
**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 2, 2023

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 August 2, 2023, Coherus BioSciences, Inc. (the “Company”) issued a press release regarding its financial results for the second quarter ended June 30, 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated August 2, 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: August 2, 2023

COHERUS BIOSCIENCES, INC.

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





Coherus BioSciences Reports Second Quarter 2023 Financial Results and Business Highlights

- Net revenue rose 81% from prior quarter to \$58.7 million -
- CIMERLI® net sales quadrupled to \$26.7 million compared to prior quarter -
- UDENYCA® autoinjector launched in late May, and YUSIMRY™ launched in July -
- Planned merger with Surface Oncology expected to significantly advance next-generation immuno-oncology pipeline -
- Conference call today at 5:00 p.m. Eastern Daylight Time -

REDWOOD CITY, Calif., August 2, 2023 -- Coherus BioSciences, Inc. ("Coherus", Nasdaq: CHRS), today reported financial results for the quarter ended June 30, 2023, and recent business highlights:

RECENT BUSINESS HIGHLIGHTS

CIMERLI®

- CIMERLI® (ranibizumab-eqrn) net product sales more than quadrupled to \$26.7 million compared to the prior quarter following the April 1, 2023 implementation of the permanent, product-specific Q-code.

UDENYCA®

- Coherus launched a single-dose, prefilled autoinjector (AI) presentation of UDENYCA® (pegfilgrastim-cbqv) on May 22, representing the first pegfilgrastim presentation innovation in eight years.
- The U.S. Food and Drug Administration (FDA) review of the prior approval supplement for Coherus' third pegfilgrastim presentation, the UDENYCA® On-body Injector (OBI), is ongoing. Coherus plans to launch UDENYCA® OBI directly upon potential approval later this year.

Toripalimab

- The FDA completed inspection of the toripalimab manufacturing site in China in May, and has scheduled the clinical site inspections in China to begin in the second half of August 2023. Coherus anticipates potential FDA approval and U.S. commercial launch of toripalimab in the second half of 2023.
- The final analysis of the JUPITER-02 clinical trial (NCT03581786) presented at the American Society of Clinical Oncology annual meeting in June demonstrated a statistically significant and clinically meaningful improvement in overall survival (OS) for nasopharyngeal carcinoma (NPC) patients who were treated with toripalimab in combination with chemotherapy versus chemotherapy alone. Median OS was 33.7 months in the chemotherapy-only treatment arm, and median OS was not reached in the toripalimab arm, with a hazard ratio of 0.63, representing a 37% reduction in risk of death (95% CI 0.45-0.89; p=0.0083).

YUSIMRY™

- Coherus launched YUSIMRY™, a Humira biosimilar, with a citrate-free and sting-free formulation delivered via a state-of-the-art autoinjector on July 3rd. YUSIMRY™ is now available for sale nationwide through retail, mail order and specialty pharmacy channels.

- Coherus announced that it had entered into a definitive agreement and plan of merger on June 16, 2023 that would result in the acquisition of Surface Oncology, Inc. ("Surface Oncology"), if completed. The merger is expected to significantly advance Coherus' next-generation immuno-oncology pipeline focused on the tumor micro-environment with clinical stage anti-IL-27 and anti-CCR8 development programs. The merger is expected to close following the Surface Oncology special meeting of stockholders scheduled on September 7, 2023.
- Patient enrollment continues in the U.S.-based Phase 1/2a dose expansion clinical trial evaluating CHS-006, a TIGIT-targeted antibody, in combination with toripalimab in patients with advanced solid tumors (NCT05757492).
- Coherus plans to file an Investigational New Drug ("IND") application by year end for CHS-1000, a novel ILT4-targeted antibody.

"In the second quarter, we had strong execution on our strategy to build an innovative immuno-oncology company funded by revenues from FDA-approved products, and we made good progress across all areas of our business. Compared to the prior quarter, net revenues increased by 81% to \$58.7 million, and we expect continued revenue growth in the second half of this year driven by continued success with CIMERLI[®], the UDENYCA[®] autoinjector and YUSIMRY[™] new product launches, as well as the launches of UDENYCA[®] On-body Injector and of toripalimab for the treatment of NPC later this year, if approved," said Denny Lanfear, Coherus' Chairman and Chief Executive Officer. "Coherus is successfully diversifying into a multi-product commercial organization with growing revenues supporting the development of our next-generation immuno-oncology franchise."

Mr. Lanfear added, "We look forward to closing the merger with Surface Oncology in the third quarter, reprioritizing our portfolio, and ultimately advancing a highly competitive, next-generation immuno-oncology clinical pipeline of innovative therapeutics focused on the tumor microenvironment. We will be well positioned to deliver the next step change in cancer treatment, with the goal of driving enhanced therapeutic benefit to patients beyond the outcomes achieved with checkpoint inhibitors alone."

