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

May 6, 2021

– Junshi Biosciences transaction is followed by rapid toripalimab progress including initiation of first BLA submission to the U.S. FDA, positive interim analysis in pivotal esophageal cancer trial, and selection for ASCO plenary session –

–Toripalimab is one of four additional Coherus product candidates projected for approval in the United States over the next two years –

– First quarter UDENYCA® net sales of $83 million –

– Conference call today at 4:30 p.m. ET –

REDWOOD CITY, Calif., May 06, 2021 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. ("Coherus" or the "Company", Nasdaq: CHRS), today reported financial results for the quarter ended March 31, 2021. The Company also provided a progress update on its anti-PD-1 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).

"Over the next two years, we project four additional Coherus product candidates will be approved in the United States, including three biosimilars and our anti-PD-1 antibody, toripalimab," said Denny Lanfear, CEO of Coherus. "We believe this diversified product portfolio has the potential to generate significant revenue growth and fuel our investments in novel immuno-oncology therapies with the potential to improve care and outcomes for cancer patients."

"With significant new clinical data and the first U.S. BLA submission underway, toripalimab is already exceeding our expectations," Lanfear continued. "During a rigorous multi-year evaluation of the global checkpoint inhibitor landscape, we defined the preclinical and clinical properties required for our investment in a PD-1 blocking antibody. Toripalimab's demonstrated potency, unique molecular properties and advanced pivotal clinical development program in numerous cancer types surpassed our stringent criteria. It is gratifying to see the accumulating external validation for toripalimab including selection for ASCO's plenary session, Breakthrough Therapy Designation from the FDA for nasopharyngeal carcinoma, and the additional recent approvals in China. We believe these developments and the external interest we have already received to evaluate potential toripalimab combinations positions this product candidate as a significant potential growth driver for Coherus for many years."

FIRST QUARTER 2021 FINANCIAL HIGHLIGHTS

- GAAP net loss of $173 million for the first quarter of 2021 was primarily driven by the $145 million upfront payment to Junshi Biosciences for U.S. and Canada rights to the anti-PD-1 antibody toripalimab and one-time charges associated with the termination of the CHS-2020 biosimilar program as part of the strategic realignment of research and development resources toward immuno-oncology.
- Non-GAAP net income for the first quarter of 2021 was $0.4 million, or $0.01 per share.
- Cash flow from operations was $1.4 million.
- Net product revenue, consisting of net sales of UDENYCA® (pegfilgrastim-cbqv) was $83 million for the first quarter of 2021. With approximately 20% share of the overall pegfilgrastim market, UDENYCA maintains its position as the leading pegfilgrastim biosimilar.
- Coherus had cash, cash equivalents and marketable securities of $400 million at March 31, 2021.
- In April 2021, the Company received $50 million from Junshi Biosciences' acquisition of 2,491,988 shares of Coherus stock at a price per share of $20.06.

PIPELINE HIGHLIGHTS

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

- Junshi Biosciences initiated the rolling submission of the biologics license application ("BLA") with the U.S. Food and Drug Administration ("FDA") for toripalimab for the treatment of recurrent or metastatic nasopharyngeal carcinoma ("NPC"). The FDA has granted toripalimab Breakthrough Therapy Designation for this indication. The BLA submission is expected to be completed mid-year 2021, with potential approval in the first half of 2022.
- Results of JUPITER-02, a randomized, double-blind, placebo-controlled, multi-center, Phase 3 clinical trial evaluating toripalimab for first-line NPC, will be featured in the plenary session and in the official press program of the 2021 ASCO Annual Meeting in early June.
- In JUPITER-06, a randomized, double-blind, placebo-controlled, multi-center, Phase 3 clinical trial with 514 patients enrolled, toripalimab in combination with paclitaxel/cisplatin as first-line treatment for patients with advanced esophageal squamous cell carcinoma ("ESCC") achieved the pre-specified primary endpoints of progression free survival ("PFS") and overall survival ("OS") at the interim analysis. Data from the study are expected later in 2021.
- Coherus and Junshi Biosciences plan to file additional toripalimab BLA supplements with the FDA over the next three years for multiple rare and highly prevalent tumor types, including non-small cell lung cancer ("NSCLC"). An ongoing Phase 3 clinical study of toripalimab in combination with standard chemotherapy as the first-line treatment of patients with advanced NSCLC reached its primary endpoint of PFS at the interim analysis in December 2020. Top-line results are

expected later in 2021.

