# 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 5, 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 August 5, 2021, Coherus BioSciences, Inc. issued a press release regarding its financial results for the second quarter ended June 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 August 5, 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: August 5, 2021

COHERUS BIOSCIENCES, INC.

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

**Coherus BioSciences Reports Second Quarter 2021 Financial Results and Immuno-oncology and Biosimilar Pipeline Progress**

*–1st line nasopharyngeal indication and 2nd/3rd line indications to be concurrently submitted 3Q 2021 in the toripalimab BLA –*

*– CHS-201 (Lucentis® biosimilar) BLA submitted to FDA –*

*–CHS-1420 (Humira® biosimilar) BLA review progressing with December target action date –*

*– Second quarter 2021 UDENYCA® net sales of $88 million –*

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

REDWOOD CITY, Calif., August 5, 2021 – Coherus BioSciences, Inc. ("Coherus" or the "Company", Nasdaq: CHRS), today reported financial results for the quarter ended June 30, 2021. The Company also provided a progress update on its PD-1 blocking antibody, toripalimab, its lead immuno-oncology candidate for the potential treatment of various solid tumors, as well as other late-stage pipeline product candidates including CHS-201, a biosimilar Lucentis® (ranibizumab), CHS-1420, a wholly owned biosimilar Humira® (adalimumab), and CHS-305, a biosimilar Avastin® (bevacizumab).

"With two biosimilar BLAs currently under FDA review and a toripalimab BLA submission expected to be completed soon, we are making strong progress toward our objective to diversify and grow our product portfolio," said Denny Lanfear, Coherus CEO. "We project that within one year we will have four approved products, including UDENYCA®, in the United States, and that in 2023 we will have five marketed products generating revenue to invest in our immuno-oncology business."

**SECOND QUARTER 2021 FINANCIAL HIGHLIGHTS**

- Net product revenue, consisting of net sales of UDENYCA® (pegfilgrastim-cbqv) was $88 million.
- GAAP net loss of $29.9 million was primarily driven by increased R&D and regulatory expenses to support the advancement of toripalimab and the biosimilar pipeline product candidates.
- Non-GAAP net loss was $27.3 million.
- At June 30, 2021, Coherus had cash, cash equivalents and marketable securities of $454.4 million.
- In April 2021, the Company received $50 million from Junshi Biosciences' acquisition of 2,491,988 shares of Coherus stock.

**PIPELINE HIGHLIGHTS**

***Coherus is planning an analyst day event in the fourth quarter of 2021***

**Toripalimab, a PD-1 blocking antibody product candidate, in collaboration with Junshi Biosciences:**

- Following a recent meeting with the United States Food and Drug Administration ("FDA"), Coherus' immuno-oncology partner, Junshi Biosciences, plans to submit the biologics license application ("BLA") for toripalimab in combination with chemotherapy for 1st line treatment of metastatic or recurrent nasopharyngeal carcinoma ("NPC") concurrently with toripalimab monotherapy in second or third line treatment of recurrent or metastatic NPC. Junshi Biosciences expects to complete the BLA submission for these indications later this quarter.
- Data from a Phase 3 clinical trial evaluating toripalimab for the treatment of non-small cell lung cancer will be presented in September at the World Conference on Lung Cancer.
- Data from a Phase 3 clinical trial evaluating toripalimab for the treatment of esophageal squamous cell carcinoma will be presented in September at the annual meeting of the European Society for Medical Oncology.

**CHS-201, a biosimilar Lucentis® (ranibizumab) product candidate in collaboration with Bioeq AG**:

- Bioeq AG recently submitted the CHS-201 BLA. Pending acceptance of the BLA by the FDA, Coherus anticipates a mid-2022 target action date for the BLA review.

**CHS-1420, a wholly owned biosimilar Humira® (adalimumab) product candidate**:

- The review of the CHS-1420 BLA is progressing with a target action date of December 2021. Coherus plans to launch CHS-1420 on or after July 1, 2023, if approved.

**CHS-305, a biosimilar Avastin® (bevacizumab) product candidate in collaboration with Innovent Biologics (Suzhou) Co. Ltd**:

- Coherus is conducting the three-way pharmacokinetic study to facilitate the potential CHS-305 BLA submission.

**SECOND QUARTER 2021 FINANCIAL RESULTS**

**Net product revenue**, consisting of net sales of UDENYCA®, was $87.6 million and $135.7 million during the three months ended June 30, 2021 and 2020, respectively, and $170.7 million and $251.9 million during the six months ended June 30, 2021 and 2020, respectively.

