Coherus BioSciences Reports Corporate Highlights and First Quarter 2019 Financial Results

May 9, 2019

REDWOOD CITY, Calif., May 09, 2019 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (“Coherus” or “the Company”, Nasdaq: CHRS), today reviewed corporate highlights and reported financial results for the quarter ended March 31, 2019.

First Quarter 2019 Company Highlights

- **UDENYCA® (pegfilgrastim-cbqv) Launch Performance Consistent with Plan**
  - Net product revenue for the first quarter of 2019 was $37.1 million following Coherus’ successful launch of UDENYCA® in the U.S. marketplace on January 3, 2019.
  - Uptake of UDENYCA® in 340B hospitals, non-340B hospitals and community oncology clinics is in line with the Company’s expectations.
  - UDENYCA® launch performance validates its broad value proposition approach and the commercial strategy Coherus implemented. This comprehensive branded biosimilar approach leverages Coherus’ robust commercial infrastructure and its comprehensive support services program, Coherus Complete www.coheruscomplete.com.
  - The Company secured transitional pass-through status in 340B hospitals from CMS effective April 1, 2019, granted for a period of 36 months, incentivizing access to UDENYCA® for Medicare patients.
  - The Company secured a $75 million credit financing with Healthcare Royalty Partners to accelerate the manufacturing and launch of UDENYCA®.
- **Legal Developments**
  - Coherus and Amgen settled the trade secret action brought by Amgen and Coherus continues to commercialize UDENYCA® across all segments.
  - The Company announced a global settlement with AbbVie securing rights to commercialize its adalimumab biosimilar candidate, CHS-1420, affording a U.S. market entry date of December 15, 2023.
  - The Company announced the filing of a patent infringement suit against Amgen directed to Amgen’s Humira® biosimilar formulation.

First Quarter 2019 Financial Results

- **Net product revenue** for the first quarter of 2019 was $37.1 million. Cost of goods sold for the first quarter of 2019 was $2.2 million, resulting in a gross profit margin of 94 percent for the first quarter of 2019.
- **Research and development (R&D)** expenses for the first quarter of 2019 were $18.8 million, as compared to $25.5 million for the same period in 2018. The decreases in R&D expenses were mainly due to the capitalization of UDENYCA® manufacturing in the first quarter of 2019.
- **Selling, general and administrative (SG&A)** expenses for the first quarter of 2019 were $32.7 million, as compared to $16.6 million for the same period in 2018. The increase in SG&A expenses in 2019, which was mainly attributable to the costs associated with commercializing UDENYCA® in the U.S.
- **Total operating expenses** decreased by $6.8 million from $60.5 million in the fourth quarter of 2019 to $53.7 million in the first quarter of 2019 primarily as a result of a reduction in UDENYCA® manufacturing pre-approval activities.
- **Cash and cash equivalents and investments in marketable securities** for the first quarter totaled $96.4 million as of March 31, 2019, as compared to $95.2 million as of March 31, 2018, and $72.4 million as of December 31, 2018.
- **Net loss** attributable to the Company for the first quarter of 2019 was ($20.0) million, or ($0.29) per share, compared to a net loss of ($44.3) million, or ($0.74) per share, for the same period in 2018.

Guidance for the Next Nine Months from March 31, 2019

- **UDENYCA® (pegfilgrastim-cbqv) biosimilar to Neulasta® (pegfilgrastim)**
  - Increase the breadth and depth of adoption across all market segments.
  - Secure reimbursement coverage among remaining national and regional payers.
- **CHS-1420, biosimilar candidate to Humira® (adalimumab)**
  - Pursue manufacturing objectives in support of the anticipated filing of a 351(k) biologic license application (BLA) in the U.S.
- **CHS-3351, biosimilar candidate to Lucentis® (ranibizumab) and CHS-2020, biosimilar candidate to Eylea® (aflibercept)**
  - Complete manufacturing technology transfer to support clinical development of CHS-3351.
  - Continue preclinical development of CHS-2020.
- **CHS-131, small molecule, PPAR-g modulator drug candidate in nonalcoholic steatohepatitis (“NASH”)**

- Initiate clinical phase program in NASH.

Conference Call Information

When: Thursday, May 9, 2019 starting at 4:30 p.m. ET
Dial-in: (844) 452-6826 (toll free) or (765) 507-2587 (international)
Conference ID: 2969536
Webcast: http://investors.coherus.com
You will be asked to register when you join the call. 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 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.

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, transitional pass-through status in 340B hospitals from CMS incentivizing access to UDENYCA®; being able to accelerate the manufacturing of UDENYCA®; Coherus' expectations regarding its ability to increase the breadth and depth of UDENYCA's adoption across all market segments and to secure reimbursement coverage among remaining national and regional payers for UDENYCA®; Coherus' ability to pursue manufacturing objectives of CHS-1420 in support of an anticipated BLA; Coherus' plan to complete the manufacturing technology transfer to support the clinical development of CHS-3351; Coherus' expectation to continue the preclinical development of CHS-2020; and Coherus' plan to initiate a clinical phase program for CHS-131 in NASH. 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, 2019, filed with the Securities and Exchange Commission on May 9, 2019 and its future periodic reports to be filed with the Securities and Exchange Commission. Our results for the quarter ended March 31, 2019 are not necessarily indicative of our operating results for any future periods.

UDENYCA® is a trademark of Coherus BioSciences, Inc.
Neulasta® is a registered trademark 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 March 31,	
	2019	**2018**
	(unaudited)	
Revenue:		
Net product revenue	$ 37,098	$ -
Operating expenses:		
Cost of goods sold	2,225	-
Research and development	18,789	25,455
Selling, general and administrative	32,683	16,577
Total operating expenses	53,697	42,032
Loss from operations	(16,599)	(42,032)
Interest expense	(4,216)	(2,408)
Other income, net	811	138
Net loss	(20,004)	(44,302)
Net loss attributable to non-controlling interest	-	5
Net loss attributable to Coherus	$ (20,004)	$ (44,297)
Net loss per share attributable to Coherus, basic and diluted	$ (0.29)	$ (0.74)
Weighted-average number of shares used in computing net loss per share attributable to Coherus, basic and diluted	69,140,697	60,122,050

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

	March 31, 2019	**December 31, 2018**
	(unaudited)	
Assets		
Cash and cash equivalents	$ 81,515	$ 72,356
Investments in marketable securities - short-term	14,918	-
Trade receivables, net	46,476	-
Other assets	43,206	27,111
Total assets	$ 186,115	$ 99,467
Liabilities and Stockholders' Deficit		
Convertible notes	$ 77,614	$ 77,319
Convertible notes - related parties	25,872	25,773
Term loan	73,124	-
Other liabilities	48,020	34,966
Total stockholders' deficit	(38,515)	(38,591)
Total liabilities and stockholders' deficit	$ 186,115	$ 99,467

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