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SRDX - Q2 2017 Surmodics Inc Earnings Call

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PRESENTATION

Operator

Good day, and welcome to the Surmodics Second Quarter 2017 Earnings Call.

Today's conference is being recorded.

At this time, I would like to turn the conference over to Mr. Andy LaFrence, Vice President of Finance and Chief Financial Officer. Please go ahead, sir.

Andrew D. C. LaFrence - *Surmodics, Inc. - CFO, Principal Accounting Officer and VP of Finance & Information Systems*

Thank you, Savanna. Good morning, and welcome to Surmodics' 2017 Second Quarter Earnings Call.

Before we begin, I would like to remind you that, during this call, we will make forward-looking statements. These forward-looking statements are covered under the provisions of the Safe Harbor Act -- from the Private Securities Litigation Reform Act of 1995 and include statements regarding Surmodics' future financial and operating results or other statements that are not historical facts. Please be advised that actual results could differ materially from those stated or implied by our forward-looking statements resulting from certain risks and uncertainties, including those described in our SEC filings. Surmodics disclaims any duty to update or revise our forward-looking statements as a result of new information, future events, developments or otherwise.

We will also refer to non-GAAP measures because we believe they provide useful information for our investors. Today's news release contains a reconciliation table to GAAP results.

This conference call is being webcast and is accessible through the investor relations section of the Surmodics website, where the audio recording of the webcast will also be archived for future reference. A press release disclosing our quarterly results was issued earlier this morning and is available on our website at www.surmodics.com.

I will now turn the call over to Gary Maharaj. Gary?

Gary R. Maharaj - *Surmodics, Inc. - CEO, President and Director*

Thank you, Andy. And good morning, everyone, and thank you for joining.

On today's call, I will provide an overview of our key achievements and an update on the execution of our strategy and plans for the remainder of fiscal 2017. And then I'll turn the call back to Andy to provide a review of our second quarter financial results and our fiscal 2017 guidance. We'll then open the call to take your questions.

Before turning to our second quarter performance, I'd like to acknowledge last week's announcement that Lisa Wipperman Heine has joined our Board of Directors. Lisa has extensive experience in the medical device industry and is currently the Chief Operating Officer at Mitralign, an innovator in transcatheter tricuspid valve therapy. Over the course of her career, Lisa spent many years in multiple leadership roles and strategic roles at Covidien. And we are happy to have Lisa join our Board of Directors and look forward to her contributions to our team.

We're pleased to report solid results for our second fiscal quarter. We achieved tangible progress towards our strategic objectives, which are driving execution in our 2 core businesses, moving forward on our whole-product solutions pipeline and outfitting our manufacturing footprint in Ireland, all of which are aimed at driving our innovative R&D initiatives while continuing to deliver solid financial performance. We are on track to becoming a valuable and enduring medical device innovator by combining our key technology assets with our deep and broad medical device customer relationships, which we intend to deliver best-in-class and "new to the world" product solutions for vascular disease. As a reminder, our core competencies are now in the areas of surface technology, drug delivery, peripheral balloon design, braided catheters and process engineering. And we are using these to build our unique portfolio of pipeline products.

In the second quarter, we demonstrated meaningful progress on our specific major fiscal 2017 objectives. These are to meet our overall revenue and profitability goals in our core businesses while managing the OUS expiration of significant royalty-generating patents in our medical coatings business; second, to invest in, and achieve significant milestones, in our drug-coated balloon programs and to secure regulatory approvals in our catheter and balloon research and development pipeline; and third, to expand our operational capacity for high-quality and cost-efficient manufacturing through continued investment.

At a high level, we grew 4.8% in the second quarter versus the second quarter last fiscal year and achieved GAAP diluted earnings of $0.04 per share. We're delighted with our top line performance, especially considering the royalty and IVD revenue headwinds we predicted in this past quarter. Because of these positive results, we are raising our revenue guidance for fiscal 2017 to an expected range of $65 million to $68 million. Andy will provide more details regarding revenue and profitability in the second quarter.

