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CORPORATE PARTICIPANTS

Gary R. Maharaj *Surmodics, Inc. - CEO, President & Director*
Timothy J. Arens *Surmodics, Inc. - CFO*

CONFERENCE CALL PARTICIPANTS

Brooks Gregory O'Neil *Lake Street Capital Markets, LLC, Research Division - Senior Research Analyst*
James Philip Sidoti *Sidoti & Company, LLC - Research Analyst*
Michael John Petusky *Barrington Research Associates, Inc., Research Division - MD & Senior Investment Analyst*
Michael Stephen Matson *Needham & Company, LLC, Research Division - Senior Analyst*

PRESENTATION

Operator

Good day, and welcome to the Surmodics Fourth Quarter Fiscal 2019 Earnings Conference Call. Today's conference is being recorded.

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

Timothy J. Arens *Surmodics, Inc. - CFO*

Thank you, Todd. Good afternoon, and welcome to Surmodics Fiscal 2019 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'll 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 -- or afternoon, excuse me, and is available on our website at surmodics.com.

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

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

Thank you, Tim. Good afternoon, and thank you for joining us. Fiscal 2019 was a great year of accomplishment for Surmodics. During the year, we made important progress on all the key initiatives we laid out at the beginning of the year. Starting with SurVeil, we completed enrollment in the TRANSCEND study on schedule despite the headwinds from the paclitaxel debate and submitted our application for CE Mark approval on schedule as well.

We also made significant advancements to our drug-coated balloon product pipeline. We both started and recently completed enrollment for the first in-human study of Avess, our arteriovenous access drug-coated balloon, and we also filed for regulatory approval to begin the first in-human study for Sundance, our sirolimus-coated balloon for below-the-knee treatment.

Turning to our nondrug delivery pipeline. We received 510(k) clearance for our Sublime radial guide sheath and have completed development of our Telemark XP coronary device. We also signed an agreement with a leading multinational medical device partner to commercialize our Telemark coronary support catheter in The United States and Europe.

We have begun to fill initial orders from our partner and expect the commercial launch to occur later in calendar 2019. Finally, we saw substantial revenue growth from our Medical Device and coatings offerings, while our IVD business continued to generate strong

operating margins in fiscal 2019. These businesses continue to provide investment funding to fuel our strategic growth initiatives.

As a result of these advancements, we delivered another excellent quarter of solid top line growth and operational performance. Total revenue for the quarter grew 34% to $30.8 million as compared with $23 million in the fourth quarter of 2018. We also reported diluted GAAP earnings of $0.26 per share and non-GAAP earnings of $0.37 per share in the fourth quarter.

While fiscal year 2019 was a terrific year within Surmodics, it was not without its challenges. The continuing debate surrounding paclitaxel-coated devices created external headwinds, many of which were beyond our control. As we look ahead to 2020, we are acutely aware that the paclitaxel debate will continue to influence the future of the therapeutic modality, including our own drug-coated balloon applications.

We are encouraged by the amount of data that has been recently published that demonstrate an ongoing and significant attenuation of the mortality signal from randomized trials and a complete absence of the signal in very large, real-world observational studies.

All that said, I'm quite proud of our team's ability to execute even amidst some unpredictably choppy waters and look forward to continuing to achieve our goals in fiscal 2020. This year, we'll build on the advancements we achieved during fiscal 2019 with the following strategic objectives. First, to ensure the continued success of SurVeil, specifically to perform high-quality patient follow-up for the primary endpoint analysis. Second, to obtain CE Mark and to make substantial progress towards achieving the FDA approval. The next key of strategic objective is to continue to make meaningful advances in the product development and regulatory approvals across our entire product pipeline. And finally, the third, to continue to optimize revenue and cash flow performance from our legacy businesses in both Medical Devices and Diagnostics, which fuel our strategic growth initiatives.

Starting with SurVeil, we were very pleased to complete enrollment of our TRANSCEND clinical study in the fourth quarter as planned. As a reminder, the TRANSCEND trial enrolled 446 patients at 65 global sites and will evaluate the safety and efficacy of the SurVeil drug-coated balloon compared with the commercially available DCB in treating peripheral arterial disease in the upper leg. The clinical data from TRANSCEND will ultimately provide insight into relevant clinical questions regarding long-term patient level data out to 5 years.

TRANSCEND comes at a very important time for the vascular and interventional community. With the discussion around paclitaxel there is shifting focus to follow-up and long-term monitoring of patients through the rigorous collection of high-quality data. As such, the next stage of the TRANSCEND study will require rigorous and high-quality follow-up of these patients to generate the data and to perform the primary endpoint analysis required for PMA submission.

Thorough follow-up past the 1-year primary endpoint through 5 years will especially be important given the current debate on paclitaxel-containing devices. We are committed to this robust data collection and recently launched a specific patient follow-up program, new to this type of clinical to ensure that the vital data are thoroughly collected and reviewed.

In regard to our CE Mark submission for SurVeil, we have submitted all required modules to the European notified body on schedule and sufficient time to receive the CE Mark by December 2019. However, we were recently informed by the notified body that they have decided to temporarily pause the review of new CE Marks for paclitaxel devices given the ongoing debate concerning the long-term mortality signal. The notified body has stated that this decision will be reviewed as additional data are generated. Their decision has nothing to do with the completeness of our file, nor the safety and performance of our SurVeil DCB. While such events were unanticipated and outside of our control, we remain confident in the capability of our devices and the quality of the data that supports its regulatory approval.

