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CHRS - Q4 2019 Coherus BioSciences Inc Earnings Call

EVENT DATE/TIME: FEBRUARY 27, 2020 / 9:30PM GMT

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PRESENTATION

Operator

Ladies and gentlemen, thank you for standing by, and welcome to the Coherus BioSciences 2019 Fourth Quarter Earnings Conference Call. My name is May, and I will be your conference operator for the call today. (Operator Instructions) And as a reminder, this conference call is being recorded. I would now like to turn the call over to David Arrington, Vice President of Investor Relations and Corporate Affairs. Please go ahead.

David Arrington - *Coherus BioSciences, Inc. - VP of IR & Corporate Affairs*

Thank you, May, and good afternoon, everyone. After close of market today, we issued a press release on our fourth quarter and year-end financial results. This release can be found on the Coherus BioSciences website. Joining me for today's call will be Denny Lanfear, Coherus' CEO; Dr. Jean Viret, Chief Financial Officer; Vince Anicetti, Chief Operating Officer; and Thomas Fitzpatrick, Chief Legal Officer.

Before we begin our formal remarks, I would like to remind you that 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 filings with the SEC. In addition, Coherus BioSciences does not undertake any obligation to update any forward-looking statements made during the call.

I will now turn the call over to Denny.

Dennis M. Lanfear - *Coherus BioSciences, Inc. - Chairman, President & CEO*

Thank you, David, and welcome, everyone, to our Q4 earnings call. Today, we will cover 4 broad areas for you. First of all, I'll review the performance of UDENYCA, both Q4 2019 and the entire year with which of course, we're very pleased. Secondly, we'll review the progress on our pipeline, including both our wholly owned, internally developed assets as well as our in-licensed products and we will provide you an update with respect to our thinking on our CHS-131 small molecule. Following that, I'll make a few remarks about the company's further transaction efforts for 2020 before handing it off to our Chief Financial Officer, Jean Viret, who will review our financial performance for the quarter and the year.

First, with respect to the company's commercial performance of UDENYCA, we are very pleased we met our goal of achieving 20% or more market share by the end of 2019 as guided in our Q2 earnings call last year. These market share gains were achieved across all segments: 340B hospitals, non-340B hospitals, clinics and against both prefilled syringe and on-body injector formats.

During 2019, we made substantial progress with both our national and regional payers, achieving over 95% access for UDENYCA patients. We believe this performance validates our overarching commercial strategy as conceived prior to launch with our focus on branded biologics positioning, robust guaranteed supply, comprehensive patient support services such as Coherus Complete as well as individualized contracting to support biosimilar conversion, all in the context of ASP pricing discipline to preserve long-term value. During 2020, you will see the company's commercial efforts continue in a highly integrated and effective manner to pursue additional market share gains.

Now let me make a few remarks with respect to our pipeline. 1 year after launch, the success of UDENYCA has validated our biosimilar business model. As a result, our pipeline strategy is now focused on leveraging our R&D and commercial strengths in selected therapeutic areas that can provide the greatest value to patients and the health care system while also generating the best return for our shareholders.

Let me first discuss the company's ophthalmology franchise with respect to our Lucentis biosimilar in-licensed from Bioeq. We are currently focused on supporting our partner to generate the additional manufacturing data as requested by FDA and expect to resubmit application upon completion of these efforts and certain regulatory interactions. With respect to our CHS-2020 Eylea biosimilar, we are very pleased with our progress and are now in a position to initiate commercial scale GMP manufacturing efforts in support of the expected Phase III clinical trials in 2021 with launch projected in 2025.

As we have previously discussed, these products will compete in a $6 billion anti-VEGF U.S. market with favorable order of entry and competitive dynamics. Ophthalmology is reimbursed under the buy-and-bill model, a reimbursement dynamic in which we have demonstrated proficiency, and biosimilar market conversion, delivering greater patient access and health care system savings.

Now with respect to our immunology franchise and CHS-1420, our HUMIRA biosimilar, over the past year and the quarter, we have held a series of Type 3 meetings with FDA and have now gained concurrence with FDA on the analytical and clinical strategy in support of the BLA filing in the second half of 2020. We've also made good progress with the further development of our manufacturing strategy for this product and preparing for a large-scale launch in mid-2023. As we have discussed previously, we believe this will be an $18 billion market in the U.S. prior to our launch and we expect to take our fair share of that market as we leverage our biosimilar commercial infrastructure.