Regarding our second objective, which relates to our pipeline portfolio of innovative whole-product solutions, we continue to make progress. Starting with our drug delivery programs, we have targeted several aggressive milestones over the next several quarters. We are seeking regulatory approval to initiate the next clinical development phase of our SurVeil paclitaxel drug-coated balloon for the treatment of femoral and popliteal disease. To this end, we are currently in detailed discussions with the relevant regulatory agency as we propose our plans for the next clinical trial with SurVeil. This is a major step and not without some risks given that it involves external regulatory review and time lines that are not directly within our control. We continue to drive for full resolution and a favorable outcome in the next several months. We're also working in parallel with our clinical CRO, that is our full contract research organization, to in parallel identify these clinical sites in the relevant geographies to conduct this clinical trial. We now expect incrementally higher activity with our CRO in fiscal 2017, which will increase our R&D expenses. Andy will go into more detail on the financial impact in his section. We are pleased that the clinical trial design has been completed and the principal investigators have been chosen.

On our sirolimus-based below-the-knee drug-coated balloon program, we continue to make progress using our own internally developed platform and our 014 balloon catheter. We completed a major dosing study that has helped us to decide the optimal drug dose that can provide optimal biological effect with the maximum safety margin.

Turning to our nondrug delivery pipeline. We expect to complete all the relevant regulatory submissions for 3 new products before the end of this fiscal third quarter. We're on track with our target to receive late fourth quarter regulatory clearances for each product, namely 2 peripheral balloons and a microcatheter, each using advanced versions of our coating chemistry. We are on plan and have actually completed the designs of our 014 and 018 peripheral balloon catheters, incorporating our Serene hydrophilic coating. And we have also begun work on the next wave of product innovations that we are targeting for approvals in calendar 2018, which will help us build our platform and accelerate top line growth.

And finally, with respect to operational readiness in our Ballinasloe, Ireland facility, we have installed and qualified new clean rooms and labs in the second quarter, which are now capable of manufacturing both drug delivery and nondrug delivery products. We also continued to invest in our coating equipment to increase our hydrophilic coating services offering to our many strategic customers who have manufacturing facilities in

Ireland. We have effectively doubled our footprint in our Irish facility, and we are installing and validating the new processes that will give us important scale and ability to react quickly to ramp production in line with our whole-product solutions strategy.

Our progress in each of these areas continue to guide our capital allocation choices in fiscal 2017. We believe that the best way for Surmodics to maximize long-term shareholder value is to accelerate investments in the core research and development programs that enable us to capitalize on our strategic assets to develop unique product solutions. This investment is critical to our long-term success. Our objective is to generate consistent revenue growth in the midteens on a constant currency basis within the next 3 years and to generate EBITDA margins greater than 30% within 5 years. We believe that fiscal 2017 is a pivotal investment year and expect to see the initial returns from these investments via an acceleration in revenue growth beginning in fiscal '18.

It's an exciting time at Surmodics, and we're encouraged by our strong performance and operational progress. Rest assured that our allocation of capital will be accomplished in a characteristically disciplined fashion that our track record demonstrates and that you have come to expect from us.

I will now turn the call over to Andy to provide more details on our second fiscal quarter 2017 results as well as our outlook for the remainder of the year. Andy?

Andrew D. C. LaFrence - *Surmodics, Inc. - CFO, Principal Accounting Officer and VP of Finance & Information Systems*

Thank you, Gary.

We're happy to report that revenue in the second quarter of fiscal 2017 rose 4.8% to $17.5 million compared with $16.7 million in the second quarter of last year, driven by continued strength in the Medical Device segment. On a GAAP basis, our diluted earnings totaled $0.04 per share compared to $0.06 per share in the prior year quarter. We delivered operating income of $1.7 million in the second quarter of fiscal 2017, down from $2.2 million in the prior year period. Operating margin decreased from 13.4% to 9.6% in the current year quarter.

Declines in GAAP earnings per share, operating income and margin in the current year quarter reflect increased R&D spend to support our whole-product solutions, product development and regulatory submissions, offset by a $1 million or $0.07 per share gain related to fair value adjustments to the Creagh Medical contingent consideration payments. Further, prior year second quarter GAAP results included a $1.1 million out-of-period adjustment, or $0.05 per share, to correct a cumulative overstatement of royalty revenue, of which $1 million related to years prior to fiscal 2016; as well as 6 -- $0.6 million of acquisition-related costs.

