# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 8, 2016

# COHERUS BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 001-36721 (Commission File Number) 27-3615821 (IRS Employer Identification Number)

333 Twin Dolphin Drive, Suite 600 Redwood City, CA 94065 (Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (650) 649-3530

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:						
	Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)					
	Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)					
	Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))					
	Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))					

#### **Item 2.02 Results of Operations and Financial Conditions**

On August 9, 2016, Coherus BioSciences, Inc. (the "Company") issued a press release regarding its financial results for its second quarter ended June 30, 2016. The full text of the press release is furnished as Exhibit 99.1 to this Form 8-K.

This information in this Item 2.02 of this Form 8-K and the Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

#### **Item 8.01 Other Events**

On August 8, 2016, the Company issued a press release reporting that its ongoing Phase 3 study of CHS-1420, its adalimumab (Humira®) biosimilar candidate, in patients with psoriasis, met its primary endpoint. The full text of this press release is furnished as Exhibit 99.2 to this Form 8-K.

On August 9, 2016, the Company issued a press release reporting that it submitted a 351(k) biologics license application to the United States Food and Drug Administration for CHS-1701, its pegfilgrastim (Neulasta®) biosimilar candidate. The full text of this press release is furnished as Exhibit 99.3 to this Form 8-K.

#### Item 9.01 Financial Statements and Exhibits.

#### (d) Exhibits.

Exhibit

No.	<u>Description</u>
99.1	Press release entitled "Coherus BioSciences Reports Second Quarter 2016 Financial and Operating Results" dated August 9, 2016
99.2	Press release entitled "Coherus BioSciences Announces Positive Topline Phase Three Results for CHS-1420 (Humira® Biosimilar Candidate) in Patients with Psoriasis" dated August 8, 2016
99.3	Press release entitled "Coherus BioSciences Submits 351(k) Biologics License Application to U.S. Food and Drug Administration for CHS-1701 (Pegfilgrastim Biosimilar Candidate)" dated August 9, 2016

#### **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 9, 2016 COHERUS BIOSCIENCES, INC.

By: /s/ Jean-Frédéric Viret
Name: Jean-Frédéric Viret

Title: Chief Financial Officer

## EXHIBIT INDEX

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99.3	Press release entitled "Coherus BioSciences Submits 351(k) Biologics License Application to U.S. Food and Drug Administration for CHS-1701 (Pegfilgrastim Biosimilar Candidate)" dated August 9, 2016				

## Coherus BioSciences Reports Second Quarter 2016 Financial and Operating Results

Continued execution on multiple fronts positions the company strongly for the second-half of 2016 and beyond

REDWOOD CITY, Calif., August 9, 2016 — Coherus BioSciences, Inc. (Nasdaq: CHRS), today reported financial results and reviewed corporate events for the second quarter ended June 30, 2016.

## Corporate Highlights for the Second Quarter 2016 Include:

- Immunology (anti-TNF) therapeutic franchise:
  - CHS-1420 (adalimumab (HUMIRA®) biosimilar)
    - Received favorable decision from the Patent Trial and Review Board (PTAB) for the United States Patent and Trademark Office (USPTO) instituting Coherus' petition for Inter Partes Review (IPR) of AbbVie's U.S. patent 8,889,135 ("the '135 patent"), 9,017,680 and 9,073,987 (patents '680 and '987, respectively), which are all related to the dosing regimen for AbbVie's Humira (adalimumab) to treat rheumatoid arthritis.
    - Issued patents from the USPTO for U.S. patents 9,340,611; 9,340,612 and 9,346,880 generally concerning the formulations of adalimumab, the active biologic ingredient in Coherus' Humira biosimilar.
  - CHS-0214 (etanercept (Enbrel®) biosimilar)
    - Completed enrollment on two Phase 1 bridging studies.
- Multiple sclerosis therapeutic franchise:
  - CHS-131 (new chemical entity therapeutic)
    - Reported a positive Phase 2b randomized, double-blind, placebo-controlled clinical study.
    - Demonstrated approximately a 50 percent statistically significant decrease in the incidence of new contrast-enhancing lesions over six months when compared to placebo.

#### Financial highlights for the Second Quarter 2016 include:

- Announced the pricing of an underwritten public offering totaling 4,025,000 shares of its common stock at a price to the public of \$18.00 per share before deducting the underwriting discount, resulting in \$69.0 million to Coherus net of all fees. All of the shares of the common stock sold in the offering were offered by Coherus.
- Received \$30.0 million milestone payment from Baxalta related to the last patient, last visit in the global CHS-0214 Phase 3 trials.

