IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, v. COHERUS BIOSCIENCES, INC. Defendant.	Case No. 17-546 (LPS) (CJB)

COHERUS BIOSCIENCES INC.'S OPENING BRIEF IN SUPPORT OF MOTION FOR STAY PENDING RESOLUTION OF COHERUS'S MOTION TO DISMISS

Kenneth L. Dorsney (#3726)
Richard K. Herrmann (#405)
MORRIS JAMES LLP
500 Delaware Avenue, Suite 1500
Wilmington, DE 19801
(302) 888-6800
kdorsey@morrisjames.com

OF COUNSEL:

Bradford P. Lyerla
Louis E. Fogel
Aaron A. Barlow
Chad J. Ray
Jonathon M. Studer
JENNER & BLOCK LLP
353 N. Clark Street
Chicago, IL 60654
(312) 222-9350

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I. INTRODUCTION

Coherus BioSciences, Inc. ("Coherus") moves for a stay of discovery and of this Court's oral order dated July 18, 2017 ("the July 18 Order") pending resolution of Coherus's case-dispositive motion to dismiss. Coherus seeks a stay to preserve the Court's and the parties' resources. Preservation of resources is especially important to Coherus—a new start-up biosimilar company that has no products and, because of a recent FDA rejection of its drug application, will have no revenue until its anticipated mid-2018 launch of the product at issue in this case.

This case is different from typical drug cases in two respects. Not only is Amgen's case exceptionally weak, but since the lawsuit was filed, the timing for Coherus's launch has been delayed by at least a year. Each of these factors justifies a stay.

On the face of the complaint, Amgen's theory of infringement is so plainly meritless that Coherus moved to dismiss the Complaint under FED. R. CIV. P. 12(b)(6) in lieu of answering. Under Third Circuit law, "motions to dismiss filed under [Rule 12(b)(6)] should typically be resolved before discovery begins." *Levey v. Brownstone Inv. Group, LLC*, 590 F. App'x 132, 137 (3d Cir. 2014) (internal quotation marks omitted). Amgen's infringement claim is meritless as a matter of law. Amgen concedes there is no literal infringement and, given its clear prosecution history disclaimers, offers no plausible basis for proving its doctrine of equivalents theory.

Weak case though it is, Amgen can use its vast resources to bankrupt Coherus with unnecessary litigation expenses before Coherus can launch. While these expenses might have been manageable when Coherus expected to launch its product by the Fall of 2017, a recent development has made it even more important that Coherus be spared unnecessary and unreasonable litigation costs. The FDA recently rejected Coherus's drug application by issuing a Complete Response Letter ("CRL"). Coherus estimates that the FDA's rejection will most likely delay launch of that product by approximately one year. Coherus must now stretch its financing over the ad-

ditional year it will take to bring the product to market. Since receiving the FDA's rejection, Coherus already has laid off one-third of its workforce to preserve its cash.

Amgen will not be unduly prejudiced by a stay. This is clear from Amgen's past conduct during the BPCIA pre-litigation information exchange, commonly referred to as the "patent dance." Throughout the patent dance, Amgen resisted Coherus's efforts to have this case filed earlier. Coherus served its non-infringement positions early and attempted to accelerate the last phase of the dance so the lawsuit could be filed as soon as possible. Amgen, however, took almost the maximum time permitted by statute for every step in the dance and then tried to introduce additional delays before filing this lawsuit. Furthermore, the recent CRL has delayed Coherus' anticipated launch so that, even with a six-month stay, Amgen will still have more time to conduct discovery before Coherus's launch than was expected when the lawsuit was filed.

Accordingly, based on the factors governing motions to stay discussed below, a stay is appropriate here and should be granted.

II. NATURE AND STAGE OF THE PROCEEDINGS

Amgen filed its complaint against Coherus on May 10, 2017 alleging infringement of U.S. Patent No. 8,273,707. The complaint, based on the Biologics Price Competition and Innovation Act ("BPCIA"), attempts to block entry of biosimilar competition to Amgen's biologic drug product Neulasta®. On June 1, 2017, Coherus responded to the complaint by filing a motion to dismiss under FED. R. CIV. P. 12(b)(6). (D.I. 10.) Briefing on Coherus's motion to dismiss was completed on June 22, 2017.

Coherus has not yet answered the complaint. On July 18, 2017, this Court issued an order instructing the parties to jointly file various documents, including a Case Management checklist and a proposed Scheduling Order.

III. SUMMARY OF THE ARGUMENT

Amgen's complaint does not allege literal infringement, nor could it, since the sole asserted patent requires a chemical compound that Coherus does not use in its manufacturing process. Instead, Amgen relies only on the doctrine of equivalents. But that infringement theory is improper as a matter of law because Amgen argued during prosecution that the chemical compound Coherus uses is in the prior art and is not an example of the patented invention. Accordingly, Coherus moved to dismiss Amgen's complaint. No discovery is necessary to resolve Amgen's motion.

A well-founded dispositive motion filed before discovery begins weighs strongly in favor of staying discovery until the motion is decided. As the Third Circuit has explained, because "[t]he Rule 12(b)(6) procedure streamlines litigation by dispensing with needless discovery and fact finding, . . . motions to dismiss filed under it should typically be resolved before discovery begins." *Levey*, 590 F. App'x at 137 (internal citations and quotation marks omitted).

Other factors that courts consider in deciding to stay discovery (*i.e.* stage of litigation and prejudice to the non-moving party) also weigh in favor of a stay here. The case is just beginning: Coherus has not answered the complaint and discovery has not started. Amgen will not be harmed by a stay and the recent rejection of Coherus's FDA application adds an additional year of time before Coherus will be able to market its product in the United States.

Accordingly, the requested stay should be granted.

IV. STATEMENT OF FACTS

This case arises under the BPCIA. Coherus filed an abbreviated Biologics License Application ("aBLA") with the FDA requesting a license to market a biosimilar version of Amgen's Neulasta. As part of the BPCIA's pre-litigation exchanges (the so-called "patent dance"), Co-

herus provided Amgen with a copy of its aBLA, including sections that set out the only legally relevant description of the manufacturing process Coherus will use to make its product.

A. Amgen Drags Its Feet During the Patent Dance.

Within days of the FDA accepting Coherus's aBLA the parties started the patent dance, beginning with Coherus providing to Amgen a complete copy of the aBLA. (Ex. 1.) This triggered a series of subsequent steps, including the exchange of detailed infringement and invalidity contentions, that occurred this past winter. The dance is a stepwise process and the deadline for each step is triggered off the completion of the previous step. 42 U.S.C. § 262(*l*)(2)-(6). Thus, finishing a step early accelerates the entire process. Because there were so few patents involved in this process here, Coherus accelerated the dance by completing its steps prior to the statutory deadlines.

But Amgen did not reciprocate, and instead drew the patent dance out as long as possible. For example, Coherus served its detailed statement of infringement and invalidity contentions three weeks earlier than the deadline; whereas Amgen served its responsive statement on the second to last day possible—despite having decided to raise just one patent for the case. (Ex. 2; Ex. 3; Ex. 4; 42 U.S.C. § 262(*l*)(3)(B)(ii) and § 262(*l*)(3)(C).)

Within two business days of receiving that responsive statement, Coherus informed Amgen it should immediately commence the patent litigation (Ex. 5); however, Amgen refused. Surprisingly, Amgen instead requested a telephone conference the following week "in order to negotiate which patent(s) should be included in [the litigation]." (Ex. 6 at 2.) Given there was only one patent at issue, and therefore nothing to negotiate, Amgen's insistence upon a delayed negotiations period was apparently only meant to create additional delay before filing suit:

> Please note that, in our view, the negotiations required under [the patent dance statute] are necessarily mutual and cannot be started by one party unilaterally. The 15-day statutory period for such ne-

> gotiations would begin with the proposed [telephone] conference [next week]. We do not agree that negotiations have begun or that the period to negotiate pursuant to [the patent dance statute] ends on April 10, 2017.

(Ex. 6 at 2.) Nevertheless, Coherus accommodated Amgen's request for a "negotiation" on which patent should be subject of this lawsuit. But even after this pointless negotiation was completed (with the expected outcome), Amgen waited until almost the last possible day to file this lawsuit. The parties agreed that Amgen had to file its lawsuit not later than 30 days after April 11, 2017. (Ex. 7.) And Amgen filed the lawsuit on May 10, 2017. (D.I. 1.)

B. Coherus Promptly Files Its Motion To Dismiss.

After the lawsuit was filed, Coherus did not request an extension of time to respond to Amgen's complaint. Instead, twenty-one days after service of the complaint, Coherus filed a motion to dismiss under FED. R. CIV. P. 12(b)(6) on the grounds that no plausible theory of infringement could encompass the accused Coherus process either literally or under the doctrine of equivalents. (D.I. 9.)

The Rule 12 motion is based on the process parameters set forth in Coherus's aBLA (which is the only process for which Coherus is seeking FDA approval) and on the prosecution history of Amgen's asserted patent. (D.I. 10 at 8-9.) These documents set forth all the facts relevant to the motion to dismiss, and they are fully in Amgen's possession. None of these facts will change, and as explained in the moving papers, the Court is entitled to consider them in resolving a Rule 12 motion. Coherus's Rule 12 motion turns only on (1) the legal effect of Amgen's disclaimers in prosecution history and (2) the statements Amgen made in the asserted patent's specification. (*Id*. at 12-17.) If either of those issues is resolved in Coherus's favor, this case is over. Even if the Court resolves issues raised in Amgen's favor, such a ruling will streamline discovery because it will narrow the infringement issues in this case.

