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Q2 2020 Surmodics Inc Earnings Call

EVENT DATE/TIME: APRIL 29, 2020 / 9:00PM GMT

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PRESENTATION

Operator

Good day, and welcome to the Surmodics Second Quarter Fiscal 2020 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.

Timothy J. Arens *Surmodics, Inc. - VP of Finance & CFO*

Thank you, John. Good afternoon, and welcome to Surmodics' Fiscal 2020 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 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 reconciliation tables 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 this afternoon 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. I want to begin by recognizing the worldwide impact of the COVID-19 pandemic and the challenges that we are collectively experiencing as a result of this global pandemic. Accordingly, I want to include in our discussion today, how we have responded and how we are positioned, both operationally and financially, for the long term. We are indeed facing an unprecedented time in our history, with circumstances that are evolving day by day. While the full impact of COVID-19 is uncertain, our healthy balance sheet, confidence in our supply chain and dedicated team will enable us to manage through this challenging time.

It's little known that Surmodics occupies a unique place in the supply chain for vascular devices and diagnostic reagents. Our products are used expansively in thousands of vascular devices and diagnostic tests every day, in both elective and acute procedures. As an essential supplier of enabling technologies for the diagnosis and treatment of patients in need, we have undertaken extensive measures to both continue production and to ensure the health and safety of our team. We have implemented our pandemic preparedness plan. Yes, we actually did have one. I have appointed Joe Stich according to that plan, he is our Senior VP of IVD and Human Resources, as our Chief Pandemic Officer, with the intent to ensure the necessary executive leadership and speed of decision-making.

Beginning with our team, our employees involved in essential services, including manufacturing operations and customer support, have been working on-site in both our U.S. and Irish facilities. We have implemented measures to ensure the safety of our on-site team, including staggered shifts and social distancing protocols to decrease the risk of exposure to COVID-19.

Within our Medical Device business, COVID-19 has resulted in the delay of procedures deemed elective, which negatively impacted our Medical Device business, beginning late in Q2, and is expected to continue to a more significant degree in coming quarters. The extent and duration of these impacts depend on the multitude of factors that are difficult to forecast, resulting in our decision to suspend the guidance. Notably, our IVD business experienced 21% growth in Q2 and, at first blush, did not appear to be negatively impacted by COVID-19. I'm quite pleased with our second quarter results in this environment and will leave it to Tim to discuss in greater detail.

In response to COVID-19, we have taken steps to manage our operating expenses and preserving liquidity, while continuing to execute on our strategic objectives to position us for long-term value creation. We're fortunate to be in a solid position financially with our continuous focus on optimizing revenue and cash performance. As far as our whole-product solutions commercialization strategy, I'm quite pleased that Cook Medical and Surmodics are proud to announce a new agreement in which Cook Medical will distribute 2 new Surmodics products, namely our hydrophilic PTA .014" and .018" balloon catheters. We've had an excellent long-standing relationship with Cook, where they use our innovative surface modification technology with many of their vascular platform -- products and platforms. We're excited to expand on this partnership with these new .014" on .018" balloon platforms. These balloon catheters, which will launch in the U.S. later in 2020, can be used to help patients who are suffering from below-the-knee critical limb ischemia. We have already shipped the initial orders for this product to Cook.

Moving to our product pipeline and our 3 platforms: DCB programs, thrombectomy and vascular treatment for radial access. We remain on track with respect to these strategic objectives and their timeline.

First, let's discuss our SurVeil DCB. I am pleased to note that the notified body is in the latter stages of reviewing our CE Mark application. While it's still too early to comment on the outcome of the review process, we remain highly confident in the data and the strength of our application. As far as the TRANSCEND pivotal trial for SurVeil goes, we continue to conduct 12-month follow-up visits with patients in the TRANSCEND trial. We have observed some delays with respect to the follow-up window, depending on the site location and as a direct result of the COVID 19 impact. We are engaging with the FDA on how to best treat this delayed, out-of-window and/or missing data. The FDA clearly understands the current limitations of trial management during this pandemic, including on-time follow-up and recently released a guidance document on this very topic. Nonetheless, we are working with the site research coordinators and investigators individually to maximize in-window primary endpoint follow-up. We remain confident in the amount of data we expect to have to demonstrate both the safety and efficacy of our SurVeil drug-coated balloon.

With respect to AVess, we have completed the clinical data collection of our first-in-human study as planned, and are finalizing the clinical study report. We had planned to release these data last week in a late-breaking trial presentation by Professors Andrew Holden from Auckland, New Zealand; and Professor Ramon Varcoe from Sydney, Australia, at the well-known Charing Cross Symposium in London last week. Unfortunately, the symposium, like all others of its type, was canceled due to COVID-19. We are looking for the appropriate forum to present these important late-breaking trial data.

