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Q2 2021 Surmodics Inc Earnings Call

EVENT DATE/TIME: APRIL 28, 2021 / 12:30PM GMT

CORPORATE PARTICIPANTS

Gary R. Maharaj *Surmodics, Inc. - CEO, President & Director*
Timothy J. Arens *Surmodics, Inc. - Senior VP of Finance & Information Technology and 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 Second Quarter Fiscal 2021 Earnings Conference Call. Today's conference is being recorded. At this time, I'd like to turn the conference over to Mr. Tim Arens, Senior Vice President of Finance and Chief Financial Officer. Please go ahead.

Timothy J. Arens ***Surmodics, Inc. - Senior VP of Finance & Information Technology and CFO***

Thank you, Stephanie. Good morning, and welcome to Surmodics' Fiscal 2021 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 morning 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 morning, and welcome to Surmodics' Fiscal Second Quarter 2021 Earnings Call. We had an excellent second quarter. Every cylinder was firing in the Surmodics engine. We recognized $10.8 million of revenue from the SurVeil clinical report milestone. We saw a return to growth in our Medical Device Coatings royalty portfolio. And we made solid progress on the execution of our key strategic objectives during the quarter. To top it off, our IVD business delivered record revenue performance. My thanks go out to the entire Surmodics team for their continued dedication.

Total revenue for the quarter increased 53% to $35 million in the second quarter of fiscal '21 compared to $22.8 million in the prior year quarter. In our second quarter, our performance benefited from the achievement of the $15 million SurVeil clinical report milestone, of which we recognized $10.8 million in Q2. Excluding the impact of this business milestone payment, total revenue grew 6% as both our Medical Device and IVD businesses delivered year-over-year revenue growth. We reported diluted GAAP earnings per share of $0.58 and non-GAAP earnings per share of $0.62 in the second quarter. During our second quarter, I was pleased with our progress on our key strategic objectives for fiscal '21. As a reminder, they are first, complete the final PMA submission to the FDA for our SurVeil drug-coated balloon. Second, continue the advancement of our robust product pipeline. And third, to optimize cash flow from the IVD and Medical Device businesses to fuel our strategic growth initiatives.

Starting with SurVeil, as we discussed on our last earnings call, the results of the TRANSCEND study of our SurVeil Drug-Coated Balloon were presented in January. These data demonstrated that SurVeil is noninferior to the IN.PACT Admiral DCB in both the primary safety and efficacy endpoints, despite the IN.PACT device having 75% more paclitaxel on board. Our team is in the process of collecting and

assembling the final data package for PMA submission. As we have previously communicated, this includes, as required by the FDA, a minimum threshold of mortality follow-up data for patients at 2 and 3 years from the time of their treatment. As part of our SurVeil development and distribution agreement with Abbott, in Q2, we received a $15 million milestone payment from Abbott associated with the successful completion of the clinical report that demonstrated these primary safety and efficacy endpoints in the TRANSCEND clinical study. As previously communicated, there remains a final $30 million milestone payment upon successful PMA of SurVeil by the FDA. Based on the timing of the last patient to be enrolled in the TRANSCEND study, we are still on target to submit to FDA for PMA in Q4 of this fiscal year. And we continue to expect that we'll be in a position to receive PMA by the end of calendar year 2021. While decisions related to SurVeil's launch timing are ultimately to be made by our partner Abbott, all conversations with Abbott have led us to believe that SurVeil's commercial launch, including Europe, is most likely to occur following U.S. PMA approval.

Moving to our Sundance DCB, as a reminder, enrollment was completed ahead of schedule in January for our SWING first-in-human clinical study for our Sundance below-the-knee sirolimus coated balloon. Several patients have completed their 6-month follow up visits and we anticipate that the remaining follow-up visits will be completed by late August. We are excited about the potential for Sundance to provide an important and effective therapy for patients suffering from critical limb-threatening ischemia. With an estimated 1 million Medicare patients treated for CLI annually and very few effective treatment options and no current FDA-approved drug coated balloons, our Sundance drug-coated balloon has the potential to be a game-changing therapeutic option. We look forward to sharing our 6-month data later in calendar year 2021.

