

DIVISION OF CORPORATION FINANCE UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

September 3, 2014

<u>Via E-mail</u> Donald M. Lanfear President and Chief Executive Officer Coherus BioSciences, Inc. 201 Redwood Shores Parkway, Suite 200 Redwood City, CA 94065

Re: Coherus BioSciences, Inc. Draft Registration Statement on Form S-1 Confidentially Submitted August 4, 2014 CIK No. 0001512762

Dear Mr. Lanfear:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

<u>General</u>

 Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications. Similarly, please supplementally provide us with any research reports about you that are published or distributed in reliance upon Section 2(a)(3) of the Securities Act of 1933 added by Section 105(a) of the Jumpstart Our Business Startups Act by any broker or dealer that is participating or will participate in your offering.

- 2. Please confirm that the graphics included in your registration statement are the only graphics you will use in your prospectus. If those are not the only graphics, please provide any additional graphics prior to their use for our review.
- 3. We note that you have submitted an application for confidential treatment relating to several of your exhibits. Please be advised that we will review this application separately and comments issued as a result of that review, if any, must be resolved prior to your filing a request for acceleration.
- 4. Please revise to ensure that all graphical information presented in your prospectus, such as the pipeline chart on the first page of your prospectus summary and page 89, and the charts on pages 92, 97 and 98, is sufficiently large to be legible to the average reader.

Prospectus Summary, page 1

- 5. We note that your Phase 1 study for CHS-1701 "did not meet bioequivalence" and that you are planning an additional PK study comparing CHS-1701 and Neulasta. Moreover, your Phase 3 trials will be initiated, at the earliest, in 2015. Accordingly, please revise your chart on page 1 and 89 so that the arrow for the CHS-1701 row clearly reflects that this product candidate is still effectively in Phase 1, notwithstanding that you have completed your first Phase 1 trial.
- 6. We note your statement on page 4 and 96 that "(w)e have successfully advanced CHS-1701 through completion of a Phase 1 PK/PD study in healthy volunteers." Please modify your disclosure as necessary to put this assertion in its proper context with your disclosure on page 98 that your Phase 1 study of CHS-1701 "did not meet bioequivalence due to geometric mean values ranging slightly above the allowed upper confidence interval (125%) on all three variables" and that you will perform additional Phase 1 studies before advancing to Phase 3. In addition, please explain the significance of failing to meet the study's three designated bioequivalence endpoints and clarify your ability to rely on the post-hoc bioequivalence analysis performed for purposes of future applications for marketing approval.

Risks Associated with Our Business, page 5

7. Please expand the 5th and 7th bullets to provide more specificity with respect to the unique risks posed by the various global regulatory pathways and the Biologics Price Competition Act of 2009, respectively.

Corporate Information, page 5

8. On page 6, please state that your election to opt out of the JOBS ACT extended transition periods is irrevocable.

The Offering, page 7

9. Please break out your anticipated use of proceeds among your product candidates.

Risk Factors

10. Please add a stand-alone risk factor that discusses the technical challenges inherent in developing protein therapeutics, including information similar to the disclosure that appears on page 86 of the Business section. Please also add a related bullet to the list of risk factors on page 5 of your prospectus summary.

<u>Risks Related to the Discovery and Development of Our Product Candidates</u> <u>"If we are not able to demonstrate biosimilarity of our biosimilar product candidates to the</u> <u>satisfaction of regulatory authorities . . .," page 16</u>

11. Please amend this risk factor to note the failure of your Phase 1 study of CHS-1701 to meet the endpoints established for bioequivalence with Neulasta and that additional Phase 1 studies will be conducted before proceeding to Phase 3.

"The development, manufacture and commercialization of biosimilar products ...," page 19

12. Please specify when the original BLAs for Enbrel and Humira were approved, and in which geographic markets.

Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies Stock-Based Compensation Common Stock Options, page 75

13. Please note we may have additional comments on your accounting for stock compensation once you have disclosed an estimated offering price. Please provide us with a quantitative and qualitative analysis explaining the difference between the estimated offering price and the fair value of each equity issuance through the date of effectiveness for the preceding twelve months.

