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SRDX - Q4 2017 Surmodics Inc Earnings Call

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PRESENTATION

Operator

Good day, and welcome to the Surmodics Fourth Quarter and Fiscal Year 2017 Conference Call. Today's conference is being recorded.

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

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

Thank you, Mindy. Good morning, and welcome to Surmodics' 2017 Fourth 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 Safe Harbor provisions of 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'll now turn the call over to Gary Maharaj. Gary?

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

Thank you, Andy. Good morning, everyone, and thank you for joining. We had a busy and productive year, and our fourth quarter results reflect strong top line performance and our continued focus on maintaining solid operational results even as we invest in our new product pipeline.

On today's call, I'll provide an overview of our key achievements and our strategy going into the fiscal 2018. Then, I'll turn the call over to Andy to provide a review of our fourth quarter financial results and our fiscal 2018 guidance. We'll then open the call to take your questions.

In the fourth quarter, as we reflect on our fiscal 2017 results, we demonstrated excellent progress on each of our three major objectives. As a reminder, these were, one, 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; two, to invest in and achieve significant milestones in our drug-coated balloon programs and secure regulatory approvals in our catheter and balloon R&D pipeline; and third, to expand our capacity of high-quality and cost-efficient manufacturing.

Let's step through the Q4 results for each of these. Revenue grew by 10.5% versus the year-ago period, and we achieved GAAP diluted earnings of $0.03 per share. We are pleased with this performance, especially considering the royalty headwinds we faced this quarter because of the expiration of our third-generation hydrophilic patents, and our accelerated investments in our new product pipeline.

As you may recall from earlier press releases, as a result of these investments, we accomplished several important milestones. We secured FDA IDE approval to start the TRANSCEND trial, the pivotal trial of our SurVeil drug-coated balloon, which is a head-to-head comparison versus the market-leading Medtronic Admiral IN.PACT drug-coated balloon. We recently enrolled the first patient in TRANSCEND, and intend to run a rigorous, high-quality trial with a world-class team of principal investigators that we have engaged.

Next, the results of our PREVEIL early feasibility clinical study on the SurVeil drug-coated balloon were presented by Dr. Gary Ansel at the VIVA meeting recently in September. The data demonstrated an absence of any safety signals, good device performance, and excellent clinical improvement in the 13 patients followed up through six months. We also received FDA clearance and CE Mark for our unique hydrophilic-coated 014 balloon catheter for below-the-knee angioplasty. This uses our Serene hydrophilic coating. We're confident that this highly-deliverable, low-profile PTA catheter will provide clinicians an effective tool for accessing and crossing even the most complex peripheral lesions.

Finally, our design and manufacturing facility fit-out in Ireland is nearly complete. We are now capable of making both drug delivery and non-drug delivery devices in Ireland. We have doubled our manufacturing footprint and have the ability to quickly ramp up production in line with our whole product solution strategy. Our target is to be able to manufacture all our approved medical devices at large scale by Q2 of fiscal 2018.

Our hard work and investments throughout the year culminated in these strong fourth quarter accomplishments. We set up Surmodics right where we want to be as we enter fiscal '18, namely to be in a position to invest in clear R&D and clinical programs that will drive consistent long-term shareholder value.

In fiscal 2018, we intend to accomplish three major goals. These are execute the TRANSCEND trial in a high-quality, rigorous, and efficient manner. To that end, we are planning to have the full complement of clinical sites up and running by the end of fiscal '18. Two, advance the R&D whole products solutions pipeline by securing regulatory approvals for at least four new products in fiscal 2018, and filing for the first human use of at least one of the following: our below-the-knee drug-coated balloon program, our AV fistula drug-coated balloon program, depending on the quality of the preclinical results; and three, finalize and further delineate our commercialization strategy with our potential distribution partners for medical device sales.

Our long-term goals of generating double-digit top-line growth by 2019 and generating EBITDA margins at or above 30% by 2021 are in our sights, and we believe very attainable.

Moving to our clinical programs, our biggest priority is TRANSCEND, which is our pivotal trial for SurVeil, our paclitaxel drug-coated balloon. We announced enrollment of our first patient last month, marking a major milestone for the company as we work towards our goal of improving clinical outcomes for peripheral artery disease patients. We look forward to ramping up enrollment of additional sites through the coming year.

