CERUS CORP

FORM 8-K
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 25, 2014

CERUS CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	**000-21937**	**68-0262011**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2550 Stanwell Drive
Concord, California 94520
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (925) 288-6000

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 Results of Operations and Financial Condition

On February 25, 2014, Cerus Corporation (the "Company") held a conference call to report its fiscal 2013 fourth quarter and year-end financial results. A copy of the transcript of this conference call is attached as Exhibit 99.1 to this current report and is incorporated herein by reference.

The information in this report, including the exhibit hereto, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of Section 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

The following exhibit is furnished with this report:

99.1 Transcript of earnings conference call held on February 25, 2014 to report Registrant's fiscal 2013 fourth quarter and year-end financial results.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CERUS CORPORATION

Dated: February 28, 2014

By: /s/ KEVIN D. GREEN
Kevin D. Green
Vice President, Finance and Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
99.1	Transcript of earnings conference call held on February 25, 2014 to report Registrant's fiscal 2013 fourth quarter and year-end financial results.

CERUS CORPORATION

Moderator: Lainie Corten
February 25, 2014
4:15 p.m. ET

Operator: Good day, ladies and gentlemen, and welcome to the Cerus Corporation's Fourth Quarter 2013 Results Conference Call. At this time, all participants are in a listen-only mode.

Later, we will give a question and answer session and instructions will follow at that time. If anyone should require assistance during the conference, please press star then zero on your touchtone telephone to reach an operator.

As a reminder, this conference call is being recorded. I would now like to introduce your host for today's conference, Lainie Corten. Please proceed.

Lainie Corten: Thank you, operator, and good afternoon. I'd like to thank everyone for joining us today. With me on the call are Obi Greenman, Cerus' President and Chief Executive Officer; Kevin Green, our Chief Financial Officer; Carol Moore, our Senior Vice President of Regulatory Affairs, Quality and Clinical; and also Larry Corash, our Chief Medical Officer.

Cerus issued a press release today announcing our financial results for the fourth quarter and year ended December 31, 2013, and describing the company's recent business highlights. You can access a copy of this announcement on the company Web site at cerus.com.

I would like to remind you that during this call, we will be making forward-looking statements regarding the company's products, prospects and results, including expectations for future sales growth and performance, new

customers and 2014 revenue; the anticipated impact resulting from strategic changes to Cerus' distributor relationship; the expected financial and other benefits from the company's amended agreement with its manufacturer of disposable kits; the anticipated timing, completion and potential approval of the company's modular PMA submissions to FDA; the potential commercial launch of the INTERCEPT Blood system for plasma and platelets in North America and of the red blood cell system in Europe, including anticipated marketing activities and expenses in support thereof; also future operating expenses and cash utilization; research and development activities and the expenses related thereto; and the timing of completing our ongoing clinical trials including the reporting of data from these trials. The company's actual results may differ materially from those suggested by forward-looking statements the company will be making, and the company assumes no obligation to update guidance or other forward-looking statements.

I call your attention to the disclosure in the company's SEC filings, in particular, Cerus' quarterly report for the fiscal period ended September 30, 2013, on Form 10-Q, including the section entitled Risk Factors. This call will be archived temporarily on our Web site and will not be updated during that time.

On today's call, Obi will provide an introduction followed by quarterly financial results from Kevin. Carol will then provide an update on our development programs and regulatory submission. We'll conclude our prepared remarks with commentary from Obi, who will provide an outlook for 2014.

And now it's my pleasure to introduce Obi Greenman, Cerus' President and Chief Executive Officer.

William Greenman: Thanks, Lainie. I'd like to thank everyone for joining us today on our Q4 call. 2013 was a defining year for Cerus in our over 20-year history with initiation of U.S. regulatory reviews for both INTERCEPT plasma and platelets. This culminated in submission of all 4 modules of the INTERCEPT plasma PMA, and 2 of the 3 modules for the INTERCEPT platelet PMA.

Globally, we continue to achieve commercial progress in Europe, CIS and the Middle East and to submit for regulatory approvals in many new countries where blood safety issues are a growing concern. Despite this progress, we were disappointed in the latter part of 2013 by decelerating growth trends in some of our distributor markets. Distributors are an important source of revenue for us, representing an approximately half of our annual sales.