#### Second Quarter and year-to-date 2016 Financial Results

**Total revenue** for the second quarter of 2016 was \$14.1 million, as compared to \$6.9 million in the second quarter of 2015. Total revenue for the six months ended June 30, 2016 was \$26.4 million, as compared to \$12.7 million for the same period in 2015. The increase over the same period in 2015 was due to increased recognition of Baxalta collaboration revenue as a result of receiving four development milestone payments totaling \$130.0 million since March 31, 2015

**Research and development (R&D)** expenses for the second quarter of 2016 were \$65.5 million compared to \$56.9 million for the same period in 2015. R&D expenses for the six months ended June 30, 2016 were \$130.9 million, as compared to \$93.4 million for the same period in 2015. Increases in R&D expenses were mainly attributable to proceeding with clinical activities associated with our Phase 3 clinical study in psoriasis for CHS-1420, advances in other product candidates in our pipeline, and hiring additional personnel to support both late-development and early-stage activities, and were offset by a decrease in costs related to BLA-enabling studies for CHS-1701.

**General and administrative (G&A)** expenses for the second quarter of 2016 were \$11.3 million, compared to \$8.8 million for the same period in 2015. G&A expenses for the six months ended June 30, 2016 were \$22.7 million, as compared to \$14.9 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 first quarter of 2015, 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 second quarter of 2016 was \$70.0 million, or \$1.72 per share, compared to \$58.8 million, or \$1.56 per share, for the same period in 2015.

**Cash and cash equivalents** totaled \$220.9 million as of June 30, 2016, compared to \$179.6 million as of March 31, 2016. Cash used in operations was \$27.4 million in the second quarter of 2016 as compared to \$76.3 million in the first quarter of 2016. Excluding the \$30.0 million milestone payment received from Baxalta, cash used in operations was approximately 25% less in the second quarter compared to the first quarter of 2016.

#### Guidance for the Second Half of 2016:

- Oncology therapeutic franchise:
  - CHS-1701 (pegfilgrastim (Neulasta®) biosimilar)
    - Reported in July positive follow-on pharmacokinetic/pharmacodynamic (PK/PD) study.
    - Reported in August submission of 351(k) BLA.
    - Initiate commercial partnering discussions for certain ex-U.S. territories.
    - Anticipated submission of Marketing Authorization Application (MAA) in the fourth quarter.
- Immunology (anti-TNF) therapeutic franchise:
  - CHS-0214 (etanercept biosimilar)
    - Complete two Phase 1 bridging studies.
    - Expect MAA acceptance in conjunction with partner Baxalta (now part of Shire) in late 2016.

- CHS-1420 (adalimumab biosimilar)
  - Reported in August positive interim Phase 3 clinical trial in psoriasis at 16-weeks.
  - Complete Phase 3 clinical trial in psoriasis in Q4 2016.
  - Expect a 351(k) BLA acceptance in the U.S. late Q4/Q1 2017.
  - Continue to advance intellectual property strategy.
- Partnering discussions for the immunology (anti-TNF) therapeutic franchise have begun, targeting an agreement in the first half of 2017.
- File one investigational new drug (IND) application for a second wave biosimilar candidate.

#### **Conference Call Information**

When: Tuesday, August 9, 2016 at 4:30 p.m. ET

Dial-in: (844) 452-6826 (toll free) or (765) 507-2587 (International)

Conference ID: 46774291

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 for one year.

#### About Coherus BioSciences, Inc.

Coherus is a leading 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 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, complete bridging studies and MAA acceptance for CHS-0214, complete trials 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 March 31, 2016, filed with the Securities and Exchange Commission on May 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 June 30,		Six Months Ended June 30,		
	<b>2016</b> (unau	2015	2016 (unaudi	2015	
Revenue:	(unau	anea)	(unauai	iea)	
Collaboration and license revenue	\$ 14,068	\$ 6,866	\$ 26,427	\$ 12,676	
Total revenue	14,068	6,866	26,427	12,676	
Operating expenses:					
Research and development	65,544	56,944	130,857	93,411	
General and administrative	11,260	8,817	22,658	14,908	
Total operating expenses	76,804	65,761	153,515	108,319	
Loss from operations	(62,736)	(58,895)	(127,088)	(95,643)	
Interest expense	(2,354)	_	(3,191)	_	
Other expense, net	(5,060)	(139)	(5,409)	(4,230)	
Net loss	(70,150)	(59,034)	(135,688)	(99,873)	
Net loss attributable to non-controlling interest	183	224	333	338	
Net loss attributable to Coherus	\$ (69,967)	\$ (58,810)	\$ (135,355)	\$ (99,535)	
Net loss per share attributable to Coherus, basic and diluted	\$ (1.72)	\$ (1.56)	\$ (3.39)	\$ (2.80)	
Weighted-average number of shares used in computing net loss per share attributable to Coherus, basic and diluted	40,698,309	37,672,748	39,897,142	35,536,889	

