Coherus BioSciences Reports Second Quarter 2016 Financial and Operating Results

Aug 9, 2016

Continued execution on multiple fronts positions the company strongly for the second-half of 2016 and beyond

REDWOOD CITY, Calif., Aug. 09, 2016 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Nasdaq:CHRS), today reported financial results and reviewed corporate events for the second quarter ended June 30, 2016.

Corporate Highlights for the Second Quarter 2016 Include:

- Immunology (anti-TNF) therapeutic franchise:
  - CHS-1420 (adalimumab (HUMIRA®) biosimilar)
    - Received favorable decision from the Patent Trial and Review Board (PTAB) for the United States Patent and Trademark Office (USPTO) instituting Coherus' petition for Inter Partes Review (IPR) of AbbVie's U.S. patent 8,889,135 ("the '135 patent"), 9,017,680 and 9,073,987 (patents '680 and '987, respectively), which are all related to the dosing regimen for AbbVie's Humira (adalimumab) to treat rheumatoid arthritis.
    - Issued patents from the USPTO for U.S. patents 9,340,611; 9,340,612 and 9,346,880 generally concerning the formulations of adalimumab, the active biologic ingredient in Coherus' Humira biosimilar.
  - CHS-0214 (etanercept (Enbrel®) biosimilar)
    - Completed enrollment on two Phase 1 bridging studies.

- Multiple sclerosis therapeutic franchise:
  - CHS-131 (new chemical entity therapeutic)
    - Reported a positive Phase 2b randomized, double-blind, placebo-controlled clinical study.
    - Demonstrated approximately a 50 percent statistically significant decrease in the incidence of new contrast-enhancing lesions over six months when compared to placebo.

Financial highlights for the Second Quarter 2016 include:

- Announced the pricing of an underwritten public offering totaling 4,025,000 shares of its common stock at a price to the public of $18.00 per share before deducting the underwriting discount, resulting in $69.0 million to Coherus net of all fees. All of the shares of the common stock sold in the offering were offered by Coherus.
- Received $30.0 million milestone payment from Baxalta related to the last patient, last visit in the global CHS-0214 Phase 3 trials.

Second Quarter and year-to-date 2016 Financial Results

Total revenue for the second quarter of 2016 was $14.1 million, as compared to $6.9 million in the second quarter of 2015. Total revenue for the six months ended June 30, 2016 was $26.4 million, as compared to $12.7 million for the same period in 2015. The increase over the same period in 2015 was due to increased recognition of Baxalta collaboration revenue as a result of receiving four development milestone payments totaling $130.0 million since March 31, 2015.

Research and development (R&D) expenses for the second quarter of 2016 were $65.5 million compared to $56.9 million for the same period in 2015. R&D expenses for the six months ended June 30, 2016 were $130.9 million, as compared to $93.4 million for the same period in 2015. Increases in R&D expenses were mainly attributable to proceeding with clinical activities associated with our Phase 3 clinical study in psoriasis for CHS-1420, advances in other product candidates in our pipeline, and hiring additional personnel to support both late-development and early-stage activities, and were offset by a decrease in costs related to BLA-enabling studies for CHS-1701.

General and administrative (G&A) expenses for the second quarter of 2016 were $11.3 million, compared to $8.8 million for the same period in 2015. G&A expenses for the six months ended June 30, 2016 were $22.7 million, as compared to $14.9 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, costs associated with stock options granted since the first quarter of 2015, 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 second quarter of 2016 was $70.0 million, or $1.72 per share, compared to $58.8 million, or $1.56 per share, for the same period in 2015.

Cash and cash equivalents totaled $220.9 million as of June 30, 2016, compared to $179.6 million as of March 31, 2016. Cash used in operations was $27.4 million in the second quarter of 2016 as compared to $76.3 million in the first quarter of 2016. Excluding the $30.0 million milestone payment received from Baxalta, cash used in operations was approximately 25% less in the second quarter compared to the first quarter of 2016.