Now as mentioned, we are now focused on oncology, ophthalmology and inflammation. We have determined that CHS-131, our small molecule program currently in development with NASH, while highly valuable, does not align with the company's strategic priorities, and thus, we plan to pursue strategic alternatives for this asset. We believe that focusing on our core biosimilar business in these key therapeutic areas is in the best interest of generating shareholder value.

Consistent with this, the company is pursuing additional oncology-focused licensing transactions to further leverage our commercial infrastructure and R&D capabilities. We will, of course, be providing you additional updates on these over 2020 as matters arise.

Now I'll let the company's Chief Financial Officer, Dr. Jean Viret, review the quarter and full year financials. Jean?

Jean-Frédéric Viret - *Coherus BioSciences, Inc. - CFO*

Thank you, Denny. I will now review the main financial results for our full year and fourth quarter 2019. First, let me review at the very top level our financial progress since January 1, 2019.

We became cash flow positive in the second quarter of 2019, and we have remained cash flow positive for the subsequent 2 quarters. Our cash flow from operations for the entire year was $28.4 million and $17.7 million for the fourth quarter of 2019. We anticipate that our cash flow from operating activities will remain positive during 2020, both on an annual and quarterly basis.

Second, our cash position increased steadily through 2019. We started the year with $72.4 million in cash and cash equivalents and ended the year with $177.7 million, a more than $100 million increase as a result of borrowing $73 million to commercially launch UDENYCA in January 2019 and generating cash from the sale of UDENYCA across all health care provider segments.

Third, our balance sheet has strengthened considerably. We ended the year with slightly over $400 million in total assets. The balance sheet is up fourfold since the beginning of 2019, which was shy of $100 million. Similarly, our working capital more than quadrupled from $51.2 million at the beginning of 2019 to $228 million by the end of the year.

Let me review now the main aspects of our income statement. Net product revenue for fourth quarter 2019 was $123.9 million. Cost of goods sold for the same quarter was $7.8 million, resulting in a gross profit margin of 94%. Net product revenue for the full year was $356.1 million, resulting in a gross margin of 95%.

Research and development expenses for the fourth quarter of 2019 were $34.9 million as compared to $26.7 million for the same period in 2018. The increase in R&D expenses for the quarter year-over-year was mainly due to the expensing of $11.1 million in upfront and milestone payments to Bioeq for the development of Bioeq's Lucentis biosimilar in the fourth quarter of 2019.

R&D expenses for the fiscal year 2019 were $94.2 million as compared to $110.2 million for the same period in 2018. Here, the decrease in R&D expenses full year-over-year was due primarily to the capitalization of UDENYCA manufacturing costs that had a $33.9 million impact since the approval of UDENYCA in November 2018. This decrease was offset by the increase of $15.6 million, primarily related to $11.1 million upfront and milestone payments to Bioeq and the development of our other biosimilar product candidates.

Selling, general and administrative expenses for the fourth quarter of 2019 were $36.1 million as compared with $33.8 million for the same period in 2018. SG&A for the full year 2019 were $137 million as compared to $94.2 million over the same period in 2018. The increases in SG&A expenses for the quarter year-over-year and the full year-over-year were mainly attributable to an increase in sales force personnel and related commercial functions in connection with the commercialization of UDENYCA.

Net income attributable to Coherus for the fourth quarter of 2019 was $39.2 million or $0.53 per share on a fully diluted basis compared to a net loss of $62.6 million or $0.92 per share on a basic and fully diluted basis for the same period in 2018. Net income attributable to Coherus for 2019 was $89.8 million or $1.23 per share on a fully diluted basis compared to a net loss of $209.3 million or $3.22 per share on a basic and fully diluted basis for 2018.

Now I would like to turn the call back to Denny for his concluding remarks.

Dennis M. Lanfear - *Coherus BioSciences, Inc. - Chairman, President & CEO*

Thanks, JV. We are, of course, pleased with our financial and commercial performance both in Q4 2019 and the year 2019 overall, and as you've seen, we achieved over 20% market share. Further, we are pleased with our advancement of the company's mission to increase access to patients and increase savings in the health care system. We have in-licensed 2 biosimilar products, 1 in ophthalmology and 1 in oncology, recognizing the highly synergistic characteristics between those 2 markets and providing further opportunity to leverage our current commercial footprint. Lastly, we believe we are making very good progress in putting in place the company's 5-year growth plan and project to have 6 or more approved products in the portfolio by 2025.

