclude from net income (loss), and the related per share measures, stock-based compensation expense, certain acquisition-related expenses, amortization of intangible assets, gain on divestiture, impairments of intangible assets, contingent consideration, loss on debt extinguishment and restructuring charges related to our reduction in workforce. These non-GAAP financial measures are not prepared in accordance with GAAP, do not serve as an alternative to GAAP and may be calculated differently than similar non-GAAP financial information disclosed by other companies. Coherus encourages investors to carefully consider its results under GAAP, as well as its supplemental non-GAAP financial information and the reconciliation between these presentations set forth below, to more fully understand Coherus' business.

Coherus believes that the presentation of these non-GAAP financial measures provides useful supplemental information to, and facilitates additional analysis by, investors. In particular, Coherus believes that these non-GAAP financial measures, when considered together with its financial information prepared in accordance with GAAP, can enhance investors' and analysts' ability to meaningfully compare Coherus' results from period to period, and to identify operating trends in Coherus' business. Coherus also regularly uses these non-GAAP financial measures internally to understand, manage and evaluate its business and to make operating decisions.

Coherus BioSciences, Inc.
Reconciliation of GAAP Net Income (Loss) to Non-GAAP Net Loss
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended	
	March 31,	
	2024	2023
GAAP net income (loss)	\$ 102,875	\$ (75,729)
Adjustments:		
Stock-based compensation expense ⁽¹⁾	7,319	11,333
Gain on Sale Transaction, net	(153,647)	—
Impairment of out-license asset and remeasurement of CVR liability, net	6,772	—
Restructuring charges related to reduction in workforce ⁽¹⁾	—	4,876
Amortization of intangible assets	930	—
Non-GAAP net loss	<u>\$ (35,751)</u>	<u>\$ (59,520)</u>
GAAP		
Net income (loss) per share, basic	\$ 0.91	\$ (0.96)
Net income (loss) per share, diluted	\$ 0.83	\$ (0.96)
Shares used in computing basic net income (loss) per share	112,749,306	79,268,853
Shares used in computing diluted net income (loss) per share	125,529,971	79,268,853
Non-GAAP		
Net loss per share, basic and diluted	\$ (0.32)	\$ (0.75)
Shares used in computing basic and diluted net loss per share	112,749,306	79,268,853

(1) In the quarter ended March 31, 2023, stock-based compensation of \$1.0 million was classified within Restructuring charges related to reduction in workforce.