Due to the weaker-than-expected growth in several distributor territories, we are reporting 2013 sales of $39.7 million, short of our 2013 annual guidance of $41 million to $43 million. Due to the critical role played by our distributors, we evaluate their performance on an ongoing basis. Over the course of 2013, we implemented several changes designed to improve market penetration and distributor territories, including additional sales, technical and marketing support, as well as supplementary training to improve the effectiveness of distributor field personnel. More recently, we began transitioning certain countries to new distribution partners who we feel are capable of improved performance compared to the companies they are replacing, as we did in the Russian market in the last part of 2013.

For 2014, we will continue our focus on optimizing INTERCEPT penetration in key regions, including taking the option to transition some of these markets to a Cerus direct sales effort that provides full visibility into sales execution. Discussions regarding these distributor changes are currently in progress. We do not anticipate any disruption for end user customers as a result of these transitions.

We believe that INTERCEPT should be the standard of care in transfusion medicine in all markets, and it's important that our distribution partners share our sense of urgency to reach this goal. In the near term, we expect revenues will be negatively impacted as a consequence of these strategic decisions. We currently estimate that it will take approximately 1 to 2 quarters to work through distributor inventories during the transition period. And as such, we believe guidance of $38 million to $40 million in 2014 sales, or flat sales, is appropriate at this time.

Longer term, we anticipate a positive impact from these changes as they will serve to improve our visibility into these markets and potentially provide for more predictable ongoing sales growth. While we are optimistic about bringing on significant new customers in our direct markets in 2014, we will not be factoring that possible upside into our guidance since we are not currently able to predict whether and when this adoption will occur. Similar to our approach last year, we will provide updates when we make substantial steps forward.

Now I'd like to turn the call over to Kevin for more discussion of our financial results.

Kevin Green: Thank you, Obi. Revenue for Q4 was $9.2 million, culminating, as Obi mentioned, in full year 2013 revenue of $39.7 million. Year-over-year, 2013 product revenue represented an increase of approximately 8 percent. Relatively consistent with prior periods, disposable kits represented more than 90 percent of product revenue.

Our 2014 guidance of $38 million to $40 million includes the assumption that the changes we intend to initiate for distributor transitions in certain regions may temporarily impact our volume of INTERCEPT kit sales as distribution partners sell through their kit inventory prior to our direct sales team taking over local customer accounts. We believe these transitions will largely take place in the near term. Therefore, our guidance contemplates a potentially disproportionate impact to revenue in the first half. In the event that we transition to new distribution partners or move to selling direct in certain territories, it may take longer for us to be paid with some companies or customers taking longer to pay invoices than the payment terms we have been experiencing with the original distributor. However, we believe that these strategic actions will allow us to maintain and potentially improve pricing and therefore, margins, creating a potentially healthier business and improved operating contribution from these regions.

Back to 2013 results. Gross margins during the fourth quarter were 47 percent, up sequentially from 35 percent in Q3, and relatively stable compared to the 51 percent realized during the fourth quarter of 2012.

I'd like to note that beginning in January of this year, we began operating under an amended manufacturing agreement with Fresenius-Kabi, our disposable kit manufacturer.

The new terms differ from our prior contract in 2 important aspects. First, the amended agreement establishes a fixed schedule of pricing for our kits over the next several years with lower pricing for each successively higher tier of production volume. In contrast to our prior contract terms, this new structure should provide more stable cost of goods going forward with less quarterly volatility than we've reported previously.

Second, under the new terms, Fresenius-Kabi is now sourcing and purchasing certain high-cost long lead time components directly from us. Historically, we procure these components and carry them as work in process on our balance sheet, providing them to Fresenius-Kabi at no cost. The result was a less efficient use of our cash and variability in scrap charges for these high-cost components.

Turning now to operating expenses. Total operating expenses for Q4 were $12.1 million, flat compared to Q3 and up from $9 million during Q4 of 2012. For the full year 2013, operating expenses were $45.4 million compared to $33.5 million incurred in 2012.