Business, page 83

14. To the extent practicable, please minimize the use of highly technical terminology in this section and elsewhere in the registration statement that may be unfamiliar to lay investors. If the use of such terms is necessary, please give the meaning and significance of such terms in plain language that may be readily understood by a person not acquainted with this industry or scientific field. By way of example only and not as an

exhaustive list, an explanation of the following terms should accompany their first usage in the registration statement.

- endogenous (page 83);
- granulocyte (page 83);
- monoclonal antibodies (page 86);
- post-translational modifications (page 86);
- cell sub-type selection (page 86);
- geometric ratio (page 87);
- protein stabilization (page 87);
- moiety (page 90);
- cellular receptors (page 90);
- down-regulating (page 90);
- lineage-specific (page 95);
- monocytes, fibroblasts and endothelial cells (page 95);
- neutrophils (page 95);
- pegylated (page 96);
- covalent (page 95);
- necropsy and gross necropsy (page 97); and
- lymphocytes, eosinophils and basophils (page 97);

Our Approach, page 86

15. In the next-to-last bullet that appears on page 87, please briefly explain how your formulation technology will allow you to "innovate around" patent protected formulations.

Five Key Steps to Biosimilar Drug Development, page 88

- 16. Please summarize your meetings with regulators by providing the approximate dates of such meetings, the regulatory body with whom you met and the general nature of discussions.
- 17. On page 89, please provide a brief but straightforward explanation of the three bioequivalence parameters listed. For example, when you discuss $AUC_{0\rightarrow t}$, you should explain the concept of area under the concentration-time curve and what precisely is measured.

Development Portfolio, page 89

- 18. Please indicate for each of your product candidates the location of each of your clinical studies and whether you filed an Investigational New Drug Application, or equivalent request for approval, covering such studies. If an application was not filed, please explain why.
- 19. We note that your developmental plans call for you to proceed from Phase 1 trials of your lead candidates directly to Phase 3. In your discussion of the FDA approval process on page 105, however, you talk about the typical progression of three sequential phases of clinical trials used to support BLAs for marketing approval. Please address how developmental strategy differs from the typical route for biologics, the basis of your belief that this direct progression to Phase 3 is viable, any risks involved and any specific discussions you have had with regulatory agencies about this.
- 20. With respect to the graphs that appear on pages 92, 97 and 98, please provide a brief narrative accompanying the illustrations that explains the major points the pictures are meant to symbolize. For example, consider adding a legend of some kind to the graphs to help readers interpret the information.

CHS-1420 (Our Adalimumab (Humira) Biosimilar Candidate), page 93

21. In your discussion of CHS-1420, please clarify the relationship, in layman's terms, between Humira's ability to block signaling through the TNF pathway and the effect on various inflammatory diseases. Similarly, please explain the significance of Humira's ability to bind activating Fcy receptors and complement component C1q.

CHS-1701 (Our Pegfilgrastim (Neulasta) Biosimilar Candidate), page 96

- 22. Please explain, in terms comprehensible to the non-specialist, what a luminescence assay is, how CHS-1701 stimulates the proliferation of NFS-60 leukemia cells and clarify the significance of this proliferation with respect to the accelerated development of neutrophils that pegfilgrastim is designed to facilitate.
- 23. In your discussion of your in vivo comparability studies of CHJS-1701 on page 97, the significance of your observations is not sufficiently clear. Please explain the following in layman's terms and clarify the significance of each with respect to conclusions about bioequivalence :
 - increases in ANC, monocytes, lymphocytes, eosinophils and basophils;
 - decrease in red blood cell parameters and platelet counts;
 - increase in the myleloid:erythroid ratio in bone marrows;
 - increased hematopoiesis at necropsy and the fact that, at necropsy, microscopic findings were observed in multiple marrow-bearing areas; and

• exposure PK parameters

Manufacturing, page 99

24. We note your statement here that you have entered into commitments with your contract manufacturers as well as your statement in the first risk factor on page 27 regarding your other arrangements with various suppliers. Please indicate whether these commitments involve binding contracts between you and these companies and, if so, disclose their material terms here and file such contracts as exhibits. Alternatively, if you believe these agreements are not material to your operations, please explain why in your response.