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

- Bioeq AG expects to file the CHS-201 BLA mid-year 2021, following a supportive pre-BLA meeting with the FDA earlier in the first quarter of 2021. Bioeq reviewed new manufacturing data with the FDA, which the agency requested last year, as well as other elements of the BLA filing.

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

- The FDA accepted for review the BLA for CHS-1420 and assigned a target action date in December 2021. The FDA has completed the on-site portion of the pre-approval drug substance CMC inspection, with no Form 483s being issued. 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 initiated the three-way pharmacokinetic study to facilitate the potential BLA submission. Recruitment into the study has been slower than expected as a result of the COVID-19 pandemic, and Coherus now expects data from this study around year end 2021.

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

FIRST QUARTER 2021 FINANCIAL RESULTS

Net product revenue, consisting of net sales of UDENYCA®, was $83 million for the first quarter of 2021. Net Product revenue declined in comparison to the prior quarter and the first quarter of 2020 due to an increase in discounts and allowances, as well as a reduction in ex-factory units sold due to seasonal fluctuations in wholesale inventory levels in the fourth quarter of 2020 and the first quarter of 2021.

Research and development (R&D) expenses for the first quarter of 2021 were $203.5 million, compared to $33.1 million for the same period in 2020. The increase was mainly due to the $145 million upfront payment to Junshi Biosciences upon the closing of the collaboration agreement in March, the $11.5 million charge related to the termination of the CHS-2020 program, and higher development costs in support of the advancement of toripalimab and the biosimilar pipeline product candidates.

Selling, general and administrative (SG&A) expenses were $39.4 million in the first quarter of 2021 as compared to $35.4 million in the year ago quarter. The increase was primarily driven by an increase in stock based compensation expense.

Net loss for the first quarter of 2021 was $172.9 million, or $2.37 per share on a diluted basis, compared to a net income of $35.6 million, or $0.48 per share on a diluted basis for the same period in 2020.

Non-GAAP net income for the first quarter of 2021 was $0.4 million, or $0.01 per share on a diluted basis, compared to non-GAAP net income of $49.8 million, or $0.67 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 income and a reconciliation to the most directly comparable GAAP measures.

Cash, cash equivalents and investments in marketable securities were $399.5 million as of March 31, 2021, compared to $541.2 million at year end 2020. Subsequent to quarter end, Coherus received $50 million from Junshi Biosciences’ acquisition of 2,491,988 shares at a price per share of $20.06.

2021 FINANCIAL OUTLOOK

Coherus expects UDENYCA® revenue and market penetration to rise in the second half of 2021, assuming the COVID-19 pandemic recedes and treatment patterns normalize, and subject to pricing trends in the overall pegfilgrastim market.

Excluding the $145 million upfront payment made to Junshi Biosciences in the first quarter, Coherus projects full year R&D and SG&A expenses in a range of $370 million to $400 million. External R&D spending is focused on manufacturing-related activities in preparation for the potential launch of toripalimab and CHS-1420, if approved, and development activities for CHS-305 and for 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 March 31, 2021 to be filed with the Securities & Exchange Commission on May 6, 2021.

Conference Call Information

When: Thursday, May 6, 2021 starting at 4:30 p.m. ET

Dial-in: (800) 446-2782 (Toll-Free U.S. and Canada) or (847) 413-3235 (International)

Conference ID: 50149707

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

Please join the conference call at least 10 minutes early to register. The webcast will be archived on the Coherus website.

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.