We believe the company's success to date is driven by our focus on areas where we have successfully aligned our commercial and R&D capabilities with market opportunity and patient needs. I'm happy now to take any questions you may have as we go. Operator?

David Arrington - *Coherus BioSciences, Inc. - VP of IR & Corporate Affairs*

Thank you very much, Denny. I'll hand this over to the operator to take questions from the line.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Your first question is from the line of Mohit Bansal.

Mohit Bansal - *Citigroup Inc, Research Division - VP and Analyst*

Congrats on the progress and launch in 2019. Maybe if you can touch upon UDENYCA going forward. Now that it has been a couple of months since you have seen a new player in the market and the other -- Mylan has been talking about more supply. So what sort of competition you are seeing in the marketplace at this point? And when we try to project or try to think about 2020 and beyond, how should we think about UDENYCA? Can it grow from here? Or do you think you could maintain the share here?

Dennis M. Lanfear - *Coherus BioSciences, Inc. - Chairman, President & CEO*

Thanks, Mohit. As you recall, last year, right at launch, we were asked to forecast the entire year. And I'll reply to that at that time, at a similar point last year, that once we have enough data points throughout the year, we'll be able to do that. And for 2020, we see further growth for UDENYCA and we're committed to that. However, the uncertainties with respect to Sandoz's actual performance and the potential future entrants at this particular point in time, we're not able to provide you an absolute number.

I would make the point though, that there's 3 biosimilar players plus the originator in the market. And the UDENYCA users are those which have already converted and therefore, there's more value to be had in the conversion of the Neulasta -- existing Neulasta users, which is the high-priced option to a biosimilar. So that is to say that the biosimilar benefit, they're primarily derived from converting patients from Neulasta and thus, we expect the additional market entrants to put additional pressure on Neulasta's share, which is still quite substantial in the market, as you know.

Lastly, I would say, with respect to Sandoz, we haven't seen a lot of movement in terms of market share thus far with that.

Mohit Bansal - *Citigroup Inc, Research Division - VP and Analyst*

Got it. And if I may ask one more, regarding your Avastin biosimilar candidate, so can you just help us understand the time lines here? So the 3-way study you had to perform, you started the study before talking to the FDA or after talking to the FDA? And how much FDA input would be necessary in designing that study versus -- I mean could FDA input change your strategy there? That's what I'm getting to.

Dennis M. Lanfear - *Coherus BioSciences, Inc. - Chairman, President & CEO*

Well, of course, the FDA input could change one's strategy. We believe that it's prudent to review that entire program with the FDA before initiating any studies, even if they were at risk and even if they were modest in cost. We are, of course, continuing our diligence on both those assets, both the Avastin asset and the Rituxan asset, consistent with our agreement. We don't have any further updates for you with respect to advancing those programs at the current time, it's been about a month only since we did that. But we'll be happy to update you. Probably on the next call, we'll have a little more to say about that.

Mohit Bansal - *Citigroup Inc, Research Division - VP and Analyst*

And anything we should think about in terms of R&D spend, which could go up because of this deal at least in this quarter? Any lumpiness in the spend this year?

Jean-Frédéric Viret - *Coherus BioSciences, Inc. - CFO*

Yes. We expect R&D expenses to increase somewhat modestly because we're only going to be focused on our in-house molecule, which is CHS-2020 for R&D. We're filing CHS-1420, so there may be some manufacturing run that needs to be done. So it will increase but modestly.

Operator

Your next question is from the line of Douglas Tsao.

Douglas Dylan Tsao - *H.C. Wainwright & Co, LLC, Research Division - MD & Senior Healthcare Analyst*

Denny, just -- are you ready to give an update in terms of when you might be in position to launch your own Onpro or sort of extended-release delivery device?

Dennis M. Lanfear - *Coherus BioSciences, Inc. - Chairman, President & CEO*

Thanks for the question, Doug, very much. So I would say that we are very pleased with the progress that we're making on our Onpro device. But no, we are not in a position where we're ready to update the market and project, for example, when it would launch and so on. We have not disclosed just at what stage of development that product currently is in. And we probably won't say too much about that until we're much closer to the launch window for it, primarily for competitive reasons.

