Coherus BioSciences Reports Fourth Quarter and Full Year 2018 Financial Results

Feb 28, 2019

REDWOOD CITY, Calif., Feb. 28, 2019 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Nasdaq: CHRS), today reviewed corporate events and reported financial results for the quarter and full year ended December 31, 2018.

Fourth Quarter 2018 and Recent Corporate Highlights Include:

- On November 2, 2018, the U.S. Food and Drug Administration (FDA) approved UDENYCA™ (pegfilgrastim-cbqv) for patients with non-myeloid cancer receiving myelosuppressive chemotherapy associated with a clinically significant incidence of febrile neutropenia. UDENYCA™ is Coherus' first drug to receive FDA and European Commission approval.
- In November 2018, Coherus received Q-Code medical billing status for UDENYCA™ from the Centers for Medicare and Medicaid Services, which became effective January 1, 2019.
- On January 3, 2019, Coherus launched UDENYCA™ commercially in the U.S.
- On January 7, 2019, Coherus entered into a $75 million senior secured credit facility agreement with Healthcare Royalty Partners.
- In January 2019, Coherus entered into settlement and license agreements with AbbVie Inc. that grant the company global, royalty-bearing, non-exclusive license rights under AbbVie's intellectual property to commercialize CHS-1420 (adalimumab (Humira®) biosimilar).

Fourth Quarter and Full Year 2018 Financial Results:

Research and development (R&D) expenses for the fourth quarter of 2018 were $26.7 million, as compared to $31.5 million for the same period in 2017. R&D expenses for the fiscal year 2018 were $110.2 million, as compared to $162.4 million for the same period in 2017. The decreases in R&D expenses were mainly due to the completion of the clinical trials and related manufacturing for the immunology biosimilar drug candidates, CHS-0214 (etanercept (Enbrel®) biosimilar) and CHS-1420. These cost decreases were partially offset by increased costs associated with the manufacturing of UDENYCA™. Coherus had approximately 330,000 cumulative units of UDENYCA™ released as of December 31, 2018.

Selling, general and administrative (SG&A) expenses for the fourth quarter of 2018 were $33.8 million, as compared to $15.0 million for the same period in 2017. SG&A expenses for the fiscal year 2018 were $94.2 million, as compared to $71.3 million for the same period in 2017. The increases in SG&A expenses in 2018 were mainly attributable to the costs associated with hiring a sales force and completing the commercial functions and infrastructure to launch and sell UDENYCA™ in the U.S.

Cash and cash equivalents and investments in marketable securities for the fourth quarter totaled $72.4 million as of December 31, 2018, before receiving $73.1 million in net proceeds from the senior secured credit facility in January 2019, or a pro forma total of $145.5 million, as compared to $117.2 million as of September 30, 2018. Cash used in operations was $47.4 million during the fourth quarter of 2018, as compared to $42.8 million during the third quarter of 2018.

Net loss attributable to Coherus for the fourth quarter of 2018 was ($62.6) million, or ($0.92) per share, compared to a net loss of ($49.1) million, or ($0.84) per share, for the same period in 2017. Net loss attributable to Coherus for 2018 was ($209.3) million, or ($3.22) per share, compared to a net loss of ($238.2) million, or ($4.48) per share, for 2017.

Guidance for the Next Twelve Months from December 31, 2018:

UDENYCA™ (pegfilgrastim-cbqv), Neulasta® (pegfilgrastim) biosimilar

- Secure receipt of transitional pass-through status in 340-B hospitals in April 2019.
- Increase penetration of patient and provider support programs and access portals.
- Secure parity payment status with all national and local payers.

CHS-1420 (adalimumab (Humira®) biosimilar)

- Pursue manufacturing objectives in support of the anticipated filing of a 351(k) biologic license application (BLA) in the U.S.

CHS-3351 (ranibizumab (Lucentis®) biosimilar) and CHS-2020 (aflibercept (Eylea®) biosimilar)

- Complete manufacturing technology transfer to support clinical development of CHS-3351.
- Continue preclinical development of CHS-2020.

Conference Call Information

When: Thursday, February 28, 2019 starting at 4:30 p.m. ET
Dial-in: (844) 452-6826 (toll free) or (765) 507-2587 (International)
Conference ID: 3398069
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.

Fourth quarter and full year 2018 financial results, are posted on the Coherus website at http://investors.coherus.com.

About Coherus BioSciences, Inc.

Coherus BioSciences 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 BioSciences is positioned as a leader in the global biosimilar marketplace. Coherus BioSciences commercializes UDENYCA™ (pegfilgrastim-cbqv) in the U.S. and has received regulatory approval for UDENYCA™ in the European Union. Coherus BioSciences is advancing two late-stage clinical products towards commercialization, CHS-1420 (adalimumab biosimilar) and CHS-0214 (etanercept biosimilar), and developing a robust pipeline of future products in ophthalmology (including CHS-3351, a ranibizumab biosimilar, and CHS-2020, an aflibercept biosimilar), as well as CHS-131, a small molecule for nonalcoholic steatohepatitis (NASH) and multiple sclerosis. For additional information, please visit www.coherus.com.

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

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' expectations regarding commercial sales of UDENYCA™ in the U.S., its reimbursement status and its ability to increase penetration of patient and provider support programs and access portals; Coherus' ability to pursue manufacturing objectives of CHS-1420 in support of a BLA; Coherus' plan to complete manufacturing technology transfer to support clinical and continued preclinical development of CHS-3351. 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, 2018, filed with the Securities and Exchange Commission on February 28, 2019 and its future periodic reports to be filed with the Securities and Exchange Commission. Our results for the quarter and year ended December 31, 2018 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)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
	(unaudited)			
Revenue:				
Collaboration and license revenue	$ -	$ -	$ -	$ 1,556
Total revenue	–	–	–	1,556
Operating expenses:				
Research and development	26,662	31,488	110,239	162,389
Selling, general and administrative	33,840	14,978	94,177	71,303
Total operating expenses	60,502	46,466	204,416	233,692
Loss from operations	(60,502)	(46,466)	(204,416)	(232,136)
Interest expense	(2,434)	(2,400)	(9,684)	(9,552)
Other income (expense), net	340	(203)	4,691	3,402
Net loss	(62,596)	(49,069)	(209,409)	(238,286)
Net loss attributable to non-controlling interest	–	2	70	116
Net loss attributable to Coherus	$ (62,596)	$ (49,067)	$ (209,339)	$ (238,170)
Net loss per share attributable to Coherus, basic and diluted	$ (0.92)	$ (0.84)	$ (3.22)	$ (4.48)
Weighted-average number of shares used in computing net loss per share attributable to Coherus, basic and diluted	68,089,486	58,343,720	65,034,827	53,133,620

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

	December 31, 2018	December 31, 2017
Assets		
Cash and cash equivalents	$ 72,356	$ 126,911
Other assets	27,111	35,700
Total assets	$ 99,467	$ 162,611
Liabilities and Stockholders' Equity (deficit)		
Convertible notes	$ 77,319	$ 76,206
Convertible notes-related parties	25,773	25,204
Other liabilities	34,966	30,666
Total stockholders' equity (deficit)	(38,591)	30,535
Total liabilities and stockholders' equity (deficit)	$ 99,467	$ 162,611

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