Now I know you're acutely interested in the results. And what I can say at this time is that the trial was successful. It provided important safety data on AVess, and provided directional data regarding the efficacy of the device that was quite encouraging. Now keep in mind, while the number of subjects were small, 12 subjects, the freedom from revascularization at 6 months was greater than 90%. We are excited to release these detailed first-in-human trial results of our AVess drug-coated balloon, but in the clinical forum it deserves, within the next 6 months.

Finally, on our Sundance sirolimus-coated balloon for below-the-knee disease, we were poised to initiate the Sundance trial as early as March. We have already received the regulatory and ethics committee approvals in some of the relevant geographies. However, due to COVID-19 and the sequestering of at least one of our investigators because of a presumed contact, we had to delay. We hope there will be safe and favorable conditions by the end of Q4 to initiate the trial, but it's quite difficult to predict when we can work with the sites to initiate the study. While we are disappointed, we have controlled what we can and will initiate this trial as early as safely feasible.

We continue to make progress on our radial platform and have filed for clearance with FDA on our .014" radial balloon catheter. This device can access the vasculature via the radial artery and treat below-the-knee lesions. We have started work on our .018" peripheral

balloon catheter to treat more proximal vessels behind and above the knee, via radial access.

With respect to Pounce, our unique arterial thrombectomy system, we have an active submission for the 510(k) approval with the FDA clearance, and are responding to requests from the agency for more data, which requires actual further device testing. So stay tuned.

As you can see, we have been focused on our key fiscal 2020 strategic objectives as -- even as we confront this COVID-19 pandemic. Our capital allocation strategy remains intact, and we are appropriately maintaining the investments and pacing for critically strategic programs even as we ensure that we have the liquidity for the long run to continue to operate Surmodics.

Finally, early in April, we had a realignment of executive responsibilities that will improve our execution. Teri Sides, our Chief Marketing Officer, will become our Senior Vice President of Product Development and the Chief Marketing Officer. Teri has held this role successfully 14 years ago, at my last company, resulting in the launch of multiple market-leading products that have to-date treated millions of patients. She was a founding member of our drug-coated balloon program and has 26 patents issued, pending and even expired, given her 28-plus years in the industry. Joe Stich will add HR organization to his responsibilities as our Senior Vice President of IVD and HR. Joe is an amazingly culturally aligned leader in the organization with several decades of leadership experience and an excellent choice for the HR position as well, as we continue to build the Surmodics culture. He's supported by a terrific HR team, both in the U.S. and in Ireland. Charlie Olson will report directly to me as the Senior Vice President of Commercial Development for Medical Devices. Charlie has been in the industry for over 25 years and held his position at Surmodics for almost 19 years. He's been responsible for signing over 250 commercial agreements, up to including the recent Cook agreement. And finally, this will free up Tom Greaney, our Chief Operating Officer, to focus on a quite essential component of our strategy, which is to be able to scale up our products in these partnership agreements in a high-quality, cost-efficient environment. Tom is simply the most capable executive to lead this effort, given his decades of experience in both combination products, that is with drug and peripheral medical devices. And also, Dr. Nusrath Sultana will continue to lead our clinical efforts as a VP of Clinical Affairs with her over 20 years of experience in this area.

I want to thank our Surmodics team for their contributions for supporting our customers and patients. I'm proud of our team and our unwavering efforts through these challenging times. I also want to thank our health care providers who are on the front lines for each -- for us each day. We are deeply grateful for their service and dedication to help us in overcoming this pandemic.

I'll now turn the call over to Tim to provide more details on our second quarter fiscal '20 results, including some further prospective impact that the COVID-19 pandemic is having on our company financials and details of our liquidity position. Tim?

Timothy J. Arens ***Surmodics, Inc. - VP of Finance & CFO***

Thank you, Gary. During today's call, I will provide an overview of our second quarter operating performance. As noted in our press release issued this afternoon, due to the uncertainty created by the COVID-19 pandemic, we are withdrawing our full year guidance. However, I will provide some commentary to help provide insight into the impact of COVID-19 on our company. These comments are based on circumstances that exist today, which we acknowledge are highly fluid and are likely to change.

