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 8, 2023

COHERUS BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	001-36721	27-3615821
(State or other jurisdiction of incorporation)	(Commission File Number)	(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 8, 2023, Coherus BioSciences, Inc. (the "Company") issued a press release regarding its financial results for the first quarter ended March 31, 2023. 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.

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

Date: May 8, 2023

COHERUS BIOSCIENCES, INC.

By: /s/ McDavid Stilwell
Name: McDavid Stilwell
Title: Chief Financial Officer

Coherus BioSciences Reports First Quarter 2023 Financial Results and Business Highlights

– UDENYCA® autoinjector approved and ready for May 2023 launch –

– CIMERLI® product-specific Q-code now facilitating electronic reimbursement following April 1 activation –

– FDA inspection of toripalimab manufacturing site scheduled for May 2023 –

– Toripalimab launch anticipated in Q3 2023, if approved –

– YUSIMRY™ ready for planned July 2023 launch –

– FDA review of UDENYCA® OBI BLA supplement progressing; launch anticipated in 2023, if approved –

– Net product revenue of $32.4 million in the first quarter 2023 –

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

REDWOOD CITY, Calif., May 08, 2023 – Coherus BioSciences, Inc. (“Coherus”, “the Company”, Nasdaq: CHRS), today reported financial results for the quarter ended March 31, 2023 and recent business highlights:

RECENT BUSINESS HIGHLIGHTS

CIMERLI®

- On April 1st, the permanent, product-specific Q-code assigned to CIMERLI® (ranibizumab-eqrn) by the U.S. Centers for Medicare & Medicaid Services (CMS) became active, enabling more efficient, electronic billing processes and reducing time to reimbursement for providers. Demand increased sharply as expected in April, with over 7,000 units of CIMERLI® shipped, exceeding in one month 70% of Q1 unit sales.

UDENYCA®

- The FDA approved a single-dose, prefilled autoinjector (AI) presentation of UDENYCA® (pegfilgrastim-cbqv) on March 3, 2023, which represents the first presentation innovation in the pegfilgrastim space in eight years and highlights Coherus’ commitment to developing innovative treatments that expand access and address the needs of patients undergoing cancer treatment. Coherus plans to launch UDENYCA® AI later this month.
- The FDA review of the prior approval supplement for Coherus’ third pegfilgrastim presentation, the UDENYCA® on-body injector (OBI), is ongoing, and Coherus plans to launch UDENYCA® OBI directly upon potential approval later this year.

Toripalimab

- The U.S. Food and Drug Administration (FDA) has notified the Company that it plans to conduct the required inspection of the toripalimab manufacturing facility in China later in May 2023. The inspections, previously hindered by COVID-related travel restrictions, are part of the FDA’s review of the biologics license application (BLA) for toripalimab, a PD-1 inhibitor for the treatment of nasopharyngeal carcinoma (NPC). Coherus anticipates potential FDA approval and commercial launch of toripalimab in the U.S. in Q3 2023.
- Positive toripalimab clinical data will be presented at the upcoming 2023 ASCO Annual Meeting including the final overall survival analysis for JUPITER-02 in NPC, updated overall survival analysis for CHOICE-01 in advanced non-small cell lung cancer (NSCLC), interim analysis of event-free survival for NEOTORCH in Stage II/III NSCLC, and clinical data for TORCHLIGHT in advanced triple-negative breast cancer.

YUSIMRY™

- Preparations are underway for commercial launch in Q3 2023 of YUSIMRY™, a Humira biosimilar with a citrate-free and sting-free formulation delivered via a state-of-the-art autoinjector. Coherus has invested in robust, large-scale manufacturing capabilities to ensure ample supply upon launch.
- The FDA recently approved YUSIMRY prior approval supplements for the autoinjector presentation and for large-scale drug supply manufacturing.

Novel Immuno-oncology Pipeline

- Patient recruitment is underway in the U.S.-based Phase 1/2 clinical trial of CHS-006, a TIGIT-targeted antibody in combination with toripalimab in patients with advanced solid tumors (NCT05757492).
- Coherus expects to file an IND by year end for CHS-1000, a novel ILT4-targeted antibody.

“With the approval of the UDENYCA® autoinjector, the activation of the CMS-assigned Q-code and the other product launches planned across our diversified portfolio, we are well positioned for accelerated revenue growth for the remainder of 2023 and beyond. We continue to sharply focus on commercial execution, and are already beginning to see the impact of the Q-code on CIMERLI® sales at the start of the second quarter,” said Denny Lanfear, Coherus’ Chairman and Chief Executive Officer. “Innovative presentations offering differentiated value, such as the UDENYCA® autoinjector launching this month, as well as the UDENYCA® on-body injector presentation, with anticipated approval and launch later in the year, will offer patients and physicians unprecedented choice in their treatment options, driving market share gains and long-term value for the franchise.”

