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): September 13, 2024

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

N/A
(Former name or former address, if changed since last report)

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	**CHRS**	**The Nasdaq Global Market**

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 7.01 Regulation FD Disclosure

On September 13, 2024, the Company provided an update regarding its supply chain, including steps designed to strengthen its full supply chain to meet increasing demand for its UDENYCA product lines over the long term while reducing costs. UDENYCA is a single dose biosimilar to Neulasta (pegfilgrastim), licensed in three formulations (prefilled syringe, autoinjector, and prefilled syringe co-packaged with an on-body injector) that allow doctors and patients to choose which format best fits the patients' needs and lifestyle.

The Company's U.S.-based, third-party Contract Manufacturing Organization ("CMO") for final packaging recently informed the Company of its over-commitments and capacity constraints at its final labeling and packaging facility that will cause a temporary UDENYCA supply interruption. The delays in production are related only to labeling and final packaging and do not concern availability or supply of the UDENYCA active pharmaceutical ingredient or manufacturing of the UDENYCA drug product or finished product components.

Coherus projects channel supply to be substantially depleted by mid-October as inventories draw down. Concurrently, based on target production schedules provided by the CMO, the Company expects manufacturing to resume in mid-October, with product availability to begin to resume by early November.

The Company is dedicated to ensuring that its commercial products reach the patients who rely on them in a timely and efficient manner. The Company has used this same CMO for final packaging across multiple products for more than ten years without incident or interruption. The Company is working closely with the CMO to address the delay.

The Company also will be working closely with its wholesalers and prescribers to minimize any disruption caused by the temporary supply interruption. Among other actions, the Company has put in place expedited shipping measures to get product to customers as quickly as possible when supply resumes. The Company is also accelerating its existing plans, initiated in early 2024 as part of a strategic effort, to strengthen, diversify, and supplement its final packaging capabilities. In connection with this effort, the Company has engaged an additional final packaging and labeling CMO, executed requisite agreements, and is planning to manufacture product by the end of 2024, with commercial supply from that CMO expected to commence in the first quarter of 2025.

Supply Chain Investments and Expansion

Since 2021, the Company has invested more than $30 million with the goal of diversifying and increasing its product production across the entire supply chain. These efforts include the following:

- Drug Substance Manufacturing. The Company has invested approximately $25 million since 2021 with the goal of doubling its drug substance manufacturing capacity to a final product equivalent of approximately 1 million UDENYCA doses. The Company also secured FDA approval for the use of frozen bulk product with three-year expiration. This enabled the Company to increase its production capacity and extend product stability, limiting the risk for potential outages.
- Drug Product Fill Manufacturing. The Company has invested more than $6 million since 2023 to significantly increase its drug product fill manufacturing capacity, enabling the Company to produce approximately 1.5 million UDENYCA doses annually.
- Drug Packaging and Labeling Manufacturing. As noted above, the Company has secured a second final packaging and labeling CMO. Once qualification of manufacturing at the second facility is completed and commercially operational, the Company expects that this will more than double its UDENYCA packaging and labeling capacity to over 1 million packaged UDENYCA units.

The Company projects that these actions will collectively reduce the production cost of UDENYCA by approximately one-third from current levels.

The Company reconfirms 2024 R&D and SG&A Expense Guidance

The Company is working closely with customers to minimize the impact of the supply interruption, and its goal is to offset the short-term revenue impact with sales later in the fourth quarter. The Company will provide an update regarding this matter in conjunction with its third quarter 2024 earnings announcement. The Company today reaffirmed its previous guidance for combined R&D and SG&A expenses for 2024, which are expected to be in the range of $250 to $265 million for 2024. This guidance includes approximately $40 million of stock-based compensation expense and excludes the effects of acquisitions, collaborations, investments, divestitures including expenses incurred on behalf of and reimbursed by Sandoz Inc. and Hong Kong King-Friend Industrial Company Ltd. to satisfy the Company's obligations under the transition services agreements with those entities, restructuring, the exercise of rights or options related to collaboration programs, and any other transactions or circumstances not yet identified or quantified. This guidance is subject to a number of risks and uncertainties, including those described in the section entitled "Forward-Looking Statements" below.

Forward-Looking Statements

Except for the historical information contained herein, the matters set forth in this Current Report on Form 8-K 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, statements about guidance and projections for R&D and SG&A expenses for 2024; statements about the production cost of UDENYCA; statements about future revenue and sales; statements about increasing the Company's packaging and labeling capacity; expectations about the timing or ability of the Company to have an operational second facility available for packaging; statements about the risk of potential outages; and statements about the resumption of manufacturing and supply for UDENYCA at the Company's existing packaging CMO and statements about growing demand for the Company's products. Such risks and uncertainties include, among others, the risk of the Company's reliance on third-party CMOs to supply its products; the risk of manufacturing our products in conformance with regulatory requirements and to scale up supply capacity; the risk of manufacturing delays; the risk of our CMOs complying with extensive FDA regulatory requirements; risks of the Company's competitive position; risks of litigation; and the risks and uncertainties of the regulatory approval process. All forward-looking statements contained in this Current Report on Form 8-K speak only as of the date hereof. The Company undertakes no obligation to update or revise any forward-looking statements. For a further description of the significant 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 Company's business in general, see the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2024, filed with the Securities and Exchange Commission on August 8, 2023, including the section therein captioned "Risk Factors" and in other documents that the Company files with the Securities and Exchange Commission.

This information in this Item 7.01 of this Form 8-K 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.

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: September 13, 2024

COHERUS BIOSCIENCES, INC.

By: /s/ Dennis M. Lanfear
Name: Dennis M. Lanfear
Title: Chief Executive Officer