Revenue for the second quarter of fiscal 2020 grew slightly to $22.8 million as compared with $22.7 million in the second quarter of 2019. Our second quarter revenue was negatively impacted by the previously communicated expiration of our fourth-generation hydrophilic coating patent as well as by the postponement of procedures as a result of COVID-19. Medical Device revenue declined approximately $1 million, or 6%, to $16.3 million in the second quarter. Impacting second quarter revenue was a significant reduction in royalty revenue driven both by the expiration of the fourth-generation hydrophilic coating patent and by our COVID-19-related procedure postponements. We saw a strong performance from our In Vitro Diagnostics business, which delivered quarterly revenue of $6.5 million in the second quarter, a 21% increase over the prior year. Order volume from customers of our distributed antigen products, which fluctuates quarter-to-quarter, grew significantly in Q2 compared to the prior year. Additionally, we continue to see demand expansion for our microarray DNA slide products. Our second quarter royalty and license fee revenue totaled $8.2 million, down $1.7 million or 17% from the prior year period. As I mentioned, primary impacts were the expiration of our fourth-generation patents and COVID-related procedure postponements. Our SurVeil distribution and development agreement with Abbott Vascular generated revenue of $1.5 million in the second quarter and was essentially flat with the year ago period, and in line with expectations at this stage of the clinical study.

Product sales of $11.8 million during the second quarter increased $1.9 million or 19% compared with the year ago period. Performance was broad-based and driven by increased demand from In Vitro Diagnostic customers as well as from our Medical Device customers. Both of our business segments saw double-digit product sales growth.

I want to take a moment to echo Gary's earlier comments. As a manufacturer and supplier of critical components for diagnostic tests and medical devices, our talented and dedicated operations team continues to come to work each day to ensure the availability of our products and enabling technologies in our customers' supply chains. For this, we are all very much appreciative.

Unlike our royalty revenue, which has been impacted by COVID-19 through the second quarter, we did not see the pandemic unfavorably impact our product sales, which have historically been approximately 40% of our revenue. Today, as in the past, we have visibility into the majority of our Medical Device and In Vitro Diagnostic product sales from customer purchase orders going out 4 to 6 weeks or longer. While the future is uncertain, our recent experience has seen consistent demand for our Medical Device products and coating reagents. Since March, our In Vitro Diagnostics business continues to manufacture and ship product to the majority of our customers in a manner consistent with the pre-COVID environment. While it is too early to speak to future potential, we have seen increased interest in our chemical components from customers who are involved in COVID-related research programs and the development and commercialization of diagnostic tests to detect the presence of antibodies that signify the previous presence of the virus.

R&D services revenue of $2.8 million was essentially flat with the prior year period, with steady demand from our Medical Device coatings customers. Since March, we are seeing a pullback in customer demand for coating services related to the COVID pandemic as our customers are experiencing the effects of procedure postponements.

The Medical Device business reported an operating loss of $1.5 million in the second quarter compared to an operating loss of $23,000 in the year ago period. Medical Device operating results were unfavorably impacted by the decline in current quarter revenue, a $650,000 favorable adjustment in the claim reserve in the prior year and a $300,000 prior year contingent consideration gain. Medical Device operating expenses, excluding product costs, had a neutral impact on the quarter, with an increase in SG&A expense, offset by a decline in R&D expense, which was primarily related to the reduced clinical study costs.

IVD revenue of $6.5 million in the second quarter was up $1.1 million or 21% compared with the prior year quarter. Performance was broad-based, and as previously mentioned, benefited from sales growth of our distributed antigen products and DNA slide products. IVD operating margin in the second quarter was 53%, as compared with 54% in the prior year quarter. Operating margin was impacted by a shift in revenue mix toward products with relatively lower gross margins. Product gross margins were down slightly in the quarter at 68% as compared with 68.7% in the prior year quarter as improvements in our medical device product gross margin were offset by the impact of unfavorable product mix within our IVD business.

Before I comment on the second quarter operating expenses, let me share our thinking on how we are responding to the current environment. Our leadership team is continually assessing controllable discretionary spend with an eye toward operating expense and cash management. As a result, we have implemented several cost-saving measures, including delaying certain capital investments and hiring as well as reducing discretionary operating expenses where possible without sacrificing investments in our key strategic initiatives.

As a percentage of revenue, second quarter fiscal 2020 R&D expenses, including cost of clinical and regulatory activities, totaled 52% compared with 60% in the year ago period. R&D expense was $11.9 million for the quarter, down $1.6 million from the year ago period. The decline in R&D expense was driven by a decline in current year TRANSCEND and other clinical study costs as well as prior year activities to establish SurVeil commercial production capacity. As Gary mentioned, during the remainder of fiscal 2020, we continue to work towards initiating our first-in-human clinical study of our Sundance below-the-knee sirolimus drug-coated balloon, and advance development efforts on several products related to our Pounce thrombectomy and Sublime radial access platforms. SG&A expenses in the second quarter of fiscal 2020 were $6.7 million or 30% of revenue compared to 22% of revenue in the prior year period. SG&A expense was impacted by a prior year $650,000 reduction to expense for a claim that was settled in the period for less in the amount we had reserved. Personnel and other investments to support product pipeline development and preparation for product market evaluations also contributed to the increase.

