Coherus BioSciences Reports Fourth Quarter and Full Year 2020 Financial Results

- Product revenues of $476 million for full year 2020, $110 million for the fourth quarter of 2020 -
- Expanding late-stage opportunities with Junshi Biosciences immuno-oncology collaboration with first BLA filing expected this year -
- Pipeline progress with CHS-1420 (adalimumab biosimilar) BLA accepted by FDA and FYB201 (ranibizumab biosimilar) BLA on track for mid-year filing -
- Conference call and webcast today at 4:30 p.m. ET -

REDWOOD CITY, Calif., Feb. 24, 2021 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. ("Coherus" or the "Company", Nasdaq: CHRS), today reviewed recent corporate events and reported financial results for the quarter and full year ended December 31, 2020.

UDENYCA® (pegfilgrastim-cbqv) delivered strong results in 2020:

- $476 million in net sales for the full year; $110 million for the fourth quarter.
- With excellent commercial execution in the face of COVID-19 headwinds, maintained position as leading pegfilgrastim biosimilar in the United States with 21% share of the overall pegfilgrastim market and nearly 50% share of the pre-filled syringe segment.

Financial strength to execute on our immuno-oncology and biosimilar pipeline and commercial plans:

- Cash flow from operating activities was $154 million for 2020 and $33 million for the fourth quarter of 2020.
- Coherus had cash and cash equivalents of $541 million at December 31, 2020.
- Net income was $132 million for 2020, or $1.62 per share on a diluted basis, and for the fourth quarter of 2020 was $10 million, or $0.12 per share on a diluted basis.

"We are very pleased with the strong performance of UDENYCA® in the face of challenging COVID-19 conditions in 2020 and with the recent progress of our biosimilar pipeline candidates," said Denny Lanfear, Chief Executive Officer of Coherus. "With our recently announced collaboration with Junshi Biosciences, we are building a focused immuno-oncology franchise atop the strong foundation of UDENYCA® and our late-stage Lucentis®, Avastin® and Humira® biosimilar candidates. As our commercial biosimilar portfolio expands, we expect to generate strong cash flows to leverage into commercialization of toripalimab, if approved, as well as development of PD-1 combination therapies to drive longer-term growth."

Pipeline Progress and Recent Corporate Highlights

- **Immuno-oncology collaboration with Junshi Biosciences**: In February, Coherus announced a collaboration with Junshi Biosciences for the development and commercialization of Junshi Biosciences' anti-PD-1 antibody, toripalimab, in the United States and Canada. Upon satisfaction of closing conditions, which is expected to occur in the first quarter 2021, Coherus and Junshi Biosciences will co-develop toripalimab, and Coherus will be responsible for all commercial activities in the United States and Canada.
  - The U.S. Food and Drug Administration ("FDA") has granted breakthrough therapy designation to toripalimab for third-line nasopharyngeal carcinoma ("NPC"), and Coherus expects the first toripalimab biologics license application ("BLA") to be filed with the FDA for this indication in 2021. On February 20, 2021, Junshi Biosciences announced the approval in China of toripalimab for the treatment of patients with recurrent or metastatic NPC after failure of at least two lines of prior systemic therapy.
  - 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").

- **FYB201, a biosimilar Lucentis® (ranibizumab) product candidate in collaboration with Bioeq AG**: Bioeq expects to file the FYB201 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. Coherus plans to launch CHS-1420 on or after July 1, 2023, if approved.

- **IBI-305, a biosimilar Avastin® (bevacizumab) product candidate in collaboration with Innovent Biologics (Suzhou) Co. Ltd**: Earlier in the first quarter of 2021, Coherus initiated the three-way pharmacokinetic study required prior to potential BLA submission later this year.

Fourth Quarter and Full Year 2020 Financial Results

Net product revenue, consisting of net sales of UDENYCA®, was $110.4 million for the fourth quarter of 2020 compared to $123.9 million for the same period in 2019. The decline was primarily due to an increase in discounts and allowances incurred, which was partially offset by an increase in the number of units of UDENYCA® sold. Net product revenue for 2020 was $475.8 million compared to $356.1 million for 2019, an increase of $119.7 million. The increase was primarily due to an increase in the number of units of UDENYCA® sold, which was partially offset by an increase in discounts and allowances incurred during the year ended December 31, 2020.