C. The FDA Rejection Of Coherus's aBLA Delays Product Launch And Imposes Additional Costs On Coherus.

In mid-June 2017, the FDA issued a Complete Response Letter ("CRL") in response to Coherus's aBLA for pegfilgrastim. (Fleming Decl. at ¶ 6.) While the CRL is a rejection of Coherus's aBLA in its present form, Coherus can address the issues raised in the CRL and then resubmit a revised aBLA under the same application number. Consequently, the CRL will delay Coherus from marketing pegfilgrastim by approximately a year—six months for Coherus to prepare and submit new information to the FDA, and, upon acceptance of the resubmitted application, another six months for the FDA to issue a decision. (Ex. 8 at 4.)

This delay forces Coherus—a biosimilar startup with no revenues—to stretch its limited resources over an additional 12-month period. To survive this extended period, Coherus must slash its spending by approximately 50% for the second half of 2017 and first half of 2018. (Ex. 8 at 4.) As part of this effort, Coherus recently laid off one-third of its employees. (Fleming Decl. at ¶ 7.)

V. ARGUMENT

A. Governing Law

In exercising its discretion to grant a motion to stay, this Court has typically considered three factors: "(1) whether granting the stay will simplify the issues for trial; (2) the status of the litigation, particularly whether discovery is complete and a trial date has been set; and (3) whether a stay would cause the non-movant to suffer undue prejudice from any delay, or allow the movant to gain a clear tactical advantage." *Ever Win Int'l Corp. v. RadioShack Corp.*, 902 F. Supp. 2d 503, 505 (D. Del. 2012). In evaluating the prejudice factor, "the court necessarily performs a balancing, comparing the burdens that a stay or the denial of a stay would impose upon the respective parties." *ImageVision.Net, Inc. v. Internet Payment Exchange*, 2012 WL 5599338, at *3

(D. Del. Nov. 15, 2012); *see also Gold v. Johns-Manville Sales Corp.*, 723 F.2d 1068, 1076 (3d Cir. 1983) (balancing the potential hardship with respect to both parties).

B. The Court Should Stay Discovery And The July 18 Order Until The Motion To Dismiss Is Resolved.

As discussed below, all three factors weigh in favor of granting a stay.

1. Granting A Stay Would Simplify The Issues For Trial, And Possibly Eliminate The Need For One.

The pending motion to dismiss is a key reason to grant a stay. The motion presents multiple reasons why all of Amgen's claims fail as a matter of law. Those issues are dispositive issues on Amgen's infringement claim, and will likely need to be decided at some point in the case. Resolution of them now is likely to make discovery unnecessary—or at the very least to simplify the issues so the parties can engage in more focused discovery.

As the Third Circuit has recognized, Rule 12(b)(6) "streamlines litigation by dispensing with needless discovery and factfinding" and, therefore, motions to dismiss "should typically be resolved before discovery begins." *Levey*, 590 F. App'x at 137 (internal citations and quotation marks omitted). Consistent with that purpose, discovery should be stayed while the Court resolves the potentially case-dispositive issues raised in Coherus's motion to dismiss. *See Actelion Pharms. Ltd. v. Apotex Inc.*, 2013 WL 5524078, at *5 (D. N.J. Sept. 6, 2013) (holding that the simplification factor favored the Rule 12 movant because the motion was not frivolous or without basis in law; movant was not required to show a "clear and unmistakable" likelihood of success); *see also Novartis Corp. v. Dr. Reddy's Labs., Ltd.*, 2004 WL 2368007 (S.D.N.Y. Oct. 21, 2004) (granting a stay in the early stages of discovery because FDA proceedings on whether a drug could be marketed had potential to moot the patent case). Even if issues are resolved in Amgen's favor, that would likely narrow the issues for discovery and be a key factor the parties

would consider in preparing the Case Management Order and other documents in response to the July 18 Order.

2. Coherus Will Suffer Financial Hardship If A Stay Is Denied, Whereas Amgen Will Not Suffer Hardship If A Stay Is Granted.

Coherus will suffer financial hardship if a stay is denied. Pegfilgrastim was expected to be Coherus's first product to market, but the CRL letter, the company's response to it, and the FDA's review, if it accepts a resubmission from Coherus, will most likely delay the launch until at least June 2018. (Ex. 8 at 4.) Coherus therefore must stretch its limited financing for an additional 12 months. (*Id*.) It has already been forced to lay off one-third of its workforce. (Fleming Decl. at ¶ 7.) Denial of the stay would require Coherus to divert its limited resources to conduct and defend discovery related to legally insufficient claims. Such an injustice would be contrary to the purpose of Rule 12(b)(6). *Levey*, 590 F. App'x at 137.

By contrast, Amgen will not suffer hardship if a stay is granted. Rather, Amgen has already chosen to delay this litigation. *Supra,* at 3-5. During the patent dance, Amgen used every opportunity to slow things down and delay the date it would have to file this lawsuit, including taking the position that the parties needed to spend an additional 15 days "negotiating" which "patent(s)" to litigate when Amgen had admitted that only one patent was arguably infringed and only one patent could possibly be litigated. (Ex. 6.)

Whereas Coherus accelerated the dance by serving its non-infringement statement three weeks early and requested Amgen to file this case as early as possible, Amgen used all but a few of the maximum allowed days under the statute for its responses. *Supra* at 3-5. Thus, Amgen is in no position to argue that it will be prejudiced if the requested stay reduces the length of time for discovery before potential FDA approval of the Coherus aBLA.

Indeed, even if the court stays this case for six months, Amgen will still have more time before Coherus's launch than it could have expected when the lawsuit was filed in May 2017, which was already much later than it could have been filed if Amgen, like Coherus, had accelerated the patent dance steps. In May 2017 when Amgen filed its complaint, a response from the FDA on Coherus's application was due in June 2017 and, if favorable, Coherus would have launched by the mid-second half of 2017. (Fleming Decl. at ¶ 5.) If Coherus had answered the complaint and the Court had ordered discovery to commence shortly thereafter, there would have been less than four months of time before Coherus would have been able to commercially market its approved product in the United States.

In June, however, the FDA rejected Coherus's application—meaning that Coherus will likely not be able to launch until the middle of next year at the earliest. (Ex. 8 at 4.) Thus, if the Court stays this case for six months and ends up denying Coherus's motion to dismiss, Amgen will still have about six months of discovery before Coherus can likely launch—almost twice as much time as was expected when Amgen filed its complaint.

Accordingly, Amgen cannot contend that it will be significantly prejudiced by a stay, nor can it deny that its own dilatory behavior during the patent dance will have contributed to any perceived time pressure. The prejudice factor therefore also favors Coherus.

3. A Stay Of Discovery Pending The Motion To Dismiss Is An Eminently Logical Way To Conserve Judicial and Party Resources.

Because this motion has been brought at the earliest stage of litigation, the final factor that courts consider in granting a stay favors a stay here too. This factor weighs strongly in favor of granting a stay if discovery has not begun. *See Kaavo Inc. v. Cognizant Tech. Solutions Corp.*, 2015 WL 1737476, at *3 (D. Del. Apr. 9, 2015) (M.J., Burke) (holding that stage-of-litigation factor "strongly" favored stay where Case Management Conference had been held, but

discovery had not begun); *Ever Win*, 902 F. Supp. 2d at 508 (M.J., Burke) ("Because Defendant's motion to stay was filed early in this case, this factor weighs strongly in favor of a stay."); *Novartis*, 2004 WL 2368007, at *3 (granting a stay in the early stages of discovery). Here, discovery has not yet begun and no case management proceedings have occurred. Therefore, under *Kaavo* and *Ever Win*, this factor "strongly" favors a stay.

Amgen's baseless patent infringement claim simply does not justify the substantial costs of beginning discovery before the adequacy of the complaint is considered by the Court. In the unlikely event that Amgen's complaint survives Coherus's motion to dismiss, there will still be sufficient time to provide Amgen the information that it may need before Coherus's anticipated new launch date.

Because this Court regards a stay of discovery pending a dispositive motion "an eminently logical" way to "prevent wasting time and effort" and to "make the most efficient use of judicial resources," *Coastal States Gas Corp. v. Dep't of Energy*, 84 F.R.D. 278, 282 (D. Del. 1979), it should grant the stay.

VI. CONCLUSION

For all of the foregoing reasons, Coherus respectfully requests that the Court stay discovery, and the July 18 Order pending the Court's decision on Coherus's motion to dismiss.

Dated: July 25, 2017

/s/ Richard K. Herrmann

Kenneth L. Dorsney (#3726)
Richard K. Herrmann (#405)
MORRIS JAMES LLP
500 Delaware Avenue, Suite 1500
Wilmington, DE 19801
(302) 888-6800
kdorsey@morrisjames.com

OF COUNSEL:

Bradford P. Lyerla
Louis E. Fogel
Aaron A. Barlow
Chad J. Ray
Jonathon M. Studer
JENNER & BLOCK LLP
353 N. Clark Street
Chicago, IL 60654
(312) 222-9350

Exhibit 1

353 N. CLARK STREET CHICAGO, IL 60654-3456

JENNER&BLOCK LLP

Louis E. Fogel
Tel +1 312 923 2661
LFogel@jenner.com

October 14, 2016

VIA EMAIL AND FIRST CLASS MAIL

Wendy Whiteford
Vice President, Law
Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320
<wendy@amgen.com>

Re: Coherus BioSciences' Disclosure Pursuant to 42 U.S.C. §§ 262(*l*)(1) and (*l*)(2)(A)

Dear Ms. Whiteford

I write on behalf of Coherus BioSciences, Inc. to inform you that on October 6, 2016, the FDA accepted the filing of Coherus's Abbreviated Biologics License Application No. 761039 for CHS-1701, a pegfilgrastim (Neulasta) biosimilar candidate.