Now turning to income taxes. We recorded an income tax benefit of $1.9 million in the second quarter as compared with an income tax benefit of $162,000 in the prior year period. The current year tax benefit was a result of our ability under the CARES Act to carry back net operating losses to periods where the statutory tax rate was 35% versus our current tax rate of 21%. Both periods reflect the impact of nontax benefited amortization and operating losses in Ireland. On a GAAP basis, our diluted earnings per share were $0.11 in the second quarter as compared with $0.09 in the prior year quarter. On a non-GAAP basis, our earnings per share were $0.04 in the second quarter of fiscal 2020 versus $0.07 in the prior year quarter. Non-GAAP EPS was reduced by $0.13 for discrete tax benefit recognized under the CARES Act for the carryback of those net operating losses.

Moving to the balance sheet. We continue to have a strong cash position and no debt. In the second quarter, we began with $48.3 million of cash in short-term investments and generated $2.2 million of cash from operating activities. During the quarter, we paid $1 million for an installment obligation associated with our fiscal 2018 Embolitech asset acquisition as well as $600,000 for capital expenditures. As of March 31, 2020, we had cash and short-term investments totaling $48.4 million. We are taking a thoughtful and disciplined approach to manage our balance sheet and protect our liquidity as we navigate the uncertainty surrounding the COVID pandemic. Early on in the COVID outbreak, our business units decided to increase their inventory levels to ensure we are protected in the event of supply chain disruptions. From a liquidity perspective, we are prudently managing our $33 million bond portfolio. During our third quarter, over 50% of the portfolio matures and will roll into cash and money market accounts, with the remainder maturing over the subsequent 9 months. Overall, we are in a solid financial position and believe our expense and cash management discipline, and our focus on cash flow and liquidity will serve us well in these uncertain times.

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

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And our first question comes from Brooks O'Neil with Lake Street Capital Markets.

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

It sounds like you're managing well in this uncertain environment. So congratulations on that. I have a few questions. So first, I was just curious if you could share with us what your device revenue would have been without the postponements. And maybe a little bit broader, can you just help us -- I know you have a lot of different customers, and I assume they behave differently up and down the line. But what in general are you seeing from your device customers in terms of their behavior now? And maybe just one more related to this and then I have a bunch more, but would you expect to see a bounce back in revenue when these postponable procedures begin to be done again in the health care marketplace?

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

Brooks, I'll take the last part of the question, and Tim has some really well-developed analysis of the first part. We have heard and seen that the fourth calendar quarter could be a time of bounce back and pent-up procedures depending on the type of procedures, but it's really difficult for us to predict. We have an aggregate portfolio in coronary, peripheral, structural heart and neurovascular procedures, in the vascular space, at least. So we simply don't know. They talk about a V-shaped recovery. They talk about a U-shaped recovery. If anything -- we have to be prepared for a U-shaped, a lopsided U-shaped recovery, where the new norm may not still be as good as it is today. But we also have to prepare with our customers as a critical supplier for a rebound where we know they are caught flat-footed in inventory. One of our larger customers are -- they've shifted from like, my gosh, Surmodics, we got a shorter supply and we'll take whatever you can send, to recognizing in their liquidity management that high inventory levels may not be in their best interest from a working capital viewpoint. And so it's a dynamic thing where we don't know because of the uncertainty, but we have to be prepared to get back up to sustainable inventory levels very quickly. It's a challenge. I'll tell you that. Our working capital needs, Tim manages really well. But we're lucky in where we can quickly convert from -- in many respects, at least in the reagent areas, from raw materials to reagents. Device side is not as quick of a conversion. And so we're watching that dynamic, we'll prepare for the worst, but have plans that we're not caught off-guard if things -- if a V-shaped recovery does happen. I know I'd answer on the question (inaudible)

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

No. It's very helpful.

Timothy J. Arens ***Surmodics, Inc. - VP of Finance & CFO***

Thank you, Brooks, for the questions. So you had a couple of questions in there. One of them was what type of revenue impact are we seeing on our Med Device business as it pertains to COVID-19 for Q1. And what I'll tell you is it's all in the royalty revenue stream. So we're really not seeing much of an impact here as it pertains to the product revenue. You saw in Q2, we saw revenue growth of 20% in the product sales and we saw double-digit revenue growth, both within the diagnostics as well as within our Med Device business. I will just say that we do have calls on a weekly basis with the teams to get an update in terms of where POs are standing and what we're hearing from customers. Generally speaking, what we're hearing and what we're seeing from a PO perspective is what we've anticipated and expected. That being said, we fully appreciate that as the postponed procedures continue, there -- our customers are likely building inventory. And at some point, we'll probably reach that level where they may be looking to order fewer reagents and products from us as they work through their inventory. But it's too difficult for us to get a read on that. And we're not getting clarity from the customers at this point yet, but we're staying on top of that.