As we anticipated and have discussed in previous calls, operating expenses increased during 2013 largely as a result of our ongoing efforts to support the U.S. PMA processes for both our platelets and plasma programs and to a lesser extent, increased clinical activity for our red blood cell program. Looking ahead, we anticipate operating expenses may increase as we make decisions to add resources in advance of a potential U.S. commercial launch and as we implement these strategic changes for some distributor markets, as previously mentioned.

In addition, cost may increase as we evaluate the general appetite for and our ability to accelerate the necessary activities to bring our red cell technology to market in Europe.

When looking at our bottom line, net loss for Q4 was $5.9 million compared to $1.7 million during Q4 of 2012. For the full year, net losses were $43.4 million as compared to $15.9 million in 2012. Beyond operating results, a significant contributor to the 2013 net loss was the noncash charge of $15.1 million for the mark-to-market valuation of our outstanding warrants. Of the total 6 million warrants outstanding at December 31, 2013, 2.4 million warrants expire in Q3 of this year with the remainder expiring in November of 2015.

Now looking at the balance sheet. We ended Q4 with cash and short-term investments of $57.7 million, compared to $26.7 million at the end of 2012 and $53.3 million at the end of the third quarter.

And with that, I'd like to turn the call over to Carol, who will discuss our regulatory progress and development programs.

Carol Moore: Thank you, Kevin. I'll start with an update on the status of our U.S. regulatory submissions for plasma and for platelets. In November, we submitted the fourth and final PMA module for INTERCEPT plasma. The full PMA has been accepted, and we are in active dialogue with the FDA as they progress through their review activities.

In terms of timing for an approval decision, we continue to expect this could happen as early as the second half of this year. For INTERCEPT platelets, we submitted our second of 3 planned modules in December. Our third and final module was originally scheduled for submission in late March, but we now expect to file this module in Q2. The later filing is driven by a combination of expecting to need time to answer FDA questions on module 2, which we'll receive in late March, and to complete an in vitro platelet validation study currently in progress for inclusion in module 3. Based on this timeline change, we are now projecting that a review decision for platelets will happen in 2015.

I'd like to remind you that the timing I've just mentioned for the plasma and platelet review decisions represents our best estimate at this time. Review timelines are variable, and we will provide ongoing updates each quarter as we make progress and continue our dialogue with FDA.

Moving on to our INTERCEPT red cell development programs. We continue to make progress on our 3 ongoing clinical studies. In Europe, our Phase III acute anemia trial remains on track to read out in the second half of this year. Enrollment in our chronic Phase III trial continues to proceed at a slow pace.

Consistent with our update last quarter, we continue to believe that chronic trial will require at least 3 years to complete. We are continuing to evaluate options to accelerate the completion of this trial, as well as our overall strategy and timeline for a potential European red cell approval. Finally, in the U.S., our Phase II red cell study is ongoing, and we still expect to report data in the second half of this year.

And now I'd like to turn the call over to Obi.

William Greenman: Thank you, Carol. We are confident that taking decisive action on our representation in important regions will provide us increased visibility into these markets and correspondingly, better sales performance in the future.

The distributor changes we plan in the near term should position us to deliver ongoing revenue growth in the second half of 2014, as we mature our global commercialization presence and efforts. Many of the major EMEA markets and customers are taking a serious and disciplined look at the role that INTERCEPT can play in securing their blood supply.

As in years past, we have chosen not to incorporate those possible upsides into our guidance, but we remain optimistic that the tide is moving in favor of pathogen inactivation, and that our decade of clinical data from routine years is critical to the decision-making process.

We look forward this year to a possible FDA review decision for plasma, as well as completing our PMA submission for platelets. We also plan to submit platelet and plasma applications for Canadian approval. In parallel with these efforts, we are, therefore, also spending significant time in planning for the potential launch of INTERCEPT in North America with the recent hires for

our commercial team. It is great to be benefiting from their insights into the U.S. market dynamic, and we are increasingly excited about how we might position INTERCEPT upon its approval.

Finally, the development and clinical teams are making steady progress on the INTERCEPT red cell clinical studies. The deployment of the red cell process to numerous study sites has been seamless, and the in vitro data generated from these collaborations continues to be show promise. We believe it is increasingly evident that the process is robust and easily transferable.