And as a reminder, TRANSCEND is expected to enroll approximately 446 patients at up to 60 clinical sites in the U.S. and 18 sites in Europe. The randomized trial will evaluate the SurVeil drug-coated balloon for the treatment of peripheral artery disease in the upper leg compared to the Medtronic IN.PACT Admiral drug-coated balloon. This trial is among the first level one studies to compare a next-generation drug-coated balloon with one that is currently commercially available.

In Europe, we are evaluating our strategy and timing assumptions for our study to obtain the CE Mark, taking into consideration evolving European regulations. To provide some background, SurVeil design reflects our longstanding leadership in the development of drug delivery and surface technology for vascular devices. The device includes a proprietary drug excipient formulation for the balloon coating, and is manufactured using

a proprietary process to improve coating uniformity and distribution. Preclinical data have demonstrated three to five times higher target tissue concentration, a more evenly distributed and durable drug effect, and, importantly, a lower incidence of downstream drug concentrations as compared with other commercially-available first-generation drug-coated balloons.

As mentioned earlier, the results of our early feasibility study, the PREVEIL trial, demonstrated an absence of safety signals and clinical improvements in the 13 patients at six-month follow-up. These were evidenced as demonstrated by their walking scores. There was also 100% binary patency and freedom from target lesion revascularization, and a six-month late lumen loss, which is a measure of how much a vessel diameters have decreased, was 0.27 millimeters, which is on the lower end of published data from other drug-coated balloon studies.

Moving on to our sirolimus-based below-the-knee DCB program, we're continuing to make excellent progress using our own internally-developed 014 balloon platform as a carrier. We're working through all of the detailed preclinical data and studies requiring the package that we'll use to submit for our first-in-human clinical trial. Expect that this data will take much of 2018 to compile and finalize.

We have also made progress in developing our AV fistula drug-coated balloon. As discussed previously, we have the technology to address and maintain access for fistula patency, which are major frustrations for patients undergoing renal dialysis, and that can add dramatically to the cost of care. We're continuing to evaluate our emerging preclinical data set, and will determine the possibility to even further accelerate this program in fiscal 2018. Here again, our goal is to obtain the clinical data and clarity to file for regulatory approval to conduct a first-in-human study.

The decision of which of these studies will go forward first depends on the quality of the preclinical data that we develop in each of these programs.

In total, we plan to invest $13 million to $16 million externally on our drug-coated balloon platforms in fiscal 2018. This represents up to a 67% increase in external R&D spending on these programs compared to fiscal 2017, and we estimate that we will spend up to several million dollars on both the below-the-knee and AV fistula drug-coated development programs to gain clarity for their respective regulatory approvals.

Now, given the large market opportunities for both of these indications, we believe that these are worthwhile investments for our shareholders.

Now, turning our focus towards non-drug delivery R&D pipeline, we're making headway with the products in development using advanced versions of our coating chemistry, our catheter and balloon technology, although regulatory timing remains a bit unpredictable. This in some cases is translating into an iterative process in which we incorporate feedback from the U.S. FDA as we optimize our design. While we are confident this is the right strategy to be successful, it is in some cases lengthening the development time for these products.

Our micro-catheter development and regulatory approval has been delayed from the timelines noted in our third quarter call. This unique device uses our Surmodics Pristine hydrophilic coating. While we submitted our application to the FDA early in the third quarter of 2017, the agency has requested more data. We have, in our view, completed this testing and generated the data required, and plan to resubmit this filing in November. For the 018 peripheral balloon catheter incorporating our Serene hydrophilic coating, we're continuing to work through our final design specifications and testing. Once we have internal confirmation that we were able to achieve our rigorous design specifications, we will then submit this to the agency for 510(k) clearance.

Recall that we are developing best-in-class differentiated devices in each category, and as a result, we do not freeze our designs until they exceed our internal, exceedingly rigorous competitive performance benchmarks. While the ultimate timing is beyond our control, we are confident that we'll receive clearances for these products in the first part of fiscal 2018.

Looking ahead, we have also begun work on the next wave of product innovations for which we are targeting regulatory filings and the clearance in calendar 2018, which will help us further build out our platform to achieve top line growth. We'll discuss more about these R&D programs in future calls as we get closer to the actual regulatory filing.