We fully expect to continue the dialogue with this notified body during the coming months. While we do not believe that this is an insurmountable setback, we no longer expect to obtain CE Mark by calendar year-end 2019 as previously expected.

Due to the uncertainty surrounding the timing of the CE Mark, we've chosen to exclude any financial impact of obtaining the CE mark and EU commercialization from SurVeil from our revenue and EPS guidance for fiscal 2020 until we have better information.

Moving to our second strategic focus for fiscal 2020, our ever strengthening pipeline. Recall that we have 3 main platforms within this pipeline. The first is vascular drug delivery via drug-coated balloons, namely SurVeil, Avess and Sundance. The second is our thrombectomy platform, the 3 thrombosis in multiple vascular beds, including arterial and venous thrombosis, pulmonary embolism and neovascular applications. And the third is the treatment of vascular disease via radial access, a new frontier that has a potential to revolutionize patient care by combining the best elements of what I call the Trifecta, improved clinical outcomes, improved patient satisfaction and reduced health care costs.

At Surmodics, we have an innovative team with a unique ability to develop these differentiated products that solve real and meaningful problems. I'm not aware of any company of our size that can innovate across such a broad spectrum of differentiated platforms to create shareholder value.

Starting with our DCB pipeline. During the quarter, we submitted our application for regulatory approval to initiate the first in-human study for Sundance, our sirolimus-based DCB for below-the-knee disease. This device leverages our unique proprietary excipient on our in-house, best-in-class .014" PTA balloon platform, yet with a low dose of sirolimus. Given the preclinical data we have generated and analyzed, we believe Sundance has the potential to be a revolutionary product in the field of drug-coated balloons. Recently, we were granted Breakthrough Device Designation status by the FDA for Sundance and we expect to start enrollment in the back part of fiscal 2020.

We also recently completed enrollment of our first in-human study for Avess, our arteriovenous access drug-coated balloon. We expect the 6-month clinical data from this study by early Q3 and we'll update you in the next clinical development steps for Avess later in the year after we have evaluated results from our first in-human trial.

We are encouraged by the recent positive clinical data shown by other devices in this space.

Turning to our nondrug delivery pipeline. We continue to make progress in our radial artery access and thrombectomy platforms, and remain committed to accelerating the development of these platforms in fiscal 2020.

We expect to submit for 510(k) clearance on at least 3 new devices in these platforms. Our thrombectomy device known as Pounce is uniquely designed to be easy to use and has a potential to remove organized thrombus from peripheral vessels without capital equipment and minimal blood loss. We are on track with the development activities and are targeting regulatory clearance by Q3 fiscal '20.

Moving on to our radial platform. We received FDA 510(k) clearance for our Sublime guide sheath in the second quarter of fiscal '19 and expect to secure 510(k) clearance of our 2.5-meter long .014" transradial PTA balloon catheter by the third quarter of fiscal '20. We've also begun the development of other radial access therapeutic devices, including the .018" transradial PTA balloon catheter designed to treat the more proximal femoropopliteal vessels.

These will provide complementary devices for our Sublime radial guide sheath. This is just the start of our intent to build a complete line of radial access products. I'm happy to announce that early this week, we signed an agreement with a leading multinational medical device partner for the worldwide commercialization of our .014" and .018" PTA balloon catheters. At the request of our partner, we've agreed to withhold announcing their identity until they formally launch these products, which we expect will occur during the second quarter of fiscal '20.

Finally, our Medical Devices and IVD business segments continue to drive commercial excellence. While our Medical Device business segment faced significant headwinds this year due to the expiration of our generation 4, hydrophilic-coating technology as well as revenue recognition from the upfront and milestone payments from the SurVeil agreement with Abbott, we are continuing to see growth and uptake of our generation 5, Serene-coating technology, which has a much longer patent term.

Net of the patent expirations, the revenue from our Medical Device coating portfolio continues to grow in the low to mid-single digits.

Meanwhile, revenue growth from our IVD business unit continues to outperform the immunoassay market growth of 3%, while generating excellent operating margin. Overall, our business fundamentals are sound, and we are well positioned to create shareholder value over long term despite this uncertainty created by the paclitaxel matter. Our goal remains to deliver double-digit revenue growth on an annual basis, which we expect will resume in fiscal '21. We're also targeting EBITDA margins of greater than 25% beginning in fiscal 2022.

I'll now turn the call over to Tim to provide more details on our fourth quarter fiscal 2019 results as well as our outlook for fiscal 2020. Tim?

Timothy J. Arens *Surmodics, Inc. - CFO*

Thank you, Gary. Revenue for the fourth quarter of fiscal 2019 grew 34% to $30.8 million as compared with $23 million in the fourth quarter of 2018. Our fourth quarter results include $5.1 million of revenue recognized from the $10 million TRANSCEND patient enrollment milestone payment received during the quarter.

Looking at our 2 business units, Medical Device delivered outstanding 46% growth, increasing $7.9 million to $24.8 million in the fourth quarter. For our In Vitro Diagnostics business, fourth quarter fiscal 2019 revenue, which is predominantly comprised of product sales, totaled $6 million, down slightly compared with the year ago period.

