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, 2021

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, 2021, Coherus BioSciences, Inc. issued a press release regarding its financial results for the third quarter ended September 30, 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 November 8, 2021.
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, 2021

COHERUS BIOSCIENCES, INC.

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

Coherus BioSciences Reports Third Quarter 2021 Results

– Key milestones achieved driving near-term commercial product portfolio expansion –

– Three BLAs now under FDA review: PD-1 inhibitor toripalimab, biosimilar Lucentis®, biosimilar Humira® –

– Multiple additional applications to FDA expected in 2022 –

– UDENYCA® delivers 3rd quarter 2021 net sales of $83 million –

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

REDWOOD CITY, Calif., November 8, 2021 – Coherus BioSciences, Inc. ("Coherus" or the "Company", Nasdaq: CHRS), today reported financial results for the quarter ended September 30, 2021 and highlighted recent achievement of key milestones toward potential near-term expansion of the commercial product portfolio:

ACHIEVEMENT OF KEY MILESTONES DRIVING NEAR-TERM COMMERCIAL PRODUCT PORTFOLIO EXPANSION

- Successful UDENCYA® on-body injector clinical trial is expected to enable 2022 submission of a prior approval supplement to the UDENYCA® BLA.
- FDA accepted the BLA for CHS-201, a biosimilar Lucentis® (ranibizumab), and assigned a target action date of August 2022.
- FDA review of the BLA for CHS-1420, a biosimilar Humira® (adalimumab), is advancing toward the target action date in December 2021.
- FDA accepted the toripalimab BLA for advanced nasopharyngeal carcinoma and granted priority review with a target action date of April 2022.
- Positive esophageal squamous cell carcinoma Phase 3 clinical data is expected to enable submission of a toripalimab BLA supplement in 2022.
- Positive progression free survival data (PFS) from the CHOICE-01 Phase 3 clinical trial evaluating toripalimab in non-small cell lung cancer were presented in September. A final analysis of PFS and an additional interim overall survival analysis are expected by early first quarter 2022, after which Coherus and partner Junshi Biosciences plan to discuss a potential submission of a BLA supplement with FDA.

THIRD QUARTER 2021 FINANCIAL HIGHLIGHTS

- Net product revenue, consisting of net sales of UDENYCA® (pegfilgrastim-cbqv), was $82.5 million.
- GAAP net loss of $38.5 million was driven by lower net product revenue and increased R&D and regulatory expenses to support the development and regulatory submissions of toripalimab and biosimilar pipeline product candidates.
- Non-GAAP net loss was $26.6 million, adjusting for $11.9 million in stock-based compensation expense.
- At September 30, 2021, cash, cash equivalents and marketable securities were $468.7 million.

"With three BLAs currently under FDA review, and positive clinical data expected to enable submission of multiple additional applications for marketing authorization in 2022, we are making rapid progress toward our goals to diversify and grow our commercial product portfolio," said Denny Lanfear, Coherus CEO. "UDENYCA® continues to provide strong funding for Coherus as we invest in our pipeline and prepare for a succession of anticipated new product launches in 2022 and 2023."

THIRD QUARTER 2021 FINANCIAL RESULTS

Net product revenue, consisting of net sales of UDENYCA®, was $82.5 million and $113.6 million during the three months ended September 30, 2021 and 2020, respectively, and $253.2 million and $365.4 million during the nine months ended September 30, 2021 and 2020, respectively. The decreases were primarily due to a decrease in the number of units of UDENYCA® sold during the three and nine months ended September 30, 2021, as well as an increase in discounts and allowances during the nine months ended September 30, 2021.

Cost of goods sold (COGS) was $21.3 million and $9.0 million during the three months ended September 30, 2021 and 2020, respectively, and $45.5 million and $26.0 million during the nine months ended September 30, 2021 and 2020, respectively. Until 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 COGS now fully reflects per unit acquisition cost. Additionally, COGS for the third quarter of 2021 included a $5.2 million write-off 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, 2021 was $54.1 million compared to $38.9 million for the same period in 2020, an increase of $15.2 million which was mainly the result of higher development and regulatory costs in support of the advancement of pipeline product candidates. For the nine months ended September 30, 2021, R&D expense was $312.3 million compared to $98.1 million for the same period in 2020, an increase of $214.2 million which included the $136.0 million upfront license fee paid to Junshi Biosciences in 2021.

Selling, general and administrative (SG&A) expense for the three months ended September 30, 2021 was $39.9 million compared to $32.0 million for the three months ended September 30, 2020, an increase of $7.9 million which was primarily driven by increased commercialization expenses to support UDENYCA® sales. For the nine months ended September 30, 2021, SG&A expense was $119.7 million compared to $101.4 million for the same period in 2020, an increase of $18.3 million, which was primarily due to an increase of $10.7 million in stock-based and other compensation expense and an increase in UDENYCA® commercialization expenses.

Net loss for the third quarter of 2021 was $38.5 million, or $(0.49) per share on a diluted basis, compared to a net income of $27.9 million, or $0.33 per share on a diluted basis for the same period in 2020.

