# 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): November 8, 2018

# **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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company  $\Box$ 

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

On November 8, 2018 Coherus BioSciences, Inc. issued a press release regarding its financial results for its third quarter ended September 30, 2018. 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 9.01 Financial Statements and Exhibits.

(d) <u>Exhibits</u>.

Exhibit<br/>No.Description99.1Press release dated November 8, 2018.

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: November 8, 2018

#### COHERUS BIOSCIENCES, INC.

By: /s/ Jean-Frédéric Viret

Name: Jean-Frédéric Viret Title: Chief Financial Officer

# Coherus BioSciences Reports Corporate Highlights and Third Quarter 2018 Financial Results

REDWOOD CITY, Calif., November 8, 2018 — Coherus BioSciences, Inc. (Nasdaq: CHRS), today reviewed corporate highlights and reported financial results for the quarter ended September 30, 2018.

#### Third Quarter 2018 and Recent Corporate Highlights Include:

- On September 25, 2018, the European Commission (EC) approved UDENYCA<sup>™</sup> by granting marketing authorization in all European Union member states.
- On November 2, 2018, the U.S. Food and Drug Administration (FDA) approved UDENYCA<sup>™</sup> (pegfilgrastim-cbqv) for patients with cancer receiving myelosuppressive chemotherapy. UDENYCA<sup>™</sup> is Coherus' first drug to receive FDA or EC approval.
- In preparation for a comprehensive launch of UDENYCA<sup>™</sup>, Coherus completed the hiring of about 70 sales representatives covering seven territories as well as the hiring of other personnel for our commercial groups and teams.

#### Third Quarter 2018 Financial Results:

**Research and development (R&D)** expenses for the third quarter of 2018 were \$31.6 million compared to \$42.6 million for the same period in 2017. R&D expenses for the nine months ended September 30, 2018 were \$83.6 million, as compared to \$130.9 million for the same period in 2017. The decreases in R&D expenses were mainly due to the completion of our clinical trials and related manufacturing for the immunology biosimilar drug candidates, CHS-1420 (adalimumab (Humira<sup>®</sup>) biosimilar) and CHS-0214 (etanercept (Enbrel<sup>®</sup>) biosimilar). These cost decreases were partially offset by the costs associated with the manufacturing of UDENYCA<sup>™</sup>.

**General and administrative (G&A)** expenses for the third quarter of 2018 were \$25.4 million, compared to \$14.0 million for the same period in 2017. G&A expenses for the nine months ended September 30, 2018 were \$60.3 million, as compared to \$56.3 million for the same period in 2017. The increases in G&A expenses in 2018 were mainly attributable to the costs associated with hiring a sales force and completing the commercial infrastructure to launch and sell UDENYCA<sup>™</sup> in the U.S.

**Net loss** attributable to Coherus for the third quarter of 2018 was (\$58.8) million, or (\$0.87) per share, compared to a net loss of (\$59.0) million, or (\$1.09) per share, for the same period in 2017.

**Cash and cash equivalents and investments in marketable securities** – totaled \$117.2 million as of September 30, 2018, compared to \$159.8 million as of June 30, 2018. Cash use in operations of \$42.8 million during the third quarter of 2018 was lower than guidance of \$48 to \$53 million.

#### Guidance for next twelve months from September 30, 2018:

#### UDENYCA™ (pegfilgrastim-cbqv), Neulasta biosimilar

• Anticipate U.S. commercial launch in January 2019.

## CHS-1420 (adalimumab (Humira®) biosimilar)

• Pursue manufacturing objectives in support of the anticipated filing of a 351(k) biologic license application (BLA) in the U.S. at the end of 2019.

## CHS-3351 (ranibizumab (Lucentis®) biosimilar) and CHS-2020 (aflibercept (Eylea®) biosimilar)

- Complete manufacturing technology transfer and continue clinical development of CHS-3351.
- Continue preclinical development of CHS-2020.

# CHS-131 (small molecule drug candidate in nonalcoholic steatohepatitis "NASH")

• Anticipate initiation of Phase 2 clinical trial in NASH.

# **Conference Call Information**

When: Thursday, November 8, 2018 at 4:30 p.m. ET Dial-in: (844) 452-6826 (toll free) or (765) 507-2587 (International) Conference ID: 7181479 Webcast: <u>http://investors.coherus.com</u>

Please join the conference call at least 10 minutes early to register. The webcast will be archived on the Coherus website.