As for the whole products commercialization, we are currently evaluating a number of partners for our approved devices. At this time, it would be premature to provide any detailed commentary on these discussions. We're looking forward to providing more clarity in the next two quarters.

It's an exciting time at Surmodics. We're investing in and making good progress in our R&D programs. We are on track to becoming a leading and enduring medical device innovator by combining our key technology assets with our medical device customer relationships to develop world-class, market-leading, creative products for vascular disease. We're encouraged by our clinical, regulatory, and development achievements, coupled with our ongoing top-line performance and operational progress.

I'll now turn the call over to Andy to provide more details of our fourth quarter fiscal 2017 results, as well as our outlook for 2018. Andy?

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

Thank you, Gary. We are happy to report that revenue for the fourth quarter of fiscal 2017 was $20.1 million as compared with $18.2 million in the fourth quarter of last year. Revenue in the fourth quarter of fiscal 2017 included a $1.1 million license fee. On a GAAP basis, our diluted earnings totaled $0.03 per share as compared with $0.20 per share in the prior year quarter. We delivered operating income of $0.4 million in the fourth quarter of fiscal 2017, down from $4.1 million in the prior year quarter. Operating margin decreased to 2.2% in the current quarter as compared with 22.5% in the fourth quarter of fiscal 2016.

The declines in GAAP earnings per share, operating income, and margin in the current year quarter as compared with the prior year quarter reflect previously disclosed increases in R&D spend to support our whole products solutions, product development, and regulatory submissions. On a non-GAAP basis, quarterly earnings per share were $0.18 per share in the fourth quarter of fiscal 2017 versus $0.26 per share in the prior year quarter.

Turning now to our two business units, medical device reported revenue of $14.7 million, an increase of $1 million as compared with the year-ago period. Looking at the specific areas within medical device, fourth quarter royalty and license fee revenue totaled $9.2 million, up $1.2 million from the prior year quarter. The increase in royalty and license fee revenue is attributable to the previously-noted $1.1 million license fee.

Product sales decreased $0.2 million from the prior year quarter due to lower shipments. Medical device customer research and development revenue were essentially flat in the current quarter as compared with the fourth quarter of fiscal 2016. This unit generated $0.3 million of operating income in the fourth quarter versus $4.2 million in the prior year quarter. The medical device operating income change was impacted by the previously described planned increase in investments related to our whole product solution strategy and a $0.4 million impairment charge related to [three] medical [intangible] assets, and was partially offset by the $1.1 million license fee.

For in vitro diagnostic segment, fourth quarter fiscal 2017 revenue, which consist of product sales, totaled $5.3 million as compared with $4.5 million in the prior year period, an increase of 19.8%. IVD revenue in the fourth quarter reflected strong growth in stabilization, BioFX, microarray slide and antigen product sales, which more than offset the previously disclosed decline from a significant microarray customer that was acquired by one of its competitors. IVD operating income was $2.4 million as compared with $1.8 million in the fourth quarter of 2016. Operating margin increased to 44.4% versus 40.8% in the prior year quarter due to improved gross margins resulting from favorable product mix and the increased operating leverage from higher revenue.

Product gross margins for the quarter were 62.4% of product sales as compared with 65.1% in the prior year quarter. The change in gross margin percentage resulted from unfavorable product mix, primarily lower reagent sales, and higher revenue from antigens, a product we distribute from our German partner.

As a percentage of revenue, fourth quarter R&D expenses were 48.4% versus 29.2% in the year-ago period. R&D expense of $9.7 million for the quarter was up $4.4 million from last year. As we have stated before, we anticipate R&D expense would increase in the second half of fiscal 2017 as we accelerated our whole product solution strategy, including advancing our SurVeil drug-coated balloon human clinical trials and other proprietary products.

SG&A expenses in the fourth quarter of fiscal 2017 were 26.5% of revenue versus 27.6% in the prior year period. On a dollar basis, SG&A in the fourth quarter of fiscal 2017 totaled $5.3 million as compared with $5 million a year ago.