Non-GAAP net loss for the third quarter of 2021 was $26.6 million, or $(0.34) per share on a diluted basis, compared to non-GAAP net income of $39.7 million, or $0.47 per share on a diluted basis for the same period in 2020. See "Non-GAAP Financial Measures" below for a discussion on how Coherus calculates non-GAAP net (loss) income and a reconciliation to the most directly comparable GAAP measures.

Cash, cash equivalents and investments in marketable securities were $468.7 million as of September 30, 2021, compared to $454.4 million at June 30, 2021.

2021 FINANCIAL OUTLOOK

Excluding the upfront payment made to Junshi Biosciences in the first quarter, Coherus projects full year 2021 R&D and SG&A expenses in a range of $370 million to $400 million. R&D spending is focused on development, regulatory and other activities in preparation for the potential launch of toripalimab, as well as manufacturing-related and regulatory activities for CHS-1420 (Humira® biosimilar), development activities for CHS-305 (Avastin® biosimilar), and additional presentations of UDENYCA®. Increases in SG&A spending in 2021 are primarily driven by marketing activities and headcount to support UDENYCA® and the potential launches in 2022 of toripalimab and CHS-201 (Lucentis® biosimilar).

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 and the section titled "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 to be filed with the Securities & Exchange Commission on November 8, 2021.

Coherus is planning to host an analyst day event in January 2022.

Conference Call Information

When: Monday, November 8, 2021 starting at 5:00 p.m. ET

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

Conference ID: 1838568

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

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

About Coherus BioSciences

Coherus is a commercial stage biopharmaceutical company with the mission to increase access to cost-effective medicines that can have a major impact on patients' lives and to deliver significant savings to the health care system. Coherus' strategy is to build a leading immuno-oncology franchise funded with cash generated by its commercial biosimilar business. Coherus markets UDENYCA® (pegfilgrastim-cbqv) in the United States and through 2023 expects to launch toripalimab, an anti-PD-1 antibody, as well as biosimilars of Lucentis®, Humira®, and Avastin®, if approved.

For additional information, please visit www.coherus.com.

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, the potential for UDENYCA® net sales to continue to provide strong funding for Coherus' operations, investments in its pipeline programs and anticipated commercial launches of new products; Coherus' ability to submit a prior approval supplement to the UDENYCA® BLA on schedule during 2022; the potential approval of the CHS-201 biosimilar candidate to Lucentis® (ranibizumab) in August 2022 and Coherus' ability to launch the product, if approved; the potential approval of the toripalimab BLA for nasopharyngeal carcinoma in April 2022, and Coherus' ability to launch the product, if approved; the timing of a final PFS and additional interim overall survival analysis in the toripalimab clinical trial in non-small cell lung cancer; the potential for Coherus and Junshi Biosciences to file with the FDA for additional indications for toripalimab, including esophageal squamous cell carcinoma or lung cancer, and the timing of these BLA supplement filings; the timing of the FDA's approval decision for CHS-1420, a Humira® (adalimumab) biosimilar, and the risk that the product may not be approved on time, if at all; Coherus' ability to continue other CHS-1420 activities to advance toward a projected market entry in the United States on or after July 1, 2023; Coherus' ability to advance the CHS-305 biosimilar candidate to Avastin® (bevacizumab) in-licensed from Innovent toward an expected 351(k) BLA submission with the U.S. FDA in 2022, the risk that the product may not be approved on time, if at all, and Coherus' ability to launch the biosimilar candidate to Avastin® in the United States; the potential submission of additional applications for marketing authorization to the FDA in 2022; the timing of the analyst day event Coherus is planning for January 2022; and Coherus' ability to meet its R&D and SG&A expenses guidance for the full fiscal year 2021. 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; the risks and uncertainties of the regulatory approval process, including the timing of Coherus' regulatory filings; the risk that Coherus is unable to complete commercial transactions and other matters that could affect the availability or commercial potential of Coherus' biosimilar drug candidates; and the risks and uncertainties of possible patent litigation. All forward-looking statements contained in this press release speak only as of the date on which they were made. Coherus undertakes no obligation to update or revise any forward-looking statements. For a further description of the 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 three and nine months ended September 30, 2021, to be filed with the Securities and Exchange Commission on November 8, 2021 and its future periodic reports to be filed with the Securities and Exchange Commission. Our results for the quarter ended September 30, 2021 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,	
	2021	2020	2021	2020
Revenue:				
Net product revenue	$ 82,503	$ 113,551	$ 253,180	$ 365,405
Operating expenses:				
Cost of goods sold	21,280	9,000	45,487	25,994
Research and development	54,085	38,851	312,343	98,131
Selling, general and administrative	39,925	31,984	119,661	101,386
Total operating expenses	115,290	79,835	477,491	225,511
(Loss) Income from operations	(32,787)	33,716	(224,311)	139,894
Interest expense	(5,771)	(5,656)	(17,166)	(15,495)
Other income, net	30	56	102	548
Net (loss) income before income taxes	(38,528)	28,116	(241,375)	124,947
Income tax provision	—	183	—	2,411
Net (loss) income	$ (38,528)	$ 27,933	$ (241,375)	$ 122,536
Net (loss) income per share:				
Basic	$ (0.49)	$ 0.39	$ (3.22)	$ 1.72
Diluted	$ (0.49)	$ 0.33	$ (3.22)	$ 1.52
Weighted-average number of shares used in computing net (loss) income per share:				
Basic	79,013,240	71,649,350	74,984,811	71,138,973
Diluted	79,013,240	87,470,337	74,984,811	82,043,469