Regarding our Avess AV fistula DCB, we are completing the build-out of the full matrix of balloon sizes to treat stenosed AV fistulas. Our team is now beginning the process of product validation efforts. Concurrent with these activities, we continue to assess the optimal regulatory and clinical strategy for our Avess drug coated balloon.

Next is our Sublime radial access platform. Earlier this month, we announced that we successfully completed the first clinical cases using our Sublime Radial Access Guide Sheath and the Sublime Radial Access .014 Rx PTA dilatation catheter. Since then, we have continued to receive favorable physician feedback on their experiences with these devices. As we expected, the feedback has been consistently positive with physicians commenting on the ease of use, push ability, trackability and lesion cross ability of the products. During our last earnings call, I mentioned that we had encountered some delays in the scale-up manufacturing validation of our Sublime .014 catheter. Based on the hard work of our team, we have completed these important and necessary validations.

Regarding our follow-on offering, the Sublime Radial Access .018 PTA dilation catheter, we filed our 510(k) earlier this month. As with all of our applications and submissions with the FDA, we expect that we will have additional information to share on the clearance of this device in the coming months. The Sublime .018 catheter will complement our Sublime .014 catheter, allowing physicians to treat the entire limb segment via radial access with balloon angioplasty.

And finally, I'd like to give a brief update on our Pounce thrombectomy platform. Our teams are working diligently to complete product and process validations that allow us to be ready to conduct limited clinical evaluations of the product later this year.

Regarding our third strategic priority, our Medical Device and IVD business segments, we continue to deliver solid performance. We're seeing strong growth and uptake of our Serene coating technology, which offers advanced performance benefits, including lower particulates and best-in-class lubricity. In addition, we were pleased to see our coating royalty revenue return to growth in Q2.

In our IVD business, we continue to deliver strong operating performance driven by our focus on customer service, commercial excellence and our goals standard product performance. Revenue from our IVD business unit was up 9% this quarter versus the prior year to a record $7.1 million, while generating excellent operating margins that once again exceeded 50%. These core offerings continue to be the bedrock of our operating performance, funding not only their own steadily growing operations and business value, but also fueling our strategic growth initiatives. Our strong operating performance and execution on our strategic objectives is the result of tactical perseverance, a pool of talented team members that we have continued to build on and develop behind the scenes, and a rigorous process of dynamic capital allocation. While it may be early, we have improved our competitive positioning and the capability so that when we believe the global economic future brightens in the post-COVID world, we can continue to accelerate the programs that build long-term shareholder value. After living through a challenging and unpredictable period this past year, I was pleased to see our strong

Q2 performance and believe that better times lie ahead. Consequently, we believe that now is an appropriate time to provide our financial outlook for the remainder of fiscal 2021, which Tim will cover in a moment.

In closing, we have delivered exceptional results in our second quarter in our IVD and Medical Device businesses, and we're successfully executing on all of our strategic objectives, including our product development, clinical and regulatory efforts. 2021 is and has been about execution, and I firmly believe we have a dedicated world-class team at Surmodics to position us for the bright future we have in front of us. Tim?

Timothy J. Arens ***Surmodics, Inc. - Senior VP of Finance & Information Technology and CFO***

Thank you, Gary. During today's call, I will provide an overview of our second quarter operating performance and provide our outlook for full year fiscal 2021. Revenue for the second quarter of fiscal 2021 increased 53% to $35 million, which includes $10.8 million of revenue recognized from the $15 million clinical report milestone under our SurVeil distribution and development agreement with Abbott. This compares to $22.8 million in the prior year. Excluding the impact of this milestone payment, as Gary mentioned, our second quarter revenue grew 6%.

Our Medical Device revenue increased 71% to $27.9 million, which includes a clinical report milestone revenue. Excluding the impact from this milestone payment, second quarter Medical Device revenue grew 5% year-over-year. Our In Vitro Diagnostics business grew 9% to a record $7.1 million, driven by broad-based demand for our diagnostic test component products and development projects. Our second quarter royalty and license fee revenue totaled $20.1 million, up $11.8 million from the prior year period, primarily as a result of the $10.8 million impact from the $15 million milestone payment.

