



## Coherus BioSciences Reports Fourth Quarter and Year End 2015 Financial and Operating Results

Feb 29, 2016

*Completed Private Convertible Financing of \$100 million*

*Completed Positive Immunogenicity Registration Trial for CHS-1701*

*Completed Two Positive Phase 3 Registration Trials for CHS-0214*

*Announced Addition of Two Pipeline Assets*

REDWOOD CITY, Calif., Feb. 29, 2016 (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, 2015.

### 2015 and Current Highlights

- Financial:
  - Closed on \$100 million private placement of convertible notes with 60% premium in February 2016.
  - Received milestone payments totaling \$100 million under existing collaboration on CHS-0214 with Baxalta Incorporated (Baxalta).
  - Received \$112 million net proceeds from a follow-on public offering of 4,137,931 shares of common stock at \$29.00 per share in April 2015.
- Oncology therapeutic franchise:
  - CHS-1701 (pegfilgrastim (Neulasta®) biosimilar)
    - Met primary endpoints in an immunogenicity study in healthy volunteers initiated in 2015 and completed in February 2016.
    - Met pharmacodynamic (PD) endpoint, as well as the maximum concentration ( $C_{max}$ ) pharmacokinetic (PK) endpoint in a pivotal PK/PD study initiated in March 2015 and completed in October 2015. As a result of first period Neulasta anomalous results, did not meet area-under-the-curve endpoints.
    - Coherus believes the program will be acceptable as is, to support a Marketing Authorization Application (MAA).
    - Initiated follow-on PK/PD study in January 2016, which will be part of the evidence to support market authorization applications in the United States.
  - Announced pipeline addition of CHS-5217 (bevacizumab (Avastin®) biosimilar).
- Immunology (anti-TNF) therapeutic franchise:
  - CHS-0214 (etanercept (Enbrel®) biosimilar)
    - Met primary endpoints in a Phase 3 trial in psoriasis, announced November 2015.
    - Met primary endpoint in a Phase 3 trial in rheumatoid arthritis, announced January 2016.
  - CHS-1420 (adalimumab (HUMIRA®) biosimilar)
    - Initiated a Phase 3 trial in psoriasis in August 2015.
    - Filed petitions in the U.S. Patent Office for Inter Partes Review of AbbVie U.S. Patents 8,889,135; 9,017,680 and 9,073,987 relating to 40 mg bi-weekly dosing of adalimumab for rheumatoid arthritis.
- Ophthalmology therapeutic franchise:
  - Announced pipeline addition of CHS-3351 (ranibizumab (Lucentis®) biosimilar).

"In 2015, we brought all three of our lead first wave products closer to registration and finished the year in a strong financial position with over \$158 million in cash. This is now complemented with an additional \$100 million from the proceeds of senior unsecured convertible notes," said Denny Lanfear, President and Chief Executive Officer of Coherus. "In addition, we clearly understand the unique market dynamics specific to different biosimilars, and the need for tailored commercial approaches. As such, we have organized our pipeline into four therapeutic area franchises: oncology, immunology, ophthalmology and multiple sclerosis. We intend to retain the U.S. commercial rights for our oncology franchise and to seek partnerships for our other franchises."

### Fourth Quarter and Year-End 2015 Financial Results

**Total revenue** for the fourth quarter 2015 was \$10.2 million, as compared to \$6.5 million in the fourth quarter of 2014. The increase over the same period in 2014 was due to increased recognition in Baxalta collaboration revenue as a result of achieving three development milestones totaling \$100.0 million in 2015, including two milestones in the fourth quarter of 2015. Total revenue for the fiscal year 2015 was \$30.0 million, as compared to \$31.1 million in 2014. The lower revenue for the full year 2015 over the same periods in 2014 was due to the full recognition of a \$10.0 million substantive milestone payment 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 fourth quarter 2015 were \$51.4 million compared to \$26.9 million for the same period in 2014. R&D expenses were \$213.1 million in 2015 compared to \$78.2 million in 2014. Increases in R&D expenses were mainly attributable to a transition to

Phase 3 and Biologics License Application (BLA) enabling studies for CHS-0214, CHS-1420 and CHS-1701, as well as manufacturing efforts to support clinical trial supply and product registration activities. Less impactful were additional costs associated with the preclinical development of second wave product pipeline and personnel expenses.

**General and administrative (G&A)** expenses for the fourth quarter 2015 were \$11.0 million, compared to \$6.2 million for the same period in 2014. G&A expenses were \$36.0 million in 2015 compared to \$17.6 million in 2014. Changes in G&A expenses were mainly attributable to employee-related expenses, 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 fourth quarter 2015 was \$52.4 million, or \$1.35 per share, compared to \$29.1 million, or \$1.47 per share, for the same period in 2014. Net loss attributable to Coherus was \$223.3 million, or \$6.01 per share, in 2015 compared to \$87.1 million, or \$10.64 per share, in 2014.