#### Coherus BioSciences, Inc.

# **Condensed Consolidated Balance Sheets**

(in thousands)

	June 30, 2016 (unaudited)	December 31, 2015
Assets	,	
Cash and cash equivalents	\$220,916	\$ 158,226
Other assets	30,185	54,158
Total assets	\$251,101	\$ 212,384
Liabilities and Stockholders' Deficit		
Deferred revenue	88,050	94,959
Convertible notes	99,627	_
Other liabilities	125,372	124,354
Total stockholders' deficit	(61,948)	(6,929)
Total liabilities and stockholders' deficit	\$251,101	\$ 212,384

#### CONTACT:

Patrick O'Brien Senior Vice President, Investor Relations Coherus BioSciences, Inc. pobrien@coherus.com +1 (650) 649-3527

# Coherus BioSciences Announces Positive Topline Phase Three Results for CHS-1420 (Humira® Biosimilar Candidate) in Patients with Psoriasis

REDWOOD CITY, Calif., August 8, 2016 — Coherus BioSciences, Inc. (NASDAQ: CHRS), today reported topline results from an ongoing Phase 3 clinical study of CHS-1420, an adalimumab (Humira®) biosimilar candidate. This study met its primary endpoint 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. The 95% confidence intervals for the difference between treatment groups fell well within the prespecified margin. CHS-1420 and Humira were similarly well tolerated with similar safety profiles in this study.

"We are pleased that this study met the 12-week primary equivalence endpoint for PASI-75 and are very confident that the 24-week results will be similar to those observed at Week 12," said Barbara Finck, M.D., Chief Medical Officer of Coherus. "These results confirm that CHS-1420 has a similar efficacy and safety profile to that of Humira, as no clinically meaningful differences were observed."

This was a confirmatory, randomized, double-blind, active-control, parallel-group, 3-part study in patients with active, moderate to severe, chronic plaque psoriasis. In treatment period 2, half the subjects randomized to Humira will cross-over to CHS-1420, modeling a chronic patient's transition to a biosimilar. Comparative safety, including immunogenicity, and durability of response to CHS-1420 and Humira at week 16 and 24 are key secondary endpoints. These data will be presented at an upcoming scientific conference. The full dataset through treatment period 2 will be available in Q4 2016 and included in the Biologic License Application (BLA) submission anticipated to follow.

"Coming after four other successful Phase 3/BLA-enabling studies this year with two other programs, this positive Phase 3 result further validates the scientific, clinical and technical capabilities of Coherus BioSciences as a world-class biosimilar company," said Denny Lanfear, President and Chief Executive Officer of Coherus. "We believe such capabilities, taken together with our strong intellectual property focus and continued positive developments with patents and IPRs, put us in excellent position to launch CHS-1420 in 2018."

#### About Coherus BioSciences, Inc.

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Humira® is a registered trademark of AbbVie Inc.

CONTACT:
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# Coherus BioSciences Submits 351(k) Biologics License Application to U.S. Food and Drug Administration for CHS-1701 (Pegfilgrastim Biosimilar Candidate)

REDWOOD CITY, Calif., August 9, 2016 – Coherus BioSciences, Inc. (NASDAQ: CHRS), today announced submission of the biologics license application (BLA) for CHS-1701, a pegfilgrastim (Neulasta®) biosimilar candidate, to U.S. FDA under the 351(k) pathway.

The BLA submission is supported by similarity data from analytical, pharmacokinetic, pharmacodynamic and immunogenicity studies comparing CHS-1701 and Neulasta.

"The CHS-1701 BLA submission marks a significant milestone in our ongoing transition to a commercial company in a transformational year for Coherus as we continue to focus on execution of our strategic plan." said Denny Lanfear, President and CEO of Coherus BioSciences. "Pegfilgrastim is the largest selling oncology product in the U.S., and CHS-1701 is the cornerstone of our oncology franchise. We believe we have a strong, competitive and order-of-entry position with this product. We anticipate our oncology portfolio to include an Avastin® biosimilar, as well as other oncology biosimilar product candidates."

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Neulasta® is a registered trademark of Amgen Inc.

 $Avastin^{\circledR}$  is a registered trademark of Genentech.

Contact:

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