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): February 17, 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 February 17, 2022, Coherus BioSciences, Inc. issued a press release regarding its financial results for the fourth quarter and full year ended December 31, 2021. 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 February 17, 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: February 17, 2022

COHERUS BIOSCIENCES, INC.

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

Coherus BioSciences Reports Fourth Quarter and Full Year 2021 Results

– YUSIMRY™ (adalimumab-aqvh), Coherus' second product, approved by FDA on December 17, 2021 –

– BLAs under FDA review for PD-1 inhibitor toripalimab and CIMERLI™ (ranibizumab-ranq) –

– New FDA filings expected in 2022 for UDENYCA® on-body injector and additional toripalimab indications –

– UDENYCA® delivered net sales of $73 million in 4Q 2021; $327 million in FY 2021 –

– Conference call and webcast today at 5:00 p.m. ET –

REDWOOD CITY, Calif., February 17, 2022 – Coherus BioSciences, Inc. ("Coherus" or the "Company", Nasdaq: CHRS), today reported financial results for the quarter and full year ended December 31, 2021 and highlighted recent achievement of key milestones toward the Company's key strategic initiatives:

RECENT EXECUTION ON KEY STRATEGIC INITIATIVES

Building an innovative immuno-oncology company:

- U.S. Food and Drug Administration ("FDA") granted toripalimab BLA priority review for nasopharyngeal carcinoma ("NPC") and assigned a target action date of April 30, 2022.
- Toripalimab in combination with chemotherapy demonstrated a statistically significant overall survival benefit in prespecified interim analysis of Phase 3 clinical trial in patients with non-small cell lung cancer.
- Initiated process to exercise option to license JS006, a TIGIT targeted antibody being evaluated in combination with toripalimab in an ongoing Phase 1/2 clinical trial.
- Advancing internal immuno-oncology antibody into IND enabling studies.

Diversifying and growing the commercial product portfolio:

- FDA approved YUSIMRY™ (adalimumab-aqvh), a Humira® biosimilar, on December 17, 2021.
- FDA accepted for review the BLA for CIMERLI™ (ranibizumab-ranq), a Lucentis® biosimilar, and assigned a target action date in August 2022.
- UDENYCA® (pegfilgrastim-cbqv) on-body injector ("OBI") achieved both pharmacokinetic and pharmacodynamic bioequivalence in randomized clinical trial, enabling prior approval supplement filing with FDA in 2022; if approved, a UDENYCA OBI would compete directly with Neulasta® Onpro® which retains approximately 50% share of the overall pegfilgrastim market.

"We have made rapid progress transforming Coherus into an innovative immuno-oncology company supported by income from a diversified portfolio of FDA-approved products. In 2022, we expect to launch two new products, if approved, including our first immuno-oncology antibody, toripalimab, addressing an unmet need in nasopharyngeal carcinoma, as well as CIMERLI. We also plan to initiate a clinical trial in North America evaluating toripalimab in combination with JS006, a TIGIT-targeted antibody," said Denny Lanfear, CEO of Coherus. "Looking ahead to 2023, we project accelerating revenue growth with the planned launch of FDA-approved YUSIMRY into the $17 billion Humira® market and the introduction of the UDENYCA on-body injector, if approved, a new presentation that would enable us to address the remaining $1.2 billion Neulasta® Onpro® segment of the pegfilgrastim market where there is currently no biosimilar competition."

Fourth Quarter and Full Year 2021 Financial Results

Net revenue, consisting of net sales of UDENYCA, was $73.4 million for the fourth quarter of 2021 compared to $110.4 million for the same period in 2020. Net revenue for 2021 was $326.6 million compared to $475.8 million for 2020. The declines for the fourth

quarter and full year 2021 were primarily due to a decrease in the number of units of UDENYCA sold as well as a decline in net realized price due to increased competition and COVID-19 impacts.

Cost of goods sold ("COGS") was $12.1 million and $11.7 million during the three months ended December 31, 2021 and 2020, respectively, and $57.6 million and $37.7 million for the full years 2021 and 2020, respectively. Through the first quarter of 2021, Coherus sold inventory that was manufactured and expensed prior to the approval of UDENYCA in late 2018. This inventory was depleted in the first quarter of 2021, and since then COGS fully reflects per unit acquisition cost of UDENYCA. UDENYCA COGS also includes a mid single digit royalty on net sales payable through the first half of 2024.

Research and development ("R&D") expenses for the fourth quarter of 2021 were $50.8 million, compared to $44.6 million for the same period in 2020. The increase was mainly due to higher regulatory and development costs in support of the advancement of multiple pipeline product candidates. R&D expense for 2021 was $363.1 million compared to $142.8 million for 2020. The increase of $220.3 million was primarily due to the $136.0 million upfront license fee paid to Junshi Biosciences and also due to costs incurred in the development of YUSIMRY, toripalimab and additional presentations of UDENYCA.

