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 8, 2022

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 November 8, 2022, Coherus BioSciences, Inc. issued a press release regarding its financial results for the third quarter ended September 30, 2022. 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 November 8, 2022
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: November 8, 2022

COHERUS BIOSCIENCES, INC.

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

Coherus BioSciences Reports Third Quarter 2022 Results and Provides Business Update

– UDENYCA® net sales of $45.4 million in the third quarter 2022 –

– CIMERLI™ launched in the United States on October 3rd –

– Planning underway for 2023 commercial launches of toripalimab, YUSIMRY™ and UDENYCA® OBI –

– Conference call today at 5 p.m. ET –

REDWOOD CITY, Calif., November 8, 2022 – Coherus BioSciences, Inc. ("Coherus" or the "Company", Nasdaq: CHRS), today reported financial results for its fiscal third quarter ended September 30, 2022 and recent business highlights:

RECENT BUSINESS HIGHLIGHTS

- CIMERLI™ (ranibizumab-eqrn), was approved in August 2022 by the U.S. Food and Drug Administration (FDA) as a biosimilar product interchangeable with Lucentis® (ranibizumab injection), with 12 months of interchangeability exclusivity. Coherus launched CIMERLI on October 3, 2022.
- CIMERLI™ achieved leading biosimilar market share within the first four weeks of launch, and 2023 net sales of CIMERLI™ are projected to exceed $100 million.
- Toripalimab, a PD-1 inhibitor for the treatment of nasopharyngeal carcinoma, is under review by FDA, with a biologics license application (BLA) target action date of December 23, 2022. Thus far, travel restrictions related to the COVID-19 pandemic have hindered the FDA's ability to complete inspections in China. Coherus and partner Junshi Biosciences are currently engaged in discussions with the FDA regarding opportunities to complete the inspections.

"We are pleased with the launch of our new revenue growth driver, CIMERLI™, which builds on the success we demonstrated with UDENYCA®, our first product, that also rapidly overtook a large, first-to-market competitor. This is the first of four product launches transforming Coherus into a multi-product company. In 2023, we plan to launch YUSIMRY™, our FDA-approved Humira® biosimilar, and upon FDA approval, toripalimab and our UDENYCA® on-body injector presentation," said Denny Lanfear, Coherus' Chairman and Chief Executive Officer. "Given projected topline growth from these launches and prudent expense management, we are targeting a return to profitability in 2024."

THIRD QUARTER 2022 FINANCIAL RESULTS

Net revenue, consisting primarily of net sales of UDENYCA®, was $45.4 million and $82.5 million during the three months ended September 30, 2022 and 2021, respectively, and $165.7 million and $253.2 million during the nine months ended September 30, 2022 and 2021, respectively. The decline in both periods 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 $35.2 million and $21.3 million during the three months ended September 30, 2022 and 2021, respectively, and $55.9 million and $45.5 million during the nine months ended September 30, 2022 and 2021, respectively, reflecting decreases in the number of units of UDENYCA® sold as well as a reserve taken in the third quarter 2022 of $26.0 million against inventory at risk of expiration. COGS for the third quarter and first nine months of 2021 included the write-down of $5.2 million of inventory that did not meet Coherus' acceptance criteria. UDENYCA® COGS also includes a mid-single digit royalty on net sales payable through the first half of 2024.

Research and development (R&D) expense for the three months ended September 30, 2022 and 2021 was $45.8 million and $54.1 million, respectively. The decrease was driven by lower development costs, which was partially offset by higher compensation expense. For the nine months ended September 30, 2022 and 2021, R&D expense was $170.3 million and $312.3 million, respectively.

The decrease was primarily due to the $136.0 million upfront license fee paid to Junshi Biosciences in 2021, which was partially offset by the $35.0 million option exercise fee for CHS-006 in the first quarter of 2022.

Selling, general and administrative (SG&A) expense was $44.8 million and $39.9 million during the three months ended September 30, 2022 and 2021, respectively, and $144.9 million and $119.7 million during the nine months ended September 30, 2022 and 2021, respectively. The increases were primarily driven by higher commercialization expenses in preparation for the commercial launch of CIMERLI™ in 2022 and multiple new product launches anticipated in 2023, including, of toripalimab, YUSIMRY™, and the on-body injector presentation of UDENYCA®.

