Coherus BioSciences Reports Third Quarter 2020 Financial Results

Nov 5, 2020

– Third Quarter UDENYCA® Net Sales of $113.6 Million –
– Net Income of $27.9 Million –
– Non-GAAP Net Income of $39.7 Million –

REDWOOD CITY, Calif., Nov. 05, 2020 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (“Coherus” or the “Company”, Nasdaq: CHRS), today reviewed corporate events and reported financial results for the third quarter and nine months ended September 30, 2020.

“In September, Coherus celebrated its ten year anniversary, and I am thrilled by what we have accomplished at this milestone,” said Denny Lanfear, Coherus President and CEO. “Coherus is fully integrated with competencies in research, development, and commercialization, and we are successfully fulfilling our mission to deliver value to patients by providing them access to cost effective drugs that can have a major impact on their lives. Moreover, our Udenyca business is generating significant cash flow, enabling investments in our pipeline of product candidates which, if approved, would expand our addressable market opportunity from $4 billion to $30 billion.”

Third Quarter 2020 and Recent Corporate Highlights

- Net product revenue for the third quarter of 2020 was $113.6 million, and net income was $27.9 million, or $0.33 per share on a diluted basis.
- Non-GAAP income during the third quarter of 2020 was $39.7 million, or $0.47 per share on a diluted basis.
- Cash flow from operating activities was $47.4 million for the third quarter of 2020.

Third Quarter 2020 Financial Results

Net product revenue for the third quarter of 2020 was $113.6 million. Cost of goods sold for the third quarter of 2020 was $9.0 million, resulting in a gross profit margin of 92%.

Research and development (R&D) expense for the third quarter of 2020 was $38.9 million, as compared to $21.6 million for the same period in 2019. R&D expense for the nine months ended September 30, 2020 was $98.1 million, as compared to $59.2 million for the same period in 2019. The increase in R&D expense in both periods was primarily due to preparations for the biologics license application (BLA) filing of CHS-1420, Coherus’ biosimilar to Humira® (adalimumab), as well as other pipeline activities.

Selling, general and administrative (SG&A) expense for the third quarter of 2020 was $32.0 million, as compared to $31.8 million for the same period in 2019. SG&A expense for the nine months ended September 30, 2020 was $101.4 million, as compared to $101.0 million for the same period in 2019.

Cash, cash equivalents and investments in marketable securities for the third quarter increased to $503.4 as of September 30, 2020, as compared to $456.5 million as of June 30, 2020 and $177.7 million as of December 31, 2019. The increase in the third quarter of 2020 is primarily due to generating $47.4 million in net cash from operating activities.

Net income for the third quarter of 2020 was a $27.9 million, or $0.33 per share on a diluted basis, compared to $47.0 million, or $0.63 per share on a diluted basis for the same period in 2019.

Non-GAAP net income for the third quarter of 2020 was $39.7 million, or $0.47 per share on a diluted basis, compared to non-GAAP income of $55.7 million, or $0.74 per share on a diluted basis for the same period in 2019. See “Non-GAAP Financial Measures” below for a discussion on how the Company calculates non-GAAP net income and a reconciliation to the most directly comparable GAAP measures.

Guidance for the Next Twelve Months from September 30, 2020

Coherus will continue to lay the foundation for long-term growth across its three therapeutic areas:

Oncology

- Deliver continued unit share growth with UDENYCA® against all Neulasta® dosage forms, while maintaining average selling price (“ASP”) discipline, leveraging the validated branded-biosimilar strategy of offering a robust value proposition across all key customer segments.
- Advance the Company’s 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 pharmacokinetic (“PK”) study, the timing of required interactions with the FDA, as well as completion of analytical similarity exercises.

Ophthalmology

- Facilitate Bioeq’s resubmission of a 351(k) BLA with the FDA for the biosimilar candidate to Lucentis® (ranibizumab) in 2021.
- Advance the Company’s internally developed CHS-2020 biosimilar candidate to Eylea® (aflibercept) to a projected Phase 3 clinical trial initiation in 2021, with launch projected in 2025, if approved.