Selling, general and administrative ("SG&A") expenses were $50.1 million for the fourth quarter of 2021, compared to $37.7 million for the same period in 2020. The increase was driven primarily by increased commercialization expense to support UDENYCA sales. For the full year 2021, SG&A expenses were $169.7 million, compared to $139.1 million for the prior year. The year-over-year increase is primarily due to costs incurred in support of UDENCYA commercial activities, as well as an increase in stock-based compensation expense.

Cash and cash equivalents were $417.2 million as of December 31, 2021, compared to $541.2 million as of December 31, 2020. During 2021, Coherus used $37.4 million in operating activities and $138.4 million in investing activities, including $136.0 million in an upfront payment to Junshi Biosciences. The Company received net cash proceeds of $51.9 million from financing activities related to the issuance of common stock to Junshi Biosciences, as well as proceeds from the exercise of stock options and from purchases under the employee stock purchase plan.

Net loss for the fourth quarter of 2021 was $45.7 million, or $(0.60) per share on a diluted basis, compared to net income of $9.7 million, or $0.12 per share on a diluted basis for the same period in 2020. Net loss for 2021 was $287.1 million, or $(3.81) per share on a diluted basis, compared to net income of $132.2 million, or $1.62 per share on a diluted basis for 2020.

Non-GAAP net loss for the fourth quarter of 2021 was $35.1 million, or $(0.46) per share on a diluted basis, compared to non-GAAP income of $18.6 million, or $0.23 per share on a diluted basis for the same period in 2020. Non-GAAP net loss for 2021 was $88.5 million, or $(1.17) per share on a diluted basis, compared to non-GAAP income of $176.7 million, or $2.16 per share on a diluted basis for 2020. See "Non-GAAP Financial Measures" below for a discussion on how Coherus calculates non-GAAP net income (loss) and a reconciliation to the most directly comparable GAAP measures.

2022 Guidance

Coherus projects combined R&D and SG&A expenses in 2022 to be in the range of $415 million to $450 million, excluding a potential $25 million milestone payable upon FDA approval of the toripalimab BLA for nasopharyngeal carcinoma and the $35 million fee to exercise the option for the license to JS006, which is expected to close in the first quarter of 2022. The projected increase compared to 2021 is driven primarily by costs the Company expects to incur with the anticipated launches of two new products, toripalimab and CIMERLI, as well as manufacturing and development costs for additional presentations of UDENYCA and for FDA-approved YUSIMRY, which Coherus is planning to launch in 2023.

This financial guidance 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 items 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, Feb. 17, 2022, starting at 5 p.m. ET

Dial-in: (844) 452-6826 (Toll-Free U.S. and Canada) or (765) 507-2587 (International)

Conference ID: 3677018

Webcast: https://investors.coherus.com/upcoming-events

Please dial-in 15 minutes early to ensure a timely connection to the call.
Fourth quarter and full year 2021 financial results are posted on the Coherus website at https://investors.coherus.com/.

About Coherus BioSciences

Coherus is a commercial stage biopharmaceutical company building an innovative immuno-oncology franchise funded with cash generated by 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 biologics license application for toripalimab for the treatment of metastatic or recurrent nasopharyngeal carcinoma is currently under priority review by the FDA, with a target action date of April 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® in the United States, and expects to launch the FDA-approved Humira® biosimilar YUSIMRY™ (adalimumab-aqvh) in the United States in 2023. The FDA is currently reviewing the biologics license application for CIMERLI™ (ranibizumab-ranq), a Lucentis® biosimilar, with a target action date of August 2022. Coherus is also developing CHS-305, a biosimilar of Avastin® (bevacizumab).

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 an innovative immuno-oncology franchise; Coherus' ability to generate cash; Coherus' investment plans; Coherus' expectations for the launch date of YUSIMRY™ (adalimumab-aqvh); projections for combined R&D and SG&A expenses in 2022; expectations for launches of new products and payments of milestone expenses; expectations of future accelerating revenue growth; estimations about the size of the HUMIRA® market; and expectations of the UDENYCA on-body injector to gain approval and address a large market segment. 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 the drug development position of Coherus' competitors; 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, including accepting trial data from outside of the United States; the risk of Coherus' execution of its change in strategy from a focus on biosimilars to a strategy using cash from biosimilars 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' Annual Report on Form 10-K for the year ended December 31, 2020, filed with the Securities and Exchange Commission on February 25, 2021, its subsequent Quarterly Reports on Form 10-Q, including the sections therein captioned "Risk Factors" and in other documents it files with the Securities and Exchange Commission.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Net revenue	$ 73,371	$ 110,419	$ 326,551	$ 475,824
Costs and expenses:				
Cost of goods sold	12,104	11,673	57,591	37,667
Research and development	50,762	44,628	363,105	142,759
Selling, general and administrative	50,052	37,693	169,713	139,079
Total costs and expenses	112,918	93,994	590,409	319,505
(Loss) income from operations	(39,547)	16,425	(263,858)	156,319
Interest expense	(5,793)	(5,671)	(22,959)	(21,166)
Other (expense) income, net	(385)	6	(283)	554
Net (loss) income before income taxes	(45,725)	10,760	(287,100)	135,707
Income tax provision	—	1,052	—	3,463
Net (loss) income	$ (45,725)	$ 9,708	$ (287,100)	$ 132,244
Net (loss) income per share:				
Basic	$ (0.60)	$ 0.13	$ (3.81)	$ 1.85
Diluted	$ (0.60)	$ 0.12	$ (3.81)	$ 1.62
Weighted-average number of shares used in computing net (loss) income per share:				
Basic	76,828,940	72,223,970	75,449,632	71,411,705
Diluted	76,828,940	87,713,218	75,449,632	83,491,898

