Coherus BioSciences Reports Corporate Highlights and Third Quarter 2019 Financial Results

Nov 6, 2019

REDWOOD CITY, Calif., Nov. 06, 2019 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (“Coherus” or the “Company”, Nasdaq: CHRS), today reviewed corporate highlights and reported financial results for the quarter ended September 30, 2019.

Third Quarter 2019 Company Highlights

- UDENYCA® (pegfilgrastim-cbqv) continues as the U.S. market-leading pegfilgrastim biosimilar, achieving approximately 19% of unit market share at the end of September 2019, delivering on the promise of biosimilars for patients, providers and payers.
- Net product revenue for the third quarter of 2019 was $111.7 million, and net income was $47.0 million, or $0.63 per share on a fully diluted basis for the third quarter. Net income was $50.6 million or $0.69 per share on a fully diluted basis for the nine months ending September 30, 2019. Cash flow from operations was $55.0 million for the quarter. Cash, cash equivalents and investments in marketable securities was $170.5 million at September 30, 2019.
- The company completed two business development transactions:
    - The Company acquired exclusive rights from Bioeq IP AG, (“Bioeq”) a Swiss biopharmaceutical joint venture, to commercialize Bioeq’s Lucentis® (ranibizumab) biosimilar candidate in the United States. Bioeq plans to file a Biologics License Application (“BLA”) with the U.S. Food and Drug Administration (“FDA”) in the fourth quarter of 2019 and Coherus plans to launch the product in the United States in 2021, applying its proficiencies and infrastructure developed for the oncology therapeutic commercial environment to the ophthalmology therapeutic commercial environment.
    - Coherus and Pfizer entered into a license and settlement agreement relating to Coherus’ patents and applications for patents directed to Humira® (adalimumab) formulations.
- The Company further advanced its internal ophthalmology product candidate, CHS-2020, a biosimilar candidate to Eylea® (aflibercept).

Third Quarter 2019 Financial Results

- **Net product revenue** for third quarter of 2019 was $111.7 million. Cost of goods sold for the third quarter of 2019 was $6.4 million, resulting in a gross profit margin of 94% for the third quarter of 2019.
- **Research and development (R&D)** expense for the third quarter of 2019 was $21.6 million compared to $31.6 million for the same period in 2018. R&D expenses for the nine months ended September 30, 2019 were $59.2 million, as compared to $83.6 million for the same period in 2018. The decrease in R&D expense in both periods was primarily due to the capitalization of UDENYCA® manufacturing costs since the approval of UDENYCA® on November 2, 2019 and a decrease in costs related to impairment loss, facilities, supplies and materials.
- **Selling, general and administrative (SG&A)** expense for the third quarter of 2019 was $31.8 million, as compared to $25.4 million for the same period in 2018. SG&A expense for the nine months ended September 30, 2019 was $101.0 million, as compared to $60.3 million for the same period in 2018. The increase in SG&A expense in 2019 was primarily attributable to the costs related to commercializing UDENYCA® in the United States, which included personnel and third-party services costs for commercial and marketing initiatives.
- **Cash, cash equivalents and investments in marketable securities** for the third quarter totaled $170.5 million at September 30, 2019, as compared to $111.9 million at June 30, 2019 and $72.4 million at December 31, 2018.
- **Net income** attributable to the Company for the third quarter of 2019 was $47.0 million, or $0.63 per share on a fully diluted basis, compared to a net loss of ($58.8) million, or ($0.87) per share on a basic and fully diluted basis for the same period in 2018.