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) allows for the confidential exchange of certain information between a subsection (k) applicant and the reference product sponsor. Coherus hereby provides Amgen, as the reference product sponsor for Neulasta, confidential access to "a copy of the application [Coherus] submitted to the Secretary under subsection (k)." 42 U.S.C. § 262(*l*)(2)(A). Please note that there were six pre-acceptance supplemental submissions, and that these supplements should be referred to for the most up-to-date content of their respective sections.

This disclosure is provided to Amgen subject to the BPCIA's default confidentiality provisions. 42 U.S.C. § 262(*l*)(1). Please send me by Monday, October 17, 2016, the names and contact information for the limited group of recipients under subsection 262(*l*)(1)(B) that should receive login credentials to access the disclosure.

If you have any questions about the foregoing, or the information we are providing, do not hesitate to contact us.

Sincerely,

Louis Fogel

Louis E. Fogel

Exhibit 2

PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP

1285 AVENUE OF THE AMERICAS
NEW YORK, NEW YORK 10019-6064
TELEPHONE (212) 373-3000

LLOYD K GARRISON (1946-1991)
RANDOLPH E PAUL (1946-1956)
SIMON H RIFKIND (1950-1995)
LOUIS S WEISS (1927-1950)
JOHN F WHARTON (1927-1977)

WRITER S DIRECT DIAL NUMBER
212-373-3212

WRITER S DIRECT FACSIMILE
212-492-0212

WRITER S DIRECT E-MAIL ADDRESS
ngroombridge@paulweiss.com

UNIT 3601 OFFICE TOWER A BEIJING FORTUNE PLAZA
NO 7 DONGSANHUAN ZHONGLU
CHAOYANG DISTRICT
BEIJING 100020
PEOPLE S REPUBLIC OF CHINA
TELEPHONE (86-10) 5828-6300

12TH FLOOR HONG KONG CLUB BUILDING
3A CHATER ROAD CENTRAL
HONG KONG
TELEPHONE (852) 2846-0300

ALDER CASTLE
10 NOBLE STREET
LONDON EC2V 7JU U K
TELEPHONE (44 20) 7367 1600

FUKOKU SEIMEI BUILDING
2-2 UCHISAIWAICHO 2-CHOME
CHIYODA-KU TOKYO 100-0011 JAPAN
TELEPHONE (81-3) 3597-8101

TORONTO-DOMINION CENTRE
77 KING STREET WEST SUITE 3100
PO BOX 226
TORONTO ONTARIO M5K 1J3
TELEPHONE (416) 504-0520

2001 K STREET NW
WASHINGTON DC 20006-1047
TELEPHONE (202) 223-7300

500 DELAWARE AVENUE SUITE 200
POST OFFICE BOX 32
WILMINGTON DE 19899-0032
TELEPHONE (302) 655-4410

MATTHEW W ABBOTT
EDWARD T ACKERMAN
JACOB A ADLERSTEIN
ALLAN J ARFFA
ROBERT A ATKINS
DAVID J BALL
SCOTT A BARSHAY
JOHN F BAUGHMAN
LYNN B BAYARD
DANIEL J BELLER
CRAIG A BENSON
MITCHELL L BERG
MARK S BERGMAN
DAVID M BERNICK
JOSEPH J BIAL
BRUCE BIRENBOIM
H CHRISTOPHER BOEHNING
ANGELO BONVINO
JAMES L BROCHIN
RICHARD J BRONSTEIN
DAVID W BROWN
SUSANNA M BUERGEL
PATRICK S CAMPBELL*
JESSICA S CAREY
JEANETTE K CHAN
GEOFFREY R CHEPIGA
ELLEN N CHING
WILLIAM A CLAREMAN
LEWIS R CLAYTON
JAY COHEN
KELLEY A CORNISH
CHRISTOPHER J CUMMINGS
CHARLES E DAVIDOW
THOMAS V DE LA BASTIDE III
ARIEL J DECKELBAUM
ALICE BELISLE EATON
ANDREW J EHRLICH
GREGORY A EZRING
LESLIE GORDON FAGEN
MARC FALCONE
ROSS A FIELDSTON
ANDREW C FINCH
BRAD J FINKELSTEIN
BRIAN P FINNEGAN
ROBERTO FINZI
PETER E FISCH
ROBERT C FLEDER
MARTIN FLUMENBAUM
ANDREW J FOLEY
ANDREW J FORMAN*
HARRIS B FREIDUS
MANUEL S FREY
ANDREW L GAINES
KENNETH A GALLO
MICHAEL E GERTZMAN
ADAM M GIVERTZ
SALVATORE GOGLIORMELLA
ROBERT D GOLDBAUM
NEIL GOLDMAN
ROBERTO J GONZALEZ*
CATHERINE L GOODALL
ERIC GOODISON
CHARLES H GOOGE, JR
ANDREW G GORDON
UDI GROFMAN
NICHOLAS GROOMBRIDGE
BRUCE A GUTENPLAN
GAINES GWATHMEY, III
ALAN S HALPERIN
JUSTIN G HAMILL
CLAUDIA HAMMERMAN
BRIAN S HERMANN
MICHELE HIRSHMAN
MICHAEL S HONG
DAVID S HUNTINGTON
AMRAN HUSSEIN
LORETTA A IPPOLITO
BRIAN M JANSON
JAREN JANGHORBANI
MEREDITH J KANE
JONATHAN S KANTER
ROBERTA A KAPLAN
BRAD S KARP
PATRICK N KARSNITZ
JOHN C KENNEDY
BRIAN KIM
ALAN W KORNBERG
DANIEL J KRAMER
DAVID K LAKHDHIR
STEPHEN P LAMB*
JOHN E LANGE
GREGORY F LAUFER
DANIEL J LEFFELL
XIAOYU GREG LIU
JEFFREY D MARELL
MARCO V MASOTTI
EDWIN S MAYNARD
DAVID W MAYO
ELIZABETH R McCOLM
MARK F MENDELSOHN
CLAUDINE MEREDITH-GOUJON
WILLIAM B MICHAEL
TOBY S MYERSON
JUDIE NG SHORTELL*
CATHERINE NYARADY
JANE B O BRIEN
ALEX YOUNG K OH
BRAD R OKUN
KELLEY D PARKER
VALERIE E RADWANER
CARL L REISNER
LORIN L REISNER
WALTER G RICCIARDI
WALTER RIEMAN
RICHARD A ROSEN
ANDREW N ROSENBERG
JACQUELINE P RUBIN
CHARLES F RICK RULE*
RAPHAEL M RUSSO
ELIZABETH M SACKSTEDER
JEFFREY D SAFERSTEIN
JEFFREY B SAMUELS
DALE M SARRO
TERRY E SCHIMEK
KENNETH M SCHNEIDER
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JOHN M SCOTT
STEPHEN J SHIMSHAK
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MOSES SILVERMAN
STEVEN SIMKIN
JOSEPH J SIMONS
AUDRA J SOLOWAY
SCOTT M SONTAG
TARUN M STEWART
ERIC ALAN STONE
AIDAN SYNNOTT
MONICA K THURMOND
DANIEL J TOAL
LIZA M VELAZQUEZ
LAWRENCE G WEE
THEODORE V WELLS JR
STEVEN J WILLIAMS
LAWRENCE I WITDORCHIC
MARK B WLAZLO
JULIA MASON WOOD
JENNIFER H WU
BETTY YAP*
JORDAN E YARETT
KAYE N YOSHINO
TONG YU
TRACEY A ZACCONE
TAURIE M ZEITZER
T ROBERT ZOCHOWSKI JR

NOT ADMITTED TO THE NEW YORK BAR

December 16, 2016

CONFIDENTIAL

By Electronic Mail, Hand Delivery, and Federal Express Mail

Louis E. Fogel, Esq
Jenner & Block LLP
353 N. Clark Street
Chicago, IL 60654-3456

Dear Louis:

Pursuant to 42 U.S.C. § 262(*l*)(3)(A) and based upon the information Coherus has provided to date, Amgen identifies the following patents for which Amgen believes a claim of patent infringement could reasonably be asserted with respect to the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of Coherus Biosciences' aBLA No. 761039.

- U.S. Patent No. 6,180,391
- U.S. Patent No. 8,273,707

Further, Amgen is not prepared to license U.S. Patent Nos. 6,180,391 and 8,273,707 to Coherus at this time. However, if the parties can reach a suitable agreement

to protect Amgen's confidential information, Amgen may be willing to reconsider this position.

Sincerely yours,

/s/ Nicholas Groombridge

Nicholas Groombridge

CC: Kimberlin Morley, Esq.

Exhibit 3

353 N. CLARK STREET CHICAGO, IL 60654-3456

JENNER&BLOCK LLP

January 24, 2017

Louis E. Fogel
Tel +1 312 923 2661
LFogel@jenner.com

CONFIDENTIAL

VIA EMAIL, FIRST CLASS MAIL, AND FEDERAL EXPRESS

Nick Groombridge, Esq.
Paul, Weiss, Rifkind, Wharton & Garrison LLP
1285 Avenue of the Americas
New York, NY 10019-6064

Re: Coherus BioSciences's Abbreviated Biologics License Application No. 761039 – Detailed Statement Pursuant to 42 U.S.C. § 262(*l*)(3)(B)

Dear Mr. Groombridge,

Coherus hereby provides its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), that describes, on a claim by claim basis, the factual and legal basis that each of the two patents identified in your letter dated December 16, 2016, U.S. Patent No. 6,180,391 and U.S. Patent No. 8,273,707, are invalid or will not be infringed by the commercial marketing of the biological product that is the subject of Coherus BioSciences's aBLA No. 761039.