Guidance for the Second Half of 2016:

- Oncology therapeutic franchise:
  - CHS-1701 (pegfilgrastim (Neulasta®) biosimilar)
    - Reported in July positive follow-on pharmacokinetic/pharmacodynamic (PK/PD) study.
    - Initiate commercial partnering discussions for certain ex-U.S. territories.
    - Anticipated submission of Marketing Authorization Application (MAA) in the fourth quarter.

- Immunology (anti-TNF) therapeutic franchise:
  - CHS-0214 (etanercept biosimilar)
    - Complete two Phase 1 bridging studies.
    - Expect MAA acceptance in conjunction with partner Baxalta (now part of Shire) in late 2016.
  - CHS-1420 (adalimumab biosimilar)
    - Reported in August positive interim Phase 3 clinical trial in psoriasis at 16-weeks.
    - Complete Phase 3 clinical trial in psoriasis in Q4 2016.
    - Expect a 351(k) BLA acceptance in the U.S. late Q4/Q1 2017.
    - Continue to advance intellectual property strategy.
  - Partnering discussions for the immunology (anti-TNF) therapeutic franchise have begun, 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: Tuesday, August 9, 2016 at 4:30 p.m. ET
Dial-in: (844) 452-6826 (toll free) or (765) 507-2587 (International)
Conference ID: 46774291
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 for one year.

About Coherus BioSciences, Inc.
Coherus is a leading 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 in four therapeutic areas, oncology, immunology (anti-TNF), ophthalmology 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, 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' ability to initiate and complete partnering discussions and receive MAA acceptance for CHS-1701, complete bridging studies and MAA acceptance for CHS-0214, complete trials and receive BLA acceptance, and complete a partnering agreement for CHS-1420. 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' Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, filed with the Securities and Exchange Commission on May 9, 2016 and its future periodic reports to be filed with the Securities and Exchange Commission.

Enbrel® and Neulasta® are registered trademarks of Amgen Inc.
HUMIRA® is a registered trademark of AbbVie 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,	
	2016	2015	2016	2015
	(unaudited)		*(unaudited)*	
Revenue:				
Collaboration and license revenue	$ 14,068	$ 6,866	$ 26,427	$ 12,676
Total revenue	14,068	6,866	26,427	12,676
Operating expenses:				
Research and development	65,544	56,944	130,857	93,411
General and administrative	11,260	8,817	22,658	14,908
Total operating expenses	76,804	65,761	153,515	108,319
Loss from operations	(62,736)	(58,895)	(127,088)	(95,643)
Interest expense	(2,354)	—	(3,191)	—
Other expense, net	(5,060)	(139)	(5,409)	(4,230)
Net loss	(70,150)	(59,034)	(135,688)	(99,873)
Net loss attributable to non-controlling interest	183	224	333	338

Net loss attributable to Coherus	$ (69,967)	$ (58,810)	$ (135,355)	$ (99,535)
Net loss per share attributable to Coherus, basic and diluted	$ (1.72)	$ (1.56)	$ (3.39)	$ (2.80)
Weighted-average number of shares used in computing net loss per share attributable to Coherus, basic and diluted	40,698,309	37,672,748	39,897,142	35,536,889

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

	June 30, 2016	December 31, 2015
	(unaudited)	
Assets		
Cash and cash equivalents	$ 220,916	$ 158,226
Other assets	30,185	54,158
Total assets	$ 251,101	$ 212,384
Liabilities and Stockholders' Deficit		
Deferred revenue	88,050	94,959
Convertible notes	99,627	—
Other liabilities	125,372	124,354
Total stockholders' deficit	(61,948)	(6,929)
Total liabilities and stockholders' deficit	$ 251,101	$ 212,384

CONTACT:
Patrick O'Brien
Senior Vice President, Investor Relations
Coherus BioSciences, Inc.
pobrien@coherus.com
+1 (650) 649-3527

Coherus BioSciences, Inc.