Net loss for the third quarter of 2022 was $86.7 million, or $(1.11) per share on a basic and diluted basis, compared to a net loss of $38.5 million, or $(0.49) per share on a basic and diluted basis for the same period in 2021. Net loss for the first nine months of 2022 was $232.9 million, or $(3.00) per share on a basic and diluted basis, compared to a net loss of $241.4 million, or $(3.22) per share on a basic and diluted basis for the first nine months of 2021.

Non-GAAP net loss for the third quarter of 2022 was $74.4 million, or $(0.96) per share on a basic and diluted basis, compared to non-GAAP net loss of $26.6 million, or $(0.34) per share on a basic and diluted basis for the same period in 2021. Non-GAAP net loss for the first nine months of 2022 was $187.7 million, or $(2.42) per share on a basic and diluted basis, compared to non-GAAP net loss of $189.5 million, or $(2.53) per share on a basic and diluted basis for the first nine months of 2021. Beginning in the first quarter of 2022, the Company no longer regularly excludes upfront and milestone-based license fee payments from its non-GAAP financial information. To conform to this change, the prior period non-GAAP financial information has been recast to include upfront and milestone-based license fee payments. 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 and cash equivalents were $286.8 million as of September 30, 2022, compared to $417.2 million at December 31, 2021.

2022 R&D and SG&A Expense Guidance

Coherus is revising the guidance range of combined 2022 R&D and SG&A expenses from $375 - $395 million to a range of $375 - $385 million. This guidance includes $55 million to $60 million of stock-based compensation expense and excludes the $35 million license fee paid in the first quarter of 2022 for CHS-006 as well as a potential $25 million milestone payable upon FDA approval of the toripalimab BLA for nasopharyngeal carcinoma. 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: Tuesday, November 8th, 2022, starting at 5 p.m. ET

Please register through the following link for dial-in information and personal PIN:

https://register.vevent.com/register/BI79684ca1b45c46df988c8f9aac6f09af

Please register 15 minutes early to ensure a timely connection to the call.

A replay of the webcast will be archived at https://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 and the commercialization of our portfolio of FDA-approved therapeutics. 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. A BLA for toripalimab for the treatment of nasopharyngeal carcinoma is under review by the FDA with a target action date of December 23, 2022. Toripalimab is also being evaluated in pivotal clinical trials for the treatment of cancers of the lung, breast, liver, skin, kidney, stomach, esophagus, and bladder.

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; Coherus' investment plans; Coherus' future projections for R&D and SG&A expenses and net sales and whether it can meet those projections; Coherus' ability to rapidly expand its product portfolio and grow and diversify its revenues; Coherus' ability to return to profitability; and Coherus' ability to launch and support new products, while continuing to invest in its oncology pipeline and opportunities.

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 schedule inspections in China and the timing of Coherus' regulatory filings; the risk of FDA review issues; the risk of Coherus' execution of its change in strategy from a focus on biosimilars to a strategy using cash from its portfolio to fund an immuno-oncology franchise; the risk that Coherus is unable to complete commercial transactions and other matters that could affect the availability or commercial potential of Coherus' drug 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 the fiscal period ended September 30, 2022, to be filed with the Securities and Exchange Commission on or about November 8, 2022, 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 September 30, 2022 are not necessarily indicative of our operating results for any future periods.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net revenue	$ 45,424	$ 82,503	$ 165,690	$ 253,180
Costs and expenses:				
Cost of goods sold	35,234	21,280	55,881	45,487
Research and development	45,808	54,085	170,336	312,343
Selling, general and administrative	44,831	39,925	144,860	119,661
Total costs and expenses	125,873	115,290	371,077	477,491
Loss from operations	(80,449)	(32,787)	(205,387)	(224,311)
Interest expense	(7,540)	(5,771)	(23,089)	(17,166)
Loss on debt extinguishment	—	—	(6,222)	—
Other income (expense), net	1,339	30	1,814	102
Loss before income taxes	(86,650)	(38,528)	(232,884)	(241,375)
Income tax provision	—	—	—	—
Net loss	$ (86,650)	$ (38,528)	$ (232,884)	$ (241,375)
Basic and diluted net loss per share	$ (1.11)	$ (0.49)	$ (3.00)	$ (3.22)
Weighted-average number of shares used in computing basic and diluted net loss per share	77,746,895	79,013,240	77,520,244	74,984,811