On a non-GAAP comparative basis, quarterly earnings per share were $0.05 per share in the second quarter of fiscal 2017 versus $0.20 per share last year.

Turning now to our 2 business units.

Medical Device revenue rose to $12.7 million, increasing 9.7% from the year-ago period. The growth stemmed from product sales; royalties; as well as research, development and other revenue.

Looking at specific areas within the Medical Device segment. Second quarter royalty and license fees totaled $7.3 million or up 9.1% from last year. Royalty and license fee revenue growth in fiscal 2017 benefited, as the prior year quarter revenue was reduced by $1.1 million for the out-of-period adjustment for the customer overpayment. Without the effect of this prior year adjustment, royalty and license fee revenue decreased by 7.3%, reflecting the impact of the previously disclosed expiration of our third-generation hydrophilic patents. Product sales increased $0.1 million from the prior year quarter primarily due to increased reagent shipments. Medical Device customer research and development revenue rose $0.4 million for the quarter as a result of higher demand for contract coating services to support customer clinical trials and select product launches.

This unit generated $1.5 million of operating income in the second quarter versus $2.2 million in the prior year quarter. The Medical Device operating segment was impacted by increases in planned investments related to our whole-product strategy, partially offset by increased margin from higher revenue, the Creagh Medical contingent consideration gain and reduced acquisition-related costs.

For our In Vitro Diagnostics unit, second quarter fiscal 2017 revenue, which consists of product sales, totaled $4.8 million, a decrease of 6.3% from the year-ago period. As you'll recall, in the prior year quarter, we realized a 32% increase in revenue, which created a tough comp for IVD this quarter. Second quarter fiscal 2017 IVD revenue was impacted by the strong prior year comp as well as a decline from a significant microarray customer that had previously been acquired by one of its competitors. As previously disclosed, we expect the decline in revenue from this customer to continue through our third quarter. We expect fiscal 2017 IVD revenue will be comparable to the prior year.

IVD operating income was $2.2 million compared to $2 million in the second quarter of fiscal 2016. Operating margin increased to 46.8% versus 38.9% in the prior year quarter due to an increase -- due to an insurance recovery of $0.1 million, a favorable sales mix and lower operating costs. Product gross margins for the quarter were 67.7% of product sales compared to 64.2% in the prior year quarter. Gross margins benefited from the previously noted IVD insurance recovery and favorable sales mix.

As a percent of revenue, second quarter R&D expenses were 46.9% versus 29.1% in the year-ago period. R&D expense of $8.2 million for the quarter was up $3.3 million from last year. As we have stated before, we anticipate R&D expense to increase in the second half of fiscal 2017 as we accelerate our whole-product solutions strategy, including advancing our SurVeil drug-coated balloon. We noted our plans to increase our fiscal 2017 investments in R&D during our prior 2 quarterly calls. We further indicated during our Fiscal 2017 Guidance Call in November 2016 that our R&D expenses may increase by an additional $2 million over our then-current guidance. We now anticipate accelerating spending, in the second half of fiscal 2017, on CRO-related DCB expenditures and the allocation of more resources in Ireland to whole-product solutions product development. And as such, we now anticipate R&D expense will range between 40% and 44% of fiscal 2017 revenue.

SG&A expenses in the second quarter of fiscal 2017 were 29% of revenue versus 29.1% in the prior year period. On a dollar basis, SG&A in the second quarter of fiscal 2017 totaled $5.1 million compared with $4.9 million a year ago. The dollar increase reflects infrastructure needed to support our whole-product solutions strategy.

During the quarter, the U.S. dollar weakened, as compared to the euro. As a result, we realized a $0.2 million loss on our euro-denominated contingent consideration obligation related to the Creagh Medical acquisition. Further, based on headwinds faced in Creagh Medical's historical third-party product business, we recorded a $1.2 million gain from the reduction of contingent revenue milestone obligations to the former Creagh Medical shareholders. The net effect of these 2 items increased GAAP earnings by $0.07 per share. Despite this revenue shortfall, we remain enthusiastic with our long-term proprietary whole-product solutions strategy.

