Coherus BioSciences Reports Third Quarter 2015 Financial and Operating Results and Corporate Events

Nov 9, 2015

Pegfilgrastim PK/PD Study Completed and Adalimumab Phase 3 Study Initiated

REDWOOD CITY, Calif., Nov. 09, 2015 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Nasdaq:CHRS), a leading pure-play, global biosimilars company with late-stage clinical products, today reviewed corporate events and reported financial results for the third quarter ended September 30, 2015.

Highlights include:

- CHS-0214 (etanercept (Enbrel®) biosimilar): Coherus and Baxalta announced today that CHS-0214 met its primary efficacy endpoints in its phase 3 psoriasis clinical study.
- CHS-1701 (pegfilgrastim (Neulasta®) biosimilar): On October 1, 2015, Coherus announced topline results of its pivotal pharmacokinetic (PK) and pharmacodynamic (PD) study, which supports our plan to file a 351(k) biologics license application (BLA) in the first quarter of 2016. In addition, Coherus completed the enrollment of additional healthy volunteers in the immunogenicity study pursuant to this BLA.
- CHS-1420 (adalimumab (Humira®) biosimilar): In August 2015, Coherus initiated dosing of the Phase 3 study in psoriasis. Coherus anticipates initiating the PK bioequivalence bridging study by the end of the first half of 2016 with Phase 3 drug material and filing a BLA in the U.S. in the second half of 2016.
- In September 2015, Coherus entered into and consummated a stock purchase agreement with Baxalta Incorporated, Baxalta US Inc. and Baxalta GmbH (together, "Baxalta"). Pursuant to this agreement, Coherus sold to Baxalta an aggregate of 390,167 shares of common stock for aggregate gross proceeds of approximately $10.0 million.
- On October 15, 2015, Coherus received a $30.0 million milestone payment from Baxalta US Inc., pursuant to its August 30, 2013 license agreement, as amended. The milestone payment related to the successful demonstration of drug product stability for CHS-0214, its etanercept biosimilar candidate.
- Coherus today, pursuant to 35 U.S.C. §§ 311–319 AND 37 C.F.R. § 42, filed in the United States Patent and Trademark Office a petition for Inter Partes Review ("IPR") of AbbVie's United States Patent No. 8,889,135 entitled "Methods of Administering Anti-TNFα antibodies" directed to treating rheumatoid arthritis in a human subject via administration, every 13-15 days, of 40 mg of a human anti-TNFα antibody that includes or encompasses adalimumab.

"Coherus continued to make significant progress on all its late-stage product candidates," said Denny Lanfear, president and chief executive officer of Coherus. "We expect to file the BLA for CHS-1701 in the first quarter of 2016 and we look forward to reporting the results of the CHS-0214 rheumatoid arthritis Phase 3 clinical study in the first quarter of 2016."

Third Quarter 2015 Financial Results

Total revenue for the third quarter 2015 was $7.2 million, as compared to $16.1 million in the third quarter of 2014. Total revenue for the nine months ended September 30, 2015 was $19.8 million, as compared to $24.6 million for the same period in 2014. The lower revenue in the third quarter and nine months ended September 30, 2015 over the same periods in 2014 was due to the recognition of a $10.0 million substantive milestone from Baxalta earned in third quarter of 2014, in addition to the collaboration and license revenue recognized over the estimated period of the collaboration.

Research and development (R&D) expenses for the third quarter 2015 were $68.2 million, compared with $18.5 million for the same period in 2014. R&D expenses for the nine months ended September 30, 2015 were $161.6 million, as compared to $51.4 million for the same period in 2014. Increases in R&D expenses over the same periods were mainly attributable to an increase in clinical and manufacturing costs associated with the completion of clinical trial enrollment for the CHS-0214 Phase 3 studies, the enrollment of CHS-1701 BLA-enabling studies and the initiation of CHS-1420 Phase 3 study in psoriasis.

