Coherus BioSciences Reports Corporate Highlights and Second Quarter 2019 Financial Results

Aug 1, 2019

– Company is Profitable and Cash flow Positive from Operations for Second Quarter –
– UDENYCA® is the Market Leading Pegfilgrastim Biosimilar with Approximately 13% Market Share –

REDWOOD CITY, Calif., Aug. 01, 2019 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. ("Coherus" or "the Company", Nasdaq: CHRS), today reviewed corporate highlights and reported financial results for the quarter ended June 30, 2019.

Second Quarter 2019 Company Highlights

- Net product revenue for the second quarter of 2019 was $83.4 million and net income was $23.6 million, or $0.32 per share on a fully diluted basis. Net income was $3.6 million or $0.05 per share on a fully diluted basis for the first half of 2019. Cash flow from operations for the quarter was also positive at $12.7 million.
- Uptake of UDENYCA® (pegfilgrastim-cbqv) is progressing strongly across all segments (340B hospitals, non-340B hospitals and community oncology clinics), with increased uptake in the 340B segment after receiving transitional pass-through status from Centers for Medicare & Medicaid Services on April 1, 2019.
- After just two quarters on the market, UDENYCA® is the U.S. market leading pegfilgrastim biosimilar with greater than approximately 13% of unit market share at the end of June 2019, and it is anticipated to reach over 20% of unit market share by the end of 2019.

Second Quarter 2019 Financial Results

- **Net product revenue** for the second quarter of 2019 was $83.4 million. Cost of goods sold for the second quarter of 2019 was $0.6 million, resulting in a gross profit margin of 99 percent for the second quarter of 2019, up from 94 percent in the first quarter of 2019.
- **Research and development (R&D)** expense for the second quarter of 2019 was $18.9 million, as compared to $26.5 million for the same period in 2018. R&D expense for the six months ended June 30, 2019 was $37.7 million, as compared to $52.0 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 in the first quarter of 2019 and a decrease in CHS-0214 development costs.
- **Selling, general and administrative (SG&A)** expense for the second quarter of 2019 was $36.5 million, as compared to $18.4 million for the same period in 2018. SG&A expense for the six months ended June 30, 2019 was $69.1 million, as compared to $35.0 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, as well as legal costs in support of litigations.
- **Cash, cash equivalents and investments in marketable securities** for the second quarter totaled $111.9 million at June 30, 2019, as compared to $96.4 million at March 31, 2019 and $72.4 million at December 31, 2018. Cash flow from operations was $12.7 million for the second quarter of 2019.
- **Net income** attributable to the Company for the second quarter of 2019 was a 23.6 million, or $0.32 per share on a fully diluted basis, compared to a net loss of ($43.6) million, or ($0.68) per share on a basic and fully diluted basis for the same period in 2018.

Guidance for the Next Six Months from June 30, 2019

- **UDENYCA® (pegfilgrastim-cbqv) biosimilar to Neulasta® (pegfilgrastim)**
  - Continue as market leading pegfilgrastim biosimilar of choice.
  - Achieve 2019 exit unit market share of 20% or greater.
  - Increase penetration into all Neulasta dosage forms.
- **CHS-1420, biosimilar candidate to Humira® (adalimumab)**
  - Complete certain development objectives to support BLA filing in 2020.
- **CHS-0214, biosimilar candidate to Enbrel® (etanercept)**
  - Prepare for BLA supporting activities, pending legal developments.
- **CHS-3351, biosimilar candidate to Lucentis® (ranibizumab) and CHS-2020, biosimilar candidate to Eylea® (aflibercept)**
  - Advance the development of the ophthalmology pipeline.
- **CHS-131, small molecule, PPAR-g modulator drug candidate in nonalcoholic steatohepatitis ("NASH")**
  - Initiate clinical phase program in NASH.

Conference Call Information

When: Thursday, August 1, 2019 starting at 4:30 p.m. ET
Dial-in: (844) 452-6826 (toll free) or (765) 507-2587 (International)
Conference ID: 9268814
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 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, Coherus' ability to reach over 20% of unit market share by the end of 2019 for UDENYCA® and continue as the market leading pegfilgrastim biosimilar of choice; Coherus' ability to increase penetration into all Neulasta dosage forms; Coherus' ability to complete certain development objectives for CHS-1420 to support BLA filing in 2020; Coherus' ability to prepare for BLA supporting activities for CHS-0214 pending legal developments; Coherus' plan to advance the development of the ophthalmology pipeline; 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® 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 June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
	(unaudited)		*(unaudited)*	
Revenue:				
Net product revenue	$ 83,433	$ -	$ 120,531	$ -
Operating expenses:				
Cost of goods sold	601	-	2,826	-
Research and development	18,883	26,519	37,672	51,974
Selling, general and administrative	36,456	18,391	69,139	34,968
Total operating expenses	55,940	44,910	109,637	86,942
Income (loss) from operations	27,493	(44,910)	10,894	(86,942)
Interest expense	(4,433)	(2,417)	(8,649)	(4,825)
Other income, net	558	3,642	1,369	3,780
Net income (loss) before income taxes	23,618	(43,685)	3,614	(87,987)
Income tax provision	51	-	51	-
Net income (loss)	23,567	(43,685)	3,563	(87,987)
Net loss attributable to non-controlling interest	-	47	-	52
Net income (loss) attributable to Coherus	$ 23,567	$ (43,638)	$ 3,563	$ (87,935)
Net income (loss) per share attributable to Coherus:				
Basic	$ 0.34	$ (0.68)	$ 0.05	$ (1.42)
Diluted	$ 0.32	$ (0.68)	$ 0.05	$ (1.42)
Weighted-average number of shares used in computing net income (loss) per share attributable to Coherus:				
Basic	69,479,016	63,960,567	69,310,791	62,051,912
Diluted	72,963,972	63,960,567	72,281,564	62,051,912

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

	June 30, 2019	December 31, 2018
	(unaudited)	
Assets		
Cash and cash equivalents	$ 105,927	$ 72,356
Investments in marketable securities - short-term	5,991	-
Trade receivables, net	77,385	-
Inventory	22,798	5,671
Other assets	28,355	21,440

Total assets	$ 240,456	$ 99,467
Liabilities and Stockholders' Deficit		
Convertible notes	$ 77,916	$ 77,319
Convertible notes - related parties	25,972	25,773
Term loan	73,286	-
Other liabilities	67,267	34,966
Total stockholders' deficit	(3,985)	(38,591)
Total liabilities and stockholders' deficit	$ 240,456	$ 99,467

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