I will say that in terms of the impact on our royalty revenue, it's a little bit hard to parse apart the decline in the royalty revenue from the quarter as it pertains to the patent exploration and COVID. As you can imagine, these are interrelated and married. But I'd say probably the way we think about it, our expectation is it's probably about 50% related to the COVID impact, as a result of the declines in the procedures that we saw really coming online in March, really substantially.

You had asked what types of behaviors we're seeing from the customers. And I kind of gave you a little bit of heads up on that. We're seeing just -- at this point, what I would consider to be expected POs from our customers. We have through April, for the most part, seeing expected POs come through from the customers. But again, we'll have to see how that plays out in the coming months as inventory may become a concern for our customers.

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

Yes. That's all extremely helpful. Let me shift gears. I was pleasantly surprised to hear, it sounds like some progress of SurVeil in the EU. I'm just curious, number one, do you expect any milestone payments related to anything happening in the EU on that product? And two, can you just sort of share with us without being specific on the time line, when it might happen, but sort of what's the sequence of events post regulatory approval for that product in the EU, assuming you get it?

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

Sure. So first of all, as you know, with regulatory punditry, it's really hard to predict. But we have been working interactively with the notified body. They did pick up the file in our second quarter again, and we've been moving through interactively. So far, I would say, with our team, and I'm on a lot of those calls as well, we believe we have successfully answered all of the clinical questions. There may be a few more, I doubt it, but I can't say for sure. And I think the steps within these notified bodies that goes through a higher level review before ultimate issuance of the CE Mark. So if a CE Mark is issued, we have to clearly provide evidence of that, it's pretty straightforward, to our commercialized vision partners, Abbott. And there will be a milestone that we would receive as a result of that. Tim, I don't believe we have declared how much it is, but these are not insignificant. As you recall, our completion milestone for completing enrollment was $10 million last August. So it's of that type, I will say. And also the EBITDA and rev req impacts that we'll have. Subsequent to that in this environment and with our partner, Abbott, it's exceedingly difficult to plan the ideal launch time. I mean, in Europe right now, it surely doesn't look like a good time. In addition, Surmodics still has to have some time to be able to fulfill manufacturing the product scale. So we'll -- stay tune, we'll update you more on that as those things become imminent.

But Europe is very -- it's a difficult market right now with the -- clearly the COVID environment. We still have ongoing, as you now, the paclitaxel debate. And ultimately, when we have our trial results, it could give our partner Abbott a lot more marketing clout with the TRANSCEND study to be actually co-build a market share. So we'll call that and reserve. I think the first thing we want to make sure is make sure we're able to do whatever we can to achieve that CE Mark.

I know there was a question about the MDR. And Tim, I think they have pushed out MDR, did -- voted on it. But we're not we're not depending on that. That is outside of our window. We hope that we can get the CE Mark within our fiscal year.

Operator

And our next question comes from James Sidoti with Sidoti & Company.

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

Great. Just kind of following up where you just left off with the CE Mark. Does the recent approval from Medtronic for their balloon, does that have any sway at all with the CE people? When they see that, does that help them make them at all feel more comfortable with the paclitaxel devices?

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

Which DCB were you talking about? The AVess, the...

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

If there's an impact...

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

Yes. So yes, they've had -- I believe they have had CE Mark for some time. They got FDA, PMA approval. It's... yes. Go ahead.

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

They got the FDA approval after all the controversy. So does that have any sway at all with the CE people?

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

No. No. No, we -- the European authorities have their own particular requirements. Clearly, I think if anything, it clearly helps in the U.S. PMA process for paclitaxel device and Medtronic clearly had the data to back it up. So no, I think the way I would look at it is, the notified body was able, despite the paclitaxel issue. And I can't say much more about this, but you can imagine our urging and that we believe it's the right thing to review the file. They picked it up early this year to start the review process. And so that's why we're moving as quickly as we can through it. So -- but we are in the latter stages, it's still hard to know. I -- you never know with these things. So up and until when we get them, I imagine, we'll issue a press release at that time. So stay tuned.

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

So COVID hasn't delayed that? They are still working on that approval and...

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

Yes. I'll tell you, I know the lead reviewer, and he lives in Milan. And being on the phone with him, the last time I spoke with him, he had been locked up in his apartment for over 4 weeks. And I basically said to him, good, now you can get our -- no, I mean they have not slowed down because of COVID-19. They're working remotely.

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

Okay. And then with the radial access balloon, should we assume since the other balloons went to Cook that they will have first right of refusal for the radial access balloon as well?

