Coherus BioSciences Reports Third Quarter 2016 Operating and Financial Results

Nov 9, 2016

Continued execution on multiple fronts positions the company strongly for the remainder of 2016 and beyond

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

Corporate Highlights for the Third Quarter 2016 Include:
Oncology therapeutic franchise:

- CHS-1701 (pegfilgrastim (Neulasta®) biosimilar candidate)
  - U.S. Food and Drug Administration filing of the CHS-1701 biologics license application (BLA).
  - Positive topline results from follow-on pharmacokinetic and pharmacodynamic (PK/PD) clinical study CHS-1701-05. All co-primary endpoints for PK, Cmax and Area Under the Curve (AUC), and PD, absolute neutrophil count (ANC max and ANC AUC) were achieved.

Immunology (anti-TNF) therapeutic franchise:

- CHS-1420 (adalimumab (Humira®) biosimilar candidate)
  - Reported topline results from the ongoing Phase 3 clinical study CHS-1420-02. All primary endpoints demonstrating similarity between CHS-1420 and Humira with respect to percentage of subjects achieving 75% improvement in psoriasis area and severity index (PASI-75) at week 12 were achieved. 95% confidence intervals for the difference between treatment groups fell well within the prespecified margin. Both CHS-1420 and Humira were similarly well tolerated with similar safety profiles in this study.
  - Awarded fourth US patent, 9,382,317 on formulations excluding surfactant and polyol.
- CHS-0214 (etanercept (Enbrel®) biosimilar candidate)
  - Announced regaining all development and commercial rights previously licensed for CHS-0214 in Europe, Canada, Brazil, the Middle East and other territories from Shire plc.

Financial Highlights for the Third Quarter 2016 include:

- As a result of the termination agreement for CHS-0214 with Shire plc, Coherus recognized $162.5 million as collaboration and license revenues from payments received in prior periods in the third quarter of 2016.

Third Quarter and year-to-date 2016 Financial Results:
Total revenue for the third quarter of 2016 was $162.8 million, as compared to $7.2 million in the third quarter of 2015. Total revenue for the nine months ended September 30, 2016 was $189.3 million, as compared to $19.8 million for the same period in 2015. The increase over the same period in 2015 was due to increased recognition of collaboration revenue as a result of regaining the full development and commercial rights for CHS-0214 from Shire in Europe, Canada, Brazil, the Middle East and certain other territories.

Research and development (R&D) expenses for the third quarter of 2016 were $64.6 million compared to $68.2 million for the same period in 2015. R&D expenses for the nine months ended September 30, 2016 were $195.4 million, as compared to $161.6 million for the same period in 2015. The decrease in R&D expenses in the third quarter over the same period in 2015 was mainly due to the completion of the BLA enabling studies for CHS-1701 and the completion of two phase 3 studies for CHS-0214. The increase in R&D expenses in the first nine months of 2016 over the same period in 2015 was mainly attributable to proceeding with clinical activities associated with a Phase 3 clinical study in psoriasis for CHS-1420, advances in other product candidates, and hiring additional personnel to support both late-development and early-stage activities, partially offset by a decrease in costs related to BLA-enabling studies for CHS-1701 and a decrease in costs associated with the CHS-0214 Phase 3 trials that were completed at the end of 2015.

General and administrative (G&A) expenses for the third quarter of 2016 were $13.6 million, compared to $10.2 million for the same period in 2015. G&A expenses for the nine months ended September 30, 2016 were $36.3 million, as compared to $25.1 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, costs associated with stock options granted since the third quarter of 2015 and legal fees to support the intellectual property strategy.

Net income attributable to Coherus for the third quarter of 2016 was $83.9 million, or $1.67 per share, compared to a net loss of ($71.3) million, or ($1.86) per share, for the same period in 2015.

Cash and cash equivalents totaled $159.7 million as of September 30, 2016, compared to $220.9 million as of June 30, 2016.

Guidance for the remainder of 2016:
Oncology therapeutic franchise:

- CHS-1701 (pegfilgrastim biosimilar)
  - Anticipated acceptance of Marketing Authorization Application (MAA) in the fourth quarter 2016.
  - Continue commercial partnering discussions for certain ex-U.S. territories, targeting agreement in place in the first half of 2017.

Immunology (anti-TNF) therapeutic franchise:

- CHS-1420 (adalimumab biosimilar)
  - Complete CHS-1420-02, ongoing Phase 3 confirmatory, randomized, double-blind, active-control, parallel-group, 3-part study in patients with active, moderate to severe, chronic plaque psoriasis in the fourth quarter. Expect a 351(k) BLA submission in the U.S. in the first half of 2017.
  - To support registration of the auto-injector configuration: complete 1420-04, a usability study, in the fourth quarter of 2016, and 1420-05, a comparability study, in the first quarter of 2017.
  - Continue to advance intellectual property strategies, supporting potential 2018 launch.
  - Initiate a PK study on formulation not impacted by AbbVie US Patent 9,114,166 ('166) in the first-half of 2017.
- CHS-0214 (etanercept biosimilar)
  - Review program with European regulatory authorities in the first quarter; MAA submission expected in early 2017.
  - Present data from two Phase 3 studies at the American College of Rheumatology.
- Partnering discussions for the immunology (anti-TNF) therapeutic franchise are underway, targeting agreement in place in the first half of 2017.

Conference Call Information
When: Wednesday, November 9, 2016 at 4:30 p.m. ET
Dial-in: (844) 452-6826 (toll free) or (765) 507-2587 (International)
Conference ID: 97044191
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 Coherus BioSciences, Inc.
Coherus is a leading pure-play, global 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 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, receive MAA acceptance for CHS-0214, initiate a bioavailability study for CHS-0214, complete a Phase 3 study, a usability study, and a comparability study, initiate a PK study 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 September 30, 2016, filed with the Securities and Exchange Commission on November 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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(unaudited)		*(unaudited)*	
Revenue:				
Collaboration and license revenue	$ 162,835	$ 7,167	$ 189,262	$ 19,843
Operating expenses:				
Research and development	64,573	68,218	195,430	161,629
General and administrative	13,645	10,166	36,303	25,074
Total operating expenses	78,218	78,384	231,733	186,703
Income (loss) from operations	84,617	(71,217)	(42,471)	(166,860)
Interest expense	(2,420)	(33)	(5,611)	(33)
Other income (expense), net	1,647	(235)	(3,762)	(4,465)
Net income (loss)	83,844	(71,485)	(51,844)	(171,358)

Net loss attributable to non-controlling interest	95	151	428	489
Net income (loss) attributable to Coherus	$ 83,939	$ (71,334)	$ (51,416)	$ (170,869)
Net income (loss) per share attributable to Coherus:				
Basic	$ 1.93	$ (1.86)	$ (1.25)	$ (4.68)
Diluted	$ 1.67	$ (1.86)	$ (1.25)	$ (4.68)
Weighted-average number of shares used in computing net income (loss) per share attributable to Coherus:				
Basic	43,469,986	38,426,734	41,096,783	36,510,756
Diluted	51,581,298	38,426,734	41,096,783	36,510,756

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

	September 30, 2016	December 31, 2015
	(unaudited)	
Assets		
Cash and cash equivalents	$ 159,677	$ 158,226
Other assets	32,680	54,158
Total assets	$ 192,357	$ 212,384
Liabilities and Stockholders' Equity (Deficit)		
Deferred revenue	1,972	94,959
Convertible notes	99,938	—
Other liabilities	58,725	124,354
Total stockholders' equity (deficit)	31,722	(6,929)
Total liabilities and stockholders' equity (deficit)	$ 192,357	$ 212,384

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