Coherus is providing the information set forth in this detailed statement based on its present knowledge of the facts. This statement is provided without waiver, including, but not limited to, Coherus's right to revise, supplement, or raise additional defenses and/or prior art at any time should additional, or different, facts become available and/or there is a change in the governing law.

Sincerely,

Louis Fogel

Louis E. Fogel

Enclosure

Exhibit 4

PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP

1285 AVENUE OF THE AMERICAS
NEW YORK, NEW YORK 10019-6064
TELEPHONE (212) 373-3000

LLOYD K. GARRISON (1946-1991)
RANDOLPH E. PAUL (1946-1956)
SIMON H. RIFKIND (1950-1995)
LOUIS S. WEISS (1927-1950)
JOHN F. WHARTON (1927-1977)

WRITER'S DIRECT DIAL NUMBER
(212) 373-3212

WRITER'S DIRECT FACSIMILE
(212) 492-0212

WRITER'S DIRECT E-MAIL ADDRESS
ngroombridge@paulweiss.com

UNIT 3601, OFFICE TOWER A, BEIJING FORTUNE PLAZA
NO. 7 DONGSANHUAN ZHONGLU
CHAOYANG DISTRICT
BEIJING 100020
PEOPLE'S REPUBLIC OF CHINA
TELEPHONE (86-10) 5828-6300

12TH FLOOR, HONG KONG CLUB BUILDING
3A CHATER ROAD, CENTRAL
HONG KONG
TELEPHONE (852) 2846-0300

ALDER CASTLE
10 NOBLE STREET
LONDON EC2V 7JU, U.K.
TELEPHONE (44 20) 7367 1600

FUKOKU SEIMEI BUILDING
2-2 UCHISAIWAICHO 2-CHOME
CHIYODA-KU, TOKYO 100-0011, JAPAN
TELEPHONE (81-3) 3597-8101

TORONTO-DOMINION CENTRE
77 KING STREET WEST, SUITE 3100
P.O. BOX 226
TORONTO, ONTARIO M5K 1J3
TELEPHONE (416) 504-0520

2001 K STREET, NW
WASHINGTON, DC 20006-1047
TELEPHONE (202) 223-7300

500 DELAWARE AVENUE, SUITE 200
POST OFFICE BOX 32
WILMINGTON, DE 19899-0032
TELEPHONE (302) 655-4410

MATTHEW W. ABBOTT
EDWARD T. ACKERMAN
JACOB A. ADLERSTEIN
ALLAN J. ARFFA
ROBERT A. ATKINS
DAVID J. BALL
SCOTT A. BARSHAY
JOHN F. BAUGHMAN
J. STEVEN BAUGHMAN
LYNN B. BAYARD
CRAIG A. BENSON
MITCHELL L. BERG
MARK S. BERGMAN
DAVID M. BERNICK
JOSEPH J. BIAL
BRUCE BIRENBOIM
H. CHRISTOPHER BOEHNING
ANGELO BONVINO
JAMES L. BROCHIN
DAVID W. BROWN
SUSANNA M. BUERGEL
PATRICK S. CAMPBELL*
JESSICA S. CAREY
JEANETTE K. CHAN
GEOFFREY R. CHEPIGA
ELLEN N. CHING
WILLIAM A. CLAREMAN
LEWIS R. CLAYTON
JAY COHEN
KELLEY A. CORNISH
CHRISTOPHER J. CUMMINGS
CHARLES E. DAVIDOW
THOMAS V. DE LA BASTIDE III
ARIEL J. DECKELBAUM
ALICE BELISLE EATON
ANDREW J. EHRLICH
GREGORY A. EZRING
LESLIE GORDON FAGEN
ROSS A. FIELDSTON
ANDREW C. FINCH
BRAD J. FINKELSTEIN
BRIAN P. FINNEGAN
ROBERTO FINZI
PETER E. FISCH
ROBERT C. FLEDER
MARTIN FLUMENBAUM
ANDREW J. FOLEY
ANDREW J. FORMAN*
HARRIS B. FREIDUS
MANUEL S. FREY
ANDREW L. GAINES
KENNETH A. GALLO
MICHAEL E. GERTZMAN
ADAM M. GIVERTZ
SALVATORE GOGLIORMELLA
ROBERT D. GOLDBAUM
NEIL GOLDMAN
ROBERTO J. GONZALEZ*
CATHERINE L. GOODALL
ERIC GOODISON
CHARLES H. GOOGE, JR.
ANDREW G. GORDON
UDI GROFMAN
NICHOLAS GROOMBRIDGE
BRUCE A. GUTENPLAN
ALAN S. HALPERIN
JUSTIN G. HAMILL
CLAUDIA HAMMERMAN
BRIAN S. HERMANN
MICHELE HIRSHMAN
MICHAEL S. HONG
DAVID S. HUNTINGTON
AMRAN HUSSEIN
LORETTA A. IPPOLITO
JAREN JANGHORBANI
BRIAN M. JANSON
JEH C. JOHNSON
MEREDITH J. KANE
JONATHAN S. KANTER
ROBERTA A. KAPLAN
BRAD S. KARP
PATRICK N. KARSNITZ
JOHN C. KENNEDY
BRIAN KIM
DAVID M. KLEIN
ALAN W. KORNBERG
DANIEL J. KRAMER
DAVID K. LAKHDHIR
STEPHEN P. LAMB*
JOHN E. LANGE
GREGORY F. LAUFER
BRIAN C. LAVIN
DANIEL J. LEFFELL
XIAOYU GREG LIU
JEFFREY D. MARELL
MARCO V. MASOTTI
EDWIN S. MAYNARD
DAVID W. MAYO
ELIZABETH R. McCOLM
MARK F. MENDELSOHN
CLAUDINE MEREDITH-GOUJON
WILLIAM B. MICHAEL
JUDIE NG SHORTELL*
CATHERINE NYARADY
JANE B. O'BRIEN
ALEX YOUNG K. OH
BRAD R. OKUN
KELLEY D. PARKER
VALERIE E. RADWANER
CARL L. REISNER
LORIN L. REISNER
WALTER G. RICCIARDI
WALTER RIEMAN
RICHARD A. ROSEN
ANDREW N. ROSENBERG
JACQUELINE P. RUBIN
CHARLES F. "RICK" RULE*
RAPHAEL M. RUSSO
ELIZABETH M. SACKSTEDER
JEFFREY D. SAFERSTEIN
JEFFREY B. SAMUELS
DALE M. SARRO
TERRY E. SCHIMEK
KENNETH M. SCHNEIDER
ROBERT B. SCHUMER
JOHN M. SCOTT
STEPHEN J. SHIMSHAK
DAVID R. SICULAR
MOSES SILVERMAN
STEVEN SIMKIN
JOSEPH J. SIMONS
AUDRA J. SOLOWAY
SCOTT M. SONTAG
TARUN M. STEWART
ERIC ALAN STONE
AIDAN SYNNOTT
RICHARD C. TARLOWE
MONICA K. THURMOND
DANIEL J. TOAL
LIZA M. VELAZQUEZ
LAWRENCE G. WEE
THEODORE V. WELLS, JR.
STEVEN J. WILLIAMS
LAWRENCE I. WITDORCHIC
MARK B. WLAZLO
JULIA MASON WOOD
JENNIFER H. WU
BETTY YAP*
JORDAN E. YARETT
KAYE N. YOSHINO
TONG YU
TRACEY A. ZACCONE
TAURIE M. ZEITZER
T. ROBERT ZOCHOWSKI, JR.

*NOT ADMITTED TO THE NEW YORK BAR

CONFIDENTIAL UNDER 42 U.S.C. § 262(*l*)(1)

VIA EMAIL, FEDEX, AND FIRST CLASS MAIL

March 24, 2017

Louis E. Fogel
Jenner & Block LLP
353 N. Clark Street
Chicago, IL 60654-3456

RE: Amgen's Statement Under 42 U.S.C. § 262(*l*)(3)(C) of the BPCIA for BLA No. 761039

Dear Louis:

I write in response to your January 24, 2017 letter disclosing Coherus' statement under 42 U.S.C. § 262(*l*)(3)(B).

With respect to U.S. Patent No. 8,273,707, Amgen provides Coherus with a detailed statement under 42 U.S.C. § 262(*l*)(3)(C) describing, on a claim-by-claim basis, the factual and legal bases of Amgen's opinion that certain claims of U.S. Patent No. 8,273,707 will be infringed by the commercial marketing of the biological product that is the subject of Coherus' aBLA No. 761039; and a response to the invalidity and unenforceability assertions as to U.S. Patent No. 8,273,707 in Coherus' statement under 42 U.S.C. § 262(*l*)(3)(B).

CONFIDENTIAL UNDER 42 U.S.C. § 262(*l*)(1)

Further analysis of U.S. Patent No. 6,180,391 in view of Coherus' aBLA and other manufacturing information has caused Amgen to decide not to assert this patent in any subsequent lawsuit pursuant to 42 U.S.C. § 262(*l*)(6), and accordingly, not to present a detailed infringement opinion in this (3)(C) Statement. Consequently, a response to Coherus' invalidity and unenforceability positions—with which Amgen disagrees—is moot. The lack of a validity and enforceability discussion herein should in no way be construed to be an admission of agreement with Coherus' invalidity and unenforceability analyses, nor an admission of invalidity or unenforceability.

Please note that Amgen's Statement has been marked "Confidential Under 42 U.S.C. § 262(*l*)(l)."

Sincerely yours,

/s/ Nicholas Groombridge

Nicholas Groombridge

CC: Kimberlin Morley, Esq.