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

No. These -- because they're very -- they're substantially different. That doesn't mean Cook wouldn't have an interest as well as other companies. It's hard to tell until we actually get more clinical data on the device after we get clearance. But these are, recall, 2.5 meter long devices that can go from your wrist all the way to your big toe pretty much. And so they -- assuming we get the clearance for this, it'll be the first device like it actually in the world. So we will see who the interested parties are at that time. I will say one thing. We're very pleased with Cook. We have significant relationships in the industry and Cook has always been an excellent and long-standing partner for us. So that's a very good thing for those devices.

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

And was there any upfront payment from Cook? Or is that structured, so that you get a percentage of sales or royalties once the product hits the market?

Timothy J. Arens ***Surmodics, Inc. - VP of Finance & CFO***

Thank you for the question, Jim. Very, very similar structure to what we communicated previously with Telemark. No upfront. No milestone payments. No royalty. We manufacture the product, and then we sell it to Cook. It will show up in product revenue in the future.

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

And by the way, we're quite happy to get the CE Mark for Telemark. I mean CE Marks seem to be few and far between even for nondrug delivery devices. So getting that for our partner, Medtronic and Telemark, is also a good thing that we accomplished this quarter.

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

Okay. And then last couple for me. If you listen to Medtronic's call, their guidance for endovascular procedures was pretty wide and -- can you give us any sense on what you think procedures that your devices are used in are going to be down over the next 6 months? I mean their guidance was anywhere from 20% to 60%.

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

Yes. I'll see what I can give generally, and Tim has more of the detail. Tim, was it 8 years go, we were very highly coronary focused, right? And neither Tim nor I liked that. Coronaries was the dog-eat-dog when it comes to ASPs and stuff. So we intentionally with our team, including Charlie Olson in the team, tried to get a much better distribution in the portfolio. So coronary at onetime was almost 50% of our royalty. And so right now, Tim will have the data, but it's much more evenly distributed between coronary, peripheral, neuro and structural heart, right? Structural heart is also in there as well. It's -- I'll tell you, I have 2 kids who are doctors, and one is a cardiologist. And just some of it makes no sense because if you're having a semi heart attack, I do know, in some cases, are saying use thrombolytics, we'll just take the patient into the cath lab. But what's mystifying to us is strokes and heart attacks are not [radioactive], right? The acute emerging phenomenon, you need to treat those patients. We're hearing in some respects, and it's anecdotal, so I don't really can't rely on it, but they're not seeing a whole lot of strokes, and a lot of that is like, what happened to those patients? Are they not coming in? Are they -- it's sort of mystifying. Peripheral, we do know those, except for critical limb salvage, critical limb ischemia, a lot of peripheral procedures have been pushed out. I don't think those remain elective for long. We just don't know what we call the rebound effect. And as we've heard, I think Boston announced today as well, there might be some rebound effect in the calendar fourth quarter. But simply, I hate to say it, we -- the uncertainty is really the definition of the word, we just don't know, apart from the anecdotes we're hearing.

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

Okay. And then just the last thing for me, the comment that I always make to Tim before we hang up is that you should go back and thank the IVD guys every day because they generate the cash that funds your development on the other businesses. So it seems like they did it again this quarter.

Timothy J. Arens ***Surmodics, Inc. - VP of Finance & CFO***

Well, Jim, I can guarantee you that there are members of the IVD team who are listening to that call, and I can assure you that as much as they may hear appreciation from me, they're probably going to enjoy hearing it from you a little more.

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

Yes. IVD has always been the Robin to our Batman. So every now and then Robin comes in and -- I really like what they've done.

Operator

(Operator Instructions) Our next question comes from Mike Matson with Needham & Co.

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

So I guess I just want to try to summarize what you're saying about the COVID-19 impact here. So I'm going to kind of rattle off what I think I heard you say, and let me know if it's right or not. So it sounds like the impact is really more in the Medical Device business and then in terms of the other way you categorize your revenue, it's mainly in the royalty and license fee line and maybe a little bit in R&D line. But the product sales, you don't -- at least right now, you don't really see that being affected much. Is that a fair assessment?