Guidance for the Next Twelve Months from September 30, 2019

- **UDENYCA® (pegfilgrastim-cbqv) biosimilar to Neulasta® (pegfilgrastim)**
    - Maintain market position as the leading pegfilgrastim biosimilar of choice, continuing the validated biosimilar-specific strategy of offering a robust value proposition across all key customer segments including ample product supply.
    - Achieve 2019 exit unit market share of 20% or greater and gain additional market share beyond 20% through 2020.
    - Continue to increase penetration against all Neulasta dosage forms.
- **CHS-1420, biosimilar candidate to Humira® (adalimumab)**
    - Complete certain development and regulatory objectives to support a BLA filing in 2020.
- **Ophthalmology pipeline**
    - Facilitate the Bioeq filing of a BLA with the FDA for the biosimilar candidate to Lucentis® (ranibizumab) in the United States in the fourth quarter of 2019.
    - Advance the development of CHS-2020, a biosimilar candidate to Eylea® (aflibercept).

Conference Call Information

Date: Wednesday, November 6, 2019 starting at 4:30 p.m. ET
Connect: Dial 844.452.6826 (toll free) or 765.507.2587 (international)
Enter: Conference ID: 8589299
Webcast: http://investors.coherus.com
Please join the conference call at least 10 minutes early to register. The webcast will be archived on the Coherus website.

About UDENYCA®

UDENYCA® (pegfilgrastim-cbqv) is a PEGylated growth colony-stimulating factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. UDENYCA® drug substance manufacturing is located in Boulder, Colorado. Pegfilgrastim is one of the largest selling oncology biologics with worldwide revenues in excess of $4.5 billion in 2017.

Indication

UDENYCA® IS A LEUKOCYTE GROWTH FACTOR INDICATED TO DECREASE THE INCIDENCE OF INFECTION, AS MANIFESTED BY FEBRILE NEUTROPENIA, IN PATIENTS WITH NON-MYELOID MALIGNANCIES RECEIVING MYELOSUPPRESSIVE ANTI-CANCER DRUGS ASSOCIATED WITH A CLINICALLY SIGNIFICANT INCIDENCE OF FEBRILE NEUTROPENIA.

Limitations of Use

UDENYCA® is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

IMPORTANT SAFETY INFORMATION

Contraindication

Patients with a history of serious allergic reaction to human granulocyte colony-stimulating factors such as pegfilgrastim or filgrastim products.

Warnings and Precautions

- ***Fatal splenic rupture:*** Evaluate patients who report left upper abdominal or shoulder pain for an enlarged spleen or splenic rupture.
- ***Acute respiratory distress syndrome (ARDS):*** Evaluate patients who develop fever, lung infiltrates, or respiratory distress. Discontinue UDENYCA® in patients with ARDS.
- ***Serious allergic reactions, including anaphylaxis:*** Permanently discontinue UDENYCA® in patients with serious allergic reactions.
- ***Fatal sickle cell crises:*** Have occurred.
- ***Glomerulonephritis:*** Evaluate and consider dose-reduction or interruption of UDENYCA® if causality is likely.

Adverse Reactions

MOST COMMON ADVERSE REACTIONS (≥ 5% DIFFERENCE IN INCIDENCE COMPARED TO PLACEBO) ARE BONE PAIN AND PAIN IN EXTREMITY.

To report SUSPECTED ADVERSE REACTIONS, contact Coherus BioSciences, Inc. at 1-800-4-UDENYCA (1-800-483-3692) or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

Full Prescribing Information available at www.UDENYCA.com

About Coherus BioSciences, Inc.