Exhibit 5

353 N. CLARK STREET CHICAGO, IL 60654-3456

JENNER&BLOCK LLP

March 28, 2017

Louis E. Fogel
Tel +1 312 923 2661
LFogel@jenner.com

CONFIDENTIAL

VIA EMAIL AND FEDERAL EXPRESS

Nick Groombridge, Esq.
Paul, Weiss, Rifkind, Wharton & Garrison LLP
1285 Avenue of the Americas
New York, NY 10019-6064

Re: Coherus BioSciences's Abbreviated Biologics License Application No. 761039 – Patent Resolution Negotiation Pursuant to 42 U.S.C. § 262(*l*)(4)(A)

Dear Mr. Groombridge,

I write in response to your March 24, 2017 letter providing Amgen's statement under 42 U.S.C. § 262(*l*)(3)(C).

Coherus acknowledges Amgen's withdrawal of U.S. Patent No. 6,180,391 from the BPCIA patent exchange process, and its decision to not assert it against Coherus in a subsequent lawsuit pursuant to 42 U.S.C. § 262(*l*)(6). However, your letter is ambiguous as to whether Amgen plans to reserve the ability to assert the '391 patent in "second wave" litigation under § 262(*l*)(8), which we believe would be impermissible given Amgen's failure to provide a 3(C) statement regarding this patent.

Due to this ambiguity in your letter, Coherus provides the following alternative proposals.

If Amgen can make the representation that it has withdrawn the '391 patent from its 3(A) patent listing, and will not assert it against Coherus in *any* future lawsuit, whether under § 262 (*l*)(6) *or* § 262 (*l*)(8) or any litigation based on the Coherus CHS-1701 product as presently described in Coherus' BLA under any provision of 35 U.S.C. §271, then pursuant to 42 U.S.C. § 262(*l*)(4)(A), Coherus elects U.S. Patent No. 8,273,707 and agrees that it should be the subject of any patent infringement lawsuit under 35 U.S.C. § 271(e)(2)(C)(i). If Amgen will *not* make these representations, then pursuant to 42 U.S.C. § 262(*l*)(4)(A), Coherus elects both U.S. Patent No. 8,273,707 and U.S. Patent No. 6,180,391 for litigation pursuant to § 262(*l*)(6).

Coherus maintains its non-infringement and invalidity positions, outlined in its detailed statement, that Coherus' process does not infringe either the '707 patent or the '391 patent and that both patents are invalid and/or unenforceable.

Please let me know no later than April 7, 2017 Amgen's position regarding the '391 patent, so that negotiations under § 262*(l)*(4) can be timely concluded by the April 10, 2017 deadline, and the procedure under § 262(*l*)(5) timely begun if no agreement is reached.

Sincerely,

Louis E. Fogel

Exhibit 6

PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP

1285 AVENUE OF THE AMERICAS
NEW YORK, NEW YORK 10019-6064
TELEPHONE (212) 373-3000

LLOYD K. GARRISON (1946-1991)
RANDOLPH E. PAUL (1946-1956)
SIMON H. RIFKIND (1950-1995)
LOUIS S. WEISS (1927-1950)
JOHN F. WHARTON (1927-1977)

UNIT 3601, OFFICE TOWER A, BEIJING FORTUNE PLAZA
NO. 7 DONGSANHUAN ZHONGLU
CHAOYANG DISTRICT
BEIJING 100020
PEOPLE'S REPUBLIC OF CHINA
TELEPHONE (86-10) 5828-6300

12TH FLOOR, HONG KONG CLUB BUILDING
3A CHATER ROAD, CENTRAL
HONG KONG
TELEPHONE (852) 2846-0300

ALDER CASTLE
10 NOBLE STREET
LONDON EC2V 7JU, U.K.
TELEPHONE (44 20) 7367 1600

FUKOKU SEIMEI BUILDING
2-2 UCHISAIWAICHO 2-CHOME
CHIYODA-KU, TOKYO 100-0011, JAPAN
TELEPHONE (81-3) 3597-8101

TORONTO-DOMINION CENTRE
77 KING STREET WEST, SUITE 3100
P.O. BOX 226
TORONTO, ONTARIO M5K 1J3
TELEPHONE (416) 504-0520

2001 K STREET, NW
WASHINGTON, DC 20006-1047
TELEPHONE (202) 223-7300

500 DELAWARE AVENUE, SUITE 200
POST OFFICE BOX 32
WILMINGTON, DE 19899-0032
TELEPHONE (302) 655-4410

WRITER'S DIRECT DIAL NUMBER
212-373-3212

WRITER'S DIRECT FACSIMILE
212-492-0212

WRITER'S DIRECT E-MAIL ADDRESS
ngroombridge@paulweiss.com

April 7, 2017

By Electronic Mail

Louis E. Fogel, Esq
Jenner & Block LLP
353 N. Clark Street
Chicago, IL 60654-3456

Re: *Coherus BioSciences' Abbreviated Biologics License Application (BLA) No. 761039*

Dear Louis:

I write in response to your letter of March 28, 2017.

First, Amgen confirms that has withdrawn U.S. Patent No. 6,180,391 (the '391 patent) from its list provided pursuant to 42 U.S.C. § 262(*l*)(3)(A) regarding Coherus' recombinant methionyl human granulocyte-colony stimulating factor (r-met-Hu-G-CSF) as described in abbreviated BLA No. 761039. Amgen agrees that it will not assert that Coherus' current expression system, as described in the provided copy of Coherus' BLA No. 761039, infringes the '391 patent claims in an action brought under 42 U.S.C. §§ 262(*l*)(6), (*l*)(8) or 35 U.S.C. § 271. To be clear, Amgen's analysis and withdrawal is based upon Coherus' product and process as currently described in its BLA and Amgen

reserves its rights under the ’391 patent in the unlikely event that Coherus’ changes its expression system for r-met-Hu-G-CSF in the future.

Second, we propose that the parties engage in a telephone conference at 3 p.m. Central/4 p.m. Eastern time on April 11, or at another date and time that is mutually convenient, in order to negotiate which patent(s) should be included in an action under 42 U.S.C. § 262(*l*)(6). Please note that, in our view, the negotiations required under 42 U.S.C. § 262(*l*)(4) are necessarily mutual and cannot be started by one party unilaterally. The 15-day statutory period for such negotiations would begin with the proposed conference. We do not agree that negotiations have begun or that the period for the parties to negotiate pursuant to 42 U.S.C. § 262(*l*)(4) ends on April 10, 2017.

Please let us know if the proposed time works for you or propose alternate times for a conference.

Sincerely yours,

/s/ Nick Groombridge

Nicholas Groombridge

Exhibit 7

PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP

1285 AVENUE OF THE AMERICAS
NEW YORK, NEW YORK 10019-6064
TELEPHONE (212) 373-3000

LLOYD K. GARRISON (1946-1991)
RANDOLPH E. PAUL (1946-1956)
SIMON H. RIFKIND (1950-1995)
LOUIS S. WEISS (1927-1950)
JOHN F. WHARTON (1927-1977)

UNIT 3601, OFFICE TOWER A, BEIJING FORTUNE PLAZA
NO. 7 DONGSANHUAN ZHONGLU
CHAOYANG DISTRICT
BEIJING 100020
PEOPLE'S REPUBLIC OF CHINA
TELEPHONE (86-10) 5828-6300

12TH FLOOR, HONG KONG CLUB BUILDING
3A CHATER ROAD, CENTRAL
HONG KONG
TELEPHONE (852) 2846-0300

ALDER CASTLE
10 NOBLE STREET
LONDON EC2V 7JU, U.K.
TELEPHONE (44 20) 7367 1600

FUKOKU SEIMEI BUILDING
2-2 UCHISAIWAICHO 2-CHOME
CHIYODA-KU, TOKYO 100-0011, JAPAN
TELEPHONE (81-3) 3597-8101

TORONTO-DOMINION CENTRE
77 KING STREET WEST, SUITE 3100
P.O. BOX 226
TORONTO, ONTARIO M5K 1J3
TELEPHONE (416) 504-0520

2001 K STREET, NW
WASHINGTON, DC 20006-1047
TELEPHONE (202) 223-7300

500 DELAWARE AVENUE, SUITE 200
POST OFFICE BOX 32
WILMINGTON, DE 19899-0032
TELEPHONE (302) 655-4410

WRITER'S DIRECT DIAL NUMBER
212-373-3212

WRITER'S DIRECT FACSIMILE
212-492-0212

WRITER'S DIRECT E-MAIL ADDRESS
ngroombridge@paulweiss.com

April 20, 2017

By Electronic Mail and First Class Mail

Louis E. Fogel, Esq
Jenner & Block LLP
353 N. Clark Street
Chicago, IL 60654-3456

Re: *Coherus BioSciences' Abbreviated Biologics License Application (BLA) No. 761039*

Dear Louis:

I write to confirm the parties' agreement, as set forth in your letter of April 11, 2017, that pursuant to 42 U.S.C. § 262(*l*)(6), not later than 30 days after April 11, 2017, Amgen shall bring an action for patent infringement with respect to U.S. Patent No. 8,273,707.

For the sake of completeness, on our April 11, 2017 teleconference, the parties also agreed that U.S. Patent No. 6,180,391 will not be the subject of an action for infringement; however, in the event that Coherus introduces products or processes different from those described in the information provided, Amgen reserves the right to assert the ’391 patent.

Sincerely yours,

/s/ Nicholas Groombridge

Nicholas Groombridge

Exhibit 8

CHS-1701 BLA Update

Monday, 12th June 2017

Introduction

Patrick O'Brien

Senior Vice President, Investor Relations

Good morning everyone. Earlier this morning, we issued a CHS-1701 press release. This release can be found on the Coherus Biosciences website. Joining me for today's call will be Denny Lanfear, President, CEO and Chairman; Lisa Bell, EVP of Global Regulatory Affairs; Jean Viret, CFO; and Matt Hooper, EVP and General Counsel.