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

	September 30, 2022	December 31, 2021
Assets		
Cash and cash equivalents	$ 286,805	$ 417,195
Trade receivables, net	91,186	123,022
Inventory	105,157	93,252
Other assets	67,759	45,865
Total assets	$ 550,907	$ 679,334
Liabilities and Stockholders' Equity (Deficit)		
Accrued rebates, fees and reserve	$ 54,021	$ 79,027
Term loans	245,246	75,513
Convertible notes	225,250	332,767
Other liabilities	123,523	94,301
Total stockholders' equity (deficit)	(97,133)	97,726
Total liabilities and stockholders' equity (deficit)	$ 550,907	$ 679,334

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Cash, cash equivalents and restricted cash at beginning of the period	$ 275,924	$ 330,178	$ 417,635	$ 541,598
Net cash (used in) provided by operating activities	(37,089)	13,711	(141,171)	14,890
Purchases of investments in marketable securities	—	(31,449)	—	(171,779)
Proceeds from maturities of investments in marketable securities	—	47,700	—	62,700
Upfront and option payments to Junshi Biosciences[(1)]	—	—	(35,000)	(136,000)
Cash used in other investing activities	(457)	(261)	(1,952)	(821)
Net cash (used in) provided by investing activities	(457)	15,990	(36,952)	(245,900)
Proceeds from 2027 Term Loans, net of debt discount & issuance costs	49,489	—	240,679	—
Proceeds from issuance of common stock to Junshi Biosciences, net of issuance costs	—	—	—	40,903
Proceeds from issuance of common stock upon exercise of stock options	79	1,280	631	9,726
Proceeds from purchase under the employee stock purchase plan	—	—	1,655	1,985
Taxes paid related to net share settlement of RSUs	(321)	—	(3,621)	(1,730)
Repayment of 2022 Convertible Notes and premiums	—	—	(109,000)	—
Repayment of 2025 Term Loan, premiums and exit fees	—	—	(81,750)	—
Other financing activities	(380)	(179)	(861)	(492)
Net cash provided by financing activities	48,867	1,101	47,733	50,392
Net increase (decrease) in cash, cash equivalents and restricted cash	11,321	30,802	(130,390)	(180,618)
Cash, cash equivalents and restricted cash at end of the period	$ 287,245	$ 360,980	$ 287,245	$ 360,980
Reconciliation of cash, cash equivalents, and restricted cash				
Cash and cash equivalents	$ 286,805	$ 360,540	$ 286,805	$ 360,540
Restricted cash balance	440	440	440	440
Cash, cash equivalents and restricted cash	$ 287,245	$ 360,980	$ 287,245	$ 360,980

(1) 2021 payments include license fees of $145.0 million pursuant to the collaboration agreement with Junshi Biosciences paid in the first quarter which was partially offset by a $9.0 million credit related to the fair value of the discount for lack of marketability on the common shares purchased under the stock purchase agreement with Junshi Biosciences in the second quarter.

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 costs related to the termination of the CHS-2020 development program that Coherus announced in February 2021. Starting in the first quarter of 2022, Coherus no longer excludes upfront and milestone-based license payments from its non-GAAP financial information. Comparative prior year non-GAAP amounts were recast and now include upfront and milestone-based license fee payments. 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 (1)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
GAAP net loss	$ (86,650)	$ (38,528)	$ (232,884)	$ (241,375)
Adjustments:				
Stock-based compensation expense	12,282	11,939	39,011	40,418
Loss on debt extinguishment	—	—	6,222	—
Costs related to termination of CHS-2020 development program	—	—	—	11,503
Non-GAAP net loss	$ (74,368)	$ (26,589)	$ (187,651)	$ (189,454)
GAAP net loss per share, basic and diluted	$ (1.11)	$ (0.49)	$ (3.00)	$ (3.22)
Non-GAAP net loss per share, basic and diluted	$ (0.96)	$ (0.34)	$ (2.42)	$ (2.53)
Shares used in computing basic and diluted net loss per share	77,746,895	79,013,240	77,520,244	74,984,811

(1) Beginning in the first quarter of 2022, the Company no longer regularly excludes upfront and milestone-based license fee payments from its non-GAAP financial information. To conform to this change, the prior period non-GAAP financial information has been recast to include upfront and milestone-based license fee payments.

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