**Cost of goods sold (COGS)**, increased to $16.7 million in the second quarter of 2021 as compared to $10.1 million in second quarter of 2020. 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 the second quarter of 2021 is the first period with per unit acquisition costs fully reflected within COGS. 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 June 30, 2021 was $54.8 million compared to $26.2 million for the same period in 2020, an increase of $28.6 million. The increase was mainly due to higher development and regulatory costs in support of the advancement of toripalimab and the biosimilar pipeline product candidates. For the six months ended June 30, 2021, R&D expense was $258.3 million compared to $59.3 million for the same period in 2020, an increase of $199.0 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 June 30, 2021 was $40.3 million compared to $34.1 million for the three months ended June 30, 2020, an increase of $6.3 million which was primarily driven by increased UDENYCA commercialization expenses including an increase in sales personnel and travel. For the six months ended June 30, 2021, SG&A expense was $79.7 million compared to $69.4 million for the same period in 2020, an increase of $10.3 million, which was primarily due to an increase of $5.8 million in stock-based compensation expense and a $4.1 million increase in UDENYCA® commercialization expenses.

**Net loss** for the second quarter of 2021 was $29.9 million, or $0.40 per share on a diluted basis, compared to a net income of $59.0 million, or $0.70 per share on a diluted basis for the same period in 2020.

**Non-GAAP net loss** for the second quarter of 2021 was $27.3 million, or $0.36 per share on a diluted basis, compared to non-GAAP net income of $68.3 million, or $0.81 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 $454.4 million as of June 30, 2021, compared to $399.5 million at March 31, 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, development activities for CHS-305, 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 June 30, 2021 to be filed with the Securities & Exchange Commission on August 5, 2021.

**Conference Call Information**

When: Thursday, August 5, 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: 9146617

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, Coherus’ ability to maintain UDENYCA® market share and position as leading pegfilgrastim biosimilar in the United States; Coherus’ ability to generate increased revenue from its UDENYCA® business with anticipated market share growth, assuming treatment patterns begin to normalize as the general population is vaccinated against COVID-19; Coherus’ ability to expand its addressable market opportunity and to lay the foundation for long-term growth across its biosimilar product portfolio and immuno-oncology product pipeline; Coherus’ ability to advance the Company’s oncology biosimilar candidate to Avastin® (bevacizumab) in-licensed from Innovent toward an expected 351(k) BLA submission with the U.S. FDA in 2021, the timing of required interactions with the FDA; the risk that the product may not be approved on time, if at all; Coherus’ ability to launch Innovent’s biosimilar candidate to Avastin® in the United States; Coherus’ ability to facilitate Bioeq’s resubmission of a BLA with the FDA for the ophthalmology biosimilar candidate to Lucentis® (ranibizumab) in mid-2021 and Coherus’ ability to launch the product, if approved; Coherus’ ability to facilitate Junshi Biosciences’ submission of a toripalimab BLA with the FDA for nasopharyngeal carcinoma in 2021 and for additional indications, including lung cancer, over the next three years; 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; 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 six months ended June 30, 2021, to be filed with the Securities and Exchange Commission on August 5, 2021 and its future periodic reports to be filed with the Securities and Exchange Commission. Our results for the quarter ended June 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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2021** | **2020** | **2021** | **2020** |
| Revenue: | | | | |
| Net product revenue | $ 87,643 | $ 135,674 | $ 170,677 | $ 251,854 |
| Operating expenses: | | | | |
| Cost of goods sold | 16,696 | 10,139 | 24,207 | 16,994 |
| Research and development | 54,766 | 26,173 | 258,258 | 59,280 |
| Selling, general and administrative | 40,345 | 34,052 | 79,736 | 69,402 |
| Total operating expenses | 111,807 | 70,364 | 362,201 | 145,676 |
| (Loss) Income from operations | (24,164) | 65,310 | (191,524) | 106,178 |
| Interest expense | (5,747) | (5,408) | (11,395) | (9,839) |
| Other income, net | 11 | 423 | 72 | 491 |
| Net (loss) income before income taxes | (29,900) | 60,325 | (202,847) | 96,830 |
| Income tax provision | — | 1,294 | — | 2,227 |
| Net (loss) income | $ (29,900) | $ 59,031 | $ (202,847) | $ 94,603 |
| | | | | |
| Net (loss) income per share: | | | | |
| Basic | $ (0.40) | $ 0.83 | $ (2.73) | $ 1.33 |
| Diluted | $ (0.40) | $ 0.70 | $ (2.73) | $ 1.20 |
| | | | | |
| Weighted-average number of shares used in computing net (loss) income per share: | | | | |
| Basic | 75,559,697 | 71,099,773 | 74,203,858 | 70,880,979 |
| Diluted | 75,559,697 | 88,660,280 | 74,203,858 | 83,775,353 |