Medical Device revenue growth was broad-based. Our fourth quarter royalty and license fee revenue totaled $16.8 million, up $6.5 million from the comparable prior year quarter. During the quarter, our SurVeil distribution and development agreement with Abbott Vascular generated revenue of $7.6 million, an increase of $5.4 million.

Product sales increased $325,000 or 7%. Driving this growth was an increase in balloon catheter unit volume as well as increased reagent sales to our coatings customers.

Growth in our Medical Device coatings licensed portfolio resulted in $1.1 million of additional royalty revenue as compared with the prior year quarter.

Our fifth-generation hydrophilic coating royalty continues to deliver strong growth and contributed approximately 1/3 of the quarter's royalty revenue growth. R&D services revenue once again saw strong performance, increasing $1.1 million or 52% from the prior year quarter, driven by increasing demand from our coatings customers who require support for their pre-commercial and commercial product activity.

The continued strength of our Medical Devices coatings portfolio has positioned us to mitigate a portion of the revenue headwind expected from the fiscal 2020 expiration of our fourth-generation hydrophilic coating technology patents. The Medical Device unit reported operating income of $3.7 million in the quarter compared to a $2.1 million loss in the year ago period.

Medical Device operating results were impacted by the receipt of the milestone payment associated with the TRANSCEND enrollment completion and $1.7 million of increased R&D spend, reflecting continued investment in our innovative product development pipeline to support our future growth.

IVD revenue in the fourth quarter was down $100,000 or 1% compared with the prior year quarter. Our IVD revenue was impacted by lower sales of our distributed antigen products. Offsetting the decline in the antigen sales was growth in our organic diagnostic products and service offerings, which together were up $270,000 or 6% from the prior year quarter.

Operating margin in the fourth quarter of fiscal 2019 was 46% compared to 39% in the comparable prior year quarter. Impacting IVD operating margin were operating efficiencies and product revenue mix, which was skewed toward higher-margin products.

Product gross margins for the quarter were 65.8% of product sales as compared with 61.8% in the prior year quarter. Our fourth quarter

product gross margins were favorably impacted by both our Diagnostics and Medical Device businesses. As a percentage of revenue, fourth quarter fiscal 2019 R&D expenses, including cost of clinical and regulatory activities, totaled 47.6% compared with 54% in the year ago period. R&D expense was $14.5 million in the quarter, up $1.9 million from the fourth quarter of fiscal 2018. The increase in R&D expense was driven by increased spending on the development of our whole-product solutions pipeline, including activities to further advance our AV access and below-the-knee drug-coated balloons. As Gary mentioned, in fiscal 2020, we expect to initiate and fund our first in-human clinical study for our Sundance below-the-knee sirolimus drug-coated balloon and expect to advance development efforts on several products, including those related to our Pounce thrombectomy and Sublime radial access platforms. As a result, we expect R&D expense to range in the mid-to-high 50s as a percentage of revenue in fiscal 2020.

SG&A expenses in the fourth quarter of fiscal 2019 were 23% of revenue versus 28% in the prior year period. On a dollar basis, SG&A in the fourth quarter of fiscal 2019 totaled $7.2 million as compared with $6.5 million a year ago. Impacting the increase in SG&A expense during the quarter were increased investments to support product pipeline development and preparation for product market evaluations.

To support our strategy, we anticipate fiscal 2020 SG&A spending to be in line with this past quarter on an annualized dollar basis as we support product development as well as execute clinical evaluations on our cleared products.

We recorded an income tax expense of $564,000 in the fourth quarter of fiscal 2019 as compared with income tax benefit of $300,000 in the prior year period. Both periods reflect the impact of nontax benefited amortization, contingent consideration gains and expenses and operating losses in Ireland.

On a GAAP basis, our diluted earnings totaled $0.26 per share in the current year quarter as compared with a loss of $0.13 per share in the fourth quarter of fiscal 2018.

On a non-GAAP basis, quarterly earnings per share were $0.37 in the fourth quarter of fiscal 2019 versus $0.05 in the prior year quarter. Our balance sheet reflects the strength of our operating performance even as we make significant investments to support our strategic initiatives. Cash and investments totaled $55.3 million at quarter end and we generated cash from operating activities of $12.5 million in the fourth quarter, bringing us to $8 million for fiscal 2019.

We also invested $6 million in plant and equipment during fiscal 2019. Our current cash and investment balances and operating cash flows provide adequate capacity to support our strategic growth initiatives.

Turning now to our outlook for 2020. We expect fiscal year 2020 revenue to range from $87 million to $91 million. This outlook includes between $5.1 million and $5.5 million of revenue associated with the SurVeil-Abbott agreement as compared with $13.5 million in fiscal 2019. In addition, our guidance anticipates a $5 million to $5.5 million decline in hydrophilic-coating royalty revenue in fiscal 2020 resulting from the expiration of the patents governing our fourth-generation hydrophilic coating. Also you will recall that fiscal 2019 also included a $1 million minimum royalty from the extension of an existing hydrophilic coating technology license that will create an additional headwind in fiscal 2020.

Our fiscal 2020 guidance excludes revenue associated with the achievement of additional SurVeil milestone payments, SurVeil product sales or SurVeil profit-sharing revenue. Likewise, our guidance does not include any potential revenue that could be earned as a result of successfully executing the distribution agreement for our Avess AV access drug-coated balloon. We expect a fiscal 2019 diluted loss in the range of a loss of $0.60 to a loss of $0.30 per share.

We expect non-GAAP diluted earnings per share to range from a loss of $0.44 to a loss of $0.14.