Douglas Dylan Tsao - *H.C. Wainwright & Co, LLC, Research Division - MD & Senior Healthcare Analyst*

Okay. And Denny, just sort of thinking about your pipeline and sort of going forward, obviously, you've had a lot of success development products internally. You've recently become more aggressive from a business development standpoint. Just curious how, when you think about -- project the company forward, what's that balance between internally developed biosimilars versus ones that you can in-license that have, to some extent, been derisked by others' works?

Dennis M. Lanfear - *Coherus BioSciences, Inc. - Chairman, President & CEO*

That's a great question, Doug. I think that it's fair to say that we like the synergy that we are currently pursuing with having in-licensed products in tandem with internally developed products. I think a prime example of that is Lucentis biosimilar hand-in-hand with the Eylea biosimilar. It balances the launch timing, it balances, for example, the economic alignment issues and so on.

Similarly, with UDENYCA, wholly owned product, strong in the oncology space. And so we feel comfortable adding additional oncology products that are in license that may not have all the same sorts of margins due to licensing fees. We think that the return on investment for internally -- for externally brought in products is very high. And we also feel that leveraging the commercial footprint, both in terms of oncology and ophthalmology, is very wise, as we said, further to the overall strategy of the company.

So we look at it very much in that sort of a balance. Biosimilars are perhaps $150 million per product to develop. So you probably don't want to take all that risk with every single product. However, in each therapeutic area, you'll certainly have at least 1 product from that 2 products that you develop yourself internally. Is that helpful?

Douglas Dylan Tsao - *H.C. Wainwright & Co, LLC, Research Division - MD & Senior Healthcare Analyst*

Yes. No, no, it is. I mean, so I guess does it suggest that you'll be a little bit more selective in the opportunities that you might pursue with an internally developed biosimilar?

Dennis M. Lanfear - *Coherus BioSciences, Inc. - Chairman, President & CEO*

Well, I believe that we have -- first of all, the 2019 launch of UDENYCA, and then we have the 2023 launch of the HUMIRA biosimilar and then the 2025 launch of Eylea. So that's 3 products and what we're projecting is overall 6 products, so 3 additional licensed-in products on top of that. So I think that it's less an issue of being selected internally as I think it is an issue of maximizing the commercial and R&D synergy of bringing these products in, in each of these therapeutic areas as we find them.

Operator

Your next question is from the line of Mike Ulz.

Michael Eric Ulz - *Robert W. Baird & Co. Incorporated, Research Division - Senior Research Analyst*

Maybe just another follow-up, just sort of on BD. And I guess, specifically, you have an option with -- on a Rituxan biosimilar. Maybe you can just talk about some of the considerations in determining whether you decide ultimately to opt in on that or to pass?

Dennis M. Lanfear - *Coherus BioSciences, Inc. - Chairman, President & CEO*

Mike, thanks for the question. That's a good one. So I think that in terms of any of these products that you bring in from another country, the very first thing you have to do is understand how the FDA is going to view the clinical trials that were performed externally, right, the patient population, the particular protocol that was used, the stage of disease or the patients, the treatment period, the margins, all that.

The second thing you have to do is consider how you're going to bridge from the external product, the external innovator product, in the case of the innovator products, the Chinese Avastin or the Chinese rituximab and how you're going to bridge that to U.S. Avastin, U.S. rituximab and just what that looks like, what types of studies are you going to do analytically, bioanalytically and clinically to satisfy the FDA.

So that is the task that we have set ourselves forward on in terms of both those products at the current time. And so we don't have additional updates on you as we're in the middle of that. Happy to take another question on that, get our progress on the next call. But that's sort of the gist of the matter and the sort of things that you have to consider when bringing one of these things in from somewhere else. Hope that's helpful for you.

Operator

Your next question is from the line of Chris Schott.

Ekaterina V. Knyazkova - *JP Morgan Chase & Co, Research Division - Analyst*

This is Ekaterina on for Chris. My first question is on UDENYCA. Are you noticing any notable changes in Amgen's or hospitals' or clinics' behaviors with Sandoz coming in? Or is it simply too early to tell given kind of the limited share gains that they've made?

