Coherus BioSciences Reports First Quarter 2016 Financial and Operating Results

CHS-1420 (adalimumab biosimilar) Formulation Patents to Issue in May
Completed Private Convertible Financing of $100 million
Received $30 million Milestone Payment from Baxalta in May

REDWOOD CITY, Calif., May 09, 2016 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Nasdaq:CHRS), a leading pure-play, global biosimilars company with late stage clinical, as well as pipeline products, today reported financial results and reviewed corporate events for the quarter ended March 31, 2016.

First Quarter 2016 Highlights

- Oncology therapeutic franchise:
  - CHS-1701 (pegfilgrastim (Neulasta®) biosimilar)
    - Initiated follow-on pharmacokinetic and pharmacodynamic (PK/PD) study in January 2016, which will be part of the evidence used by Coherus to support a Biologics License Application (BLA) in the United States.
    - Met co-primary endpoints in the BLA-enabling immunogenicity study in healthy volunteers initiated in 2015 and completed in February 2016.
  - Announced pipeline addition of CHS-5217 (bevacizumab (Avastin®) biosimilar).

- Immunology (anti-TNF) therapeutic franchise:
  - CHS-0214 (etanercept (Enbrel®) biosimilar)
    - Met primary endpoint in a Phase 3 trial in rheumatoid arthritis in January 2016.
  - CHS-1420 (adalimumab (HUMIRA®) biosimilar)
    - Completed enrollment of the Phase 3 Psoriasis study in March 2016.
    - U.S patents 9,340,611 and 9,340,612 will issue to Coherus on May 17, 2016. U.S. patent 9,346,880 will issue to Coherus on May 24, 2016. These patents will expire in September 2033. The '611 patent concerns formulations of adalimumab that do not contain polyol. The '612 patent concerns formulations of adalimumab that do not contain polyol and surfactant. The '880 patent concerns formulations of adalimumab that do not contain surfactant. The issuance of these U.S. patents, along with pending foreign counterparts, reflects Coherus' ongoing efforts to create and protect intellectual property that Coherus believes will enhance its ability to commercialize a Humira biosimilar.
    - Coherus filed its petition for Inter Partes Review (IPR) of AbbVie U.S. Patent 9,114,166 ('166) entitled "Formulation of Human Antibodies for Treating TNF-α Associated Disorders". The '166 patent generally concerns an isotonic formulation of TNF-α IgG1 antibody at a protein concentration of 50 mg/ml and pH of 4.0 to 8.0. Coherus expects the U.S. Patent Office to render its decision whether to institute the IPR no later than mid-November 2016.

- Ophthalmology therapeutic franchise:
  - Announced pipeline addition of CHS-3351 (ranibizumab (Lucentis®) biosimilar).

- Financial highlights:
  - Received $30 million milestone payment from Baxalta for completing all visits in the two Phase 3 trials for CHS-0214 (etanercept (Enbrel®) biosimilar) in May 2016.
  - Closed on $100 million private placement of senior convertible notes with an initial conversion price representing a 60% premium to the average last reported sale price per share of Coherus common stock over the preceding 15 trading days in February 2016.

"We continue to have strong execution on all three late-stage programs with the lead-up to registrational submissions. In early 2016, we announced positive data in BLA-enabling and Phase 3 trials for CHS-1701 and CHS-0214 respectively, enhanced our cash position with $100 million from the proceeds of senior convertible notes, and organized our pipeline into four therapeutic area franchises: oncology, immunology, ophthalmology and multiple sclerosis," said Denny Lanfear, President and Chief Executive Officer of Coherus. "In addition, we continue to advance our adalimumab biosimilar IP strategy with our IPR filing against AbbVie's '166 formulation patent, and receipt from the U.S. Patent Office of notification that three Coherus U.S. patents on adalimumab formulations will issue this month."

First Quarter 2016 Financial Results

Total revenue for the first quarter 2016 was $12.4 million, as compared to $5.8 million in the first quarter of 2015. The increase over the same period in 2015 was due to increased recognition in Baxalta collaboration revenue as a result of receiving three development milestone payments totaling $100.0 million in 2015.

Research and development (R&D) expenses for the first quarter 2016 were $65.3 million compared to $36.5 million for the same period in 2015. Increases in R&D expenses were mainly attributable to having four on-going Phase 3 and BLA enabling studies for CHS-0214, CHS-1420 and CHS-1701 in 2016 compared to just two late-stage studies that were on-going in 2015, proceeding with preclinical activities associated with our early-stage pipeline, and hiring additional personnel to support late-development and early-stage activities.

General and administrative (G&A) expenses for the first quarter 2016 were $11.4 million, compared to $6.1 million for the same period in 2015. Changes in G&A expenses were mainly attributable to hiring employees to support legal, pre-commercial and accounting activities, legal fees to support the intellectual property strategy, and accounting fees and services related to compliance with Section 404 of the Sarbanes-Oxley Act of 2002.

Net loss attributable to Coherus for the first quarter of 2016 was $65.4 million, or $1.67 per share, compared to $40.7 million, or $1.22 per share, for the same period in 2015.