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

| | June 30, 2021 | December 31, 2020 |
|---|---|---|
| **Assets** | | |
| Cash and cash equivalents | $ 329,738 | $ 541,158 |
| Investments in marketable securities | 124,683 | — |
| Trade receivables, net | 141,825 | 157,046 |
| Inventory | 96,081 | 92,189 |
| Other assets | 47,215 | 51,256 |
| Total assets | $ 739,542 | $ 841,649 |
| **Liabilities and Stockholders' Equity** | | |
| Accrued rebates, fees and reserves | $ 83,758 | $ 81,529 |
| Convertible notes due 2022* | 80,605 | 79,885 |
| Convertible notes due 2022 - related parties* | 26,868 | 26,628 |
| Convertible notes due 2026 | 223,655 | 223,029 |
| Term loan - current portion | 11,538 | — |
| Term loan-non - current portion | 63,420 | 74,481 |
| Other liabilities | 93,478 | 75,123 |
| Total stockholders' equity | 156,220 | 280,974 |
| Total liabilities and stockholders' equity | $ 739,542 | $ 841,649 |

* The Convertible notes due 2022 and the Convertible notes due 2022 - related parties were classified in current liabilities as of June 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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2021** | **2020** | **2021** | **2020** |
| **Cash, cash equivalents and restricted cash at beginning of the period** | **$ 259,929** | **$ 193,692** | **$ 541,598** | **$ 177,908** |
| **Net cash (used in) provided by operating activities** | **$ (188)** | **$ 60,191** | **$ 1,179** | **$ 73,668** |
| Purchases of investments in marketable securities | — | (231,864) | (140,330) | (231,864) |
| Proceeds from maturities of investments in marketable securities | 15,000 | — | 15,000 | — |
| Upfront license fee payments* | 9,000 | (5,000) | (136,000) | (5,000) |
| Cash used in other investing activities | (415) | (2,384) | (560) | (4,000) |
| **Net cash provided by (used in) investing activities** | **$ 23,585** | **$ (239,248)** | **$ (261,890)** | **$ (240,864)** |
| Proceeds from issuance of Convertible Notes due 2026, net of issuance costs | — | 222,830 | — | 222,830 |
| Purchase of capped call options related to convertible notes due 2026 | — | (18,170) | — | (18,170) |
| Proceeds from issuance of common stock to Junshi Biosciences, net of issuance costs | 40,903 | — | 40,903 | — |
| Proceeds from issuance of common stock upon exercise of stock options | 4,117 | 3,302 | 8,446 | 8,105 |
| Proceeds from purchase under the employee stock purchase plan | 1,985 | 2,557 | 1,985 | 2,557 |
| Cash used in other financing activities | (153) | (97) | (2,043) | (977) |
| **Net cash provided by financing activities** | **$ 46,852** | **$ 210,422** | **$ 49,291** | **$ 214,345** |
| **Net increase in cash, cash equivalents and restricted cash** | **$ 70,249** | **$ 31,365** | **$ (211,420)** | **$ 47,149** |
| **Cash, cash equivalents and restricted cash at end of the period** | **$ 330,178** | **$ 225,057** | **$ 330,178** | **$ 225,057** |
| **Reconciliation of cash, cash equivalents, and restricted cash** | | | | |
| Cash and cash equivalents | $ 329,738 | 224,617 | $ 329,738 | 224,617 |
| Restricted cash balance | 440 | 440 | 440 | 440 |
| **Cash, cash equivalents and restricted cash** | **$ 330,178** | **$ 225,057** | **$ 330,178** | **$ 225,057** |

* 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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| GAAP net (loss) income | $ (29,900) | $ 59,031 | $ (202,847) | $ 94,603 |
| Adjustments: | | | | |
| Stock-based compensation expense | 11,595 | 9,425 | 28,479 | 18,980 |
| Upfront license fees* | (9,000) | — | 136,000 | 5,000 |
| Costs related to termination of CHS-2020 development program | — | — | 11,503 | — |
| Income tax effect of the above adjustments | — | (202) | — | (552) |
| Non-GAAP net (loss) income | $ (27,305) | $ 68,254 | $ (26,865) | $ 118,031 |
| | | | | |
| GAAP net (loss) income per share, basic | $ (0.40) | $ 0.83 | $ (2.73) | $ 1.33 |
| GAAP net (loss) income per share, diluted | $ (0.40) | $ 0.70 | $ (2.73) | $ 1.20 |
| Non-GAAP net (loss) income per share, basic | $ (0.36) | $ 0.96 | $ (0.36) | $ 1.67 |
| Non-GAAP net (loss) income per share, diluted | $ (0.36) | $ 0.81 | $ (0.36) | $ 1.48 |
| Shares used in computing basic net (loss) income per share | 75,559,697 | 71,099,773 | 74,203,858 | 70,880,979 |
| Shares used in computing diluted net (loss) income per share | 75,559,697 | 88,660,280 | 74,203,858 | 83,775,353 |

* 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
+1 (650) 395-0152