Before we begin our formal remarks, I would like to remind you we will be making forward-looking statements with respect to product development plans, all of which involve certain assumptions, risks and uncertainties that are beyond our control and could cause actual results to differ from these statements. A description of these risks can be found on our most recent Form 10Q on file with the SEC. In addition, Coherus Biosciences does not undertake any obligation to update any forward-looking statement made during this call.

Prepared Statement

Denny Lanfear

President, CEO and Chairman

Introduction

Thank you, Patrick. And good morning and thank you all for joining our call. I would like to cover three topics this morning for you and then we will be happy to take your additional questions. First, I will review for you the communication from the FDA and the key issues therein. Secondly, we will then review the company's plan to address the issues raised. And lastly, we will review the financial impact of this development to our plans and we will address those issues for us.

FDA Communication

Let me first say, we are all very disappointed with this setback to our program and our company. We greatly appreciate the support of you, our investors, and your confidence in us. We will provide the fullest understanding we can and exercise as much transparency as we can, so that you, our investors, are fully informed.

Response letter

We have received a complete response letter from FDA, pursuant to the CHS-1701 BLA. This letter primarily focused on a request to reanalyze a subset of the samples of the 04 immunogenicity study with an assay with improved sensitivity. You may recall the 04 study endpoints included percent difference in anti-drug antibodies between the groups, as well as the presence of neutralizing antibodies.

Further analysis of data was requested by FDA. In addition, the letter included manufacturing and process information requests. These included requests for various reports, some process-related summaries of data, additional information on control parameters, and other standard[?] request regarding licensing details for manufacturing processes.

In terms of our actions so far, since receiving this communication, our team has been reviewing the document and developing our plans to address the information requests made by FDA. Coherus will, of course, work interactively with FDA to address the information requests to their satisfaction, as we have on this program in the past.

Omissions

Now, let me make a few points regarding what the FDA did not ask for in these communications, to put it into better context. First, FDA did not request or suggest that a clinical study be performed in oncology patients. Secondly, the FDA did not request or suggest additional pharmacokinetic study or indicate that the data of the submitted study 05 was not adequate to support the application. Additionally, the letter does not indicate concerns by FDA in a number of manufacturing-related areas.

Specifically, concerns were not raised regarding the ability of the process qualification labs[?] to support the application. Nor was the GMP status of the 1701 bulk manufacturing or fill-finish vendors raised as an issue; or such ability of these facilities to support manufacturing [inaudible].

Immunogenicity

Let me now return to the agency's request pursuant to the immunogenicity and elaborate a bit further. As in all areas of the application, including manufacturing processes, analytical comparability, etc., it is common practice for FDA to perform an in-depth review, providing critical assessment of all procedures and analyzes, to pressure test and ensure the robustness of results.

Particularly in the development of biosimilars, regulatory agencies request developers to use the most sensitive assays to detect potential differences with the originator drug. We believed we had met that bar with the immunogenicity assays used in the 04 study. However, the agency has requested additional analyzes and information, including analyzes of a subset of samples with revised more highly sensitive assay to confirm the robustness of the results of the 04 study.

We understand the agency's approach in reviewing and pressure-testing these data, given that filgrastim is an endogenous protein. And antibodies to any endogenous protein could be very detrimental to a patient. We plan of course to fully comply with FDA's request and address the issues that they raise.

Compliance Plan

Let me now cover our plan to comply with the request, which includes the following: first, we will develop an assay consistent with the FDA's recommendations in this letter. We will re-run requested samples with this revised assay as recommended by the agency, and we will perform analyzes on this data as requested and suggested by the agency. Lastly, we will address the additional manufacturing and process-related requests and analyzes to be included in the resubmission.

Now, let me talk about that particular issue in greater detail. With respect to the requests and comments regarding manufacturing and process-related issues, as I indicated, agency has not asked for additional process qualification lots. The existing process qualification campaign lots are sufficient to support the BLA application. The FDA has requested additional

information regarding manufacturing procedures, release testing and other such details. We would categorize these requests as standard and consistent with expectations at this point in the review. These requests for detailed report summaries appear to us to be fully addressable with our existing data and experience. We plan to address these requests in a prompt and very comprehensive manner.

Lastly, I would add that in our review the manufacturing requests are not gating[?] to responding in the resubmission timing; that is to say, they will take less time to complete than the assay-related data development, although all will be submitted together at the same time.

Timing

Having covered the primary additional data requirements and our plan to address these, let me turn to overall timing. We anticipate that we will need a type 1 meeting, which is appropriate for discussing such requests. FDA's scheduling guidance is 30 days for such meetings. We believe we can generate responses to the CRL within six months. However, interactions with the agency required to confirm these timelines and their scheduling is, of course, beyond our control.

After resubmission, the agency will confirm that the resubmission has addressed the request. We will press-release this development accordingly. The agency can take up to six months to evaluate the resubmission.

Financial Plan

Now, let me turn to the third topic we wish to cover this morning, which is the financial plan and the projection. At the end of Q1 2017, the company had approximately $175 million in cash and short-term securities. During Q1 2017, the company spent $73 million for the quarter for cash use and operations, primarily due to 1701 launch preparedness, manufacturing expenses to support the BLAs underway, and clinical trial wrap-ups.

We have developed a revised financial plan for the second half of 2017 which calls for an average use of cash of $40 million per quarter, representing an annualized rate of $160 million, which is a significant reduction from the first half of 2017. Further, we project quarterly cash used of $30-35 million per quarter for the first half of 2018, for an annualized rate of $120-140 million next year.

We believe we can operate at this rate into the second half of 2018, or until product approval. This projected use of cash allows for, firstly, sufficient resources for the 1701 BLA and its actions. Secondarily, it also provides sufficient resources to complete the 1420 BLA for our [inaudible]. And lastly, it fully preserves the functionality of our biosimilar platform for advancing our portfolio.

This concludes the summary of my remarks for you this morning. We will be happy to take additional questions at this time. And we will also make ourselves available by phone all day today and throughout the week to fully answer any remaining questions that you may have.

Q&A

Mohit Bansal (Citi Group): Thanks for taking my question on immunogenicity study. So just to clarify, did the FDA ask for a reanalysis of all the patients or just a subset of patients using the new assay?

Lisa Bell: I believe what Denny said earlier was that they have asked for reanalysis of a subset of patient samples, that we feel is totally addressable within the context of the data that we have and the sample that we have.

Mohit Bansal: How big is the subset? And can you please provide more colour on what subset it is?

Denny Lanfear: We decline to disclose exactly which subset. However, I will note that patients have varying responses to a drug. All patients are a little bit different. However, the number of samples that are to be processed are well within our capability to do so and the capacity of the assays to process the samples. The actual processing time of the samples is not a rate[?]-limiting factor in this case.

Lisa Bell: I think that Denny outlined our understanding of what is required and the timeline associated to do this. And so I would say that, if it helps you in terms of the colour on what needs to be done, our assessment was done with that understanding in mind. It is, what will it take to do what the agency has asked us to do?

Mohit Bansal: And the assay FDA has requested, is this very different from what FDA has asked before to other biosimilar manufacturers? Was this a surprise to you? Just getting some sense of that.

Denny Lanfear: Yes, we are, of course, unfamiliar with what the FDA has asked other biosimilar manufacturers. However, just one more time for clarity here: we processed these samples originally with an assay that we thought was appropriate. FDA has come back to us and asked us to reprocess a certain subset of samples with a more optimized and sensitive assay. And we are going to comply with that request.

Mohit Bansal: Thank you.

Alethia Young (Credit Suisse): Thanks for taking my question. Just a couple. I am trying to get a feel for the visibility of the biosimilar pathway. Did you just learn of these issues when you were issued the CRL? Was there any hint along the way? I guess there were not, since you probably would have tried to address them. And then also on this process manufacturing, can you give us more granularity on that as far as related to how long that will potentially take to sort out? Is it a couple of months or is it all involved in [inaudible]?

Lisa Bell: Hi Alethia. I would say that, as you know, during the review, the agency asks a number of questions. We had been addressing them along the way, so we thought that we had a good understanding of what the agency was asking. What they do when they receive the data, as you may know, we have commented in the past, under the biosimilars review, the biosimilar review process is a little bit different than on new products. The new products are currently operating under a review process where they have pre-set milestones by which they can talk to the agency about their current viewpoint of the review and what issues they are identifying during the course of their review. For the biosimilars that is not currently in scope, so when you answer a question from the agency, they take their time to review what

you have sent it and do so thoughtfully. And in the course of that review they are having a variety of different discussions internally; that is our understanding. We do not always have visibility into that; in fact, I would say on the biosimilars we have less visibility compared to new molecular entities. So they have to go through that process and what we have seen now in the CRL is the outcome of their internal deliberations.

Denny Lanfear: Alethia, could you repeat your second part of your question pursuant to the manufacturing issues?

Alethia Young: You gave a generalization of certain additional related information. Is it just a paperwork matter where it should take you weeks, or is it something more onerous? It is a timing question.

Denny Lanfear: No, it is not onerous. We do not have to go off and produce more qualification lots, as I pointed out. We do not have issues with the suitability of our bulk manufacturing vendors, as we pointed out. Nor is there a problem with the inspection of the fill-finish which precludes them, as other people have seen with their products. None of those kinds of things happened.