Cash and cash equivalents totaled $179.6 million as of March 31, 2016, compared to $158.2 million as of December 31, 2015.

"This past quarter represents the high point of R&D spending in 2016, and we project a quarter-to-quarter decline in R&D spending for the rest of the year, as we complete various registration enabling efforts," said Jean Viret, Ph.D., Chief Financial Officer. "While this investment in our product registrations is essential for commercialization, we remain tightly focused on spending control in all areas."

2016 Guidance

- Oncology therapeutic franchise:
  - CHS-1701 (pegfilgrastim biosimilar)
    - Complete the follow-on PK/PD study by the end of the first half of 2016.
    - File a 351(k) BLA in the U.S. directly thereafter.
    - Initiate commercial partnering discussions for certain ex-U.S. territories.
- Immunology (anti-TNF) therapeutic franchise:
  - CHS-0214 (etanercept biosimilar)
    - Complete two Phase 1 bridging studies.
    - File for MAA in conjunction with partner Baxalta in late 2016.
  - CHS-1420 (adalimumab biosimilar)
    - Complete Phase 3 clinical trial in psoriasis in the second half of 2016.
    - File a 351(k) BLA in the U.S. directly thereafter.
    - Continue to advance intellectual property strategy.
  - Initiate partnering discussions for the immunology (anti-TNF) therapeutic franchise in the second half of 2016, targeting an agreement in the first half of 2017.
- File one investigational new drug (IND) application for a second wave biosimilar candidate.

Conference Call Information

When: Monday, May 9, 2016 at 1:30 p.m. PT

Dial-in: (844) 452-6826 (toll free) or (765) 507-2587 (International)
Conference ID: 2374783
Webcast: http://investors.coherus.com

Please join the conference call at least 10 minutes early to register.

About Coherus BioSciences, Inc.

Coherus is a leading pure-play global biosimilar platform 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 and clinical-regulatory development, Coherus is positioned as a leader in the global biosimilar marketplace. Coherus is advancing three late-stage clinical products towards commercialization, CHS-1701 (pegfilgrastim biosimilar), CHS-0214 (etanercept biosimilar) and CHS-1420 (adalimumab biosimilar), as well as developing a robust pipeline of future products, including CHS-5217 (bevacizumab biosimilar) and CHS-3351 (ranibizumab 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, including statements regarding Coherus' plans, potential opportunities, expectations, projections, goals, objectives, milestones, strategies, product pipeline, clinical studies, product development, release of data and the potential benefits of its products under development are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including Coherus' expectations regarding its ability to advance its CHS-1701, CHS-0214, CHS-1420, CHS-5217 and CHS-3351 biosimilar drug candidates, complete bridging studies for CHS-0214, complete its follow-on PK/PD study for CHS-1701, file BLAs for CHS-1701 and CHS-1420 in the U.S., file an MAA for CHS-0214 in the E.U., file one IND on a second wave biosimilar pipeline candidate, enter into collaborations for CHS-1701 commercialization ex-U.S. and advance its intellectual strategy for CHS-1420 including with respect to the issuance to Coherus of three U.S. patents on adalimumab formulations. Such forward-looking statements involve substantial risks and uncertainties that could cause our clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the clinical drug development process, including the regulatory approval process, the timing of our regulatory filings and other matters that could affect the availability or commercial potential of our biosimilar drug candidates, as well as possible patent litigation. 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, 2015, filed with the Securities and Exchange Commission on February 29, 2016 and its future periodic reports to be filed with the Securities and Exchange Commission.

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

	Three Months Ended March 31,	
	2016	**2015**
	(unaudited)	
Revenue:		
Collaboration and license revenue	$ 12,359	$ 5,810
Total revenue	12,359	5,810
Operating expenses:		
Research and development	65,313	36,467
General and administrative	11,398	6,091
Total operating expenses	76,711	42,558
Loss from operations	(64,352)	(36,748)
Interest expense	(837)	—
Other expense, net	(349)	(4,091)
Net loss	(65,538)	(40,839)
Net loss attributable to non-controlling interest	150	114
Net loss attributable to Coherus	$ (65,388)	$ (40,725)
Net loss per share attributable to Coherus, basic and diluted	$ (1.67)	$ (1.22)
Weighted-average number of shares used in computing net loss per share attributable to Coherus, basic and diluted	39,095,975	33,377,298

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

	March 31, 2016	**December 31, 2015**
	(unaudited)	
Assets		
Cash and cash equivalents	$ 179,558	$ 158,226
Other assets	46,678	54,158
Total assets	$ 226,236	$ 212,384
Liabilities and Stockholders' Deficit		
Deferred revenue	82,606	94,959
Other liabilities	210,508	124,354
Total stockholders' deficit	(66,878)	(6,929)
Total liabilities and stockholders' deficit	$ 226,236	$ 212,384

CONTACT:

Keith Vendola, M.D.
Investor Relations
Coherus BioSciences, Inc.
kvendola@coherus.com
+1 (650) 437-6239

Coherus BioSciences, Inc.