And then my second one is on Avastin. Can you talk about the competitive landscape for the product and your expectations about how many players you expect there? And does that kind of change your commercial strategy kind of given the kind of market disadvantage?

Dennis M. Lanfear - *Coherus BioSciences, Inc. - Chairman, President & CEO*

Yes. Thanks a lot. Ekaterina, I think that it's -- first of all, with respect to Amgen and the others, we -- I think it's fair to say that we haven't seen a lot of activity, which is incongruent with the defensive strategies and so forth that Amgen put forward in 2019. It's very much an Onpro-focused defensive strategy, as you know.

With respect to additional competitors such as Sandoz, I don't believe they have the reimbursement code yet. And I don't believe they'll have that for another quarter or so. I don't believe they have pass-through until mid-year about. So we'll have to see how that develops. And so far, we haven't seen, of course, any substantial inroads with respect to Sandoz, and nothing has sort of popped up in the data to us thus far.

Now with respect to Avastin, it is true that others are ahead and have various strategies in terms of launch. But I don't think that's really going to deter us from going out there and getting our fair share of the market. I believe that we've shown that we can show up third in a market like we did with UDENYCA, have a very strong value proposition, understand the customer base and understand how to go forward with the customer base and be successful.

One of the things that we are currently doing since we've done the agreement is discussing the onco mAb competitive dynamic with the customers, understanding their needs very much along the lines of what we did before we launched UDENYCA. As you recall, we did over 1,000 interviews. We talk to the payers, we went to various health care congresses and so on. We are currently in that process now and we'll be fleshing out our strategy for these onco mAbs over 2020. But I will assure you, we'll get our fair share of those markets.

Operator

Your next question is from the line of Salim Syed.

Salim Qader Syed - *Mizuho Securities USA LLC, Research Division - MD, Senior Biotechnology Analyst of Equity Research & Head of Biotechnology Research*

Congrats on all the progress, Denny and team. So one for me on accounting and then the second one just on UDENYCA. So JV, one question I had was just on the trade receivables. It looks like it's $141 million for the end of the year, which is more than 1/4 of sales. And it seems like that's a little on the high side versus other companies that I've looked at. Can you maybe just comment on the terms of the trade receivables and how you're thinking about that? And then I'll just follow-up with my UDENYCA questions after.

Jean-Frédéric Viret - *Coherus BioSciences, Inc. - CFO*

Yes, it's a good question. Actually, you should look at the trade receivables but also at the rebates and charge accrual because trade receivable is only and solely from the wholesalers, right? However, we have to disburse rebates and -- from -- under a liability account, so we have to look at them combined. Receivables now are coming between 30 and 60 days, so they're coming on a regular basis. So I expect that the $142 million will be collected by the end of tomorrow or...

Salim Qader Syed - *Mizuho Securities USA LLC, Research Division - MD, Senior Biotechnology Analyst of Equity Research & Head of Biotechnology Research*

Yes. There's just a little lumpiness in it, the timing or...

Jean-Frédéric Viret - *Coherus BioSciences, Inc. - CFO*

No, no. It's just -- if you suggest from the wholesaler side, and then you have to put -- use these proceeds, if you will, and then you have to pay the payers, and you have to pay the clinics and hospitals that have performed rebates.

Salim Qader Syed - *Mizuho Securities USA LLC, Research Division - MD, Senior Biotechnology Analyst of Equity Research & Head of Biotechnology Research*

Okay. But generally speaking, it's -- the terms there is 30 days or 60 days?

Jean-Frédéric Viret - *Coherus BioSciences, Inc. - CFO*

Some are 30 days, some are 60 days.

Salim Qader Syed - *Mizuho Securities USA LLC, Research Division - MD, Senior Biotechnology Analyst of Equity Research & Head of Biotechnology Research*

Okay. But nothing longer than 60?

Jean-Frédéric Viret - *Coherus BioSciences, Inc. - CFO*

No. And then it's very current actually.