During the quarter, the U.S. dollar continued to weaken as compared with the euro. As a result, we realized a $0.3 million foreign exchange loss on our euro-denominated contingent consideration obligation related to the Creagh Medical acquisition. We recorded an income tax benefit of $0.2 million in the fourth quarter of fiscal 2017 as compared with income tax expense of $1.5 million, or 35.5% of pretax income, in the prior year period. The current quarter income tax benefit reflects the impact of inter-company development activities performed by our Irish subsidiary. Both periods reflect the impact of non-tax benefited amortization, contingent consideration accretion, foreign currency losses, and operating losses in Ireland.

Looking at our balance sheet, which continues to be strong, cash investments totaled $48.3 million at year-end. We generated cash from operating activities of $14.1 million in fiscal 2017. We also repurchased 196,190 common shares for $4.7 million during fiscal 2017 under the company's share repurchase program. We invested $6.4 million in property and plant and equipment during fiscal 2017. Our current cash and investment balances and operating cash flow will provide adequate capacity for us to support our corporate strategy growth initiatives.

Gary noted in his remarks that we expect to accelerate our investment in our drug-coated balloon platform in fiscal 2018, and to a lesser extent our 510(k) product and CE Mark pipeline. The drug-coated balloon investment includes enrollment in the TRANSCEND clinical trial and continued development of both our below-the-knee and AV fistula programs.

As a result, we expect research and development expenses to range between 55% and 60% of fiscal 2018 revenue. We expect revenue to range from $72 million to $75 million for fiscal 2018. GAAP diluted loss is expected to be in the range of $0.50 to $0.75 per share, and we expect non-GAAP loss of $0.16 to $0.41 per share. The loss per share guidance includes a $3 million, or $0.15 per share, estimated R&D expense variability as a result of our estimated range of patient enrollment rates for our TRANSCEND study.

Gary and I are thrilled with the operational execution performance by the entire Surmodics team in fiscal 2017. Thank you for your hard work and outstanding results.

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

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Brooks O'Neil with Lake Street Capital Markets.

Brooks Gregory O'Neil - *Lake Street Capital Markets, LLC, Research Division - Senior Research Analyst*

Congratulations on a strong fourth quarter. I understand that Gary mentioned it was premature to discuss your dialogue with strategic partners, and I'm not asking for any specifics, but I was hoping you could give us a little color in terms of the responsiveness, or lack thereof, that you're finding in the marketplace as you begin to engage with potential strategic partners.

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

You know we just came back from the TCT Conference in Denver last week, and the meetings with the strategics for the 014, for example, is a product that we have regulatory approvals worldwide currently, [is] great reception on that. The next steps typically with the strategics are they'd like to get it into the hands of their clinical evaluation. So, recall, until we have regulatory approvals, these are all preclinical studies and bench-top testing. So now, we can actually, with 014, treat the tibial artery of patients with below-the-knee disease, and so that's been a great reception. We are also moving forward with some of the world's top (inaudible) below-the-knee interventionalists to get that product into their hands now that we have approval.

So, reception is quite favorable. On the products that are not yet approved, clearly the strategics can't really assess the clinical effectiveness of those products in patients. But clearly, the benchmark performance that they are looking at has also met with favorable reception. And that would include the micro-catheter and the 018.

So we believe these are products that will plug some portfolio holes in some of these strategics, and given the benchmark performance we have, the interest is high. Want to caution everyone, though, that we're not just rushing to sign a deal. We want to get the best deal. And so, the clinical evaluation of these products, which we are confident that it will allow us to then get strategics to understand the real value in these products over the next quarter or so.

Brooks Gregory O'Neil - *Lake Street Capital Markets, LLC, Research Division - Senior Research Analyst*

I'm very excited about the TRANSCEND trial. I know you're spending a lot of time and dollars on it. You commented that you're comparing it to a first-generation DCB, and I know that's an advance over what some of the competitors have done in terms of comparing a DCB with a plain balloon. But would you comment on the state of the market in terms of are we in a first-generation competitive profile, or are some of the competitors out there with second- or third-generation DCBs now, in your opinion?

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

I'll give you my opinion, and I'll leave it as my opinion, because we clearly don't -- many of these companies are our customers as well, and we love the fact that [their] technology has kept progressing.

