Coherus BioSciences Reports Second Quarter 2015 Financial and Operating Results

Aug 10, 2015

Pegfilgrastim BLA-Enabling Studies Progressing and Etanercept Phase 3 Studies Enrolled

REDWOOD CITY, Calif., Aug. 10, 2015 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Nasdaq:CHRS), a leading pure-play, global biosimilars company with late-stage clinical products, today reported financial results and reviewed corporate events for the second quarter ended June 30, 2015.

Highlights include:

- CHS-1701 (pegfilgrastim (Neulasta®) biosimilar): In May 2015, Coherus completed the enrollment of its pivotal pharmacokinetic (PK) and pharmacodynamic (PD) study, which, if positive, could support the filing of a 351(k) biologics license application (BLA). An additional immunogenicity study is underway in healthy volunteers pursuant to this BLA and is projected to conclude dosing in 2015 to support submission of the BLA in the fourth quarter of 2015 or the first quarter of 2016.
- CHS-0214 (etanercept (Enbrel®) biosimilar): In May 2015, Coherus completed the enrollment for CHS-0214 Phase 3 clinical studies in rheumatoid arthritis and in psoriasis, for which Coherus received a $35 million milestone payment from Baxalta, formerly Baxter. In April 2015, Baxalta and Coherus announced an amendment to their CHS-0214 etanercept biosimilar collaboration agreement. In aggregate, the revised milestone payments may exceed the previous Baxalta funding obligations by approximately $12 million.
- In April 2015, Coherus consummated a follow-on public offering of $120.0 million of common stock, raising approximately $112.2 million in net proceeds. The proceeds from this follow-on public offering are being used to advance Coherus' second wave pipeline products beyond its initial three first wave products, and for general corporate purposes.

"Coherus completed the enrollment of its pegfilgrastim PK/PD BLA-enabling study and expects to read out top-line data for this study in the third quarter," said Denny Lanfear, president and chief executive officer of Coherus. "We expect that we will be in position to file a BLA for CHS-1701 in the fourth quarter of 2015 or the first quarter of 2016."

Second Quarter 2015 Financial Results

Total revenue for the second quarter 2015 was $6.9 million, as compared to $5.0 million in the second quarter of 2014. Total revenue for the six months ended June 30, 2015 was $12.7 million, as compared to $8.6 million for the same period in 2014. The higher revenue in the second quarter and first half of 2015 over the same periods in 2014 was due to the recognition of increased Baxalta collaboration revenue as a result of milestone payments received and amortized over the past 12 months.

Research and development (R&D) expenses for the second quarter 2015 were $56.9 million, compared with $18.9 million for the same period in 2014. R&D expenses for the six months ended June 30, 2015 were $93.4 million, as compared to $32.9 million for the same period in 2014. Increases in R&D expenses over the same periods were mainly attributable to an increase in program costs associated with the advancement of Coherus' late-stage clinical product candidates, CHS-0214, CHS-1701, and CHS-1420 (adalimumab (Humira®) biosimilar).

General and administrative (G&A) expenses for the second quarter 2015 were $8.8 million, compared to $4.0 million for the same period in 2014. G&A expenses for the six months ended June 30, 2015 were $14.9 million, as compared to $7.4 million for the same period in 2014. Increases in G&A expenses over the same periods were mainly attributable to increased employee-related expenses and increased legal and accounting services in support of being a public company.

Net loss attributable to Coherus for the second quarter 2015 was $58.8 million, or $1.56 per share, compared to $25.0 million, or $5.96 per share, for the same period in 2014.

Cash and cash equivalents totaled $206.1 million as of June 30, 2015, compared to $115.1 million at March 31, 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 fourth quarter of 2015 or the first quarter of 2016.
- CHS-1420 (adalimumab biosimilar): Initiate Phase 3 clinical study in psoriasis in mid-2015; 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): Topline data for the psoriasis Phase 3 study in the fourth quarter of 2015 and for the rheumatoid arthritis study in the first quarter of 2016. We are expecting to file a Marketing Authorization Application (MAA) in the E.U. in 2016.

Conference Call Information

When: August 10, 2015, 1:30 p.m. PT
Dial-in: (844) 452-6826 (domestic) or (765) 507-2587 (international)
Conference ID: 86021327
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 August 24, 2015.

About Coherus BioSciences, Inc.

Coherus is a pure-play 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, initiate the Phase 3 clinical study in psoriasis and the PK bioequivalence 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., receive milestone payments under its collaboration agreement with Baxalta and advance Coherus' product pipeline. 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. 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, 2015, filed with the Securities and Exchange Commission on May 11, 2015, and its future periodic reports to be filed with the Securities and Exchange Commission.

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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,	
	2015	2014	2015	2014
	(unaudited)		*(unaudited)*	
Revenue:				
Collaboration and license revenue	$ 6,866	$ 4,458	$ 12,676	$ 7,548
Collaboration and license revenue - related party (1)	—	507	—	1,013
Total revenue	6,866	4,965	12,676	8,561
Operating expenses:				
Research and development	56,944	18,925	93,411	32,861
General and administrative	8,817	3,978	14,908	7,399
Total operating expenses	65,761	22,903	108,319	40,260
Loss from operations	(58,895)	(17,938)	(95,643)	(31,699)
Interest expense	—	(1,158)	—	(3,899)
Other expense, net	(139)	(5,974)	(4,230)	(14,642)
Net loss	(59,034)	(25,070)	(99,873)	(50,240)
Net loss attributable to non-controlling interest	224	113	338	113
Net loss attributable to Coherus	$ (58,810)	$ (24,957)	$ (99,535)	$ (50,127)
Net loss per share attributable to Coherus, basic and diluted	$ (1.56)	$ (5.96)	$ (2.80)	$ (11.99)
Weighted-average number of shares used in computing net loss per share attributable to Coherus, basic and diluted	37,672,748	4,186,822	35,536,889	4,182,053

(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)

	June 30, 2015	December 31, 2014
	(unaudited)	
Assets		
Cash and cash equivalents	$ 206,088	$ 150,392
Other assets	43,458	36,829
Total assets	$ 249,546	$ 187,221
Liabilities and Stockholders' Equity		
Deferred revenue	69,496	62,699
Other liabilities	83,686	57,765
Total stockholders' equity	96,364	66,757
Total liabilities and stockholders' equity	$ 249,546	$ 187,221

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Coherus BioSciences