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 Innovent toward an expected 351(k) BLA submission with the U.S. FDA in 2021, depending on the outcome of the three-way PK study, the timing of required interactions with the FDA; 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 months ended March 31, 2021, to be filed with the Securities and Exchange Commission on May 6, 2021 and its future periodic reports to be filed with the Securities and Exchange Commission. Our results for the quarter ended March 31, 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 March 31,	
	2021	**2020**
Revenue:		
Net product revenue	$ 83,034	$ 116,180
Operating expenses:		
Cost of goods sold	7,511	6,855
Research and development	203,492	33,107
Selling, general and administrative	39,391	35,350
Total operating expenses	250,394	75,312
(Loss) Income from operations	(167,360)	40,868
Interest expense	(5,648)	(4,431)
Other income, net	61	68
Net (loss) income before income taxes	(172,947)	36,505
Income tax provision	—	933
Net (loss) income	$ (172,947)	$ 35,572
Net (loss) income per share:		
Basic	$ (2.37)	$ 0.50
Diluted	$ (2.37)	$ 0.48
Weighted-average number of shares used in computing net (loss) income per share:		
Basic	72,832,953	70,662,185
Diluted	72,832,953	74,416,554

Coherus BioSciences, Inc.
Condensed Consolidated Balance Sheets

(in thousands)
(unaudited)

	March 31, 2021	December 31, 2020
Assets		
Cash and cash equivalents	$ 259,489	$ 541,158
Investments in marketable securities	140,014	-
Trade receivables, net	140,410	157,046
Inventory	103,678	92,189
Other assets	49,712	51,256
Total assets	$ 693,303	$ 841,649
Liabilities and Stockholders' Equity		
Accrued rebates, fees and reserve	$ 78,202	$ 81,529
Convertible notes due 2022*	80,240	79,885
Convertible notes due 2022 - related parties*	26,747	26,628
Convertible notes due 2026	223,341	223,029
Term loan	74,696	74,481
Other liabilities	82,406	75,123
Total stockholders' equity	127,671	280,974
Total liabilities and stockholders' equity	$ 693,303	$ 841,649

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

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

	Three Months Ended March 31,	
	2021	2020
Cash, cash equivalents and restricted cash at beginning of the period	**$ 541,598**	**$ 177,908**
Net cash provided by operating activities	**$ 1,367**	**$ 13,477**
Purchases of investments in marketable securities	(140,330)	—
Upfront license fee payment to Junshi Biosciences	(145,000)	—
Purchases of property and equipment and other investing activities	(145)	(1,616)
Net cash used in investing activities	**$ (285,475)**	**$ (1,616)**
Proceeds from issuance of common stock upon exercise of stock options	4,329	4,803
Taxes paid related to net share settlement of RSUs	(1,730)	(880)
Other immaterial financing activities	(160)	—
Net cash provided by financing activities	**$ 2,439**	**$ 3,923**
Net (decrease) increase in cash, cash equivalents and restricted cash	**$ (281,669)**	**$ 15,784**
Cash, cash equivalents and restricted cash at end of the period	**$ 259,929**	**$ 193,692**
Reconciliation of cash, cash equivalents, and restricted cash		
Cash and cash equivalents	$ 259,489	$ 193,252
Restricted cash – non-current	440	440
Cash, cash equivalents and restricted cash	$ 259,929	$ 193,692

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

	Three Months Ended March 31,	
	2021	**2020**
GAAP net (loss) income	$ (172,947)	$ 35,572
Adjustments:		
Stock based compensation expense	16,884	9,555
Upfront license fees expense	145,000	5,000
Costs related to termination of CHS-2020 development program	11,503	—
Income tax effect of the above adjustments	(24)	(362)
Non-GAAP net income	$ 416	$ 49,765
GAAP net (loss) income per share, basic	$ (2.37)	$ 0.50
GAAP net (loss) income per share, diluted	$ (2.37)	$ 0.48
Non-GAAP net income per share, basic	$ 0.01	$ 0.70
Non-GAAP net income per share, diluted	$ 0.01	$ 0.67

Contact
McDavid Stilwell
Chief Financial Officer
Coherus BioSciences, Inc.
IR@coherus.com
+1 (650) 395-0152

Source: Coherus BioSciences, Inc.