License fee revenue under the Abbott agreement totaled $12.5 million in the second quarter of fiscal 2021 compared to $1.5 million in the prior year quarter. Royalty revenue increased 11% to $7.5 million in the second quarter compared to $6.7 million in the prior year quarter. We saw broad-based underlying growth in our royalties portfolio, including strong double-digit growth from our Serene coating. In addition, we are seeing growth from device applications that leverage our Gen 4 technology. As a result, we anticipate no further year-over-year headwinds from the Gen 4 patent expiration. And on another positive note, in Q2, we experienced the lowest impact on royalty revenue from COVID-19 since the onset of the pandemic.

Product revenue of $11.8 million in the second quarter was essentially flat compared to the prior year quarter across both our Medical Device and In Vitro Diagnostics businesses. Our Medical Device business reported product revenue of $5.4 million and benefited from our recent distribution partnership with Cook Medical for our .014 and .018 PTA balloon catheters as well as a modest increase in our coating reagents, which was offset by softness in our legacy balloon catheter sales.

Our In Vitro Diagnostics product revenue totaled $6.4 million and was essentially flat, with increased demand for our protein stabilizers and colorimetric substrate offerings, offset by unfavorable order timing for distributed antigen products. R&D services revenue of $3.2 million was up 12% or $330,000 compared to the prior year period as our IVD business continues to benefit from increased customer development project opportunities. This was offset in part by lower coating services demand in our Medical Device business.

Product gross margins were down in the quarter at 65% as compared to 68% in the prior year quarter. Product gross margins were unfavorably impacted by product mix with a shift to relatively lower margin product lines. R&D expense, including cost of clinical and regulatory activities, was $12.9 million for the second quarter, up 8% or $940,000 as compared to the year ago period. For both R&D expense and SG&A expense, we faced difficult comparisons to the prior year period, which did not include any expense related to incentive compensation as a result of the uncertainty related to the pandemic. Also as expected, compared to the prior year, our SurVeil related R&D costs declined, including TRANSCEND.

SG&A expense in the second quarter of fiscal 2021 was $7.9 million, an increase of $1.2 million or 17% compared to the year ago. In addition to the unfavorable comparison with respect to incentive compensation, personnel and other investments to support product development and our strategic initiatives contributed to the expected increase. Our Medical Device business reported operating income of $8.6 million in the second quarter compared to an operating loss of $1.5 million in the year ago period. Medical Device operating results reflect $10.8 million in license fee revenue recognized on the Abbott milestone payment, and higher royalty revenue compared to

the prior year, offset by increases in R&D and SG&A expense.

The IVD business grew operating income by 10% or $350,000 to $3.8 million in the second quarter. Operating margin grew to 54%, up from the prior year quarter's 53% as we benefited from solid top line growth and continued focus on expense management.

Now turning to income taxes, we recorded income tax expense of $1.4 million in the second quarter compared to income tax benefit of $1.9 million in the prior year period. The current quarter's tax expense reflects strong pretax results with the receipt of the Abbott milestone payment. The prior year quarter's tax benefit was a result of our ability under the CARES Act, enacted in March 2020, to carryback net operating losses to higher tax rate periods. Both periods reflect the impact of taxable income for the full year in the U.S., nontax benefited amortization, and operating losses in Ireland. On a GAAP basis, diluted earnings per share was $0.58 in the second quarter compared to $0.11 in the prior year quarter. On a non-GAAP basis, diluted earnings per share was $0.62 in the second quarter versus $0.04 in the prior year quarter.

Moving to the balance sheet, we continue to have a strong cash position and no debt. In the second quarter, we began with $53.9 million of cash and investments and generated $16 million of cash from operating activities. During the quarter, we paid $650,000 for capital expenditures. As of March 31, 2021, we have cash and investments totaling $70 million. Our current cash and investment balances provide adequate capacity to support our strategic growth initiatives.

Turning now to our outlook for 2021, we expect fiscal year 2021 revenue to range from $101 million to $105 million. This outlook includes between $16.5 million and $17.5 million of license fee revenue associated with the Abbott SurVeil agreement. Our guidance reflects growth in royalty revenue of mid to high-single digits year-over-year. Regarding operating expenses, we anticipate an acceleration of investment in our strategic initiatives through the remainder of the year. For the full year, SG&A is expected to grow in the low double digits, and R&D spend is expected to be somewhat consistent with the prior year. In addition, we expect the full year impact of income taxes to be neutral to $1 million of tax expense.