FDA did ask for certain reports, summaries of data, things of this type. Certain additional information, additional process, detailed information, which we view, as I said in my prepared remarks, as material that we have and things that we can develop very straightforwardly. I further pointed out that the timeline for developing this additional process information, as part of the request, is shorter than the time required to do the assay development and process the samples. So this, I would characterize, as off the critical path and addressable by the company.

Alethia Young: Just a last one on clarifying the timelines that you discussed here. So you are basically saying, roughly, about six months to respond and have the conversations with the FDA, and then it could take up to six months for them to review it? Is that the shortest timeline you would think? Or am I thinking about it right?

Denny Lanfear: I believe that is an appropriate estimate in terms of developing the assay, running the samples, interacting with agency, all these kinds of things. It might be shorter or longer but we believe that is a reasonable estimate.

Ian Somio[?] (BMO): I had a couple of follow-up questions. First, I just wanted to confirm that the fill and finish plant was reviewed by the FDA and there are no additional information that is required for that to be approved. And then I had one additional follow-up question.

Denny Lanfear: Ian, thank you for your question. No, we did not run into any issues with the fill finish. Yes, the fill finish facility was inspected. I would just add that I think the team did a very good job in terms of preparing the manufacturing facilities for FDA inspections, as we have discussed prior to this. We conducted mock inspections and did remediation of various facilities that we knew the FDA would inspect. And I think by and large, in terms of the manufacturing, that worked out well for us. But no, that is not an issue.

Ian Somio: And on the assay, given that the rate-limiting step, obviously we assume that you were very comfortable with the assay used. Just wanted to make sure that there were not any findings in the assay used, or the data generated by the assay, which led to the additional development of a new assay?

Lisa Bell: I just want to make sure I understand and answer your question properly. So your question is, is it the assay that is driving the question or the data that is driving the assay?

Ian Somio: Is it the findings from the initial assay that is leading to the request for a new more sensitive assay?

Lisa Bell: No. Again, I think that, as Denny said in his remarks, our data and our conclusions from our study, we still met the pre-specified primary endpoints and outcomes. So their requests now are to reanalyze the same data with a more sensitive method. And it was a subset of the data that was presented in the BLA.

Ian Somio: Okay. And just as a follow-up, will you be willing to share the results of the assay before submitting the data to the FDA?

Denny Lanfear: We can get back to you, Ian, but I think it would be unusual to submit that data publicly prior to sharing it with FDA. However, let me just say this about that. Coherus, as you know, endeavors to be as transparent as possible with the Street and the investors in our coverage. If there are any developments which we think are appropriate along the way to make to you we will certainly do that. And I hope you appreciate that we are being as totally transparent as we can this morning in terms of the letter.

Jason McCarthy (Maxim Group): This is a follow up to the last caller. I know you did not say specifically, but in the 04 study there was some detection of neutralizing antibodies, I believe. Were there neutralizing antibodies in this subset of patients? And by increasing the stringency of your assay, does that get that to go away? The parameters would be so much more stringent that you would not be detecting neutralizing antibodies. And is there some level of neutralizing antibodies that the FDA is willing to accept in your assays?

Denny Lanfear: Jason, thank you for your question but I have to correct several of your statements. First of all, there are no neutralizing antibodies either in the 1701 group or in the Neulasta group we have studied. And no, we did not expect to see neutralizing antibodies with an additional more sensitive assay. This is a question of processing a subset of samples with a more sensitive assay, but it is not a question of trying to eradicate a certain finding with an assay. So no, we can flatly say there are no neutralizing antibodies, nor are we expecting neutralizing antibodies on re-assay.

Ken Cacciatore (Cohen & Co): A question here. I think it has been asked a couple of ways but I am not entirely sure, just kind of listening to the questions, so I will ask it again directly. What did you see in this subset, or what did the FDA see in this subset, that is different than all the other patients that they want this reanalyzed? Can you just give us the specifics of what they are seeing here? Thank you.

Denny Lanfear: Thanks for the question. And we are happy to clarify this, absolutely, for you. Lisa, can you make additional comments for Ken?

Lisa Bell: Ken, I am sorry if this was not sufficiently clear. So this is not about them seeing something in this particular subset that is raising a question for them. The objective here is to assess robustness of our results, and the data set that is appropriate for that in this case is a subset of the overall data set. So there is nothing in the data where people are sitting there wondering, or like the last question, like Denny said, we had no neutralizing antibodies in the

study. We met the study endpoint. The robustness question is a standard question that the agency will ask during a review.

Ken Cacciatore: So is it potentially just they want a random sample to confirm it? It is nothing specific here?

Lisa Bell: They are asking for an appropriate sample to address the questions that they have raised.

Denny Lanfear: So Ken, the FDA wants assays developed and executed against their studies, against certain stringent standards, and they have asked us to redevelop the assay with higher sensitivity. This is an issue of being consistent with latest FDA thinking on what is an appropriate assay, which sometimes moves over time. This is not a further issue as you suggest.

Ken Cacciatore: In your mind, is your concern level near zero? This is just a box you need to check? Or is your concern level heightened that you need to do this? Or is this just part of good drug development, no big deal, pretty standard? Science has moved forward, so is your concern level very low or is it heightened?

Denny Lanfear: The latter, Ken. This is, I think, an issue where they would like the samples processed with an assay that has been optimized for sensitivity, the results notwithstanding. The FDA, as you know, from time to time over years, issues revised guidance pursuant to assays. And they do that to protect patient safety and so on. But we have here a situation where we performed it with one assay and we have a result. And they say, 'We would like a more stringent assay. We would like a more optimized assay.' We are now going to go ahead and do that.

Ken Cacciatore: And, Denny, do you have to do this also in healthy volunteers with branded Neulasta, run this assay, so there is something for them to compare against?

Denny Lanfear: Well, we have already done that. That was the essence of the 04 study, Ken. That study had two injections of 1701 and two injections of Neulasta. And there was a look at antibodies with both groups. So this was the essence of how that study was performed.

Lisa Bell: Ken, I would just add that, to use your language, this is good drug development for any biosimilar sponsor. I think the requests from the agency are reasonable in the context of the situation that Denny described. We are developing a drug to an endogenous protein, and both we and the agency want to make sure that we are doing this [inaudible].

Ken Cacciatore: Great. Thank you for the clarification.

Chris Shah (JP Morgan): Two questions here. Maybe following up on Ken's question on this new immunogenicity assay, either qualitative or quantitative, just how much more sensitive is this going to be, relative to the assay you ran in the prior studies? And then my second question was on the revised financial plans. Are there are any programs in particular you are pulling back on here to reduce cash burn? And is the potential 1420 partner agreement have any impact on those financial plans? Thank you.

Denny Lanfear: The actual increase in sensitivity is a very difficult issue to actually quantify. I do not know how that could actually be quantified. These assays are run in various formats

including live cells and other ways. And I am certainly not an assay scientist or qualified to opine further on that. But I think the lens through which to view this is that the FDA, as time goes on, continues to raise the bar in terms of things. And this is an area. If you look back, you will see several areas in which they ask for greater and greater resolution. And this is one of those things. It is an issue of good development practice; they do not stay static. As you go forward, even, for example, in the analytical realm, they will ask you to do mass spectrometry, which is something they did not ask five years ago. So whether you are dealing with the Europeans or the US FDA, they constantly raise the bar analytically, and in other areas, to get a better view into products, both originator products and biosimilar products.

The point I made earlier was that in terms of biosimilar products, there is actually a heightened need for greater resolution analytically and otherwise. I believe there is a higher standard for that. And because they want to ensure that you are biosimilar to the originator. And I would just suggest that if you are developing a biosimilar five years from now, you will run into enhanced analytical bars. They will have other needs and things that they will look at, as techniques advance.

As a matter of fact, you can attend scientific meetings in which FDA and other scientists represent their thinking and talk about better ways to do things. So this is one of those things. There is a continuum here to be addressed and what they have said to us is we would like you now to go forward with a higher resolution assay. It does not invalidate the existing data; it does not imply anything beyond that. It just says that the bar is in a slightly different, higher place. And we intend to meet that bar.

Douglas Sell[?] (Barclays): Good morning. Thanks for taking my questions. Again, it would be helpful to get a little color in terms of the development of the asset that you will need to run it on and how long that will take. And is this a process where you will meet with the FDA and then develop the assay? Or are you going to develop the assay or should it come up with the parameters and then when you have your type 1 meeting with the agency, clear it before you go back and re-run the samples or actually perform the analysis?

Denny Lanfear: Doug, thank you for the question. The FDA, in our letter, let us know what the particular parameters of the assay had to be. They were very specific and said, 'We would like an assay that performs like this;' that is more refined and I would say more optimized than the assay that we currently had in place. So the bar has been defined and, as I just stated, we will reach that bar. We will go ahead and we will begin our efforts to develop the assay, or refine the existing assays, to the degree that they meet these new requirements. We will meet with the FDA. We will, of course, share with the FDA the data on that. We will process those samples accordingly. In terms of timing, as I indicated, there is probably some few months to develop the assay and then additional time to run the samples on the assay, produce reports, etc. And we reasonably expect this all to occur in a six-month period of time.

Douglas Sell: And, obviously, you had an abbreviated pathway in terms of performing PKPD and not testing in patients. Do you think that this request came because you did not actually run a study in oncology patients? And as a follow-up, just to clarify, in terms of the subset of patients, they were not specifically characterized patients? Do they just want a certain

number of patients? Or is there a certain profile of patient that they are looking to get this reanalysis performed on?