Timothy J. Arens ***Surmodics, Inc. - VP of Finance & CFO***

That is a really fair assessment. That's exactly what we're intending to articulate with regard to the Q2 results. And Mike, I'll just add a little bit of color, I think, as we think through what's happening or what's happened since the end of March, I would expect that we'll see our royalty revenue have an additional impact, at least during our Q3 and likely Q4 as these procedures -- and I think Jim did a nice job of framing up the question in terms of procedure postponements and what he's hearing from Medtronic as well as other med tech firms. And if we've been paying attention to what health care systems have been saying, all of this anecdotal information suggests that there is a significant decline in many different types of endovascular procedures that benefit from a coated device. And we just don't have 100% direct visibility into what's going on. It's always a bit of a delay for us. As you know, our business model is one where our customers actually sell product. And then the period following -- the quarter following their sales actually provide us with the royalty reports and the royalty payments. So we always have a little bit of a lag. So we're not looking at it from real time. So we're keenly and acutely paying attention to what others are saying. So as far as some of the R&D revenue, you did hear me correctly on the call with my prepared remarks, we are seeing a pullback in some of our coating services activities that are absolutely tied back to the postponement of procedures. And we don't have any visibility as to when that might come back on. But the product revenue has been amazingly strong in Q2. And through the month of April, we're tracking with regard to the expectations. And in some cases, maybe a little bit stronger in certain areas. But I would -- I caution our team and I would caution others to think that, that will continue. At some point, one should expect that there could be inventory management on the part of customers and even hospitals, which could have an impact in terms of our royalty revenue and reagent sales as well. Too early to call it.

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

Okay. And then just from a timing standpoint then, if your customers are seeing the big impact in their June quarters, on the -- does that mean then that, that would flow through to your September quarter? Or would that be June? On the royalties...

Timothy J. Arens ***Surmodics, Inc. - VP of Finance & CFO***

No. There's 2 things to really contemplate here and be mindful of. One is the -- we will estimate what the royalty payments will be, that's -- we're required to do that under the accounting standards. So we'll be making our best and most informed estimate in terms of what the royalty revenue will look like during this period of April through June. However, the cash flow that comes from the royalty payment will be in our Q4 for this period. So sales that our customers make for April through June, the remittance of the royalty payments would occur July through September.

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

Okay. All right. And then just on the diagnostics business. I mean you saw 21% growth this quarter, that's pretty strong, but it sounds like that, really, you don't think there was any benefit in there yet from any COVID-19-related testing or...

Timothy J. Arens ***Surmodics, Inc. - VP of Finance & CFO***

Yes. It's pretty -- I would -- if I were to characterize it, I would say it would be modest at best. Clearly, there is more interest that we've seen in April from customers that are working on COVID research as well as customers that are working on manufacturing antibody tests. So that will be something that we hope to be able to communicate a little bit more on the next earnings call. But we do have a nice business with our DNA slides that are used for flu testing. And I think many people might recall, in February and March, there was a lot of discussion with regard to what the symptoms of COVID-19 look like and very similar to the flu. And there wasn't a COVID test. So what folks were doing, were actually going to get flu test to determine whether or not they didn't have COVID-19. So they could rule out COVID-19 if they, in fact, had the flu. So that could have had a bit of an impact in the quarter, the Q2 results, as it pertain to our G&A slides.

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

Okay. All right. And then just a couple of product questions. So the thrombectomy product. You may have announced this previously, and maybe I just missed it, on an earlier call, but it sounds like you said you had submitted your 510(k) for that, then the FDA came back and had some questions, you have to do some more testing or something. Is that right?

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

Yes. We submitted for -- and we submitted some potentially broader indications for it. And what the team has gone to do in -- a product like that, this is a pretty [dug on] unique product for that indication, no capital equipment, very little blood loss and it's really on-the-table solution. So the FDA wants to assure that they have some additional data, which is not trivial. It's not hard to get, but it just takes time. When you have to go back and potentially do another animal study and generate data. So that's where that team is right now. We're hoping to resubmit that data as early -- it may slip into the fourth quarter, but it'd be great to get it back to them in the third quarter.

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

Okay. All right. And then the Sundance first-in-human trial that you said, you expect to -- at this point, you're now expecting to start that in the fourth quarter.

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

Well, we don't know. I mean, we were disappointed. We had -- we're teed up to initiate the trial. Not in all sites, but you get both the local -- the regulatory approval and ethics committee approvals. And one of our investigator is exposed to COVID, and that was the site we were kicking off first. So we had to delay that. And that was March 15 actually. And now in some of these European countries and also some of the Asia Pac countries where we have the trial sites, it's now -- now it's really difficult to get patients in for this, so to even do the site-initiation visits. So the thing we're contemplating is what we don't want to do is start the study because we said we were going to start it to [everyone] investors. And it doesn't really help. But what you really want to do is finish the study, right? And so if starting the study is synonymous, finishing the study is good. But if starting the study doesn't really do you anything and the trial goes cold. So you started, you got 1 patient and then you wait 3 months for the next one. We don't want that. We want to have momentum when we start. We want to make sure the sites are ready and they have identifiable subjects to fit this protocol. So the delays really depend on what we hear from these 7 sites. If it doesn't make sense to start, we wouldn't start it. We wouldn't start 1 site and all the other 6 are dead in the water, yes.

Operator

And our next question comes from Mike Petusky with Barrington Research.

