Coherus BioSciences Reports Fourth Quarter and Year End 2014 Financial and Operating Results

Mar 23, 2015

Strong Clinical Performance and Financial Milestones Achieved

REDWOOD CITY, Calif., March 23, 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 quarter and fiscal year ended December 31, 2014.

2014 Highlights:

- CHS-1701 (pegfilgrastim (Neulasta®) biosimilar): completed Phase 1 351(a) (novel biologic) study and transitioning to a 351(k) (biosimilar) approval pathway. In March 2015, the Company initiated a pivotal study, which, if positive, could support the filing of a 351(k) biologics license application (BLA) in the fourth quarter of 2015 or first quarter of 2016. An additional immunogenicity study is planned in healthy volunteers pursuant to this BLA and is projected to be concluded in 2015 to support submission of the BLA.
- CHS-1420 (adalimumab (HUMIRA®) biosimilar): met the primary endpoint in a pivotal clinical pharmacokinetic similarity study that compared CHS-1420 to HUMIRA® in healthy subjects in August 2014.
- CHS-0214 (etanercept (Enbrel®) biosimilar): initiated Phase 3 clinical studies in rheumatoid arthritis and in psoriasis.
- Received milestone payments totaling $70.3 million under existing collaboration with Baxter Healthcare Corporation (Baxter) in 2014.
- Closed initial public offering of 6,803,702 shares of common stock at $13.50 per share in November 2014, of which net proceeds were approximately $80.2 million.

"2014 was a strong year for Coherus in both clinical and financial accomplishments. The Company initiated several BLA enabling studies and is on track to file its first BLA with CHS-1701 in the next 12 months," said Denny Lanfear, president and chief executive officer of Coherus. "Additionally, our initial public offering created a foundation for completing the development of our three lead biosimilar product candidates."

Fourth Quarter 2014 Financial Results

Total revenue for the fourth quarter 2014 was $6.5 million, as compared to $1.2 million in the fourth quarter of 2013. The increase over the same period in 2013 was due to the recognition of Baxter collaboration revenue.

Research and development (R&D) expenses for the fourth quarter 2014 were $26.9 million compared with $9.2 million for the same period in 2013. Increases in R&D expenses were mainly attributable to an increase in program costs associated with the advancement of Coherus' late-stage clinical product candidates, CHS-0214 and CHS-1701, as well as increased personnel expenses.

General and administrative (G&A) expenses for the fourth quarter 2014 were $6.2 million, compared to $2.5 million for the same period in 2013. Increases in G&A expenses 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 fourth quarter 2014 was $29.1 million, or $1.47 per share, compared to $14.6 million, or $3.68 per share, for the same period in 2013.

Fiscal Year 2014 Financial Results

Total revenue for the fiscal year 2014 was $31.1 million, as compared to $2.8 million in 2013. The increase over the same period in 2013 was due to the recognition of Baxter collaboration revenue.

Research and development (R&D) expenses were $78.2 million compared with $31.3 million in 2013. Increases in R&D expenses were mainly attributable to an increase in program costs associated with the advancement of Coherus' late-stage clinical product candidates, CHS-0214, CHS-1420 and CHS-1701, as well as increased personnel expenses.

General and administrative (G&A) expenses were $17.6 million, compared to $7.5 million in 2013. Increases in G&A expenses 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 was $87.1 million, or $10.64 per share, compared to $53.6 million, or $16.10 per share, in 2013.

Cash and cash equivalents totaled $150.4 million as of December 31, 2014, compared to $39.6 million as of December 31, 2013.

Anticipated Near Term Milestones

- CHS-1701 (pegfilgrastim biosimilar): file 351(k) BLA in U.S. in the fourth quarter of 2015 or the first quarter of 2016.
- CHS-1420 (adalimumab biosimilar): initiate pharmacokinetic (PK) bioequivalence bridging study in 2015 with Phase 3 drug material; initiate Phase 3 clinical study in psoriasis late in the first half of 2015; file BLA in U.S. in second half of 2016.
- CHS-0214 (etanercept biosimilar): continue Phase 3 clinical studies in rheumatoid arthritis and in psoriasis; file MAA in E.U. in 2016.

Conference Call Information

When: March 23, 2015, 1:30 p.m. PT
Dial-in: 844-452-6826 (domestic) or 765-507-2587 (international)
Conference ID: 5132313
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 April 6, 2015.

About Coherus BioSciences, Inc.

Coherus is a leading pure-play, global biosimilar company with a focus on developing products for the major regulated markets. Composed of a team of industry veterans with decades of experience in bringing biologics to market, our goal is to become a worldwide leader in the biosimilar market by leveraging our biologics platform in key areas such as process science, analytical characterization, protein production and clinical-regulatory development. Coherus possesses late stage clinical products and commercialization partnerships with multinational pharmaceutical companies in Europe and Asia.

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. 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-0214, CHS-1420 and CHS-1701 biosimilar drug candidates, file BLAs for CHS-1420 and CHS-1701 in the U.S. and file an MAA for CHS 0214 in the E.U. 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' Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed with the Securities and Exchange Commission on March 23, 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 December 31,		Year Ended December 31,	
	2014	2013	2014	2013
	(unaudited)			
Revenue:				
Collaboration and license revenue - related party	$ 448	$ 506	$ 1,893	$ 2,025
Collaboration and license revenue	5,313	726	28,481	726
Other revenue	732	—	732	—
Total revenue	6,493	1,232	31,106	2,751
Operating expenses:				
Research and development	26,867	9,222	78,224	31,279
General and administrative	6,186	2,497	17,564	7,465
Total operating expenses	33,053	11,719	95,788	38,744
Loss from operations	(26,560)	(10,487)	(64,682)	(35,993)
Interest expense	—	(3,301)	(3,900)	(5,293)
Other expense, net	(2,463)	(803)	(18,595)	(12,349)
Net loss	(29,023)	(14,591)	(87,177)	(53,635)
Net (income) loss attributable to non-controlling interest	(111)	—	44	—

Net loss attributable to Coherus	$ (29,134)	$ (14,591)	$ (87,133)	$ (53,635)
Net loss per share attributable to Coherus, basic and diluted	$ (1.47)	$ (3.68)	$ (10.64)	$ (16.10)
Weighted-average number of shares used in computing net loss per share attributable to Coherus, basic and diluted	19,841,728	3,965,466	8,186,529	3,332,020

Coherus BioSciences, Inc.

Condensed Consolidated Balance Sheets

(in thousands)

	December 31, 2014	December 31, 2013
Assets		
Cash and cash equivalents	$ 150,392	$ 39,554
Other assets	36,829	7,893
Total assets	$ 187,221	$ 47,447
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Deferred revenue	62,699	42,850
Other liabilities	57,765	46,979
Convertible preferred stock	—	54,695
Total stockholders' equity (deficit)	66,757	(97,077)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 187,221	$ 47,447

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Coherus BioSciences