Mr. Lanfear continued, “Inspections of the toripalimab manufacturing facilities are scheduled for later this month, with clinical site inspections to follow. NPC patients currently have no FDA approved therapies, and toripalimab has the potential to be the new standard of care for across multiple lines of treatment, if approved. We are planning for approval and launch in the third quarter.”

FIRST QUARTER 2023 FINANCIAL RESULTS

Net revenue was $32.4 million during the three months ended March 31, 2023 and included $26.2 million of net sales of UDENYCA and $6.2 million of net sales of CIMERLI®, which was launched in October 2022. Net sales of UDENYCA® for the first quarter of 2023 were reduced by a $1.7 million charge for a contingent liability related to resolving a dispute regarding certain sales from October 2020 through December 2021. Net revenue was $60.1 million during the three months ended March 31, 2022. The decline was primarily due to a decrease in the number of units of UDENYCA® sold as well as a lower net realized price due to increased competition.

Cost of goods sold (COGS) was $16.9 million and $9.4 million during the three months ended March 31, 2023 and 2022, respectively. UDENYCA® COGS includes a mid-single digit royalty on net sales payable through the first half of 2024, and CIMERLI® COGS includes a low to mid 50% royalty on gross profits. COGS for the first quarter of 2023 also includes $3.0 million in contract modification fees with one of our manufacturers and $2.7 million in write-offs of inventory that was damaged during processing at one of our manufacturers.

Research and development (R&D) expense for the three months ended March 31, 2023 was $34.2 million. R&D expense for the three months ended March 31, 2022 was $82.9 million, which included a $35 million option exercise fee paid to Junshi Biosciences to license CHS-006, a clinical-stage TIGIT-targeted antibody, as well as development and manufacturing costs for clinical and preclinical pipeline programs.

Selling, general and administrative (SG&A) expense for the three months ended March 31, 2023 was $49.2 million compared to $48.8 million for the same period in 2022. The increase was primarily due to $1.3 million in restructuring charges from our reduction in force that occurred in the first quarter of 2023.

Net loss for the first quarter of 2023 was $75.7 million, or $(0.96) per share on a diluted basis, compared to a net loss of $96.1 million, or $(1.24) per share on a diluted basis for the same period in 2022.

Non-GAAP net loss for the first quarter of 2023 was $59.5 million, or $(0.75) per share on a diluted basis, compared to non-GAAP net loss of $77.0 million, or $(1.00) per share on a diluted basis for the same period in 2022. 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 $128.1 million as of March 31, 2023, compared to $191.7 million at December 31, 2022.

2023 Revenue and R&D and SG&A Expense Guidance
Coherus expects its 2023 net product revenue will exceed $275 million, including at least $100 million of CIMERLI® net revenue.

Coherus projects combined R&D and SG&A expenses for 2023 to be in the range of $315 to $335 million. This guidance includes approximately $50 million of stock-based compensation expense and excludes any potential collaboration upfront payments to Klinge Pharma for the in-license of its Eylea® biosimilar program or milestones payments to Junshi Biosciences due upon U.S. approval of toripalimab.

This financial guidance also excludes the effects of any potential future strategic acquisitions, collaborations or investments, 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: Monday, May 8th, 2023, starting at 5:00 p.m. Eastern Time

To access the conference call, please pre-register through the following link to receive dial-in information and a personal PIN to access the live call: https://register.vevent.com/register/BI12e6d284dae8440e91891f2cef4f2097

Please dial-in 15 minutes early to ensure a timely connection to the call.

Webcast Link: https://edge.media-server.com/mmc/p/ugoyrevj
A replay of the webcast will be archived on the “Investors” section of the Coherus website at http://investors.coherus.com.

About Coherus BioSciences
Coherus is a commercial-stage biopharmaceutical company focused on the research, development and commercialization of innovative immunotherapies to treat cancer. Coherus’ strategy is to build a leading immuno-oncology franchise funded with cash generated through net sales of its diversified portfolio of FDA-approved therapeutics.

In 2021, Coherus in-licensed toripalimab, an anti-PD-1 antibody, in the United States and Canada. The BLA for toripalimab in combination with chemotherapy as treatment for recurrent or metastatic NPC is currently under review by the FDA.

Coherus markets UDENYCA® (pegfilgrastim-cbqv), a biosimilar of Neulasta®, and CIMERLI® (ranibizumab-eqrn), a biosimilar of Lucentis®, in the U.S., and expects to launch the FDA-approved Humira® biosimilar YUSIMRY™ (adalimumab-aqvh) in the U.S. in 2023.