Immunology

- Submit the 351(k) BLA for the Company's internally developed Humira® (adalimumab) biosimilar, CHS-1420, by year end 2020, consistent with prior guidance, and continue other activities to advance toward a projected market entry in the United States on or after July 1, 2023, if approved.

Financial Guidance

- R&D and SG&A expenses combined for the full fiscal year 2020 are expected to come in at the low end of the previously stated range of $285 million to $310 million, excluding upfront or milestone payments from any potential new collaborations.

Conference Call Information

When: Thursday, November 5, 2020 starting at 4:30 p.m. ET

Webcast: at https://investors.coherus.com.

The conference call will be broadcast live in listen-only mode on the Company's investor relations website at https://investors.coherus.com/. If you would like to ask a question, the dial in number for the conference call is 844-452-6826 (Toll-Free U.S. and Canada) or 765-507-2587 (International).

Conference ID: 7079429

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

Third quarter 2020 financial results are posted on the Coherus website at https://investors.coherus.com/. The webcast will be archived on the Coherus website.

About Coherus BioSciences, Inc.

Coherus is a leading biosimilar company that develops and commercializes its own high-quality therapeutics as well as those of others seeking capable access to the United States market. Biosimilars are intended for use in place of existing, branded biologics to treat a range of chronic and often life-threatening diseases, with the potential to reduce costs and expand patient access. Composed of a team of proven industry veterans with world-class expertise in process science, analytical characterization, protein production, sales and marketing, clinical-regulatory development and commercialization. Coherus is positioned as a leader in the global biosimilar marketplace. Coherus commercializes UDENYCA® (pegfilgrastim-cbqv) in the United States and is advancing additional product candidates including CHS-1420, a Humira® (adalimumab) biosimilar, Bioeq's Lucentis® (ranibizumab) biosimilar, Innovent's Avastin® (bevacizumab) biosimilar towards commercialization, as well as CHS-2020, an Eylea® (aflibercept) biosimilar. 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 generate cash flow from its UDENYCA® business, Coherus' ability to expand its addressable market opportunity and to lay the foundation for long-term growth across its three therapeutic areas; Coherus' ability to deliver continued unit share growth with UDENYCA® against all Neulasta® dosage forms, Coherus' ability to maintain ASP discipline, leveraging the validated branded-biosimilar strategy of offering a robust value proposition across all key customer segments; 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, as well as completing analytical similarity exercises; Coherus' ability to submit a 351(k) BLA with the FDA in 2021 for the Innovent biosimilar candidate to Avastin®; Coherus' ability to launch Innovent's biosimilar candidate to Avastin® in the United States; Coherus' ability to facilitate Bioeq's resubmission of a 351(k) BLA with the FDA for the ophthalmology biosimilar candidate to Lucentis® (ranibizumab) in 2021 and Coherus' ability to launch the product, if approved; Coherus' ability to advance CHS-2020 an Eylea® (aflibercept) ophthalmology biosimilar currently in preclinical development by initiating an projected Phase 3 clinical trial in 2021, with launch projected in 2025, if approved; Coherus' ability to submit the 351(k) BLA for CHS-1420, a Humira® (adalimumab) biosimilar by year end 2020, and continue other 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 2020. 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' Annual Report on Form 10-K for the year ended December 31, 2019, filed with the Securities and Exchange Commission on February 27, 2020, its 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. Our results for the quarter ended September 30, 2020 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,	
	2020	2019	2020	2019
Revenue:				
Net product revenue	$ 113,551	$ 111,684	$ 365,405	$ 232,215
Operating expenses:				
Cost of goods sold	9,000	6,447	25,994	9,273
Research and development	38,851	21,568	98,131	59,240
Selling, general and administrative	31,984	31,828	101,386	100,967
Total operating expenses	79,835	59,843	225,511	169,480
Income from operations	33,716	51,841	139,894	62,735
Interest expense	(5,656)	(4,469)	(15,495)	(13,118)
Other income, net	56	518	548	1,887
Net income before income taxes	28,116	47,890	124,947	51,504
Income tax provision	183	847	2,411	898
Net income	$ 27,933	$ 47,043	$ 122,536	$ 50,606
Net income per share:				
Basic	$ 0.39	$ 0.67	$ 1.72	$ 0.73
Diluted	$ 0.33	$ 0.63	$ 1.52	$ 0.69
Weighted-average number of shares used in computing net income per share:				
Basic	71,649,350	69,877,693	71,138,973	69,501,835
Diluted	87,470,337	78,530,227	82,043,469	72,872,076

