



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

Aug 5, 2021

*– 1<sup>st</sup> line nasopharyngeal indication and 2<sup>nd</sup>/3<sup>rd</sup> 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., Aug. 05, 2021 (GLOBE NEWSWIRE) -- 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 1<sup>st</sup> 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](http://www.coherus.com).

UDENYCA® is a trademark of Coherus BioSciences, Inc.  
Avastin® and Lucentis® are registered trademarks of Genentech, Inc.  
Humira® is a registered trademark of AbbVie Inc.

## Forward-Looking Statements

Except for the historical information contained herein, the matters set forth in this press release are forward-looking statements within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, 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 Inovvent 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 Inovvent’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)*

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2021</b>	<b>2020</b>	<b>2021</b>	<b>2020</b>
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	<u>\$ (29,900)</u>	<u>\$ 59,031</u>	<u>\$ (202,847)</u>	<u>\$ 94,603</u>
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)*

	<b>June 30, 2021</b>	<b>December 31, 2020</b>
<b>Assets</b>		
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	<u>\$ 739,542</u>	<u>\$ 841,649</u>
<b>Liabilities and Stockholders' Equity</b>		
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	<u>156,220</u>	<u>280,974</u>
Total liabilities and stockholders' equity	<u>\$ 739,542</u>	<u>\$ 841,649</u>

\* 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
<b>Cash, cash equivalents and restricted cash at beginning of the period</b>	<b>\$ 259,929</b>	<b>\$ 193,692</b>	<b>\$ 541,598</b>	<b>\$ 177,908</b>
<b>Net cash (used in) provided by operating activities</b>	<b>\$ (188)</b>	<b>\$ 60,191</b>	<b>\$ 1,179</b>	<b>\$ 73,668</b>
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)
<b>Net cash provided by (used in) investing activities</b>	<b>\$ 23,585</b>	<b>\$ (239,248)</b>	<b>\$ (261,890)</b>	<b>\$ (240,864)</b>
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)
<b>Net cash provided by financing activities</b>	<b>\$ 46,852</b>	<b>\$ 210,422</b>	<b>\$ 49,291</b>	<b>\$ 214,345</b>
<b>Net increase in cash, cash equivalents and restricted cash</b>	<b>\$ 70,249</b>	<b>\$ 31,365</b>	<b>\$ (211,420)</b>	<b>\$ 47,149</b>
<b>Cash, cash equivalents and restricted cash at end of the period</b>	<b>\$ 330,178</b>	<b>\$ 225,057</b>	<b>\$ 330,178</b>	<b>\$ 225,057</b>
<b>Reconciliation of cash, cash equivalents, and restricted cash</b>				
Cash and cash equivalents	\$ 329,738	224,617	\$ 329,738	224,617
Restricted cash balance	440	440	440	440
<b>Cash, cash equivalents and restricted cash</b>	<b>\$ 330,178</b>	<b>\$ 225,057</b>	<b>\$ 330,178</b>	<b>\$ 225,057</b>

\* 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.

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Source: Coherus BioSciences, Inc.