Income tax expense was 67.5% of pretax income in the second quarter, up from 62.4% in the prior year period. The effective tax rate reflects an impact of nontax-benefit amortization, accretion, contingent consideration gains, foreign currency gains and operating losses. We expect income tax expense for fiscal 2017 to be in a range of $3 million to $3.5 million.

Looking at our balance sheet, which continues to be strong. Cash investments totaled $46.3 million at the end of the quarter. We generated cash flow from operations of $4.3 million in the first 6 months of fiscal 2017 and invested $2.9 million in plant and equipment during that period. Our current cash and investment balances, operating cash flows, combined with Surmodics' $30 million line of credit, provide adequate capacity to support our corporate strategic growth initiatives.

We are updating revenue and EPS guidance for fiscal 2017. Based on the strength of revenue for the first half of fiscal 2017, we now expect revenue to range from $65 million to $68 million, up from a previous range of $64 million to $68 million. GAAP diluted earnings loss guidance is now expected to be in the range of a $0.02 loss to a profit of $0.08 per share, as compared with the previous range of a $0.07 loss to an $0.08 profit per share. For clarity: GAAP EPS includes the impact of our increased revenue guidance, the expected incremental R&D investment in the second half of fiscal 2017 to support our whole-product solutions strategy and the previously discussed $0.07 per share contingent consideration fair value adjustments recorded in the quarter. Therefore, we now expect non-GAAP earnings of $0.15 per share to $0.25 per share, as compared to our prior guidance of $0.18 to $0.33 per share.

Thank you to the entire Surmodics team for your hard work and outstanding results.

Operator, this concludes our prepared remarks. We'd now like to open the call to take questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And we can take our first question from Jim Sidoti with Sidoti & Company.

James Sidoti - *Sidoti & Company, LLC - Research Analyst*

Just a couple questions on the quarter and guidance. If you look at royalties in the back half of the year, do you think they stay about level with Q2? Or do you think they decline a little bit to get to that revenue number?

Andrew D. C. LaFrence - *Surmodics, Inc. - CFO, Principal Accounting Officer and VP of Finance & Information Systems*

Well, if you look at the second half of the year, we do expect to receive a little bit more of a headwind associated with the outside-the-United-States patent expirations. So if you -- we do expect there to be a decline, and that's baked into our overall revenue guidance of $65 million to $68 million. So last year, Jim, as you might recall, our royalty and license fees were impacted somewhat by the U.S. patent expiration. And if we look at where we view this year, we're probably around $28 million to $28.5 million as our current thoughts in terms of what that number will be for fiscal 2017.

James Sidoti - *Sidoti & Company, LLC - Research Analyst*

Okay. And you talked about having 3 new products approved by the end of the fiscal year out at Ireland. Do you have partners in mind for those products? Or what's the status of that?

Gary R. Maharaj - *Surmodics, Inc. - CEO, President and Director*

Yes, well, first of all, the -- one of the products, the microcatheter, is from our Plymouth R&D team. And the balloon catheters are from Ireland. So we anticipate the submissions. And as you know, with regulatory filings, you can't totally predict, but we feel very confident that we can get those in our fourth quarter, very late. We have several strategics looking and -- those devices. Clearly, they can't do much more than benchtop our preclinical evaluation until you have the final regulatory approval, but certainly yes, there's interest in each of these devices amongst our strategic customers.

James Sidoti - *Sidoti & Company, LLC - Research Analyst*

And have you determined how that contract will look? Will there be upfront payments? Will be it a royalty on sales? Or is that still yet to be determined?

Gary R. Maharaj - *Surmodics, Inc. - CEO, President and Director*

Well, we haven't disclosed that. And since we have multiple strategics interested, for competitive reasons, we probably don't want to talk about it. But the model is really going to be we -- these are our products that we are manufacturing. We hold the regulatory clearances, and the strategic

is putting it in their bag. And so baked into the -- all of supplier transfer price to the strategic will be the margins that we will require, that we deserve from the innovation that we've created. So that's the basic model. Upfront distributor-type arrangements, we'll save for a later date.

James Sidoti - *Sidoti & Company, LLC - Research Analyst*

And where will the products be manufactured, in Ireland, or in the...

Gary R. Maharaj - *Surmodics, Inc. - CEO, President and Director*

Yes, yes. The intention is to manufacture these at the facility we are expanding that footprint in Ireland.