With that, I will now turn the call back to Gary.

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

Thank you, Tim. I want to make sure I thank all our talented team in the U.S. and in Ireland for their hard work and perseverance. We will continue the same spirit of collaboration and courage as we pursue our key objectives in fiscal 2020.

With that, we'll now open the call to questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) We will take our first question from Brooks O'Neil with Lake Street Capital Markets.

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

I'm sure you can appreciate that I'm a little surprised by the guidance. So I'm sort of struggling with that a little bit. But I'm going to ask you first, whether there are any anticipated payments for your new agreement that you talked about today with the sirolimus balloon?

Timothy J. Arens ***Surmodics, Inc. - CFO***

Well, Brooks, just to be clear on the sirolimus balloon, you're talking about the Sundance drug-coated balloon. No, there are no -- our guidance does not reflect any license fees or milestone payments associated with Sundance. As Gary remarked, this year fiscal 2020, we'll initiate the first in-human study. It's unlikely that we'll get to a point where we would negotiate a distribution agreement for Sundance and therefore unlikely that we would receive any license fees or milestone payments that would be recognized as revenue during the year.

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

All right. And Abbott Vascular has the option when we finish that first in-human study based on the clinical data to do a deal with us on that. That would not be until fiscal 2021.

Timothy J. Arens ***Surmodics, Inc. - CFO***

Yes. We'll look forward to that in another year.

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

Brooks, I wasn't sure. Just to make sure were you talking about the .014", .018" commercialization agreements we just signed, the nondrug devices?

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

Yes, yes. I'm sorry.

Timothy J. Arens ***Surmodics, Inc. - CFO***

Okay. Great. Thank you for the clarity. Brooks, there is no upfront payments that will be received for the .014", .018" PTA balloon catheter, very similar construct with what we did with the Telemark distribution agreement. We will be paid for manufacturing products for the customer. So think of it more as product revenue. There are no license fees or milestone payments that will be earned with either or any of those 3 products.

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

Okay, that's good. And then I'm just assuming, and correct me if I'm wrong, that the patent expiration in the device business that's probably been anticipated for a long time, right?

Timothy J. Arens ***Surmodics, Inc. - CFO***

It has. We've been communicating this in our K and we've made comments about this previously. The gen-4 coating royalty revenue headwind is expected to be about $5 million to $5.5 million in fiscal 2020. I'll just provide a little bit of color and commentary for those who are building constructing their models. The royalty headwind is going to be nonexistent for the most part in Q1 and the $5.5 million or the $5 million to $5.5 million headwind will be realized as we go throughout the year beginning in Q2. And you should think of it really as maybe starting around $1 million headwind in Q2 and Q3 will maybe be somewhere between $1.5 million to $2 million and Q4 will be about $2.5 million to $3 million to give you a little bit of color on how we'll get it to the $5 million to $5.5 million over the course of the year.

I'll just also share with you, Brooks, and with the folks who are listening in the call today that we expect that the headwind will continue in fiscal 2021. The headwind will probably be about half the amount that we're expecting here in fiscal 2020 and thereafter we think we'll be -- we'll see a diminishing impact and should, for the most part, have that headwind behind us, should become a tailwind in 2022.

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

Similar to the expiration of generation 3 patents a couple of years ago.

Timothy J. Arens ***Surmodics, Inc. - CFO***

Somewhat similar to that, that's correct.

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

Right. Just so we're on this topic, are there any other patent expirations that you expect to impact revenue or earnings going forward?

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

Nothing of significance, Brooks, and I showed up here in 2010. That was the biggest thing. We had 2 patent expirations in gen 3 and gen 4 and the strength of the R&D team jumped on developing a new slew of patents and products to do that. And the tough thing is it takes -- given our type of industry is a long cycle, so it takes a long time to bridge the expirations given the life cycle of the products we're talking about. So that's Serene. We're very happy. This would have been a lot worse if we didn't have Serene, which is the new generation of patents. And those patents have -- I don't want to guess what it is, but it's another...

Timothy J. Arens ***Surmodics, Inc. - CFO***

2032, I think that is the patent expiration on Serene. By the way, the 10-K, take a look at that. I think we highlight what the patent portfolio looks like in terms of the timing and also kind of how to do the math on it. But that 10-K will be issued here probably over the next month -- within the next month.

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

And the number Tim is talking about in terms of the impact is not the impact that we're receiving, it's an impact that given everything we're doing to mitigate it, that still is a net impact.

It would have been much different even in this fiscal year, if we were not acting to mitigate the size of it.

Operator

We'll take our next question from Mike Matson of Needham & Company.

Michael Stephen Matson ***Needham & Company, LLC, Research Division - Senior Analyst***

I guess, I just want to start with this announcement about the notified body issue with regard to SurVeil, getting a CE Mark. So I guess is it possible to use a different notified body? Is there someone -- is there a government agency in Europe that is saying that they can't grant 510 -- sorry, CE Mark of these products?

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

Well, first of all, clearly, those were the initial questions. Now I'll just say this, this came out of the blue. We had -- already have submitted in the modules for the medicinal of the drug that takes 210 days statutory, that's been done. The on-site CE Mark manufacturing audits have been done, the validation audits have been done and the notified body has had the clinical module since May 4. And they have not even apparently looked at it because of this, what appears to be a policy decision. As you know, and I don't want to spend -- get on the soapbox here. But as you know, in Europe, they're changing to the MDR regulations sometime in May. I believe this has to do with the feeling of risk by the notified body about granting CE Mark to category of device where there is a known mortality signal.