Finally, our fiscal 2021 revenue outlook excludes any revenue associated with the achievement of the final SurVeil milestone payment, SurVeil product sales, or SurVeil profit sharing revenue. We expect fiscal 2021 diluted earnings per share in the range of a loss of share of $0.05 to earnings per share of $0.20. We expect non-GAAP diluted earnings per share to range from $0.10 to $0.35. Operator, this concludes our prepared remarks. We would now like to open the call to questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) 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***

Congratulations on the great quarter. I had a little trouble dialing in this morning because I think somebody might have given me the wrong phone number, but I got that figured out.

Timothy J. Arens ***Surmodics, Inc. - Senior VP of Finance & Information Technology and CFO***

Thank you, Brooks. And glad you were able to join us.

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

Right. So a couple of questions. I know it's pretty early with regard to some of the pipeline projects, but can you comment at all in any of them about any interest you're seeing from potential partners up and down the line?

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

Right. Thanks, Brooks. As we said, we have been intentionally shy in terms of meeting and talking with partners. If we were talking, we would acknowledge that because we really want to develop the clinical key series, the breadth of cases in the first 50 to 100 cases with this. We are aware of interest. But as I've told our team, let's -- the real value creation here is us understanding the value of what we have

from the clinical feedback. And then so far, that's been going well. The other thing, Brooks, as you know, having done this for 33 years, we like to do -- really shake out every nuance of the product. The good and the not so good as well. And so that gives us an ability to address any feedback that comes up from product improvement or how -- usability. So really, we're still -- really have the blinders on in driving that. But as I'm aware, there is external interest. But we -- for now, we're intentionally trying to avoid those conversations.

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

Yes. That makes sense to me. Thank you for that. I'm curious, I think I heard Tim say in his prepared remarks that the R&D spending is likely to stay relatively flat. I assume that's in dollar terms. So as the revenue growth begins to accelerate, most likely in fiscal '22, I'm just checking to see if I'm right in believing that your dollar has been relatively flat, but the percentage of revenue spent is likely to begin to fall. Is that the right way to think about it?

Timothy J. Arens ***Surmodics, Inc. - Senior VP of Finance & Information Technology and CFO***

That's right, Brooks. I'll just give you a little color here. Clearly, this fiscal year compared to fiscal 2020, we expect that our R&D revenue will be somewhat flat. And if you take a look at Q1, it is really kind of a low water point here in recent quarters and kind of how we're thinking about Q3 and Q4. There is a lot of work to do, as Gary has been describing with these 3 platforms, and we will allocate capital to them appropriately. They're all extremely value-creating or have the potential to be extremely value-creating. So I will answer the question in terms of 2022. We absolutely think as a percentage of revenue, R&D spend will look like it's declining just from a percentage perspective. But as it pertains to the aggregate dollar amount, it's probably a little difficult for me to give you a whole lot of clarity on that. And the primary factors are with regard to any pivotal studies with Avess and Sundance. So stay tuned on that. There's still some thinking and potential negotiations that need to be done on those fronts. But thinking through this at the rate of maybe $50-ish million a year is probably not a bad way to think about it, with perhaps some growth on top of that based upon clinical studies.

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

Okay. That's great. That's very helpful. And just to ask one more, if I remember correctly, you had a retirement of your senior manager in Ireland. And as I think about what I hope will be a ramp-up in manufacturing activity for you guys, how do you feel about your team and your capability on the manufacturing side? Thank you very much. Again, congratulations on a terrific quarter.

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

Thanks, Brooks. And that actually is an excellent and often unasked question. Behind the scenes, we have been developing our I don't want to say bench strength, but really that's what it is, behind executive team. We have really an incredible depth shot in the company here. And that's with specific intent in areas of succession planning at all levels. And so our new executive manager in Ireland has been training for this position for many years. And really, the best news is, he's jumped in without skipping a beat. And even Tom, who left the company, would agree with that as well. Tom continues to be a mentor for this person. But not a skip in the beat at all. Our Irish team is very well served with Damian Kilcommons who is over there.

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

Great. Thank you very much.

Operator

Our next question comes from Mike Matson with Needham & Company.

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

I just wanted to reconfirm something you said. The timing on SurVeil, so you're expecting to submit the P at the final part of the modules or whatever in the fourth, fiscal fourth quarter. You said you expect to receive approval by the end of calendar '21, did I hear that correctly?