In conclusion, we are well positioned to make the changes that are needed to continue growth in our sales and to achieve our goals of future approvals and product launches for platelets and plasma in North America, and for red blood cells in Europe.

Operator, please open the call for questions.

Operator: Certainly. Ladies and gentlemen, if you have a question at this time, please press the star then the number one key on your touchtone telephone. And if your question has been answered or you wish to remove yourself form the queue, please press the pound key. Once again, if you have a question at this time, please press the star then the number one key on your touchtone telephone.

Our first question will come from the line of Jeff Elliott from Robert W. Baird.

Jeffrey Elliott: My first question's on the changes in distributor relationships. I guess, can you talk about what you're assuming in 2014 for the impact? And also can you give me a little comfort in why you're thinking the impact will be contained in the first half? And the end users won't be disrupted in that change?

William Greenman: I'll turn that over to Kevin. Thanks, Jeff.

Kevin Green: Yes. Jeff, thanks for the question. Our distributor contracts generally require, at least, 3 months of inventory to be held. And as we transition, we also want to make sure that end-user customers are not impacted. So our annual guidance contemplates a transition in the first part of the year up to 6 months.

Jeffrey Elliott: Got it. OK. And then, I guess, what gives you, I guess, confidence that the end users won't be disrupted in the process? I mean it sounds like this could be a bigger change, potentially going direct or changing distributors. I guess, what gives you – give me some comfort into your thinking behind that.

William Greenman: So I think one of the things that you guys should know is that we are very, very active in the distributor regions. So in some regions, we actually have serious FTEs on the ground, both from a sales and deployment standpoint. So I think we know the customers very, very well. I think as we sort of look strategically at all these distributor regions, we aren't definitively saying we're going direct in every country, but we're going to be sort of taking stock of the performance of the distributors and whether we can do something to improve their performance by adding resources, or do we transition distributors or do we ultimately go direct? And so I think as you look at – 50 percent of our sales comes from distributors, but we're not going to be going direct in all those markets, we're just going to be doing it on a region-by-region basis as it's not really specific to a distributor per se either.

Jeffrey Elliott: Got it. OK. And then, Kevin, can you give a little additional color on what the potential margin impact could be longer term on the change in these relationships? I guess you alluded to better potentially better pricing, but how should we think about of that in terms of modeling?

Kevin Green: Well, Jeff, I think it's a bit premature since we don't know what our ultimate end-user customer pricing will be. But I'd say that typically, we do offer, currently, distributors volume discounts based on the annual purchases. While it varies between distributor depending on the size of the territory, it can be as much as 20 percent.

Jeffrey Elliott: Got it. OK and shifting gears. I apologize if I missed this, but was there any update on the U.K. platelets validation?

William Greenman: No, we didn't provide it, but I can give you one. So basically they are NHSBT, which is the U.K. blood service, is conducting a pilot valuation of

INTERCEPT platelet sort of in routine production and transfusion. That's underway right now. And the general thinking, at least, at Cerus is that in parallel with that, there's a SaBTO policy discussion underway, and the NHSBT will sort of factor that outcome into their overall decision to go to tender likely in the second half of this year.

Operator: Our next question will come from the line of Zarak Khurshid from Wedbush Securities.

Zarak Khurshid: Can you break out the illuminator sales in the quarter?

Kevin Green: So, Zarak, typically what we've done is not getting into the granularity but discuss the percentage of kits. So it's over 90 percent, just 92 percent, I think. Is that (inaudible) getting it.

William Greenman: So, illuminator sales will be 8 percent?

Kevin Green: Yes.

William Greenman: OK.

Zarak Khurshid: Great. And then, in terms of the geographies that were impacted, can you just kind of walk us through which regions were most impacted? And then, how many distributors are we talking about here? Were there one – was there more than one that fell off or one that really accounted for the bulk of the miss?