Collaboration and License Agreements, page 100

- 25. Please amend your disclosure concerning each agreement to include a range of the royalty payments that may be made pursuant to that agreement, e.g. "(low/high) single-digits," "teens," "twenties," etc.
- 26. Please disclose the aggregate amount if milestones, if any, that may be paid to you under the agreement with Daiichi Sankyo.
- 27. Please amend your disclosure to state the aggregate milestone payments relating to the license agreements with Genentech, Inc. and Selexis SA.

Intellectual Property, page 102

28. With respect to the material patents that you have in-licensed From Daiichi Sankyo, Baxter, and any other parties, please provide disclosure about this intellectual property similar to the information you have provided for your owned patents and patent applications.

<u>Management</u> Scientific Advisory Board, page 115

29. Please briefly discuss the function of your scientific advisory board and the specific responsibilities of the board members, as well as the frequency of board meetings.

Principal Stockholders, page 146

30. To the extent not already disclosed, please revise to state the names of the individuals who have voting and/or dispositive power over the shares held by each of your 5% and greater stockholders.

Index to Audited Consolidated Financial Statements Notes to Consolidated Financial Statements 5. Collaboration and License Agreement Daiichi Sankyo, page F-18

31. Please disclose the reasons that the deliverables (i.e. license and the manufacture of the drug materials for clinical development) do not have standalone value. Refer to ASC 605-25-50-2f.

<u>Index to Financial Statements</u> <u>Unaudited Interim Condensed Consolidated Financial Statements</u> <u>Notes to Unaudited Condensed Consolidated Financial Statements</u> <u>6. Acquisition of InteKrin Therapeutics, Inc., page F-52</u>

32. Tell us why the \$2.29 per share value you determined for the Series B convertible preferred stock is significantly less than the \$4.1841 initial closing price for Series B issuances that occurred in 2012.

12.Net Loss and Unaudited Pro Forma Net Loss Per Share, F-34

33. Please include herein and in Note 10 on F-57 to your unaudited condensed consolidated financial statements reconciliations of the numerators and denominators of your basic and diluted per share computations for each period presented, as required under ASC 260-10-50-1a. If you are treating the unvested restricted shares as contingently issuable and thus excluding them from the basic and diluted denominator, include as a reconciling item. Refer to Example 3 at ASC 260-10-55-56. Also provide us your analysis with reference to the authoritative literature supporting your treatment of unvested restricted shares as contingently issuable shares.

If you intend to respond to these comments with an amended draft registration statement, please submit it and any associated correspondence in accordance with the guidance we provide in the Division's October 11, 2012 announcement on the SEC website at http://www.sec.gov/divisions/corpfin/cfannouncements/drsfilingprocedures101512.htm.

Please keep in mind that we may publicly post filing review correspondence in accordance with our December 1, 2011 policy (http://www.sec.gov/divisions/corpfin/cfannouncements/edgarcorrespondence.htm). If you intend to use Rule 83 (17 CFR 200.83) to request confidential treatment of information in the correspondence you submit on EDGAR, please properly mark that information in each of your confidential submissions to us so we do not repeat or refer to that information in our comment letters to you.

You may contact Tabatha McCullom at (202) 551-3658 or James Rosenberg at (202) 551-3679 if you have questions regarding comments on the financial statements and related

matters. Please contact Daniel Greenspan at (202) 551-3623, Scot Foley at (202) 551-3383 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Daniel Greenspan for

Jeffrey P. Riedler Assistant Director

cc: <u>Via E-mail</u> Alan C. Mendelson, Esq. Latham & Watkins LLP