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 build its immuno-oncology franchise to achieve a leading market position; Coherus’ ability to generate cash and net sales; Coherus’ investment plans; Coherus’ future projections for R&D expense, SG&A expense, net product revenue and CIMERLI® revenue; Coherus’ expectations about filing an IND for its ILT4 molecule; Coherus’ expectations about gaining approval and launching its product candidates; and Coherus’ expectations about any increased sales of CIMERLI® in future periods.

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 relating to the COVID-19 pandemic; risks related to our 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, international aspects of Coherus’ business, the need to finish inspections in China and the timing of Coherus’ regulatory filings; the risk of FDA review issues; 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 Report on Form 10-Q for the fiscal quarter ended March 31, 2023 filed with the Securities and Exchange Commission on May 8, 2023, including the section therein captioned “Risk Factors” and in other documents Coherus

files with the Securities and Exchange Commission. Coherus' results for the quarter ended March 31, 2023 are not necessarily indicative of our operating results for any future periods.

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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,	
	2023	**2022**
Net revenue	$ 32,436	$ 60,115
Costs and expenses:		
Cost of goods sold	16,874	9,370
Research and development	34,154	82,917
Selling, general and administrative	49,153	48,753
Total costs and expenses	100,181	141,040
Loss from operations	(67,745)	(80,925)
Interest expense	(9,712)	(8,969)
Loss on debt extinguishment	—	(6,222)
Other income (expense), net	1,728	32
Loss before income taxes	(75,729)	(96,084)
Income tax provision	—	—
Net loss	$ (75,729)	$ (96,084)
Basic and diluted net loss per share	$ (0.96)	$ (1.24)
Weighted-average number of shares used in computing basic and diluted net loss per share	79,268,853	77,253,699

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

	March 31, 2023	December 31, 2022
Assets		
Cash and cash equivalents	$ 16,145	$ 63,547
Investments in marketable securities	111,944	128,134
Trade receivables, net	101,458	109,964
Inventory	114,487	115,051
Other assets	58,392	64,151
Total assets	$ 402,426	$ 480,847
Liabilities and Stockholders' Deficit		
Accrued rebates, fees and reserve	$ 55,697	$ 54,461
Term loans	245,718	245,483
Convertible notes	225,900	225,575
Other liabilities	71,618	92,746
Total stockholders' deficit	(196,507)	(137,418)
Total liabilities and stockholders' deficit	$ 402,426	$ 480,847

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

	Three Months Ended March 31,	
	2023	**2022**
Cash, cash equivalents and restricted cash at beginning of the period	$ 63,987	$ 417,635
Net cash used in operating activities	(68,732)	(54,045)
Proceeds from maturities of investments in marketable securities	17,500	—
Option payment to Junshi Biosciences	—	(35,000)
Other investing activities, net	26	(615)
Net cash provided by (used in) investing activities	17,526	(35,615)
Proceeds from 2027 Term Loans, net of debt discount & issuance costs	—	191,190
Proceeds from issuance of common stock upon exercise of stock options	103	544
Proceeds from issuance of common stock under ATM Offering, net of issuance costs	6,835	—
Taxes paid related to net share settlement of RSUs	(2,781)	(2,658)
Repayment of 2022 Convertible Notes and premiums	—	(109,000)
Repayment of 2025 Term Loan, premiums and exit fees	—	(81,750)
Other financing activities	(353)	(181)
Net cash provided by (used in) financing activities	3,804	(1,855)
Net decrease in cash, cash equivalents and restricted cash	(47,402)	(91,515)
Cash, cash equivalents and restricted cash at end of the period	$ 16,585	$ 326,120
Reconciliation of cash, cash equivalents, and restricted cash		
Cash and cash equivalents	$ 16,145	$ 325,680
Restricted cash balance	440	440
Cash, cash equivalents and restricted cash	$ 16,585	$ 326,120

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 loss, and the related per share measures, stock-based compensation expense, 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 Loss to Non-GAAP Net Loss

(in thousands, except share and per share data)
(unaudited)

	Three Months Ended March 31,	
	2023	**2022**
GAAP net loss	$ (75,729)	$ (96,084)
Adjustments:		
Stock-based compensation expense[1]	11,333	12,879
Loss on debt extinguishment	—	6,222
Restructuring charges related to reduction in workforce[1]	4,876	—
Non-GAAP net loss	$ (59,520)	$ (76,983)
GAAP net loss per share, basic and diluted	$ (0.96)	$ (1.24)
Non-GAAP net loss per share, basic and diluted	$ (0.75)	$ (1.00)
Shares used in computing basic and diluted net loss per share	79,268,853	77,253,699

[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.