William Greenman: Yes, so typically we use distributors in Russia in CIS, the Middle East, Southern Europe and Latin America and, obviously, we're constantly looking at new regions to add distributors as well or to go direct in. And so I don't think we're going to break it out today on any specific area where we saw trends that weren't as we expected in the second half of the year. But that really caused us to look at the overall sort of distributor region performance, and then sort of go essentially region by region and try and figure out what we're going to do to improve performance and visibility. I think it really comes down to what I said on the call where certain distributors have different priorities with regard to their portfolio of products. And from our perspective,

we have a very high degree of urgency about making INTERCEPT the standard of care, which is our mission in transfusion medicine. So I don't know if I specifically answered your question, but maybe if you have another one I can try.

Zarak Khurshid: Yes. Sure. I guess I'm just curious about the timing of all this here. So I mean, had you been experiencing some of these issues throughout the year, and then they manifested more meaningfully in the fourth quarter? Just if you could just provide a little bit more color on that, the trend, and what actually happened in the quarter, that'd be great.

William Greenman: Yes, it was most pronounced in the fourth quarter. I think as we – as you know in this market it has sort of a prolonged sales cycle. So as we try and help our distributors perform better, we bring in sales and deployment and scientific affairs folks to try and help them add accounts more quickly.

But we did see a pronounced effect in the fourth quarter, and it really is more of something that we see over time is that at the end of the day, if we're not seeing the kind of performance we want out of a specific region, we either have 3 choices available to us. It's invest more on our nickel to improve their performance; change distributors, which we didn't as I mentioned on the call in the second half of the year in Russia; or ultimately go direct. And so we're sort of looking at each market in that context.

Zarak Khurshid: Understood. And then, with this move direct in some geographies, how does that change the kind of the expense structure going forward?

William Greenman: I'll turn it over to Kevin, but I think fundamentally just to remind you that the blood banking market is heavily consolidated almost globally. I'm sure that country-by-country basis there are not that many customers. So if you look at the SG&A footprint and deployment footprint, you need to service a country if you go direct, the operating expenses aren't that huge, but I'll turn the rest of the question over to Kevin.

Kevin Green: Well, I think topically you addressed it, Obi. And as Obi previously mentioned, we're not looking at going direct in all distributor regions but select regions where it makes sense. So the incremental investment that we

have to make will be nominal. I think our operating margins from those territories will improve as a result of more control over pricing and a small nominal investment in OpEx.

Operator: Thank you. And as a reminder, ladies and gentlemen, if you have a question at this time, please press the star then the number one key on your touchtone telephone. Once again, if you have a question at this time, please press the star then the number one key on your touchtone telephone.

Our next question will come from the line of Josh Jennings from Cowen and Company.

Joshua Jennings: Maybe if you, Obi and Kevin, if you could just walk us through the transition in Russia that you execute on the second half, and how that process went. Just to give us a little bit of a precedent case turns how this could shape up in the first half of the year in '14 in other regions?

William Greenman: Yes, so I mean potentially, we identified a new distribution partner there that we thought would be better, and potentially just transitioned from one distributor to the next one. So it was relatively seamless in that regard. I think it may be different in other countries where there – from a performance standpoint or competition standpoint, it may be more problematic.

But I think, again, it's a little bit early to sort of be too prescriptive here because of the sensitivity of the discussions with some of these distributors. So I'd really like to defer comment until we have something definitive to say.

Joshua Jennings: OK. And just on the – in terms of this dynamic change in your sales and marketing strategy in the international territories. I mean, was there anything else in Q4 that prompted this or that caused some headwinds, but is there more competition that you experienced in Q4 that's moving you towards this potential more of a direct model in these international markets?

William Greenman: I wouldn't say we – we haven't lost any customers, if that's what you're asking. I think the only customer we ever lost is in the Balearic islands, but I guess that wasn't the – I think some of it was poor performance and

conversion of customers to routine use, and also inherent delays in this business with regard to getting people to take on INTERCEPT. I think the nice thing about this business is that ultimately when they become routine users, you have sort of predictable sales. But we've experienced sort of long sales cycles in a number of the markets, and yes, sometimes distributors just aren't prioritizing INTERCEPT the way we they think they should.

Joshua Jennings: OK. And just in terms of your guidance for 2014, does that include any revenue from plasma approval in the U.S. in the second half?

William Greenman: No.

Joshua Jennings: It does not, great.