Coherus is a leading biosimilar company that develops and commercializes high-quality therapeutics for major regulated markets. 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 and clinical-regulatory development, Coherus is positioned as a leader in the global biosimilar marketplace. Coherus commercializes UDENYCA® (pegfilgrastim-cbqv) in the U.S. and has received regulatory approval for UDENYCA® in the European Union. Coherus is advancing a late-stage clinical product CHS-1420 (adalimumab biosimilar) and Bioeq's Lucentis® (ranibizumab biosimilar) towards commercialization, and early-stage clinical products, CHS-2020, an Eylea® (aflibercept biosimilar), and CHS-131, a small molecule for nonalcoholic steatohepatitis (NASH) and multiple sclerosis. 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 facilitate the Bioeq filing of a BLA with the FDA for their biosimilar candidate to Lucentis in the fourth quarter of 2019; Coherus' ability to launch the Bioeq biosimilar candidate to Lucentis® (ranibizumab) in the United States in 2021; Coherus' ability to maintain market position as the leading pegfilgrastim biosimilar of choice and to continue to validate its biosimilar-specific strategy of offering a robust value proposition across all key customer segments, including ample product supply; Coherus' ability to achieve 2019 exit unit market share of 20% or greater, gain additional market share beyond 20% through 2020 and continue to increase penetration against all Neulasta dosage forms for UDENYCA®; Coherus' plans to complete certain development and regulatory objectives to support a BLA filing in 2020 for CHS-1420; Coherus' plans to launch Bioeq's biosimilar to Lucentis in 2021, applying Coherus' proficiencies and infrastructure developed for the oncology therapeutic commercial environment to the ophthalmology therapeutic commercial environment; Coherus' ability to advance the development of CHS-2020, a biosimilar candidate to Eylea® (aflibercept); Coherus' ability to effectively license its patents and applications for patents directed to Humira® (adalimumab) formulations to Pfizer. 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, 2019, filed with the Securities and Exchange Commission on August 1, 2019 and its future periodic reports to be filed with the Securities and Exchange Commission. Our results for the quarter ended June 30, 2019 are not necessarily indicative of our operating results for any future periods.

UDENYCA® is a trademark of Coherus BioSciences, Inc.
Neulasta® and Enbrel® are registered trademarks of Amgen Inc.
Humira® is a registered trademark of AbbVie Inc.
Lucentis® is a registered trademark of Genentech, Inc.
Eylea® is a registered trademark of Regeneron Pharmaceuticals, Inc.

Coherus BioSciences, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(unaudited)		*(unaudited)*	
Revenue:				
Net product revenue	$ 111,684	$ -	$ 232,215	$ -
Operating expenses:				
Cost of goods sold	6,447	-	9,273	-
Research and development	21,568	31,603	59,240	83,577
Selling, general and administrative	31,828	25,369	100,967	60,337
Total operating expenses	59,843	56,972	169,480	143,914
Income (loss) from operations	51,841	(56,972)	62,735	(143,914)
Interest expense	(4,469)	(2,425)	(13,118)	(7,250)
Other income, net	518	571	1,887	4,351
Net income (loss) before income tax	47,890	(58,826)	51,504	(146,813)
Income tax provision	847	-	898	-
Net income (loss)	47,043	(58,826)	50,606	(146,813)
Net loss attributable to non-controlling interest	-	18	-	70
Net income (loss) attributable to Coherus	$ 47,043	$ (58,808)	$ 50,606	$ (146,743)
Net income (loss) per share attributable to Coherus:				
Basic	$ 0.67	$ (0.87)	$ 0.73	$ (2.39)
Diluted	$ 0.63	$ (0.87)	$ 0.69	$ (2.39)
Weighted-average number of shares used in computing net income (loss) per share attributable to Coherus:				
Basic	69,877,693	67,848,730	69,501,835	61,414,876
Diluted	78,530,227	67,848,730	72,872,076	61,414,876

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

	September 30, 2019	December 31, 2018
	(unaudited)	

Assets		
Cash and cash equivalents	$ 165,116	$ 72,356
Investments in marketable securities - short-term	5,377	-
Trade receivables, net	89,646	-
Inventory	37,609	5,671
Other assets	29,635	21,440
Total assets	$ 327,383	$ 99,467
Liabilities and Stockholders' Equity (Deficit)		
Convertible notes	$ 78,226	$ 77,319
Convertible notes - related parties	26,075	25,773
Term loan	73,472	-
Other liabilities	93,587	34,966
Total stockholders' equity (deficit)	56,023	(38,591)
Total liabilities and stockholders' equity (deficit)	$ 327,383	$ 99,467

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Source: Coherus BioSciences, Inc.