What I don't understand is, we can debate whether there is a mortality signal or not. But if you believe there is a mortality signal, the devices that supposedly are creating it are on the market and no action -- there is no action. So what doesn't make logical sense to me is,

if you have a new technology that doesn't have one or has data, clearly, we don't have 3-, 4-, and 5-year data. It just seems odd that you would block access to the new technology. To put a final point on it, they have said, so I don't want to -- it will be surprised that the CE Marks come out for other drug-coated devices.

They have said that they will grant additional line extension CE mark, the existing CE mark devices as long as the lesion length is shorter than the maximum lesion length, but does not exceed and the total drug content does not go up on that. So as I said, this is quite a recent development for us because we're expecting the CE mark in December.

And so what avenues do we have -- I will tell you this notified body is no different than any notified body you will go to right now, and so that's one issue. There may be other avenues, we can look including more data, more data is coming out. The German insurance data was -- you probably saw it was published 2 weeks ago by Fisinger et.al. and it absolutely shows the absence of a signal.

So we -- the reason we took it out of guidance is we want to make sure when we set guidance, we understand clearly the avenue, what we are trying to do to make sure we get the outcome we've put into guidance. And at this point, we just don't feel comfortable putting something in the guidance while we are getting our own arms around it. I know it sounds disappointing, but I don't think you all want it any other way in turn. And clearly, the impact is really the girdle in the room and the guidance we've provided in fiscal '20.

Michael Stephen Matson ***Needham & Company, LLC, Research Division - Senior Analyst***

Okay. So I guess, if you had -- so what did you take out of the guidance? Was it the - is it -- sorry, I think there's a milestone payment that you get, but then you also start -- if it were to get a CE Mark, it start potentially getting some revenue for the product itself. So you took both of those things out of the guidance?

Timothy J. Arens ***Surmodics, Inc. - CFO***

That's right, Mike. It's Tim. The best way to think about it is there is really 3 different revenue streams that could have been in the guidance here, if we would have obtained CE Mark. And I won't put too fine of a point on any of these 3 because there is a lot of variables that impact these, but the first revenue stream would be additional milestones and the revenue that would be recognized from additional milestones. So there could be one or perhaps 2 that could have been attained in '20 -- fiscal 2020 as well as SurVeil product revenue from sales would be making the European Union as well as a profit-sharing element. So we don't have -- we can't really provide a whole lot of context around what those would look like until we have more clarity to Gary's point. But I'll just say, it would go a long way to offsetting the delta here between what we generated for revenue in fiscal '19 versus what you've seen in the outlook for 2020.

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

And it sounds odd that our strategic -- one of our strategic objectives is to get the CE Mark in fiscal 2020 and it's not in our guidance. So you can understand the dilemma for us there. We're going to find a way to get the CE mark, but the timing and the impact on the year, just I'm not -- we are not comfortable putting it in guidance and guiding our investors that way.

Michael Stephen Matson ***Needham & Company, LLC, Research Division - Senior Analyst***

Yes. No, I mean I completely agree with that approach. I'm just trying to understand what it means. But -- so as far as the notified body, I mean, when you say you're going to get it approved, I mean, you're not going to have to wait until you complete the U.S. TRANSCEND trial or something like that. Are you?

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

Gosh, I hope not. When I said we're going to find a way, it's the challenge internally to our team. we hit an obstacle, and we have a difference of opinions. We're going to explore all the avenues. I mean, frankly, I think it's unfair, I'll just say that, okay? I think it doesn't allow equal market access and it doesn't make sense. So if something doesn't make sense, there's got to be a way to accomplish it. So that's what I mean to intimate by that.

Michael Stephen Matson ***Needham & Company, LLC, Research Division - Senior Analyst***

Okay. Yes, it doesn't sound like changing. You can't just go to a different notified body like, it sound like they'll have a uniform policy with this?

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

No. I agree, no. Most notified bodies are not taking any -- things are really gummed up in European if you listen to some of the other earnings calls as well in terms of getting throughput on any category of devices, not just combination products. And given the impending MDR regulations, I don't believe any notified body is going to take new stuff now. It will have to be under the MDR regulations. So -- but what I will say is given this was recent, we're buttoning up and exploring our options, and we'll be happy to share that when we have a more bona fide channel here.

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

All right. Okay. One other thing I will say, Mike, and just for the listeners, keep in mind that's up to $57 million of milestones due upon getting the approval of SurVeil. I'm talking on a cash basis, then we'll have the revenue recognition and that is potentially spread out over the next up to 7 quarters. So if you're looking at the impact of what it had in our year, we don't have the approval to speak about this particular milestone with our strategic partner Abbott yet, but it's significant cash and the concomitant revenue recognition over the next up to 7 quarters, right? So think of that -- think of it in that way.

Michael Stephen Matson ***Needham & Company, LLC, Research Division - Senior Analyst***

That's a milestone payment for the CE Mark you're talking about?

Timothy J. Arens ***Surmodics, Inc. - CFO***

No, for all remaining.

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

For all remaining milestones, of which we can't acknowledge the gorilla in the room. The CE Mark is one of them. But there are significant other milestones with the TRANSCEND clinical, and ultimately U.S. PMA approval.