**Cash** and cash equivalents totaled \$158.2 million as of December 31, 2015, compared to \$150.4 million as of December 31, 2014.

## 2016 Guidance

- Oncology therapeutic franchise:
  - CHS-1701 (pegfilgrastim biosimilar)
    - Complete a follow-on PK/PD study by the end of the first half of 2016.
    - File a 351(k) BLA in the U.S. directly thereafter.
    - Initiate commercial partnering discussions for certain ex-U.S. territories.
- Immunology (anti-TNF) therapeutic franchise:
  - CHS-0214 (etanercept biosimilar)
    - Complete two Phase 1 bridging studies addressing manufacturing changes.
    - File for MAA in late 2016.
  - CHS-1420 (adalimumab biosimilar)
    - Complete Phase 3 clinical trial in psoriasis enrollment in the first half of 2016.
    - Complete Phase 3 clinical trial in psoriasis in the second half of 2016.
    - File a 351(k) BLA in the U.S. directly thereafter.
  - Initiate partnering discussions for the immunology (anti-TNF) therapeutic franchise.
- File one investigational new drug (IND) application for a second wave biosimilar candidate.

## Conference Call Information

When: February 29, 2016, 1:30 p.m. PT  
Dial-in: (765) 507-2587 (domestic) or (844) 452-6826 (toll free)  
Conference ID: 52921197  
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 March 14, 2016.

## 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, including CHS-5217 (bevacizumab biosimilar) and CHS-3351 (ranibizumab biosimilar). For additional information, please visit [www.coherus.com](http://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, CHS-1420, CHS-5217 and CHS-3351 biosimilar drug candidates, initiate and complete bridging studies for CHS-0214, complete its PK/PD study for CHS-1701, file BLAs for CHS-1701 in the U.S., file an MAA for CHS-0214 in the E.U., file at least one IND on a second wave biosimilar pipeline candidate and enter into collaborations for CHS-1701 commercialization ex-U.S. and for its anti-inflammatory 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, 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' Annual Report on Form 10-K for the year ended December 31, 2015, filed with the Securities and Exchange Commission on February 29, 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.  
Avastin® and Lucentis® are registered trademarks of Genentech, Inc.

(in thousands, except share and per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2015	2014	2015	2014
	(unaudited)			
Revenue:				
Collaboration and license revenue	\$ 10,198	\$ 5,313	\$ 30,041	\$ 28,481
Collaboration and license revenue - related party (1)	—	448	—	1,893
Other revenue	—	732	—	732
Total revenue	10,198	6,493	30,041	31,106
Operating expenses:				
Research and development	51,433	26,867	213,062	78,224
General and administrative	10,972	6,186	36,046	17,564
Total operating expenses	62,405	33,053	249,108	95,788
Loss from operations	(52,207)	(26,560)	(219,067)	(64,682)
Interest expense	—	—	(33)	(3,900)
Other expense, net	(373)	(2,463)	(4,838)	(18,595)
Net loss	(52,580)	(29,023)	(223,938)	(87,177)
Net loss (income) attributable to non-controlling interest	189	(111)	678	44
Net loss attributable to Coherus	<u>\$ (52,391)</u>	<u>\$ (29,134)</u>	<u>\$ (223,260)</u>	<u>\$ (87,133)</u>
Net loss per share attributable to Coherus, basic and diluted	<u>\$ (1.35)</u>	<u>\$ (1.47)</u>	<u>\$ (6.01)</u>	<u>\$ (10.64)</u>
Weighted-average number of shares used in computing net loss per share attributable to Coherus, basic and diluted	<u>38,935,832</u>	<u>19,841,728</u>	<u>37,122,008</u>	<u>8,186,529</u>

(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)

	December 31, 2015	December 31, 2014
<b>Assets</b>		
Cash and cash equivalents	\$ 158,226	\$ 150,392
Other assets	54,158	36,829
Total assets	<u>\$ 212,384</u>	<u>\$ 187,221</u>
<b>Liabilities and Stockholders' Equity (Deficit)</b>		
Deferred revenue	94,959	62,699
Other liabilities	124,354	57,765
Total stockholders' equity (deficit)	<u>(6,929)</u>	<u>66,757</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 212,384</u>	<u>\$ 187,221</u>

CONTACT: ☐

Keith Vendola, M.D.  
Investor Relations  
Coherus BioSciences, Inc.  
[kvendola@coherus.com](mailto:kvendola@coherus.com)  
+1 (650) 437-6239



Coherus BioSciences, Inc.