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

	September 30, 2021	December 31, 2020
Assets		
Cash and cash equivalents	$ 360,540	$ 541,158
Investments in marketable securities	108,167	—
Trade receivables, net	136,346	157,046
Inventory	83,940	92,189
Other assets	52,733	51,256
Total assets	$ 741,726	$ 841,649
Liabilities and Stockholders' Equity		
Accrued rebates, fees and reserves	$ 84,744	$ 81,529
Convertible notes due 2022*	80,978	79,885
Convertible notes due 2022 - related parties*	26,992	26,628
Convertible notes due 2026	223,971	223,029
Term loan - current portion	17,308	—
Term loan - non-current portion	57,924	74,481
Other liabilities	119,049	75,123
Total stockholders' equity	130,760	280,974
Total liabilities and stockholders' equity	$ 741,726	$ 841,649

* The Convertible notes due 2022 and the Convertible notes due 2022 - related parties were classified in current liabilities as of September 30, 2021 and in non-current liabilities as of December 31, 2020.

Coherus BioSciences, Inc.
Condensed Consolidated Cash Flow
(in thousands)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Cash, cash equivalents and restricted cash at beginning of the period	**$ 330,178**	**$ 225,057**	**$ 541,598**	**$ 177,908**
Net cash provided by operating activities	**$ 13,711**	**$ 47,353**	**$ 14,890**	**$ 121,021**
Purchases of investments in marketable securities	(31,449)	(41,981)	(171,779)	(273,845)
Proceeds from maturities of investments in marketable securities	47,700	63,000	62,700	63,000
Upfront and milestone based license fee payments*	—	(2,500)	(136,000)	(7,500)
Cash used in other investing activities	(261)	(2,112)	(821)	(6,112)
Net cash provided by (used in) investing activities	**$ 15,990**	**$ 16,407**	**$ (245,900)**	**$ (224,457)**
Proceeds from issuance of Convertible Notes due 2026, net of issuance costs	—	(674)	—	222,156
Purchase of capped call options related to convertible notes due 2026	—	—	—	(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	1,280	4,909	9,726	13,014
Proceeds from purchase under the employee stock purchase plan	—	—	1,985	2,557
Cash used in other financing activities	(179)	(147)	(2,222)	(1,124)
Net cash provided by financing activities	**$ 1,101**	**$ 4,088**	**$ 50,392**	**$ 218,433**
Net increase (decrease) in cash, cash equivalents and restricted cash	**$ 30,802**	**$ 67,848**	**$ (180,618)**	**$ 114,997**
Cash, cash equivalents and restricted cash at end of the period	**$ 360,980**	**$ 292,905**	**$ 360,980**	**$ 292,905**
Reconciliation of cash, cash equivalents, and restricted cash				
Cash and cash equivalents	$ 360,540	292,465	$ 360,540	292,465
Restricted cash balance	440	440	440	440
Cash, cash equivalents and restricted cash	**$ 360,980**	**$ 292,905**	**$ 360,980**	**$ 292,905**

* 2021 payments includes 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 (loss) income, and the related per share measures, stock-based compensation expense, upfront and milestone payments under the license agreements, costs related to termination of a research and development program as part of a strategic realignment of research and development resources toward other development programs and the related income tax effect of those non-GAAP adjustments. 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
GAAP net (loss) income	$ (38,528)	$ 27,933	$ (241,375)	$ 122,536
Adjustments:				
Stock-based compensation expense	11,939	9,308	40,418	28,287
Upfront and milestone based license fees*	—	2,500	136,000	7,500
Costs related to termination of CHS-2020 development program	—	—	11,503	—
Income tax effect of the above adjustments	—	(77)	—	(691)
Non-GAAP net (loss) income	$ (26,589)	$ 39,664	$ (53,454)	$ 157,632
GAAP net (loss) income per share, basic	$ (0.49)	$ 0.39	$ (3.22)	$ 1.72
GAAP net (loss) income per share, diluted	$ (0.49)	$ 0.33	$ (3.22)	$ 1.52
Non-GAAP net (loss) income per share, basic	$ (0.34)	$ 0.55	$ (0.71)	$ 2.22
Non-GAAP net (loss) income per share, diluted	$ (0.34)	$ 0.47	$ (0.71)	$ 1.93
Shares used in computing basic net (loss) income per share	79,013,240	71,649,350	74,984,811	71,138,973
Shares used in computing diluted net (loss) income per share	79,013,240	87,470,337	74,984,811	82,043,469

* 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
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