Michael Stephen Matson ***Needham & Company, LLC, Research Division - Senior Analyst***

Okay. But those are independent of the CE mark?

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

Yes, they are. Yes.

Michael Stephen Matson ***Needham & Company, LLC, Research Division - Senior Analyst***

Okay. All right. And then just -- let's see, the timing for Abbott to make a decision on Avess now that the first agreement is done, would you expect that -- what's your deadline?

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

Well, we -- finishing the patient follow-up, writing the clinical report and Abbott has a very good clinical team. So we -- they would be reviewing the actual final clinical report, which will take place in our third quarter. And then they have a very short window of time of a bona fide negotiation to do a deal. So that's in our third quarter. We do not have any of that in guidance because we don't want to speculate on what are dealers or their interest is. I will say, the Medtronic data set was a good data set for me to see because it was very powerful, significant efficacy, and we will be clearly looking at Medtronic of how to get through the FDA with that PMA approval on our paclitaxel device. So all those things will be happening, we hope, by the third quarter.

Michael Stephen Matson ***Needham & Company, LLC, Research Division - Senior Analyst***

Okay. And then just final question. Does the guidance -- the 2020 guidance include the revenue from the 510(k) distribution agreements that you've already entered?

Timothy J. Arens ***Surmodics, Inc. - CFO***

It does, Mike. So the guidance does, in fact, reflect revenue for all 3 proprietary products based on these agreements that we've recently signed. And the best way to think about the guidance here is, we're really looking at anywhere -- revenue anywhere -- in 2020 anywhere from about $0.5 million to about $1 million per product. And obviously, you can imagine that it's not that precise, but within a couple of

hundred thousand for each of these products. So we'll -- I'm sure we'll be talking more about this as our partners launch our products and share with folks kind of the successful we might be seeing throughout the course of the year. But the best way to think about this is it's going to probably be more back-end of the year.

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

Because they're ramping up.

Timothy J. Arens ***Surmodics, Inc. - CFO***

They're ramping up, that's correct. I don't think we'll get a steady state revenue in those products this year.

Operator

(Operator Instructions) We'll take our next question from Jim Sidoti of Sidoti & Company.

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

Can you hear me?

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

We hear you, Jim.

Timothy J. Arens ***Surmodics, Inc. - CFO***

Jim.

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

Great. Great. A lot has been covered tonight. The first with the clinical trials, how long is the follow-up going to be now and that these patients are enrolled? Is it a 1 year?

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

Well, the -- yes, so the primary endpoint analysis, which trial is statistically designed for safety and efficacy is a 1-year follow-up. And we completed the trial in August. So 1-year follow-up, it's happening all now for the tranche of patients continuously, but the last patient follow-up, there's a window of plus or minus 30 days. But -- so can imagine by September of 2020, right? We will have followed up that patient. However, the -- we -- given this paclitaxel issue, we -- what we're trying to do is to make sure we don't lose the long-term follow-up of these patients. And so we want to make sure we follow them up in years 2, 3, 4 and 5 versus having to go hunt for data later on, even while we're on the market.

Timothy J. Arens ***Surmodics, Inc. - CFO***

That's right. That hasn't changed, Jim. It's always been a 5-year follow-up for the study. But for the submission for PMA approval from the FDA, the protocol requires a 12-month follow-up.

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

Okay. So 12 months when you look at the data and then hopefully sometime towards the end of 2020, you submit that data for approval?

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

Yes. The first thing is we share it with our partner Abbott and then we submit it for PMA approval. PMA process is -- it is a set process, but it could take some time through 2021 to get the approval.

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

All right. But probably you can submit it sometime around the end of 2020, early 2021?

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

That's calendar year. Yes. That's all planned, yes.

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

Yes. All right. And then if you were to get the CE Mark approval, can you tell us what the milestone payment from Abbott would be?

Timothy J. Arens ***Surmodics, Inc. - CFO***

Jim, we'll need to hold off on that. I think what we've characterized in the past is that, there is a handful of milestone payments and everyone was tied to a very important milestone event and they got successively larger or the potential to be successively larger than the prior milestone. That's really all I can say at this point. So just stay tuned on that.

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

Yes, it's not insignificant.

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

Okay. All right. And then in the quarter, you said you generated about $12.5 million of operating cash. I want to be just clear because you only had about $3 million or $4 million of operating earnings, how did you transform it into $12 million of cash?

Timothy J. Arens ***Surmodics, Inc. - CFO***

Yes. It's really because of the cash that we received from Abbott in the form of the $10 million milestone payment, which we didn't recognize all that revenue. We recognized, I think, $5.1 million, or we get the cash.

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

Yes.

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

Okay. So you had declining receivables in the quarter?

Timothy J. Arens ***Surmodics, Inc. - CFO***

No. So, Jim, I can talk offline if that could help, and I can walk you through the cash flow statement. But if you're looking at the P&L and trying to bridge back to the cash flow, remember the P&L reflects $5 million of revenue, right? And from the milestone payment, and then if you think about it, we recognize about $2.5 million from the SurVeil upfront and the milestone #1, right? And so if you think about it, not all of that was cash because we've received the cash in the 25 previously. But I can show you the puts in the calls here on that. But I think in your math, you're eliminating or not considering the fact that we received the $10 million, which does hit the cash flow -- the operating cash flow, but isn't hitting the P&L. And then we have $2.5 million hitting the P&L from the SurVeil upfront, which isn't hitting the cash flow. I'd be happy to walk you through that.