Denny Lanfear: Thank you. No. This result does not arise from the company not performing an efficacy study in oncology patients. This is quite a separate issue. The efficacy issue and the pharmacokinetic issue has been addressed. As I indicated, agency did not raise issue pursuant to the pharmacokinetic, pharmacodynamic study 05 in the file. Nor did the FDA ask us for an oncology study in patients. So that is not a linked thing. This is solely an issue of the FDA taking a look at the assay used in the immunogenicity study and asking us to process some other patients, a subset of other patients. It is no more complex than that. It does not read backwards or forwards into it.

Douglas Sell: And, Denny, just to clarify, this was not a specifically characterized subset of patients, they just are not asking you to rerun the assay in all the patients? So in some ways is this like a bridging to the new assay, meaning they just want to get a confirmation from everything that you have already submitted and just check the box one more time?

Denny Lanfear: This is not a bridge. Let Dr Bell try with this for you.

Lisa Bell: I think the nature of your question is more around, are we utilizing the same patients that generated the data that led to the conclusions in the 04 immunogenicity study? And the answer to that would be correct. It is just a subset of those that are appropriate for addressing the particulars of the assay that they are asking us to develop, to optimize.

Douglas Sell: But it is not like the FDA is saying, 'From the 04 study, re-run this analysis on patients who have X, Y, Z profile.' They are just asking, 'Of the 300 patients in the 04 study, just re-run it on 50 patients or 100 patients of your choosing or randomly sampled.' Does that make sense?

Denny Lanfear: No, Doug. No, that does not make sense. They have not asked for a random sampling of patients in the 04 study. They have asked for a subset of these questions to be assayed. And the reason I would go no further is because the particular strategy that the company deployed, in terms of the immunogenicity study, is proprietary. And we have not previously disclosed such publicly. And we believe this is a competitive advantage for the company. We were the first company to come up with immunogenicity studies. And there is a particular schema and approach that is used with that study, which employs a variety of assays, I would say.

So what it is fair to characterize this as is, the FDA has looked at the study and asked us to process some of these patients with a revised and enhanced assay. It is very straightforward. It is simply a question of robustness. The FDA, when they look at anything in a BLA, regardless of what data it is, will frequently pressure-test it and ask the question several different ways, in a sort of sensitivity analysis: what if you looked at it like this, or what if you looked at it like that? And this is that sort of a thing.

Douglas Sell: Okay. Thank you very much.

Mike Holdsworth (RW Baird): Thanks for taking the question. When you plan to refile, do you guys anticipate having an ad com? And then secondly, if an ad com is not scheduled, how shall we interpret that? Thanks.

Denny Lanfear: Thank you very much. I guess that is the ad com question. I will defer that one to my Executive Vice President of Global Regulatory. Lisa?

Lisa Bell: Thanks for the question. As you know and we have stated in the past, the decision to convene an ad com is solely at the discretion of the FDA. And we believe that will continue to be the fact. We do not have any reason, at this time, to believe that an ad com will be convened specifically because of the resubmission. Should the agency feel that there are any scientific issues important to review, they will discuss and make a decision on that appropriately.

Denny Lanfear: It is at the sole discretion of the FDA to have an ad com. And if we need an ad com we will be prepared for one. We had prepared for an ad com prior to this. We will be prepared later. But advisory committees are solely at their discretion. We will be happy to come and show up and present, if we are invited.

Ian Somio: I just wanted to follow up. I know the focus of the call is the US application, but any thoughts on how we should think of the European filing? Should we expect a similar request?

Lisa Bell: In terms of the European filing, that review continues. I believe in the past we might have commented the progress is as expected with the MAA. These regulatory agencies, although they might identify similar issues, typically their questions are not necessarily overlapping. So we do not necessarily foresee that the action that the agency took is dispositive to the European action. They are just progressing in parallel.

Ian Somio: Thank you very much.

Greg Gilbert (Deutsche Bank): I am sorry, I got on a little late, but is there any risk to being able to develop the assay they are asking for? Obviously, you cannot buy this at the grocery store, but I am trying to understand the risk in being able to achieve the profile they want. And then my second question is, is there any way you can be in any way specifically confident about your ability to meet that higher bar, based on what you know about your data set and the performance of the product today?

Denny Lanfear: No, this is not an assay that you can buy at the grocery store. But, no, we do not foresee technical difficulty in complying with the FDA's request in the context of deploying an assay with the heightened and optimized sensitivity as they have requested. And secondarily, we would not expect the outcome of this to be different than the assay that we did prior. However, we will re-assay the samples, as requested.

Greg Gilbert: And just as a follow-up, Denny, you mentioned some things that you were not asking for, suggesting that you are confident that the FDA is not viewing your application as deficient in other ways. Is this a case of where you would know if those things were fully reviewed already? How can you be confident that it is not a broader set of concerns?

Denny Lanfear: We are confident, and let me be really clear about this. The reason that we mentioned these issues is because we are very confident in these issues not coming up. But I will let Dr Bell address this, once again, for you.

Lisa Bell: As part of the review process, the agency has to complete the review of all assets that are filed before they can issue any action letter. So even in the case of a complete response letter, they have to complete their review. So that way, they can write a

comprehensive letter, knowing what information was provided in all parts of the BLA. So I would say that they have got to that point in issuing the complete response letter. They have reviewed everything. They have identified what things they would ideally like to see in addition in order to support a resubmission. And Denny has elaborated on those issues, in particular on the immunogenicity side, and then some additional requests on the process side. And we obviously want to confirm with the agency that our plan to address these are acceptable. But we feel that they are quite addressable.

Denny Lanfear: We chose to make these points because others in the field have run into various issues and received complete response letters, because, for example, their process qualification lots may not have been appropriate, and that is the reason for their CRL[?]. We do not have that problem. Their fill-finish facility may have run into problems, inspection, otherwise[?], or controls, or GMP status. We do not have that problem. We wanted to be clear with you, and as transparent with you as possible, exactly what things we were asked to address.

And just to recap, they would like us to deploy an assay with greater sensitivity. It is more optimized. And then do a subset of these samples. Then, secondarily, they would like responses to a number of manufacturing questions and analyzes. We feel that we have that data. We are able to generate those straightforwardly over a reasonable period of time, contained within the time for the assay. And that is the primary issues that are contained in this letter.

Greg Gilbert: That is helpful. And if I can take one last one, do you still expect to be first to market?

Denny Lanfear: That I cannot comment on. We do not have inside information on others and the status of their programmes, but I think it is fair to say some other teams have bumped into other issues. Clearly the regulators are being very, very careful with this particular molecule in this class. One team I think had pharmacokinetic studies which did not work out and failed. We do not have that problem. Other teams were sent back for various reasons. So I think the regulators are proceeding very diligently forward here and we look forward to meeting their requirements. I do not know how this is all going to pan out but we will certainly go as rapidly as we can.

Jeff Borges (Learing)[?]: Thank you very much for letting me jump in with a question. First of all, Denny, could you elaborate a little bit on this question of why these issues are cropping up with the Neulasta biosimilar but did not crop up with all the Neupogen biosimilars? What is it about the extended half-life and the percolation[?] which is increasing the scrutiny? And then secondly, you also commented on the issue of not going to the grocery store to get this. But presumably this assay has been implemented in other sites, in other labs. Have you tested any of your samples previously to the heightened level of sensitivity that is being requested by the FDA now? And in that prior testing, did you come through clean without any immunogenicity? Thanks. I appreciate it.

Denny Lanfear: Let me try to respond to your question this way and invite my colleagues to join us. First of all, no, we did not process our samples with an assay of this heightened sensitivity, as requested by the FDA previously, or we would have obviously submitted such. Secondarily, what we have done since we have received this letter is we have reached out to

contacts in the industry and we have enquired as to whether this assay is feasible to develop and how long that will take. And we are, of course, well-integrated into the environment. And while the assay may or may not have been deployed in other places, we feel that we have identified third parties who can bring this assay up. I will stop there. We may have more to say about that in the future but we feel confident that the assay requirements can be met. That is fine.

Pursuant to your question about whether [inaudible] is more difficult or challenging on the immunogenicity side, it is an interesting issue. We have said many times that the clinical biology of this product makes it probably one of the more difficult biosimilars to advance. Typically, what you have seen with this molecule is high degree of variation with the patients in terms of the pharmacokinetic issues. Several teams have been unsuccessful in terms of the PK. In ourselves, it required a three-arm study with a triple cross-over – a three by three study – to achieve the desired result.

Now in terms of filgrastim and pegfilgrastim, what is different about this molecule, of course, is it has a polyethylene glycol tail attached to it, which has its own potential immunogenicity issues, because there is endogenous peg antibodies floating all through the population. As we have said previously, polyethylene glycol exists in toothpastes and body lotions and all sorts of things, so people tend to be sensitized to polyethylene glycol. So this, actually, I think, is probably a complicating factor in terms of parsing through immunogenicity of pegfilgrastim molecules, which you do not get with a simple straightforward sequence molecule like filgrastim.

I hope that is helpful for you but I believe that both of these issues, both, firstly, the variation that one sees in terms of pharmacokinetics, and secondarily, peg being this very ubiquitous entity that is floating around, creates challenges in terms of involvement of biosimilar for this drug, clearly.

Jeff Borges: Thanks very much. That is helpful.

Denny Lanfear: Thank you very much for joining us this morning on our call to discuss the issue. We tried to be as clear as possible around the requirements of the agency as we have gone forward. We believe that we can address the requirements that the agency has gone forward. We work interactively with them. The FDA is a group of professionals dedicated to the safety and the efficacy of products. We walk right alongside them in bringing these products forward. This is particularly important in terms of a biosimilar. We will proceed to develop the assay to get the results for you. We look forward to updating you when we are successful and we appreciate your support for us in bringing this product forward for the patients and savings for the healthcare system. Thank you for joining us this morning.

[END OF TRANSCRIPT]