# FOIA CONFIDENTIAL TREATMENT REQUESTED PURSUANT TO RULE 83

Coherus BioSciences, Inc. 333 Twin Dolphin Drive, Suite 600 Redwood City, California 94065

October 15, 2019

# **VIA EDGAR**

United States Securities and Exchange Commission Washington, D.C. 20549

Attention: Ibolya Ignat

Division of Corporation Finance

Re: Coherus BioSciences, Inc.

Form 10-K for the Fiscal Year Ended December 31, 2018

Filed February 28, 2019

Form 10-Q for the Quarterly Period Ended June 30, 2019

Filed August 5, 2019 File No. 001-36721

Dear Ms. Ignat,

Coherus BioSciences, Inc. ("Coherus" or the "Company") is transmitting this letter in response to comments received from the staff of the Securities Exchange Commission (the "Staff"), contained in the Staff's letter dated October 3, 2019 ("Comment Letter"), with respect to the Company's Form 10-K for the year ended December 31, 2018 and Form 10-Q for the quarter ended June 30, 2019. For your convenience, the Staff's comment is reproduced in bold type below, followed by the Company's response thereto.

# Form 10-Q for the Quarterly Period Ended June 30, 2019

# Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

# Financial Operations Overview Cost of Goods Sold, page 32

- 1. It appears your cost of product revenues was only 0.7% and 2.3% of net product revenues for the quarter and six months ended June 30, 2019. You disclose that a portion of the costs of producing UDENYCA sold to date was expensed as research and development prior to FDA approval and therefore is not reflected in the cost of goods sold. You further state on page 14 that cost of goods sold includes a write-off of prepaid manufacturing costs of \$1.3 million and \$0.4 million due to excess and obsolete inventory. Please tell us the following:
  - the amount of estimated revenues represented by inventory on hand at June 30, 2019 for which manufacturing costs were expensed in prior periods as research and development expenses (i.e. "zero cost inventories"),

As stated in its Form 10-K and Form 10-Q referenced above, the Company expensed all costs related to manufacturing of its product UDENYCA® (including stability costs and manufacturing overhead) as incurred prior to receiving the FDA approval for UDENYCA® on November 2, 2018. UDENYCA®, a biosimilar product of Neulasta®, is manufactured in three stages:

1) bulk drug substance manufacturing, that yields the active ingredient, pegfilgrastim;

[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested by Coherus BioSciences, Inc. with respect to portions of this letter.

- 2) drug product filling, that yields syringes containing formulated pegfilgrastim; and
- 3) labeling, assembling and packaging of syringes, that yields a ready-to-sell finished good.

Because the Company needed final comments from the FDA on UDENYCA® packaging and package insert, the relatively small costs associated with the third and final stage of labeling, assembling and packaging in the manufacturing process were incurred post FDA approval, and were therefore capitalized as inventory.

As of June 30, 2019, the zero cost inventories are primarily in the form of bulk drug substance and secondarily in the form of drug product (i.e., naked syringes). As of June 30, 2019, the amount of future estimated net revenues represented by existing physical zero cost inventories at June 30, 2019 is approximately \$[\*\*\*], which assumes the current gross-to-net discount of 45% from gross sales. However, it is anticipated that the gross-to-net discount will increase resulting in lower net revenues from zero cost inventories due to two factors:

- 1) the possible future entry of other biosimilar competitor products in the United States, on top of an existing biosimilar competitor product, which launched in July 2018 (Fulphila® manufactured by Mylan N.V.), and the originator product (Neulasta® manufactured by Amgen Inc.); and
- 2) the Company's future strategic response to increasing competition and its behavior with respect to discounts and rebates, which would cause a decrease in net revenues per unit sold in future periods.

Accordingly, the Company cannot estimate reliably its gross-to-net discount and future net revenues. Please note that US-only net revenues for Neulasta® were \$3.9 billion in 2018 (Source: Amgen Inc. – Form 10-K for fiscal year ended December 31, 2018 on page 47).

#### when you expect to finish selling the zero cost inventories,

As of June 30, 2019, the Company estimated the future demand for UDENYCA® based on two assumptions:

- 1) [\*\*\*]; and
- 2) [\*\*\*].

Based on these assumptions, the Company expected to finish selling zero cost inventories during [\*\*\*].

#### if the non-current inventory relates to inventory that will not be sold due to the zero cost inventory runoff,

As of June 30, 2019, the Company anticipates that it will sell the entire non-current inventory starting after June 30, 2020 due to the product long shelf life.

# • what the shelf life of your inventory is and your consideration of whether or not any additional inventory will be determined to be obsolete in future periods, and

The shelf life of bulk drug substance, pegfilgrastim, is 12 months and the shelf life of the finished product, UDENYCA®, is 36 months, thus the combined shelf life of drug substance and drug product can be accommodated to be up to 48 months. The Company does not anticipate that any additional inventory will be determined to be obsolete in future periods.

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# what you estimate your gross margin percentage will be after the zero cost inventories are sold.

The Company cannot reliably estimate the gross margin percentage after the zero cost inventories are sold during 2021, because the Company cannot reliably estimate net revenue, since the Company may adjust its pricing strategy based on the competitive landscape and cannot reliably predict both market share and net price per unit sold.

As of June 30, 2019, the Company estimates that the gross margin would have been approximately [\*\*\*]% for both the three- and six-months ended June 30, 2019 based on its current bill of material, its current net revenue amounts, and including the [\*\*\*]% royalty on net revenues that is due to Amgen Inc. beginning on July 1, 2019. The Company anticipates that the net revenues per unit of UDENYCA® sold will decrease in future reporting periods as the market place for pegfilgrastim products is competitive, and as result, the Company anticipates its gross margin percentage will decline.

Please do not hesitate to contact the undersigned at (650) 649-3546, if you have any questions or would like additional information regarding these matters.

Sincerely,

/s/ Jean-Fréderic Viret, Ph.D. Jean-Fréderic Viret, Ph.D. Chief Financial Officer Coherus BioSciences, Inc.

cc: Dennis M. Lanfear, Chief Executive Officer, Coherus BioSciences, Inc. Alan Mendelson, Esq., Latham & Watkins LLP

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