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

Okay. And then the agreements you have in place, the 2 balloon catheters, the .014" and the .018" balloon catheters, are those not -- those are noncoated catheters, right?

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

Nondrug delivery, yes.

Timothy J. Arens ***Surmodics, Inc. - CFO***

They're coated with our hydrophilic coating, yes.

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

No, I'm sorry, nondrug coated.

Timothy J. Arens ***Surmodics, Inc. - CFO***

Correct.

Timothy J. Arens ***Surmodics, Inc. - CFO***

No drug coating on those catheters.

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

And at some point, in fiscal 2020, you'll let us know who does partner -- who that partner is?

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

Yes. I'm hoping you see the Telemark partner as early as before the end of this year when they launch.

Timothy J. Arens ***Surmodics, Inc. - CFO***

That's right.

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

They will have our name on it.

Timothy J. Arens ***Surmodics, Inc. - CFO***

That's what we understand. I think as Gary mentioned in his remarks, we've already manufactured and shipped product to the partner.

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

the first one, yes.

Timothy J. Arens ***Surmodics, Inc. - CFO***

For Telemark. And for the second agreement for the partner that will be distributing and selling the .014" and the .018", their expectation is that they would be doing a launch early in our Q2, which is Q1 of calendar year 2020.

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

Okay. And then the last one from me. I'm sorry.

Timothy J. Arens ***Surmodics, Inc. - CFO***

No, go ahead, go ahead.

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

I was going to say, the last one from me. Tim, as you said SG&A was going to tick up to the level in Q4, which was around $7 million in the quarter.

Timothy J. Arens ***Surmodics, Inc. - CFO***

Right.

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

What is that for?

Timothy J. Arens ***Surmodics, Inc. - CFO***

Yes. So there's a couple of things going on. We had in 2019, I think, it was about $24 million of SG&A expense. We had basically an offset to SG&A based upon the customer settlement. So in essence, we we'll be looking at about just under $25 million of actual SG&A expense if we didn't have that onetime benefit. But we anticipate higher IS infrastructure spend over the course of fiscal 2020, which could approach about $0.5 million. But the greatest increase in the SG&A spend for fiscal 2020 is really going to be related to hiring activities to support the product development initiatives as well as the spend to support the product clinical evaluations that we plan to execute against in fiscal 2020. So those -- that's really -- there's also a few other things that get you to the total. But those are really the big ones that are a bit different than what we spent in 2019.

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

So that's not really sales people. It's people to do the clinical studies to compare your products with what's early out there?

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

Yes. The lesson we learned with how long it took to sign these agreements, we just don't want these products to go cold and 2 things by having them continue to be exercised in the cath lab, where we get the data, also speaks to the value of what we have. And it's something that we believe will get us -- that our value and the continuous use of these products in cath lab gets a lot more attention from the strategics than just the clearance. And so continuing to exercise it, getting our -- sharpening our pencils on what we're seeing the value from end-users, we believe will ultimately get us a better deal. So...

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

Okay. So these are basically clinical specialists that are going to work in the cath lab and support and evaluate the use of the devices?

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

Absolutely, absolutely. I mean it's tough for us, and I'll give you an example, in Telemark, the initial -- some of the initial evaluation of that was done back last summer of 2018, right? And some physicians wanted it. They wanted to keep using it, and so we don't have a mechanism to do that even as we look to sign a deal. So we believe this is good. The feedback is good for us, and it connects much more intimately to these customers as feedback for our next generation of devices.

Timothy J. Arens ***Surmodics, Inc. - CFO***

That's right.

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

Okay. So how many folks, is it 10 or 15? Or can you give us some particular ballpark number for?

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

No, no, no. No, it's not 10 or 15. It might be up to 4 to cover the big interventional areas in the country.

Operator

We'll take our next question from Mike Petusky of Barrington Research.

Michael John Petusky ***Barrington Research Associates, Inc., Research Division - MD & Senior Investment Analyst***

Tim, can you remind me how much of the original $25 million milestone related to Abbott SurVeil has been recognized at this point?

Timothy J. Arens ***Surmodics, Inc. - CFO***

Great. Great question, Mike. And so I think as we've described in the past, the upfront payment is $25 million. And we're actually recognizing the $25 million over the full period, ending with the 5-year patient follow-up. And so as of September 30, we've recognized just north of 50%. I think it's 51% of that $25 million, so a little more than $12.5 million, and put a little context around that. We've done that, that revenue has been recognized over about 20 months. And so now we've got 60 more months to complete the 5-year follow-up. So we'll be recognizing the other $12.5 million over 60 months. So we recognize about 50% of the revenue over the first 25 months or 25% of the overall time that will be spent conducting the study. So it's not -- it gives you a perspective as to why we have the headwind in 2020 with regard to the SurVeil revenue. I think we're recognizing $5.1 million to $5.5 million. So I think it's a great question. And also as you think through the first milestone, the $10 million, we recognized $5.1 million of that or 51% at quarter end. And so we'll be recognizing the remaining $4.9 million of that over the next 60 months for the most part. And as Gary mentioned, it's not normally distributed. So the distribution or the recognition is really based upon the expenses that we incurred to complete the TRANSCEND study in the follow-up.