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

Yes, yes.

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

And then just wanted to see what you're hearing from the clinicians that you talk to about the TRANSCEND results. We've spoken to a few cardiologists that do a lot of peripheral procedures and it seems, honestly, it's been kind of lukewarm. People seem really entrenched with the Bard and Medtronic balloons and kind of saying things like, well, unless it's really superior to the products that are out there, it's going to be tough to switch. It's going to be tough for me to go to the VAC Committee to really kind of lobby to get this thing into the hospital, etc. So just curious what you're hearing there, how you think the product will be kind of marketed to address those issues.

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

Sure. Sure. First of all, that is completely unsurprising to us. And that is the power of having strategic partners such as Abbott, who clearly to be a best-in-class in terms of clinical marketing where we have. So that has not even started yet. So normally, the what I call clinical inertia is there. And Mike, there's always a gap between knowledge and practice in medicine. And so until we start the education informing of these physicians, and it's a fairly straightforward marketing issue. The other thing, I would say it would be more difficult for Surmodics alone to do that. But with our partner Abbott, you're selling at all levels. You're doing selling at the group contract level, at the IDN level, at the C-suite, at the physician level, and at the value analysis committees. And so we don't foresee the expected inertia as an issue whatsoever. It's just the wall you lean against. And I can predict that our partner Abbott is ready for that conversation.

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

And then just on the SWING trial for Sundance, so what is the end point of that trial? I know it's a first in human. And then what do you need to see there to progress to the pivotal trial?

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

Right. Well, it really -- as these first in human trials go, it's a safety study. We're looking for 30-day follow-up and making sure even at the 6 months how are these patients. Doing, as you know, it's critical in threatening ischemia. And so there's so many co-morbidities with these patients. And the other thing we are looking for is, and this is more on a secondary basis, is the patency of the vessel. And we're actually doing an additional step where we're actually doing a follow-up angiogram so that we can look at late lumen loss of the tibial artery itself. And what that gives us is duplex is really a binary thing, open or close of the TFVR, the velocity ratio is less than 2.5 or whatever we set. But with late lumen loss, we can actually measure the vessel and we can look for the actual size of the vessel compared to the reference diameter prior to treatment. And the nice thing about that is, even with a subset of 35 patients, it's a continuous variable, it's an actual number with decimal points behind it versus a binary variable. And so it gives us much better statistical confidence with those. But again, it really is a safety study with what we call a nice indication of efficacy. And that indication allows you to make some assumptions of the effect size of the device, the power of future pivotal. So in TRANSCEND, as you recall, we only have 13 patients. So the 35 patients there, we're really looking forward to.

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

That's helpful. And then just on Pounce, when would you expect to start working on additional indications for that product? Would you start that before you get a distribution deal in place for the arterial indication? Or would you wait until you get to that point, start to generate some sales from the product?

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

Right. In the modern era, it's like app updates on your iPhone. Version 1.5 is already in development. Version 2 is already in development. So we take a very parallel approach to this. And in fact, what we're prepared for was any feedback we received on Version 1, is going to be clouded to 1.5 and then Version 2. And the reason we use those, that nomenclature is, what will require re-regulatory filing. And so we -- if there's a lot of regulatory, if the regulatory requirements are filed, we might bundle that in a Version 2. So that's ongoing right now. And Mike, I just wanted to make sure, just on the FDA PMA, the fine print there, as you know well, is we're targeting and expect to get it by the end of the fiscal year. But as of anything regulatory, and especially PMAs, a lot of that is in the hands of how the data review proceeds with the FDA. Just to add that note.

Timothy J. Arens ***Surmodics, Inc. - Senior VP of Finance & Information Technology and CFO***