General and administrative (G&A) expenses for the third quarter 2015 were $10.2 million, compared to $4.0 million for the same period in 2014. G&A expenses for the nine months ended September 30, 2015 were $25.1 million, as compared to $11.4 million for the same period in 2014. Increases in G&A expenses over the same periods were mainly attributable to increased employee-related expenses, increased legal and accounting services in support of being a public company and increased patent legal expenses related to the prosecution of patent filings.

Net loss attributable to Coherus for the third quarter 2015 was $71.3 million, or $1.86 per share, compared to $7.9 million, or $1.79 per share, for the same period in 2014.

Cash and cash equivalents totaled $153.7 million at September 30, 2015 compared to $206.1 million as of June 30, 2015, and $150.4 million at December 31, 2014.

Anticipated Near Term Milestones

- CHS-1701 (pegfilgrastim biosimilar): File 351(k) BLA in the U.S. in the first quarter of 2016; expect to finalize commercialization strategy in the first half of 2016.
- CHS-1420 (adalimumab biosimilar): Initiate PK bioequivalence bridging study by the end of the first half of 2016 with Phase 3 drug material; file BLA in the U.S. in the second half of 2016.

- CHS-0214 (etanercept biosimilar): Expect to initiate additional studies in mid-2016 to provide comparative PK data on the CHS-0214 drug material used in the Phase 3 studies, the CHS-0214 drug material intended for commercial use, and Enbrel manufactured in Europe; expect to file a Marketing Authorization Application (MAA) in the E.U. in late 2016.

Conference Call Information

When: November 9, 2015, 1:30 p.m. PT

Dial-in: (844) 452-6826 (domestic) or (765) 507-2587 (international)

Conference ID: 69284641

Webcast: http://investors.coherus.com

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

The webcast of the conference call will be available for replay through November 24, 2015.

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. 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 and CHS-1420 biosimilar drug candidates, and initiate and complete the PK bioequivalence bridging study for CHS-1420, complete its BLA-enabling studies 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., obtain any favorable outcome in connection with its petition for IPR, and receive milestone payments under its collaboration agreement with Baxalta. 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 June 30, 2015, filed with the Securities and Exchange Commission on August 10, 2015, 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,	
	2015	2014	2015	2014
	(unaudited)		*(unaudited)*	
Revenue:				
Collaboration and license revenue	$ 7,167	$ 15,620	$ 19,843	$ 23,168
Collaboration and license revenue - related party (1)	—	432	—	1,445
Total revenue	7,167	16,052	19,843	24,613
Operating expenses:				
Research and development	68,218	18,496	161,629	51,357
General and administrative	10,166	3,979	25,074	11,378
Total operating expenses	78,384	22,475	186,703	62,735
Loss from operations	(71,217)	(6,423)	(166,860)	(38,122)
Interest expense	(33)	(1)	(33)	(3,900)
Other expense, net	(235)	(1,490)	(4,465)	(16,132)

Net loss	(71,485)	(7,914)	(171,358)	(58,154)
Net loss attributable to non-controlling interest	151	42	489	155
Net loss attributable to Coherus	$ (71,334)	$ (7,872)	$ (170,869)	$ (57,999)
Net loss per share attributable to Coherus, basic and diluted	$ (1.86)	$ (1.79)	$ (4.68)	$ (13.62)
Weighted-average number of shares used in computing net loss per share attributable to Coherus, basic and diluted	38,426,734	4,409,703	36,510,756	4,258,770

(1) Represent revenue from Daiichi Sankyo Company, a holder of more than 10% of our common stock until the closing of our initial public offering on November 12, 2014.

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

	September 30, 2015	December 31, 2014
	(unaudited)	
Assets		
Cash and cash equivalents	$ 153,691	$ 150,392
Other assets	48,621	36,829
Total assets	$ 202,312	$ 187,221
Liabilities and Stockholders' Equity		
Deferred revenue	62,295	62,699
Other liabilities	99,977	57,765
Total stockholders' equity	40,040	66,757
Total liabilities and stockholders' equity	$ 202,312	$ 187,221

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