SECOND QUARTER 2023 FINANCIAL RESULTS

Net revenue was \$58.7 million during the three months ended June 30, 2023 and included \$31.7 million of net sales of UDENYCA[®] and \$26.7 million of net sales of CIMERLI[®], which was launched in October 2022. Net revenue for the three months ended June 30, 2022, consisting primarily of UDENYCA[®] net sales, was \$60.2 million. Net revenue was \$91.2 million and \$120.3 million for the six months ended June 30, 2023 and 2022, respectively. Net revenue in the first half of 2023 was reduced by a \$1.7 million charge for a contingent liability related to resolving a dispute regarding certain UDENYCA[®] sales from October 2020 through December 2021. The declines were primarily due to a reduction in the number of units of UDENYCA[®] sold as well as a lower net realized price due to increased competition. These factors were partially offset by increasing revenue from CIMERLI[®] sales during the first two quarters of 2023.

Cost of goods sold (COGS) for the three months ended June 30, 2023 and 2022 was \$24.8 million and \$11.3 million, respectively, and \$41.7 million and \$20.6 million during the six months ended June 30, 2023 and 2022, respectively. The increases compared to prior year periods primarily result from COGS associated with CIMERLI[®] which was launched in October 2022. 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 half of 2023 also includes \$3.0 million in contract modification fees with one of our manufacturers and \$2.3 million in write-offs of inventory that was damaged during processing at one of our manufacturers. In addition, gross margins were unfavorably impacted due to product mix resulting from increased volumes of CIMERLI[®] sold following the product specific Q-code implementation on April 1st and the launch of UDENYCA[®] AI in May 2023.

Research and development (R&D) expense for the three months ended June 30, 2023 and 2022 was \$23.3 million and \$41.6 million, respectively. For the six months ended June 30, 2023 and 2022, R&D expense was \$57.4 million and \$124.5 million, respectively. The decline in R&D expense compared to the prior year periods primarily resulted from the reduction in scope of the toripalimab collaboration agreement and from the recognition in the first quarter of 2022 of the \$35.0 million option exercise fee paid to Junshi Biosciences to license CHS-006.

Selling, general and administrative (SG&A) expense was \$45.1 million and \$51.3 million during the three months ended June 30, 2023 and 2022, respectively, and \$94.3 million and \$100.0 million during the six months ended June 30, 2023 and 2022, respectively. The decline in SG&A expense compared to the prior year periods primarily reflects lower headcount.

Net loss for the second quarter of 2023 was \$42.9 million, or \$(0.49) per share on a diluted basis, compared to a net loss of \$50.2 million, or \$(0.65) per share on a diluted basis for the same period in 2022. Net loss for the first half of 2023 was \$118.6 million, or

\$(1.42) per share on a diluted basis, compared to a net loss of \$146.2 million, or \$(1.89) per share on a diluted basis for the first half of 2022.

Non-GAAP net loss for the second quarter of 2023 was \$32.8 million, or \$(0.38) per share on a diluted basis, compared to non-GAAP net loss of \$36.3 million, or \$(0.47) per share on a diluted basis for the same period in 2022. Non-GAAP net loss for the first half of 2023 was \$92.3 million, or \$(1.11) per share on a diluted basis, compared to non-GAAP net loss of \$113.3 million, or \$(1.46) per share on a diluted basis for the first half of 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 \$144.7 million as of June 30, 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 range includes stock-based compensation expense and excludes the Surface Oncology acquisition cost as well as 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: Wednesday, August 2nd, 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/BI3fdbdc05783442f89d11db6b94e74a28>

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

Webcast Link: <https://edge.media-server.com/mmc/p/irz4npdq>

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 Biologics License Application for toripalimab in combination with chemotherapy as treatment for recurrent or metastatic nasopharyngeal carcinoma is currently under review by the FDA.

Coherus markets UDENYCA® (pegfilgrastim-cbqv), a biosimilar of Neulasta®, CIMERLI® (ranibizumab-eqrn), a biosimilar of Lucentis®, and YUSIMRY™ (adalimumab-aqvh), a biosimilar of Humira®.

Neulasta® is a registered trademark of Amgen, Inc.

Lucentis® is a registered trademark of Genentech, 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 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 its ability to close the acquisition of Surface Oncology in the third quarter of 2023 or at all; Coherus' expectations about advancing its pipeline and achieving better outcomes than checkpoint inhibitors can on their own; Coherus' expectations about launching new products and Coherus' timing and ability to file an IND for CHS-1000.

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; the risks and uncertainties of the acquisition of Surface Oncology, including whether the conditions to closing of the merger can be met in a timely manner or at all; 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 June 30, 2023 filed with the Securities and Exchange Commission on August 2, 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 June 30, 2023 are not necessarily indicative of our operating results for any future periods.