James Sidoti - *Sidoti & Company, LLC - Research Analyst*

(inaudible) income. In the quarter, I know there was a onetime. It sounded like it -- there were some additional headwinds. And you accounted for that, but then you also had an adjustment for currency. Will that be part of your income statement from now on until the terms of the acquisitions are finalized?

Andrew D. C. LaFrence - *Surmodics, Inc. - CFO, Principal Accounting Officer and VP of Finance & Information Systems*

Yes, Jim, I'll give you some clarity on that. This specifically relates to the Creagh Medical acquisition. And it's disclosed in our Qs, we have an aggregate obligation of -- potential obligation, say, of EUR 12 million, which is payable in the first quarter of fiscal 2019. So the December '18 quarter, those obligations are due. And as a result of the obligation being denominated in euro versus U.S. dollar, we do need to mark to market that adjustment every quarter to the financials. And it's really going to be reflective of where the euro and dollar wind up. So at this point in time, first of all, we have not hedged that. So we're letting it float at this point in time because it's really difficult and expensive to float -- I should say, to hedge euro-denominated longs, but we do anticipate that there will be fluctuations in that. And we have been scheduling that out as non-GAAP in our non-GAAP EPS numbers.

James Sidoti - *Sidoti & Company, LLC - Research Analyst*

All right. And then can you just give a little more clarity on the onetime adjustment this quarter for the headwinds?

Andrew D. C. LaFrence - *Surmodics, Inc. - CFO, Principal Accounting Officer and VP of Finance & Information Systems*

Yes. The -- part of the contingent consideration we've pooled together in the transaction was related to managements of revenue forecasts. And as we look at the -- that business and those customers, there's been a variety of different reasons why there have been adjustments to that forecast. And without getting into too many specifics, we've -- we as the Surmodics team at the time and the Creagh Medical teams agreed that we would work together to focus on meeting the revenue of -- expectations and that there obviously would be payouts related to that. So this is just reflective of changes in that, but if you look at the long term ...

Gary R. Maharaj - *Surmodics, Inc. - CEO, President and Director*

And -- go -- those are legacy products from a capital perspective...

Andrew D. C. LaFrence - *Surmodics, Inc. - CFO, Principal Accounting Officer and VP of Finance & Information Systems*

Yes, that was a -- those are legacy products, but if you look at the long-term expectations of the business, this is a very insignificant long-term part of the business. It's just more of the nearer term based upon customers they had in hand at the time of the acquisition.

James Sidoti - *Sidoti & Company, LLC - Research Analyst*

All right. And then last question is on the SurVeil. What is the next step? Is it feedback from the FDA to start a trial? Or you still have patients to complete.

Gary R. Maharaj - *Surmodics, Inc. - CEO, President and Director*

Well, we have completed our early feasibility trial of 13 patients, and we have that data in hand. I don't want to give up publication rights to our principal investigators by saying too much about the data, but that's been completed. We haven't said which regulatory agency and which geography we intend to do the next phase of the trial, so I'll stay silent on that, but we are in that interactive discussion with the agency in terms of their view of the data and information required to conduct that trial. So we're in the midst of that at this point; hope to have, I think we had said earlier in the year, resolution of that in this third fiscal quarter.

James Sidoti - *Sidoti & Company, LLC - Research Analyst*

And will you let us know when that's resolved as soon as it happens? Or will you fix it in the conference call at the end of the quarter?

Gary R. Maharaj - *Surmodics, Inc. - CEO, President and Director*

It's let me -- I don't know, so let's say no for now.

Operator

(Operator Instructions) And we'll take our next question from Beth Lilly with Crocus Hill Partners.

Elizabeth Lilly

So here's what I wanted to understand, which is can you say a little bit more about the increased spending in the second half in terms of R&D? And it seems to me, if you're accelerating your spending, then you must be extremely optimistic about what you're seeing in terms of the trials and the data.