Research and development (R&D) expenses for the fourth quarter of 2020 were $44.6 million, compared to $34.9 million for the same period in 2019. The increase was mainly due to increased clinical development activities as well as payments for certain negotiation rights for pipeline development. R&D expense for 2020 was $142.8 million compared to $94.2 million for 2019, an increase of $48.6 million. The increase was primarily due to costs incurred in support of the BLA submission for CHS-1420 and for development activities related to other biosimilar product candidates.

Selling, general and administrative (SG&A) expenses were relatively unchanged quarter-over-quarter and year-over-year. SG&A expenses for the fourth quarter of 2020 were $37.7 million, compared to $36.1 million for the same period in 2019. SG&A expenses for 2020 were $139.1 million, compared to $137.0 million for 2019.

Cash and cash equivalents were $541.2 million as of December 31, 2020, compared to $177.7 million as of December 31, 2019. During 2020, Coherus generated $154.1 million in operating cash flow, used $14.4 million in investing activities, including $7.5 million in upfront and milestone payments to collaborators, and received net cash proceeds of $223.9 million from financing activities related to the issuance of convertible notes due in 2026, less issuance costs and the purchase of related capped call options, as well as proceeds from the exercise of stock options and from purchases under the stock purchase plan.

Net income for the fourth quarter of 2020 was $9.7 million, or $0.12 per share on a diluted basis, compared to a net income of $39.2 million, or $0.53 per share on a diluted basis for the same period in 2019. Net income for 2020 was $132.2 million, or $1.62 per share on a diluted basis, compared to a net income of $89.8 million, or $1.23 per share on a diluted basis for 2019.

Non-GAAP net income for the fourth quarter of 2020 was $18.6 million, or $0.23 per share on a diluted basis, compared to non-GAAP income of $56.7 million, or $0.75 per share on a diluted basis for the same period in 2019. Non-GAAP net income for 2020 was $176.7 million, or $2.16 per share on a diluted basis, compared to non-GAAP income of $133.1 million, or $1.82 per share on a diluted basis for 2019. 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.

2021 Guidance

Coherus projects lower UDENYCA® net sales revenue in 2021 compared to 2020. Starting from a seasonally low first quarter impacted by customer buying patterns and COVID-19, Coherus expects UDENYCA® revenue and market share to rise over the remainder of the year, assuming treatment patterns normalize as the general population is vaccinated against COVID-19.

Excluding upfront, milestone and development expenses related to the recently announced collaboration with Junshi Biosciences, which is expected to close in the first quarter of 2021, Coherus projects R&D and SG&A expenses combined will increase in 2021 to a range of $310 million to $350 million, with external R&D spending focused on manufacturing-related activities in preparation for the potential launch of CHS-1420, if approved, and development activities for IBI-305 and for additional presentations of UDENYCA®.

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: Wednesday, February 24, 2021 starting at 4:30 p.m. ET
Dial-in: (844) 452-6826 (toll free) or (765) 507-2587 (International)
Conference ID: 3770488
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.

Fourth quarter and full year 2019 financial results are posted on the Coherus website at https://investors.coherus.com/.

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.

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, 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; the risk that Coherus and Junshi Bioscience are unable to obtain regulatory clearance to close the collaboration; 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, 2020, filed with the Securities and Exchange Commission on November 5, 2020 and its future periodic reports to be filed with the Securities and Exchange Commission, including Coherus' Annual Report on Form 10-K for the year ended December 31, 2020, which the Company expects to file on February 25, 2021. Our results for the quarter and fiscal year ended December 31, 2020 are not necessarily indicative of our operating results for any future periods.

UDENYCA® is a trademark of Coherus BioSciences, Inc.

Neulasta® and Onpro® are registered trademarks of Amgen Inc.
Avastin® and Lucentis® are registered trademarks of Genentech, Inc.
Humira® is a registered trademark of AbbVie Inc.