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

	December 31, 2021	December 31, 2020
Assets		
Cash and cash equivalents	$ 417,195	$ 541,158
Trade receivables, net	123,022	157,046
Inventory	93,252	92,189
Other assets	45,865	51,256
Total assets	$ 679,334	$ 841,649
Liabilities and Stockholders' Equity		
Accrued rebates, fees and reserve	$ 79,027	$ 81,529
2022 Convertible Notes	81,359	79,885
2022 Convertible Notes - related parties	27,120	26,628
2026 Convertible Notes	224,288	223,029
2025 Term Loan	75,513	74,481
Other liabilities	94,301	75,123
Total stockholders' equity	97,726	280,974
Total liabilities and stockholders' equity	$ 679,334	$ 841,649

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Cash, cash equivalents and restricted cash at beginning of the period	$ 360,980	$ 292,905	$ 541,598	$ 177,908
Net cash (used in) provided by operating activities	(52,322)	33,124	(37,432)	154,145
Purchases of investments in marketable securities	(10,706)	—	(182,485)	(273,845)
Proceeds from maturities of investments in marketable securities	36,992	211,000	99,692	274,000
Proceeds from sale of investments in marketable securities	81,672	—	81,672	—
Upfront and milestone based license fee payments *	—	—	(136,000)	(7,500)
Cash used in other investing activities	(468)	(944)	(1,289)	(7,056)
Net cash provided by (used in) investing activities	107,490	210,056	(138,410)	(14,401)
Proceeds related to issuance of 2026 Convertible Notes, net of issuance costs	—	—	—	222,156
Purchase of capped call options related to 2026 Convertible Notes	—	—	—	(18,170)
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	673	4,414	10,399	17,428
Proceeds from purchase under the employee stock purchase plan	1,017	1,244	3,002	3,801
Cash used in other financing activities	(203)	(145)	(2,425)	(1,269)
Net cash provided by financing activities	1,487	5,513	51,879	223,946
Net increase (decrease) in cash, cash equivalents and restricted cash	56,655	248,693	(123,963)	363,690
Cash, cash equivalents and restricted cash at end of the period	$ 417,635	$ 541,598	$ 417,635	$ 541,598
Reconciliation of cash, cash equivalents, and restricted cash				
Cash and cash equivalents	$ 417,195	$ 541,158	$ 417,195	$ 541,158
Restricted cash balance	440	440	440	440
Cash, cash equivalents and restricted cash	$ 417,635	$ 541,598	$ 417,635	$ 541,598

* 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 income, and the related per share measures, which exclude from net income, and the related per share measures, stock-based compensation expense, upfront payments under its license agreements, milestone payments under its license agreements for periods prior to Q4 2021 only, the related income tax effect of those non-GAAP adjustments and costs related to the termination of the CHS-2020 development program that Coherus announced in February 2021. Starting in Q4 2021, Coherus no longer excludes milestone payments from its non-GAAP financial information. Comparative prior year amounts were not material and were not reclassified. 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 supplementary 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) Income to Non-GAAP Net (Loss) Income

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
GAAP net (loss) income	$ (45,725)	$ 9,708	$ (287,100)	$ 132,244
Adjustments:				
Stock based compensation expense	10,946	9,873	51,364	38,160
Upfront and milestone based license fee payments *	—	—	136,000	7,500
Income tax effect of the above adjustments	—	(965)	—	(1,165)
Costs related to termination of CHS-2020 development program	(292)	—	11,211	—
Non-GAAP net (loss) income	$ (35,071)	$ 18,616	$ (88,525)	$ 176,739
GAAP net (loss) income per share, basic	$ (0.60)	$ 0.13	$ (3.81)	$ 1.85
GAAP net (loss) income per share, diluted	$ (0.60)	$ 0.12	$ (3.81)	$ 1.62
Non-GAAP net (loss) income per share, basic	$ (0.46)	$ 0.26	$ (1.17)	$ 2.47
Non-GAAP net (loss) income per share, diluted	$ (0.46)	$ 0.23	$ (1.17)	$ 2.16
Shares used in computing basic net (loss) income per share	76,828,940	72,223,970	75,449,632	71,411,705
Shares used in computing diluted net (loss) income per share	76,828,940	87,713,218	75,449,632	83,491,898

* 2021 expense includes license fees of $145.0 million pursuant to the collaboration agreement with Junshi Biosciences expensed 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.

Contact
McDavid Stilwell
Chief Financial Officer
Coherus BioSciences, Inc.
IR@coherus.com