Gary R. Maharaj - *Surmodics, Inc. - CEO, President and Director*

Yes. And I'll let Andy comment on more at the detailed level, but when you think of our R&D spending, the drug delivery programs really are SurVeil and the data and the results and the ability to scale up for a large clinical. And so we're not waiting. If we wait for the regulatory approval, then we would have lost substantial time, so in parallel we are acting as if. Now there is some risk there, but we believe it's in the best interest of our shareholders to not wait while we do the prework and scale-up required for the clinical. So that's one fairly large bucket. And that's one of the reasons we have changed the earnings guidance, because we anticipate to spend more in that. The second one is our below-the-knee program, which we -- it's in the preclinical phase and we just completed that dosing study. So we have a high sense of confidence that we can freeze that product designed for the below-the-knee drug-coated balloon in this fiscal year and then scale up or get ready for a first-in-human trial of that device. The third drug-coated product program is we're in the very early stages of the AV access program. We already have balloon platforms that we believe can work with that. And I just -- I think I said last quarter Bard showed some very favorable results at the LINC meeting with AV fistula

programs, so there's a footrace to see who can get that into the clinic. And we'd certainly like to be the top 3 companies to get there into the clinic with that. So the drug delivery programs are -- clearly have a large investment footprint to be able to make progress. The nondrug delivery side, it still takes a fair amount of effort to get these 3 products, meaning the catheter and the 2 new balloon catheters that we are filing for regulatory approval on, to validate them, get them cleared and then scale up the manufacturing for that. And in addition, again we can't be sequential. We have already started work on the new products that we intend to seek approval for in fiscal '18. So when you align all of those things up, it ends up being an acceleration in the back half of this fiscal year. But I'll turn it over to Andy.

Andrew D. C. LaFrence - *Surmodics, Inc. - CFO, Principal Accounting Officer and VP of Finance & Information Systems*

Yes. I think you did a very good job of talking about the programs that are related to the increase in spend. And maybe to cut across a different angle here is that, if you think about the addition of the spend, which we now believe total spend could be in excess of $30 million for the year, about $1.2 million or so of the increase in spend is related to CRO-related costs. And quite frankly, that's just a timing issue between '17 and '18, as we gain more clarity in terms of the progression of the work with the FDA. And that's not to suggest we're accelerating, but it's more to suggest that we have more clarity with also our CRO in terms of when they expect to incur costs associated with the ramp-up of the clinical trial. We've pushed about $1.2 million of those into fiscal 2017. And then the remainder of the spend, quite frankly, is related to some of the programs that Gary talked about. And specifically, we've had some reallocation of resources in Ireland, as we talked about in the -- in our prepared remarks, as we try to support not only our drug delivery R&D investments but also support the nondrug delivery. So it really comes on the heels of and makes some -- I think, some nice progress on both aspects of the drug and nondrug delivery aspects of the pipeline development.

Elizabeth Lilly

Okay, so -- and you just -- Andy, you just mentioned a number. Did you say $1.3 million?

Andrew D. C. LaFrence - *Surmodics, Inc. - CFO, Principal Accounting Officer and VP of Finance & Information Systems*

For the CRO costs, it's about $1.2 million. And the total increase, if you'd think about the range we just provided of our R&D expenses being between 40% and 44% of revenue -- so you -- if you think about the -- our updated revenue guidance that we have right now, that would get you up to $30 million, maybe a little bit north of that, in terms of potential spend for the year.

Elizabeth Lilly

Okay, okay. And so it's -- so what I'm trying to dig down is what's the increase in the second half on spending on the projects that Gary just talked about? A dollar amount.

Andrew D. C. LaFrence - *Surmodics, Inc. - CFO, Principal Accounting Officer and VP of Finance & Information Systems*

We haven't bifurcated the amount specific to the spend from the second half of the year in terms of those particular projects, but if you think about where we're at right now, you would look at north of $16 million of spend for the rest of the year potentially in terms of R&D.

Operator

(Operator Instructions) And it appears we have no further questions at this time. I can now turn it back over to management for any additional or closing remarks.

Gary R. Maharaj - *Surmodics, Inc. - CEO, President and Director*

Thank you for all of your questions. We are delighted with our second quarter results and progress on our whole-product solutions strategy. I look forward to speaking with you in our Third Quarter Earnings Call.

Thanks, everyone.

Operator

This does conclude today's program. Thank you for your participation. You may disconnect at anytime, and have a great day.