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

A couple of questions. Gary, I thought I caught that you said that you guys had already had a written out pandemic response plan in place. I guess, a, is that true? And then, b, if it is -- when was that first written?

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

I'm embarrassed. I should have known we had -- we have a business continuity plan, and we added a plan, let's call it contain-the-pandemic preparedness plan. And you sort of dust off these things, I think we have made some adaptations to it. But we -- I mean a no-pandemic is a boilerplate document, going to serve you well. But at least a call for appointment of a pandemic -- Chief Pandemic Officer, someone to quarterback this and run with it at multiple sites. So that's what [we're using.] Our pandemic team, which is really the executive team and some of our senior managers and directors, we meet probably 4 times a week, used to be every day, but if nothing has changed between Monday and Tuesday, we'll have the meeting on Wednesday, every morning at 10:00 a.m. And there's quite a lot of things we've been rolling out to ensure the health and safety of our on-site teams. So yes. Yes.

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

Okay. What was...

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

It was the need of the development plan. So I can't take any credit.

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

Okay. Okay. And then I guess in terms of -- and maybe I missed this if you commented on this, but in terms of sort of R&D and sort of the 510(k) longer-term outlook there, are you guys -- obviously, you said you're pulling back on discretionary, on hiring, some capital projects. But in terms of your R&D related to 510(k), are you guys sort of pulling back or pushing out expenses to the right on that? Or are you just -- it's sort of business as usual there?

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

No. So our capital allocation strategy, and we talk about this, and we'll keep refining it as more data emerges and this pandemic takes its course, is really one -- as companies would say, "Our strategic plan is our strategic plan. Damn the torpedoes, we're moving ahead." We don't think it's that because you now have to balance the preservation of liquidity. And so if you could do them both, independently, then we'd be proceeding full steam ahead. The question is, given the uncertainty, we don't think we can do them both. And so instead of without cutting back R&D, I think we're narrowing the focus on the things that really matter. Things that can wait, we are allowing them to wait. But things that really have to move quickly ahead, like some of our radio products, we -- those are not changing at all. Now there is some delay. We are at stay-at-home order, both in the U.S. and in Ireland. And so it's hard to run all the projects as planned. I'll give you an example, animal labs for preclinical studies, I mean a lot of that equipment has been sequestered, appropriately so, for human use, given this pandemic. So it's not easy to get time or any time in animal, you'll have to keep going. So while we didn't intentionally delay cash expenditures, there's also a resulting delay in cash expenditures because things can't move as fast. So I don't know if that gives you an idea. But we're not wholesale pressing the brakes on our strategic initiatives, but we're being more methodical where we put the gas.

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

Okay. Let me just follow-up and see if I can dial it in a little bit for myself on that. So -- and it's not like you've promised exactly, but generally speaking, I think the view is that you guys are going to try to get 2 or 3 or 4 of these products through regulatory approval every year over the next 3, 4, 5 years. Is it possible that somewhere 6, 12, 18 months down, there's essentially a gap because of this period of time where you guys -- you couldn't push forward a couple of projects that maybe you would hope to.

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

In terms of a steady stream, I would say, I hope to not see an interruption in the steady stream. I think the cycle between steady stream might increase. So if you wanted to have 4 products per year. It's not like we'll have 4 this year and maybe none next year. It might string out to be 3. Yes. Okay. That's how we're thinking about it.

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

All right. Perfect. And then just one for Tim real quick. Tim, I think last quarter, you guys had said just in terms of your expectations commercially for the Telemark and the .014", .018" balloon catheters that maybe, in aggregate, something like $2 million to $3 million would hit in fiscal '20. Is that still ballpark-ish about your expectation?

Timothy J. Arens ***Surmodics, Inc. - VP of Finance & CFO***

Yes. Expectations really don't exist, Mike. That's the challenge of the environment. I think I made a comment that we have POs that typically go out 4 to 6 weeks or longer, which clearly doesn't get us to the end of the year. I'll tell you that we're hopeful that we might see that, but I don't have assurance that we will.

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

Yes. Just on the dynamic plan, I was just informed that we put the pandemic plan together for H1 and [1] in the year 2010. And I was here, so now I get to take the credit. Even I didn't know about it.

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

And just one last question. Tim, did you say $1.5 million associated with Abbott this quarter in terms of revs?

Timothy J. Arens *Surmodics, Inc. - VP of Finance & CFO*

I did. Yes. Yes, $1.5 million. That's correct.

Operator

That concludes today's question-and-answer session. Mr. Maharaj, I would -- at this time, I would like to turn the conference back to you for any additional or closing remarks.

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

Well, I have to say, I'm proud of our team, our employees and especially that we continue to make progress, slowly albeit, on our key strategic initiatives. And I want to say thank you for everyone today. Stay safe, everyone, and be well. Thanks.

Operator

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