# About Coherus BioSciences, Inc.

Coherus is a leading biosimilar 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, sales and marketing and clinical-regulatory development, Coherus is positioned as a leader in the global biosimilar marketplace. Coherus has received regulatory approval for UDENYCA<sup>TM</sup> (pegfilgrastim-cbqv) in the U.S. and European Union and is advancing two late-stage clinical products towards commercialization, CHS-1420 (adalimumab biosimilar) and CHS-0214 (etanercept biosimilar), and developing a robust pipeline of future products in ophthalmology (including CHS-3351, a ranibizumab biosimilar, and CHS-2020, an aflibercept biosimilar), as well as CHS-131, a small molecule for nonalcoholic steatohepatitis (NASH) and multiple sclerosis. For additional information, please visit <u>www.coherus.com</u>.

## **Forward-Looking Statements**

Except for the historical information contained herein, the matters set forth in this press release are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, Coherus' expectations regarding the commercial launch of UDENYCA<sup>™</sup> in the U.S.; Coherus' ability to pursue manufacturing objectives of CHS-1420 in support of a BLA; Coherus' plan to initiate the clinical development of CHS-3351; Coherus' expectation to continue the preclinical development of CHS-2020; and Coherus' plan to initiate a Phase 2 trial for CHS-131 in NASH. Such forward-looking statements involve substantial risks and uncertainties that could cause Coherus' actual results, performance or achievements to differ significantly from any future results, performance or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the risks and uncertainties inherent in the clinical drug development process; the risks and uncertainties of the regulatory approval process, including the timing of Coherus' regulatory filings; the risk that Coherus is unable to complete commercial transactions and other matters that could affect the availability or commercial potential of Coherus' biosimilar drug candidates; and the risks and uncertainties of possible patent litigation. All forward-looking statements contained in this press release speak only as of the date on which they were made. 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 three and nine months ended September 30, 2018, filed with the Securities and Exchange Commission on November 8, 2018 and its future periodic reports to be filed with the Securities and Exchange Commission. Our results for the quarter ended September 30, 2018 are not necessarily indicative of our operating results for any future periods.

UDENYCA<sup>™</sup> is a trademark of Coherus BioSciences, Inc. Enbrel® and Neulasta® are registered trademarks of Amgen Inc. Humira® is a registered trademark of AbbVie Inc. Lucentis® is a registered trademark of Genentech, Inc. Eylea® is a registered trademark of Regeneron Pharmaceuticals, Inc.

#### Coherus BioSciences, Inc. Condensed Consolidated Statements of Operations (in thousands, except share and per share data)

Nine Months Ended **Three Months Ended** September 30, September 30, 2018 2017 2018 2017 (unaudited) (unaudited) Revenue: Collaboration and license revenue \$ \$ \$ \$ 1,556 Operating expenses: Research and development 130,901 31,603 42,626 83,577 General and administrative 25,369 13,989 60,337 56,325 Total operating expenses 56,972 56,615 143,914 187,226 (143, 914)Loss from operations (56, 972)(56, 615)(185, 670)Interest expense (2,392)(7, 250)(2, 425)(7, 152)Other income, net 571 4,351 3,605 14 (58,826) (58,993)(146, 813)(189, 217)Net loss Net loss attributable to non-controlling interest 18 4 70 114 \$ \$ \$ Net loss attributable to Coherus (58, 808)(58, 989)\$ (146, 743)(189, 103)Net loss per share attributable to Coherus, basic and diluted \$ (0.87)\$ (1.09)\$ (2.39)\$ (3.68)Weighted-average number of shares used in computing net loss per share attributable to Coherus, basic and diluted 67,848,730 54,070,872 61,414,876 51,377,836

#### Coherus BioSciences, Inc. Condensed Consolidated Balance Sheets (in thousands)

	September 30, 2018 (unaudited)	December 31, 2017
Assets		
Cash and cash equivalents	\$ 101,202	\$ 126,911
Investments in marketable securities – short-term	15,968	—
Other assets	24,292	35,700
Total assets	\$ 141,462	\$ 162,611
Liabilities and Stockholders' Equity		
Convertible notes	\$ 77,031	\$ 76,206
Convertible notes-related parties	25,677	25,402
Other liabilities	26,360	30,468
Total stockholders' equity	12,394	30,535
Total liabilities and stockholders' equity	\$ 141,462	\$ 162,611

# CONTACT:

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