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

	September 30, 2020	December 31, 2019
Assets		
Cash and cash equivalents	$ 292,465	$ 177,668
Investments in marketable securities	210,966	—
Trade receivables, net	160,707	141,992
Inventory	85,964	55,071
Other assets	53,631	34,196
Total assets	$ 803,733	$ 408,927
Liabilities and Stockholders' Equity		
Accrued rebates, fees and reserve	$ 75,961	$ 51,120
Convertible notes due 2022	79,537	78,542
Convertible notes due 2022 - related parties	26,512	26,181
Convertible notes due 2026	222,718	—
Term loan	74,267	73,663
Other liabilities	69,007	74,207
Total stockholders' equity	255,731	105,214
Total liabilities and stockholders' equity	$ 803,733	$ 408,927

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Cash, cash equivalents and restricted cash at beginning of the period	**$ 225,057**	**$ 106,762**	**$ 177,908**	**$ 73,191**
Net cash provided by operating activities	**$ 47,353**	**$ 54,951**	**$ 121,021**	**$ 10,645**
Purchases of investments in marketable securities	(41,981)	(5,371)	(273,845)	(20,235)
Proceeds from maturities of investments in marketable securities	63,000	6,000	63,000	15,000
Upfront and milestone based license fee payments to Innovent	(2,500)	-	(7,500)	—
Purchases of property and equipment and other investing activities	(2,112)	(918)	(6,112)	(1,435)
Net cash provided by (used in) investing activities	**$ 16,407**	**$ (289)**	**$ (224,457)**	**$ (6,670)**
Proceeds (payments) related to 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 (payments) related to the term loan, net of issuance costs	—	(106)	—	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	4,909	3,789	13,014	5,184
Proceeds from purchase under the employee stock purchase plan	—	—	2,557	1,878
Cash used in other financing activities	(147)	—	(1,124)	—
Net cash provided by financing activities	**$ 4,088**	**$ 3,683**	**$ 218,433**	**$ 88,170**
Effect of exchange rate changes on cash	—	59	—	(170)
Net increase in cash, cash equivalents and restricted cash	**$ 67,848**	**$ 58,404**	**$ 114,997**	**$ 91,975**
Cash, cash equivalents and restricted cash at end of the period	**$ 292,905**	**$ 165,166**	**$ 292,905**	**$ 165,166**
Reconciliation of cash, cash equivalents, and restricted cash				
Cash and cash equivalents	$ 292,465	$ 165,116	$ 292,465	$ 165,116
Restricted cash – current	—	50	—	50
Restricted cash – non-current	440		440	
Cash, cash equivalents and restricted cash	$ 292,905	$ 165,166	$ 292,905	$ 165,166

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 September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
GAAP net income	$ 27,933	$ 47,043	$ 122,536	$ 50,606
Adjustments:				
Stock based compensation expense	9,308	8,790	28,287	26,319
Upfront and milestone based license fee payments to Innovent	2,500	—	7,500	—
Income tax effect of the above adjustments	(77)	(155)	(691)	(459)
Non-GAAP net income	$ 39,664	$ 55,678	$ 157,632	$ 76,466
GAAP net income per share, basic	$ 0.39	$ 0.67	$ 1.72	$ 0.73
GAAP net income per share, diluted	$ 0.33	$ 0.63	$ 1.52	$ 0.69
Non-GAAP net income per share, basic	$ 0.55	$ 0.80	$ 2.22	$ 1.10
Non-GAAP net income per share, diluted	$ 0.47	$ 0.74	$ 1.93	$ 1.05

Contact

David S. Arrington
Investor Relations & Corporate Affairs
Coherus BioSciences, Inc.
darrington@coherus.com
+1 (650) 395-0196

Source: Coherus BioSciences, Inc.