And let me just offer a little more color. Mike, thank you for the question, it's very thoughtful. And with regard to Pounce and clot removal, Gary's comments, his response is really in regard to arterial. You had asked the question also with regard to how are we

thinking and framing up maybe other indications that could leverage our patent portfolio and the technology. And all I can really share at this moment is the team has really done a thorough identification of what the problems are with other indications and kind of what a value proposition might need to look like and have begun to think through kind of some of the design requirements, etc. So we're informing ourselves in terms of what needs to be done to be able to create a technology that can be effective. And then trying to make sure that we can leverage that insight and understanding with the technology that we have or what do we need to do to complement it. So stay tuned on that. But I would like to go back to your question or your comment with regard to some of the clinician feedback that you received. And look, Gary and I aren't in a position to speak for Abbott, but what I will tell you is that there is clearly, from what we're hearing, higher market sensitivity with regard to drug dose and coating formulations. That bodes very well for Surmodics' technology and I think it could bode very well for Abbott in marketing the technology. I think there is also a real key thing to understand and that is Abbott has a very complementary bag of product offerings that are used in conjunction with the drug-coated balloon. And so I wouldn't underestimate the power that Abbott has from a marketing perspective, but also just from a portfolio perspective to ensure that there's going to be traction with SurVeil once it's launched. So we're all excited, and we're anticipating great things, and we'll stay tuned until the launch begins.

Operator

(Operator Instructions) Our next question comes from Jim Sidoti with Sidoti & Company.

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

I just want to say for all the sell side, we're glad that Brooks was able to get that number straightened out and get on the call. But anyway, the questions I had related to performance. You have 3 products in the pipeline. And it's kind of neat that we're able to talk about things beyond SurVeil, that there is a future beyond that, and that you're coming to the close of that. But if you look at the 3 products beyond SurVeil, the below-the-knee balloon, the AV access balloon and then the thrombectomy device, can you just kind of give us a sense on, of those 3, which is the biggest opportunity and which is the nearest term opportunity?

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

Tim will talk about the addressable markets and stuff beyond that. But just keep in mind, there's also the Sublime Radial Access platform. So it's really that in addition to the 3 you mentioned.

Timothy J. Arens ***Surmodics, Inc. - Senior VP of Finance & Information Technology and CFO***

I think it's a really great question now. We haven't really given a lot of perspective here in terms of Avess and Sundance, and I'll just start -- I'll start there. Our teams are evaluating and assessing the regulatory and clinical approach. Folks may have seen some recent data that's been published, 2-year data on one of the balloons, I believe it's the Medtronic balloon. The data looks really good. We're very optimistic about what we have with regard to Avess. It's a large market opportunity in terms of the overall number of patients that require some help with the stenosed graft. And we think that drug-coated balloons are going to have a pretty big future to play in there in that space. Sundance is really exciting below the knee. There is no option. We've heard the news with regard to Bard and the panel decision not to grant them approval to move forward with marketing the device. We're hearing that others have dropped out of the market or the space on development efforts. There's still a row of decline here, but we are pretty optimistic in these early stages here with regard to Sundance. We'll know a whole lot more later in the fall. By the end of the calendar year here, we expect to be in a position to share the data on the first-in-human study, but that could be game changing. That could be a significant opportunity where there could be high penetration with a drug-coated balloon to treat critical limb ischemia. And depending on what might happen with our partner Abbott, it might just help support and quite frankly strengthen the drug-coated balloon portfolio, having both something to treat lesions above-the-knee as well as below the knee. But that will take a bit longer from a study perspective. We've seen that the Avess studies or AV access studies tend to be conducted a little bit faster. And so we'll have to just wait and see. But if things go really well, we have a couple of tigers, if you will, in the portfolio that we expect over the next several years can generate revenue. Whether it's in the form of license fees and milestones initially and product, and perhaps maybe some other form, maybe profit sharing in the future, yet to be determined, but super excited.

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

And just on the -- radial thrombectomy is well-characterized in people, sort of the staff, the market in terms of excitement and value from thrombectomy. And so if we look at arterial, clearly, we do have veinous and pulmonary embolism on tap. And as Tim alluded to

