# 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 18, 2019**

# COHERUS BIOSCIENCES, INC.
**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-36721** | **27-3615821** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(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 ☐

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 8.01 Other Events**

On March 18, 2019, Coherus BioSciences, Inc. (“the Company”) issued a press release reporting that the Centers for Medicare and Medicaid Services approved the Company’s Neulasta® biosimilar, UDENYCA™ (pegfilgrastim-cbqv), for transitional pass-through payment status in the hospital outpatient setting. Effective April 1, 2019, UDENYCA™ is granted 36 months of transitional pass-through status. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference into this Item 8.01.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release dated March 18, 2019 |

**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, 2019

COHERUS BIOSCIENCES, INC.

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

**Exhibit 99.1**

**Coherus BioSciences Receives Transitional Pass-Through Status from CMS**

REDWOOD CITY, Calif., March 18, 2019 — Coherus BioSciences, Inc. (Nasdaq: CHRS), today announced that the Centers for Medicare and Medicaid Services (CMS) approved UDENYCA™ (pegfilgrastim-cbqv) biosimilar for transitional pass-through payment status in the hospital outpatient setting. Effective April 1, 2019, UDENYCA™ is granted 36 months of transitional pass-through status.

Transitional pass-through payment status for Medicare reimbursement in the hospital outpatient setting has been established by Congress to incentivize access for Medicare patients to biosimilars and novel therapies.

“We launched UDENYCA™ with a significantly lower list price, 33% below that of Neulasta®,” said Denny Lanfear, President and CEO of Coherus. “We applaud the Centers for Medicare and Medicaid Services for establishing transitional pass-through status and expanding access to therapies such as UDENYCA™ for the nation’s Medicare patients.”

Under the program, reimbursement for UDENYCA™ in the 340B hospital outpatient setting will be calculated at list price, also known as the Wholesale Acquisition Cost (WAC) for UDENYCA™+ 6%. Once the CMS Average Sales Price (ASP) for UDENYCA™ is established, reimbursement will be calculated at the ASP for UDENYCA™ + 6% of the ASP for Neulasta®, for the remainder of the pass-through status effective period. By comparison, Neulasta® is currently reimbursed at its Average Sales Price (ASP) – 22.5%.

For more information on biosimilar reimbursement please access Coherus COMPLETE: www.coheruscomplete.com/provider-resources.html

**About Coherus BioSciences, Inc.**

Coherus BioSciences 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 BioSciences is positioned as a leader in the global biosimilar marketplace. Coherus BioSciences commercializes UDENYCA™ (pegfilgrastim-cbqv) in the U.S. and has received regulatory approval for UDENYCA™ in the European Union. Coherus BioSciences 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 www.coherus.com.

**About UDENYCA™**

UDENYCA™ (pegfilgrastim-cbqv) is a PEGylated growth colony-stimulating factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies

receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. UDENYCA™ drug substance manufacturing is located in Boulder, Colorado. Pegfilgrastim is one of the largest selling oncology biologics with worldwide revenues in excess of $4.5 billion in 2017.

**INDICATION**

UDENYCA™ is a leukocyte growth factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Limitations of Use

UDENYCA™ is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

**IMPORTANT SAFETY INFORMATION**

**CONTRAINDICATION:** Patients with a history of serious allergic reaction to human granulocyte colony-stimulating factors such as pegfilgrastim or filgrastim products.

**WARNINGS AND PRECAUTIONS:**

- ***Fatal splenic rupture:*** Evaluate patients who report left upper abdominal or shoulder pain for an enlarged spleen or splenic rupture.
- ***Acute respiratory distress syndrome (ARDS):*** Evaluate patients who develop fever, lung infiltrates, or respiratory distress. Discontinue UDENYCA™ in patients with ARDS.
- ***Serious allergic reactions, including anaphylaxis:*** Permanently discontinue UDENYCA™ in patients with serious allergic reactions.
- ***Fatal sickle cell crises:*** Have occurred.
- ***Glomerulonephritis:*** Evaluate and consider dose-reduction or interruption of UDENYCA™ if causality is likely.

**ADVERSE REACTIONS:** Most common adverse reactions (³ 5% difference in incidence compared to placebo) are bone pain and pain in extremity.

**To report SUSPECTED ADVERSE REACTIONS, contact Coherus BioSciences, Inc. at 1-800-4-UDENYCA (1-800-483-3692) or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.**

Full Prescribing Information available at www.UDENYCA.com

**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 commercial sales of UDENYCA™ in the U.S., its reimbursement status in the 340B hospital outpatient setting and its ability to expand access to UDENYCA™ for Medicare patients. 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' Annual Report on Form 10-K for the year ended December 31, 2018, filed with the Securities and Exchange Commission on February 28, 2019 and its future periodic reports to be filed with the Securities and Exchange Commission. Our results for the quarter and year ended December 31, 2018 are not necessarily indicative of our operating results for any future periods.

UDENYCA™ is a trademark of Coherus BioSciences, Inc.
Neulasta® is a registered trademarks of Amgen Inc.

CONTACT:

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