William Greenman: I think we're looking for an approval in the second half, an approval decision in the second half of this year for plasma. But really sales wouldn't be – we're not planning on sales in the second half of 2014.

Joshua Jennings: OK. And can you give us any update in terms of – you build out your sales and marketing leadership starting in January? And I assume you're having more discussion with U.S. blood centers in front of potential FDA approval. Any kind of feedback in terms of the enthusiasm level or and any hurdles that you're seeing that you may face?

William Greenman: I think that the ongoing concern about bacterial contamination of platelets is very real, and the costs of trying to address that are significant. I guess, I also would defer or refer you to the FDA Seebri Web site, where they have at least published that they will issue a guidance document on bacterial contamination of platelets this year, it's not prescribed us to a specific date, but it is part of the official record now on the FDA Web site. So we believe that, that is something that does lead to blood center interest in the INTERCEPT technology. And I think just nice thing about having commercial folks on the ground here in North America is they really have, they have a lot of insights into the market dynamics, both on the blood center side, but also on the interface between the blood center and the hospitals. And if anything, they bring a new sense of enthusiasm to the company.

Joshua Jennings: And last question for me. Just on the platelet PMA submission. Can you just remind us what, from a data perspective, is included in the submission? I mean, I assume it's the SPRINT trial data, the haemovigilance data from Switzerland and France, the euroSPRITE data but – is there anything else that's included in the clinical data package?

William Greenman: Gosh, you want to take that, Carol or Larry.

Carol Moore: Sure. The clinical data was provided in the module 2, which went into December. So in module 3, you pull everything together. So it contains all of the manufacturing information it contains summaries of the clinical data. It's the last module, it kind of completes the PMA with a full picture of both the clinical, preclinical and manufacturing processes to manufacture the platelet product.

Joshua Jennings: OK, but just on the clinical data you submitted in module 2 then, what's included in that package?

Carol Moore: Yes. It's our SPRINT, it's our euroSPRITE, it's our haemovigilance, it's all the market experience we've had. It's everything we've learned from publications on our product. It's really anything that we've gathered up over the years with regard to the use of INTERCEPT platelets in the commercial market, as well as in the clinical market or in the clinical studies, I should say.

Operator: Our next question will come from the line of Zarak Khurshid from Wedbush Securities.

Zarak Khurshid: In terms of the delay here, the slight delay in platelet approval for the U.S., can you just quantify it a little bit? Is this a couple of months push out or a quarter? Any color there would be helpful.

William Greenman: Carol, do you want to address that?

Carol Moore: Sure. I think that it's really a matter of the timing of the last module, and we know that it's a minimum of 180 days after you file the last module. So that's why I think we're anticipating conservatively that the last module will go in sometime in Q2, and 180 days from that puts us pretty much at the end of the year. So we feel that a conservative assessment of the timing to review the application to answer questions puts us into 2015.

Operator: Our next question will come from the line of Thomas Yip from MLV & Co.

Thomas Yip: So my first question is since from what I can see, the anticipated approval timeline in the U.S. for both plasma and platelets are around the same time or rather they're close to each other. Do you see them being launched separately or will there be a single unified launch?

William Greenman: We just have to see what the timing ultimately looks like. I think just given how close they potentially are in time, looking at 2015 is sort of what we're shooting for with regard to launch timing because of the approval decision for plasma wouldn't take place until the second half, anyway, of this year.

Thomas Yip: OK, OK. And what kind of impact do you – I mean, I know it's still relatively early, but what kind of impact do you see a potential U.S. launch will impact the gross margin?

William Greenman: The gross margin or the growth revenue? I guess the way I look at is we're obviously not sort of forecasting revenue growth coming from the launch yet until we have a better idea as to what the approval looks like with regard to label claims, et cetera. And so I think we'll really try and defer that commentary until that date.

Operator: And at this time, I'm not showing any further questions. I would now like to turn the call back over for any closing remarks.

William Greenman: Well, thank you, all, for joining us today. Once again, we look forward to updating you again on our next call in late April. Thanks very much.

Operator: Ladies and gentlemen, thank you for participating in today's conference. This does conclude the program, and you may all disconnect. Everyone, have a great day.

END