Michael John Petusky ***Barrington Research Associates, Inc., Research Division - MD & Senior Investment Analyst***

Okay. All right. That's helpful. And then on the coatings patent expiration, so I remember last time this occurred a few years ago. You guys gave somewhat scary sort of guidance on the net impact originally and then it ended up every quarter. You guys were able to sort of

mitigate more than it seemingly than you would had anticipated. Is there any sense that you essentially have modeled sort of the same way you did originally and that maybe Serene can kind of close this $5 million to $5.5 million hold more than maybe you've guided?

Timothy J. Arens ***Surmodics, Inc. - CFO***

That's right. We'd like to think that we're pretty conservative in our guidance. And clearly, we do have growth in the Serene royalty portfolio, which is helping to mitigate some of the patent expiration impact, what the generation-4 coating. I think there's really 2 elements here. So if you think about the headwind of $5 million to $5.5 million from the gen-4 coating royalty, there might be -- we might see some benefits in 2020 from the gen-4 coating royalty, meaning customer sales of the products could be higher than what we're thinking, which would generate more royalty, albeit at a step-down rate, which would help. And then as you think through the math here, and this expiration, I think we've been pretty clear in the past on gen 3, it's the same mechanics. But a lot of the impact is based upon when the customer manufactured the product, not just when they sell the product.

So our forecast is trying to estimate what's in the channel based upon the PRL-3 experience as well as the expiration of patents outside the U.S., which happens basically in another year. And so the PRL-3 experience is similar to what -- or the PRL-4 experience is similar to what we had with PRL-3 will be pretty darn close with the $5 million to $5.5 million headwind. But if we're off on either of those inputs, then we might have a more favorable or less favorable impact. But this is our guidance. We feel highly confident about this. And typically, what we'd like to do, Mike, and I think you've come to realize this. If we're wrong, we prefer to be -- to have a favorable impact on the P&L.

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

Yes. And we didn't -- we looked -- those are our first time going through that patent expiration of PRL-3. So we learned at that time there was more product in the channel than we assumed. But I wouldn't say that we did this -- we're hoping for the same result. We trued that up a little bit understanding that. So this is a more secure guidance. But as Tim said, it could vary.

Timothy J. Arens ***Surmodics, Inc. - CFO***

It's one way how we could possibly exceed the guidance or perhaps maybe revise guidance upward in the future. But given where we sit today, I wouldn't be -- if we felt it was going to come in stronger, we'd have a different guidance and we'd have a different headwind that would be presenting. So -- but stay tuned. We'll -- I'm sure we'll be covering this as we go through the year.

Michael John Petusky ***Barrington Research Associates, Inc., Research Division - MD & Senior Investment Analyst***

Okay. All right. Would you guys be willing to share what percentage of R&D related to SurVeil in fiscal '19?

Timothy J. Arens ***Surmodics, Inc. - CFO***

This is a great question. And I'm thinking -- I don't know that I have all the details in front of me here because, clearly, as you can imagine, there's external costs and I'm happy to share that with you. I think we spent somewhere between $11 million and $12 million on the TRANSCEND study in fiscal 2019, but that doesn't include any of the people here. So the comp and the benefits that also are reflected in R&D expenses where these folks are actually helping to manage this. And also, we're creating products, right, that are going to be either used or were used in the study as well as products that were being used for submissions that may be used for regulatory submissions and the like and getting ready for manufacturing product once we get commercial. So there is more expense where I'm going, Mike, than the $11 million to $12 million that was spent on TRANSCEND. So -- but just I don't have those numbers in front of me.

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

I think the tough thing is as we get commercialization already, that all has to go to R&D.

Timothy J. Arens ***Surmodics, Inc. - CFO***

That's right.

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

It's not cost of good.

Timothy J. Arens *Surmodics, Inc. - CFO*

It's not insignificant.

Michael John Petusky *Barrington Research Associates, Inc., Research Division - MD & Senior Investment Analyst*

Okay. So what I was trying to get at is what might be the delta in fiscal '20 versus fiscal '19? So I mean...

Timothy J. Arens *Surmodics, Inc. - CFO*

Let me help you with that. So you noticed that the R&D spend is going to be lower in 2020 versus 2019. I think we came in around $53 million in 2019. And if we do the math in terms of mid-50s to high 50s as a percentage of revenue, you're going to find that we might be around $50 million to $51 million of R&D expense. So in essence, we're going to be spending, perhaps, $2 million to $3 million less in 2020. A good chunk of the reduced spend is going to be coming from that TRANSCEND clinical study, which I just mentioned, I think $11 million to $12 million. It's going to be up to $6 million I think in 2020, give or take a few hundred thousand dollars, but it gives you a perspective that we're accelerating the spend on some of the other things like the Sundance study as well as some of the work that we're doing just on the development of the proprietary products.

Michael John Petusky *Barrington Research Associates, Inc., Research Division - MD & Senior Investment Analyst*

Okay. Great. And just last one. I just want to make sure I heard it right. Did you guys say that there's $52 million left in milestones across all?

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

Up to $57 million.

Timothy J. Arens *Surmodics, Inc. - CFO*

It's 5-7.

Operator

This concludes our questions. I'll now turn it back to Gary Maharaj for closing remarks.

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

Well, thank you for listening to the earnings call today and look forward to updating you on our first quarter earnings call in the next quarter, and have a great evening. Thanks, everybody.

Operator

Thank you, ladies and gentlemen. This concludes today's call. You may now disconnect.