UDENYCA®, CIMERLI® and YUSIMRY™, 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		Six Months Ended	
	June 30,		June 30,	
	2023	2022	2023	2022
Net revenue	\$ 58,716	\$ 60,151	\$ 91,152	\$ 120,266
Costs and expenses:				
Cost of goods sold	24,848	11,277	41,722	20,647
Research and development	23,267	41,611	57,421	124,528
Selling, general and administrative	45,144	51,276	94,297	100,029
Total costs and expenses	<u>93,259</u>	<u>104,164</u>	<u>193,440</u>	<u>245,204</u>
Loss from operations	(34,543)	(44,013)	(102,288)	(124,938)
Interest expense	(9,943)	(6,580)	(19,655)	(15,549)
Loss on debt extinguishment	—	—	—	(6,222)
Other income (expense), net	1,617	443	3,345	475
Loss before income taxes	(42,869)	(50,150)	(118,598)	(146,234)
Income tax provision	—	—	—	—
Net loss	<u>\$ (42,869)</u>	<u>\$ (50,150)</u>	<u>\$ (118,598)</u>	<u>\$ (146,234)</u>
Basic and diluted net loss per share	\$ (0.49)	\$ (0.65)	\$ (1.42)	\$ (1.89)
Weighted-average number of shares used in computing basic and diluted net loss per share	87,269,614	77,554,717	83,469,247	77,405,040

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

	<u>June 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Assets		
Cash and cash equivalents	\$ 72,920	\$ 63,547
Investments in marketable securities	71,792	128,134
Trade receivables, net	141,308	109,964
Inventory	127,835	115,051
Other assets	55,736	64,151
Total assets	<u>\$ 469,591</u>	<u>\$ 480,847</u>
Liabilities and Stockholders' Deficit		
Accrued rebates, fees and reserve	\$ 84,210	\$ 54,461
Term loans	245,963	245,483
Convertible notes	226,228	225,575
Other liabilities	87,954	92,746
Total stockholders' deficit	<u>(174,764)</u>	<u>(137,418)</u>
Total liabilities and stockholders' deficit	<u>\$ 469,591</u>	<u>\$ 480,847</u>

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2023	2022	2023	2022
Cash, cash equivalents and restricted cash at beginning of the period	\$ 16,585	\$ 326,120	\$ 63,987	\$ 417,635
Net cash used in operating activities	(38,915)	(50,037)	(107,647)	(104,082)
Purchases of investments in marketable securities	(19,507)	—	(19,507)	—
Proceeds from maturities of investments in marketable securities	47,250	—	64,750	—
Proceeds from sale of investments in marketable securities	13,282	—	13,282	—
Option payment to Junshi Biosciences	—	—	—	(35,000)
Other investing activities, net	340	(880)	366	(1,495)
Net cash provided by (used in) investing activities	41,365	(880)	58,891	(36,495)
Proceeds from 2027 Term Loans, net of debt discount & issuance costs	—	—	—	191,190
Proceeds from issuance of common stock under ATM Offering, net of issuance costs	(74)	—	6,761	—
Proceeds from issuance of common stock under Public Offering, net of issuance costs	53,625	—	53,625	—
Proceeds from issuance of common stock upon exercise of stock options	14	8	117	552
Proceeds from purchase under the employee stock purchase plan	1,337	1,655	1,337	1,655
Taxes paid related to net share settlement of RSUs	(305)	(642)	(3,086)	(3,300)
Repayment of 2022 Convertible Notes and premiums	—	—	—	(109,000)
Repayment of 2025 Term Loan, premiums and exit fees	—	—	—	(81,750)
Other financing activities	(272)	(300)	(625)	(481)
Net cash provided by (used in) financing activities	54,325	721	58,129	(1,134)
Net increase (decrease) in cash, cash equivalents and restricted cash	56,775	(50,196)	9,373	(141,711)
Cash, cash equivalents and restricted cash at end of the period	\$ 73,360	\$ 275,924	\$ 73,360	\$ 275,924
Reconciliation of cash, cash equivalents, and restricted cash				
Cash and cash equivalents	\$ 72,920	\$ 275,484	\$ 72,920	\$ 275,484
Restricted cash balance	440	440	440	440
Cash, cash equivalents and restricted cash	\$ 73,360	\$ 275,924	\$ 73,360	\$ 275,924

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		Six Months Ended	
	June 30,		June 30,	
	2023	2022	2023	2022
GAAP net loss	\$ (42,869)	\$ (50,150)	\$ (118,598)	\$ (146,234)
Adjustments:				
Stock-based compensation expense ⁽¹⁾	10,077	13,850	21,410	26,729
Loss on debt extinguishment	—	—	—	6,222
Restructuring charges related to reduction in workforce ⁽¹⁾	—	—	4,876	—
Non-GAAP net loss	\$ (32,792)	\$ (36,300)	\$ (92,312)	\$ (113,283)
GAAP net loss per share, basic and diluted	\$ (0.49)	\$ (0.65)	\$ (1.42)	\$ (1.89)
Non-GAAP net loss per share, basic and diluted	\$ (0.38)	\$ (0.47)	\$ (1.11)	\$ (1.46)
Shares used in computing basic and diluted net loss per share	87,269,614	77,554,717	83,469,247	77,405,040

⁽¹⁾ In the six months ended June 30, 2023, stock-based compensation of \$1.0 million was classified within Restructuring charges related to reduction in workforce.