But I see many of the devices in Europe. There are probably 10-plus devices in Europe where this technology field really initiated. Those I consider more the generation one devices, so we're happy to see those get to market. The devices that were approved in the United States so far, I see those as generation two devices. I think what we're working on is a generation three device. And the market continues to grow. The IMS data is certainly showing that the IN.PACT device is currently the U.S. market-leading product.

But our device really takes it a notch further in terms of really being efficient in the drug transfer to the tissue. It's not what you have on the delivery truck. It's what gets into the restaurant and people's bellies, at the end of the day, and that is where we really perform really well. And having a lot of drug that's really not getting to the target tissue, potentially causing distal emboli, we believe there are more elegant solutions. So that's the basis of the third-generation device that we have.

Brooks Gregory O'Neil - *Lake Street Capital Markets, LLC, Research Division - Senior Research Analyst*

Would you say that your expectations for spending on R&D and such for fiscal '18 have increased substantially, or [have] they -- largely in line with what you have been communicating in the recent past? And thanks a lot, and again, congratulations on the progress.

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

As we came out of last quarter's earnings call, we talked about the fact that we anticipated an increase in spend, and I think we evolved around the mid-$30 million of spend for fiscal 2018, that we would be at least at that level. And as we looked at the preclinical data and worked through our fiscal 2018 plan, as Gary talked about, that both the below-the-knee and AV fistula programs, we decided that it was worth the additional several million dollars for each one of these programs to get clarity in terms of which one we would bring to the clinic.

So we have done some additional accelerated spending. And the other thing we received, as well, is more clarity around the TRANSCEND study. As you well know, we signed a CRO agreement, which was disclosed. And as we work through the modeling there, we're able to get a better refinement in terms of what that spend might be. So all the spending that we have right now, I wouldn't say we're surprised by it. It's a very conscious part of us in terms of efficient capital allocation to create long-term shareholder value.

Operator

Jim Sidoti with Sidoti & Company.

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

Can you just, first, give us a little more color on the $1.1 million license fee in the quarter, what that was for?

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

Without getting into a lot of the details, we had a customer arrangement, and the customer was sold. And as a result of that, we had some joint technology that we had developed with this customer, and they, at the end of the day, decided they wanted to own that technology. So it was really a license fee and a technology acquisition fee with this customer. (inaudible) it's a one-timer.

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

In terms of the R&D spend for fiscal '18, can you give us a sense how that's going to ramp first half of year, second half of the year? I assume it takes time to get these sites up and running. So can you give some sense how that'll step up?

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

Yes. Again, we don't generally give quarterly guidance, but there will be, I would say, a pretty steady state of spend in the first three quarters, and then I'd say the fourth quarter will have probably a 15% to 20% increase in spend over the first three quarters.

So you do the math, and I can walk you through that. You're probably near $10 million the first three quarters, and then bump it up to maybe $12 million in the fourth quarter. But again, a lot of that's going to be dependent upon the variability of the ramp-up of the clinical sites, as well as the patients, and that's why we commented that our EPS range includes a $3 million variant specifically related to the enrollment rates on the TRANSCEND study.

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

On the royalty in Europe, will we continue to see the royalty revenues face that tougher comp than the first half of the year? And when should that anniversary?

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

As we talked about, I'll walk you back a little bit to '17. We initially anticipated a $5 million to $6 million headwind in '17 as we gave the initial guidance, and then we walked down to more of a $3.5 million, $4 million headwind later in the year as we saw better-than-expected performance from our customers. And a lot of that had to do with customers that had more sales outside the U.S. than what the mix in the model originally had in the beginning of the year.

So as you look into fiscal 2018, we do anticipate having another $2.5 million to $3 million, $3.5 million headwind in terms of the third-generation coating technology, and a lot of that is just a carryover from '17 related to the good performance we had. And just a little bit more color around that. I would say, of that headwind, about two-thirds of that will be in the beginning of the year, the first half of the year, and that'll taper down for the back end then.

Operator

(Operator Instructions) And that does conclude today's question-and-answer session. At this time, I'd turn the conference back to management for any additional or closing remarks.

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

Thank you all for your questions. We're pleased at our fourth quarter results and our progress in our whole product solution strategy. And we look forward to speaking with you on our first quarter earnings call soon. Thank you.

Operator

This concludes today's call. Thank you for your participation. You may now disconnect.