earlier, we try to give a protective space for the development teams within concept development. A lot of companies rush to what we call solution space very quickly. We love to stay painfully in what we call problem definition space. And what I can say is that in problem definition space, there are key holes in the performance of all of the current devices. And for Surmodics to take on a project, we clearly want to address those issues before we come up with a concept and IP associated with it. But Sublime, the radial continues to be a sleeper in this market just because the total addressable market is really pending on OBLs. And as OBLs continue, office space labs continue to grow. But I may have said it in the last earnings calls, what you have to believe is, given the profound potential clinical outcome benefits to those patients, some really dramatic fixed asset cash flow and then profits that accrue to the OBLs, as they're able to conduct more procedures because of radial access at the end of the day. And then a really dramatic, and this is often misunderstood, of patient satisfaction. The physicians I have talked to about these devices believe that products like these are going to make them win because it's better for the patient, it's more satisfying for the patient and their office-based labs. Once they cover those fixed asset utilizations with a couple of extra procedures you can get from radial access because of the discharge time being much shorter, is pretty much all free cash flow. So it's one of those things where the market is not developed yet, but we are positioning ourselves, because our thesis is that cannot help but grow because it's solving 3 critical issues in U.S. healthcare today. At the same time, I don't know -- I frankly don't know of another product platform that actually can accomplish that. So we're excited about that opportunity as well.

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

So with regard to timing, I know you're hesitant to give long-term guidance, but would you be surprised if 1 or 2 of these products was a significant contributor to revenue by let's say fiscal 2023 or 2024?

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

Absolutely. Absolutely.

Timothy J. Arens ***Surmodics, Inc. - Senior VP of Finance & Information Technology and CFO***

Well, quite frankly, Jim, we're hoping for more than one. Let me replace the word hope with expecting.

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

And the binding issue for Surmodics right now from, at least for us, an investor point of view, is getting those points on the board. I think sometimes what we don't articulate or doesn't get across as -- it's almost too much to say one company has -- I think I said it the last time, if we were a company with only one of these platforms, I think investors would read us better. But counterintuitive because we have 4 exciting areas that we're working on and the 3 product platforms, so it almost seems like you maybe discount all of them. Versus additively look at all of them. But really putting points on the board as we get these things out in terms of revenue and EBITDA growth is really what we're after.

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

And then just one last one, on the quarter that just ended, Tim, you said the IVD business had about $6.5 million of sales, flat a year ago. But then on the release, you reported there was about $7 million of revenue from that business. So is there royalty revenue coming in from that business?

Timothy J. Arens ***Surmodics, Inc. - Senior VP of Finance & Information Technology and CFO***

I might be misunderstanding the question, Jim, but let me attempt to answer here what I think you're asking. If I referred to the IVD revenue as being $6.5 million, that was an error. The IVD revenue was $7.1 million and grew about 9%. So if I did make a reference to $6.5 million, I'm going to be honest with you, I'm not sure what that was intending to do.

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

All right. Maybe I misheard that then. And of that $7 million, is that boosted by COVID testing? Or is that all your core business?

Timothy Arens: No. It's predominantly core business. I think we've talked here, over the last few quarters, we have a couple of customers who've leveraged some of our chemical components for serology tests. But we're not seeing, unfortunately, a big uptake in terms of serology tests, probably for a number of reasons. So the impact on the quarter has been de minimis.

Operator

Our next question comes from Mike Petusky with Barrington Research.

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

Let's stick with IVD. It's not talked about very often. But Gary, I'm just wondering, I mean when you look at that business, if you looked at it as a standalone asset, I mean, you've got nice top line growth, you got 50% op margins. I mean, what's that asset worth standalone in your view? I mean, have you guys assessed that? Or do you have anything you can say around that?

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

Yes. Tim will answer some of the granularity there. We keep, always keep, just to keep us aligned on some of the ports type analysis of the portfolios and the business, operating businesses we have. And the IVD business on an EBITDA basis has continued to grow remarkably, and we believe it will grow -- continue to grow like that in the future on an EBITDA basis. And so the factor is, the multiple on that has actually changed, Tim, I think, positively in the last year in the diagnostic space. So it's whatever range you put on the multiple of EBITDA of that business. But the short answer is handsome growth in that business, value-wise.

Timothy J. Arens ***Surmodics, Inc. - Senior VP of Finance & Information Technology and CFO***

Mike, it's just Joe and the diagnostics team, great solid team, have really done a lot here with this business over the past several years. You've seen revenue continually coming in, in the mid to high-single digits. When we first started talking a little bit more about operating margins with the segment, we were below 40%. I don't know, Gary, if it was 8 years ago or so, but here we are, 54% for the quarter. We continue to probably achieve a 50% or higher operating margin more often than not. And so, if you just frame it up, I think the revenue is -- we could be looking at $26 million or higher revenue in terms of millions of dollars in 2021. You know what the operating margin is, 50-ish percent.

