# 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): March 16, 2015

# 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)

201 Redwood Shores Parkway, Suite 200 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 8.01 Other Events

On March 16, 2015 Coherus BioSciences, Inc. (the "Company") received written feedback from the Food and Drug Administration (FDA) on its biologic enabling license (BLA) clinical development program for CHS-1701, its pegfilgrastim biosimilar candidate. Pursuant to the FDA feedback, the Company initiated a pivotal pharmacodynamics and pharmacokinetics study on the CHS-1701 development plan. 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 351(k) (biosimilar) license application for CHS-1701 in Q4 2015 or Q1 2016.

The foregoing is only a summary of the material terms of the written feedback from the FDA and does not purport to be a complete description of such feedback.

A copy of the press release announcing the finalization of the CHS-1701 BLA enabling clinical program is attached hereto as Exhibit 99.1.

# Item 9.01 Financial Statements and Exhibits.

# (d) Exhibits.

Exhibit No. Description

99.1 Press Release dated March 17, 2015

# **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: March 19, 2015 COHERUS BIOSCIENCES, INC.

By: /s/ Jean-Frédéric Viret
Name: Jean-Frédéric Viret
Title: Chief Financial Officer

# EXHIBIT INDEX

Exhibit No.

No. <u>Description</u>

99.1 Press Release dated March 17, 2015

# Coherus Finalizes CHS-1701 BLA Enabling Clinical Program and Initiates Pivotal Pharmacokinetic and Pharmacodynamic Study

REDWOOD CITY, Calif., March 17, 2015 — Coherus BioSciences, Inc. (NASDAQ: CHRS), a leading pure-play, global biosimilars company with late-stage clinical products, today announced that it has finalized the Biologics License Application (BLA) enabling clinical program for CHS-1701, a pegfilgrastim biosimilar candidate, and initiated a pivotal pharmacokinetics and pharmacodynamics (PK/PD) study pursuant to feedback received from the U.S. Food and Drug Administration (FDA) on the CHS-1701 development plan. 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 351(k) (biosimilar) license application for CHS-1701 in Q4 2015 or Q1 2016.

An application submitted under section 351(k) of the Public Health Service Act must contain among other things, information demonstrating that the biologic product is biosimilar to a reference product based upon the totality of data derived from analytical studies, animal studies and a clinical study or studies, all of which impact final approval.

Coherus management will discuss its CHS-1701 program further on its fourth quarter and year end 2014 financial results conference call Monday, March 23, 2015 at 1:30 p.m. PT / 4:30 p.m. ET for which the dial-in numbers are: 844-452-6826 (domestic) or 765-507-2587 (international); Conference ID: 5132313. Additionally, the live and archive webcasts will be available at http://investors.coherus.com.

#### **About CHS-1701**

Pegfilgrastim (Neulasta®), the reference product for CHS-1701, is a pegylated form of the recombinant human G-CSF analog, filgrastim. Neulasta® is approved in the United States and Europe and is indicated as a treatment to reduce the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia. Coherus is developing CHS-1701 as a proposed biosimilar to Neulasta®.

## 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**

To the extent that statements contained in this press release are not descriptions of historical facts regarding Coherus, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including statements regarding the ability of Coherus to obtain regulatory approval from the FDA for CHS-1701, its ability to submit a 351(k) (biosimilar) license application for CHS-1701 on its desired timeline and the potential benefits of CHS-1701. Such forward-looking statements involve substantial risks and uncertainties that relate to future events and the actual results could differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the biosimilar development process, including the regulatory approval process, the timing of the actions of regulatory bodies and other governmental authorities, clinical results, changes in laws and regulations, product quality or supply for CHS-1701 and Neulasta® and patient safety. 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 the business of the company in general, see the company's current and future reports filed with the U.S. Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014.

Neulasta® is a registered trademark of Amgen Inc.

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