Salim Qader Syed - *Mizuho Securities USA LLC, Research Division - MD, Senior Biotechnology Analyst of Equity Research & Head of Biotechnology Research*

Okay, got it. And then just on UDENYCA. Denny, if I may, on UDENYCA, when I look at consensus, consensus seems to be modeling on a quarter like Q1 over Q4 and a Q2 over Q1, sort of flattish sales. And so at the end of the year, you got to something like $460 million for 2020. In the press release, it mentions that you plan to increase penetration and maintain price, which should imply quarter-over-quarter growth. So are you willing to say that consensus is undermodeling what your qualitative guidance suggests?

Dennis M. Lanfear - *Coherus BioSciences, Inc. - Chairman, President & CEO*

Well, I appreciate the question, Salim, and I don't mind you asking. But no, I'm not willing to make further comments with respect to the overall -- the consensus at this particular point in time.

I think that we are confident we'll have additional share penetration throughout 2020, quarter-to-quarter, probably be lumpy as things go forward and so on. But we are uncertain of exactly how the pricing will evolve with respect to the various competitors and so on. Sandoz is going to show up and so forth.

So -- but overall, I think we're going to do quite well as far as maintaining the trajectory on share growth. But I can't really nail it down for you further than that at this particular point in time.

Salim Qader Syed - *Mizuho Securities USA LLC, Research Division - MD, Senior Biotechnology Analyst of Equity Research & Head of Biotechnology Research*

Okay. Last one for me and then I'll hop in the queue again. Some people comment on the UDENYCA long-term trajectory as being -- it's a bimodal peak or single peak or when the -- when does Coherus assume peak sales, is there a general framework that you guys think about internally? Because there's going to be pricing pressure at some point perhaps, right? I mean should people be thinking about peak sales here being 2 years into launch or 3 years into launch? Like how are you guys generally thinking about that?

Dennis M. Lanfear - *Coherus BioSciences, Inc. - Chairman, President & CEO*

Well, I would observe that the buy-and-bill Medicare Part B space is quite a bit different in terms of financial incentives and overall market structure than, for example, the Part D space. And one of the things that I would emphasize is that it is not in the interest of any market participant to aggressively cut prices and prematurely diminish their ASP.

So I think when some folks have looked at this market, they may have not focused sufficiently on the fact that the market participants, if they wish to have staying power in the market and wish to have a multiyear trajectory with some steadiness in that market, we'll be conservative in terms of price decreases in the context of trying to gain share, right?

So I think that while we have not guided the Street as to how we see the trajectory, I would say sometime in the 2- to 3-year time frame, we would probably see peak sales and then a gentle roll-off thereafter. But I think we'll see how things evolve through 2020 to nail that down a little closer for you. But I would again make the point though that Medicare Part B is a space where there are incentives to maintain pricing and not simply go in and cut pricing because there's certainly a cost to that as to how long your product will last in the market.

Operator

Your next question is from the line of Jason McCarthy.

Michael Okunewitch - *Maxim Group LLC, Research Division - Equity Research Associate*

This is Michael Okunewitch on for Jason. I'd like to get your idea on the biosimilar Lucentis launch, because I know that one of the key advantages of that in-license was that it basically moved you guys up to the front position. So I'd like to see what's the delay? Are you still projecting that you're going to be the first biosimilar on the market?

Dennis M. Lanfear - *Coherus BioSciences, Inc. - Chairman, President & CEO*

Yes. Michael, that's a very fair question. The additional manufacturing work required, that the FDA wanted to see as far as the movement of this piece of equipment, as we indicated earlier, is like 4 months' worth of work. And as soon as we schedule that and wrap that up, we can go ahead and get the file resubmitted.

We don't have guidance for you right now as to exactly how fast that can get scheduled. We're scheduling that sort of as we speak. And so it's difficult to address your question in terms of when do we think. I would say that we believe that we will get that file resubmitted certainly within 2020, which should get it approved in 2021. But I don't have any further granularity for you, unfortunately, at this time in terms of actual timing or I would tell you. I hope that's helpful.

Operator

Thank you. Ladies and gentlemen, this concludes today's conference call. Thank you for your participation and have a wonderful day. You may all disconnect.

Dennis M. Lanfear - *Coherus BioSciences, Inc. - Chairman, President & CEO*

Thank you.

Jean-Frédéric Viret - *Coherus BioSciences, Inc. - CFO*

Thank you.

Dennis M. Lanfear - *Coherus BioSciences, Inc. - Chairman, President & CEO*

See you on the next call. Bye-bye.