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,	
	2020	**2019**	**2020**	**2019**
Revenue:				
Net product revenue	$ 110,419	$ 123,856	$ 475,824	$ 356,071
Operating expenses:				
Cost of goods sold	11,673	7,805	37,667	17,078
Research and development	44,628	34,948	142,759	94,188
Selling, general and administrative	37,693	36,070	139,079	137,037
Total operating expenses	93,994	78,823	319,505	248,303
Income from operations	16,425	45,033	156,319	107,768
Interest expense	(5,671)	(4,483)	(21,166)	(17,601)
Other income, net	6	721	554	2,608
Net income before income taxes	10,760	41,271	135,707	92,775
Income tax provision	1,052	2,044	3,463	2,942
Net income	$ 9,708	$ 39,227	$ 132,244	$ 89,833
Net income per share:				
Basic	$ 0.13	$ 0.56	$ 1.85	$ 1.29
Diluted	$ 0.12	$ 0.53	$ 1.62	$ 1.23
Weighted-average number of shares used in computing net income per share:				
Basic	72,223,970	70,208,351	71,411,705	69,679,916
Diluted	87,713,218	78,360,388	83,491,898	73,185,943

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

	December 31, 2020	December 31, 2019
Assets		
Cash and cash equivalents	$ 541,158	$ 177,668
Trade receivables, net	157,046	141,992
Inventory	92,189	55,071
Other assets	51,256	34,196
Total assets	$ 841,649	$ 408,927
Liabilities and Stockholders' Equity		
Accrued rebates, fees and reserve	$ 81,529	$ 51,120
Convertible notes due 2022	79,885	78,542
Convertible notes due 2022 - related parties	26,628	26,181
Convertible notes due 2026	223,029	—
Term loan	74,481	73,663
Other liabilities	75,123	74,207
Total stockholders' equity	280,974	105,214
Total liabilities and stockholders' equity	$ 841,649	$ 408,927

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

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Cash, cash equivalents and restricted cash at beginning of the period	**$ 292,905**	**$ 165,166**	**$ 177,908**	**$ 73,191**
Net cash provided by operating activities	**$ 33,124**	**$ 17,710**	**$ 154,145**	**$ 28,355**
Purchases of investments in marketable securities	—	—	(273,845)	(20,235)
Proceeds from maturities of investments in marketable securities	211,000	5,400	274,000	20,400
Upfront and milestone based license fee payments	—	(11,075)	(7,500)	(11,075)
Purchases of property and equipment and other investing activities	(944)	(387)	(7,056)	(1,822)
Net cash provided by (used in) investing activities	**$ 210,056**	**$ (6,062)**	**$ (14,401)**	**$ (12,732)**
Proceeds related to issuance of Convertible Notes due 2026, net of issuance costs	—	—	222,156	—
Purchase of capped call options related to convertible notes due 2026	—	—	(18,170)	—
Proceeds related to the term loan, net of issuance costs	—	—	—	72,955
Proceeds from common stock offering, net of underwriters discounts, commissions and offering costs	—	—	—	8,153
Proceeds from issuance of common stock upon exercise of stock options	4,414	374	17,428	5,558
Proceeds from purchase under the employee stock purchase plan	1,243	1,641	3,800	3,519
Principal payments for finance lease obligations and other financing activities	(144)	(815)	(1,268)	(815)
Net cash provided by financing activities	**$ 5,513**	**$ 1,200**	**$ 223,946**	**$ 89,370**
Effect of exchange rate changes on cash	—	(106)	—	(276)
Net increase in cash, cash equivalents and restricted cash	**$ 248,693**	**$ 12,742**	**$ 363,690**	**$ 104,717**
Cash, cash equivalents and restricted cash at end of the period	**$ 541,598**	**$ 177,908**	**$ 541,598**	**$ 177,908**
Reconciliation of cash, cash equivalents, and restricted cash				
Cash and cash equivalents	$ 541,158	$ 177,668	$ 541,158	$ 177,668
Restricted cash – non-current	440	240	440	240
Cash, cash equivalents and restricted cash	$ 541,598	$ 177,908	$ 541,598	$ 177,908

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 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 Income to Non-GAAP Net Income
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
GAAP net income	$ 9,708	$ 39,227	$ 132,244	$ 89,833
Adjustments:				
Stock based compensation expense	9,873	7,272	38,160	33,591
Upfront and milestone based license fee payments	—	11,075	7,500	11,075
Income tax effect of the above adjustments	(965)	(909)	(1,165)	(1,416)
Non-GAAP net income	$ 18,616	$ 56,665	$ 176,739	$ 133,083
GAAP net income per share, basic	$ 0.13	$ 0.56	$ 1.85	$ 1.29
GAAP net income per share, diluted	$ 0.12	$ 0.53	$ 1.62	$ 1.23
Non-GAAP net income per share, basic	$ 0.26	$ 0.81	$ 2.47	$ 1.91
Non-GAAP net income per share, diluted	$ 0.23	$ 0.75	$ 2.16	$ 1.82

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Source: Coherus BioSciences, Inc.