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

It's not capital intensive.

Timothy J. Arens ***Surmodics, Inc. - Senior VP of Finance & Information Technology and CFO***

Not capital-intensive at all. Almost all of that's dropping straight down to EBITDA. It's not unlikely to think that your EBITDA dollars in terms of a range is probably going to be somewhere in the teens, mid-teens in the millions. And we've seen multiples range from 13x to 18x. It's a wonderful gem of a business, and it continues to increase in value each year. So I'll let you do the math. I think some of you have done the math and have kind of indicated that it's pretty valuable.

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

I think we like the question because behind the scenes, because we don't trump up these businesses, the value has grown substantially. And it's not for sale.

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

Fair enough. Okay. So I wanted to just, for my own clarity, maybe everybody else knows this, but for my own clarity, the $30 million that's still on the table from Abbott related to SurVeil and regulatory clearance, is all of that associated with regulatory clearance? Or is part of that related to the filing? And then when you get the first part of that, the revenue recognition, how much of that $30 million is likely to be recognized either in the quarter or right in the next quarter sort of after you achieve the milestone?

Timothy J. Arens ***Surmodics, Inc. - Senior VP of Finance & Information Technology and CFO***

Thank you for the question. The $30 million, there's really a bright line on this one. It's pretty clear. PMA approval, FDA PMA approval, one thing. And so upon receipt of the approval, there is a $30 million milestone payment that will be received. If you take a look in the investor deck, and I think we're going to be posting the updated deck here probably later today or tomorrow, so stay tuned, but if you look at the investor deck, you'll see we have a slide in there that kind of helps folks appreciate how to contemplate how these milestone and license fee payments are recognized. I think for the full year 2021, it's about 76%, 77%, somewhere in there. So for example, the $15 million, we'd be recognizing a good chunk of that, the $10.8 million right away here in Q2. But for the full year, you just can take $15 million, multiply it by 75%, 76%, 77%, that will tell you the range. It's going to be a little bit higher because -- for PMA, for the $30

million, because we expect that we'll have incurred more of the costs associated with the TRANSCEND study. And that milestone payment, Gary, we expect we'll be able to achieve that PMA approval here by the end of the calendar year. So it would probably be maybe somewhere closer to 80%. But yes, I would expect it would be north of 76%, 77%, but probably not a bad way to think about it, 80% could be conservative.

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

Okay, so 80% of the $30 million could be recognized immediately?

Timothy J. Arens ***Surmodics, Inc. - Senior VP of Finance & Information Technology and CFO***

Yes, immediately.

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

And then just one more question. So $70 million between cash and available for sale securities, I mean, $70 million, I think that's the most sort of cash or equivalents that you guys have had in a while. Does that change your way of thinking about capital allocation at all? Does it make you want to go deeper in some R&D spend? Or can you just talk about if that changes anything in terms of your thinking around capital allocation? Thanks.

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

Yes. You know, and you recall this time last year, we and as everyone were prioritizing liquidity and having healthy balance sheets. I think for us, we continue to look at our balance sheet as a dynamic tool for growth. As I said in the past, it's a static indicator of performance. So using that balance sheet is always something we consider how to dynamically allocate capital and grow the business eventually. Coming out of this, what we hope is a post-COVID world with a rebound in economic metrics. We also always have a healthy corporate development initiative. We don't talk much about it, but we're always -- Tim and the team were always sifting to find great technologies, great things that complement where we're going, intellectual property. So that will always be in play for the balance sheet is there. But then on the capital allocation, I'll turn it over to Tim as well.

Timothy J. Arens ***Surmodics, Inc. - Senior VP of Finance & Information Technology and CFO***

Yes. No, it's a really great question, and it's a fair question. We're really fortunate to be in a position with $70 million of cash and investments on the balance sheet. And boy, if you would have asked Gary and I about a year ago if we would have thought that it would have looked like this, I think both of us would have said too much uncertainty to call it.

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

But we were aiming for it.

Timothy J. Arens ***Surmodics, Inc. - Senior VP of Finance & Information Technology and CFO***

But Mike, capital allocation, Surmodics has a history here of share repurchases. We do have an authorization in place. It always comes down to whether or not we think that we can utilize the cash that we have to further enhance and grow shareholder value creation. So not signaling that we would be doing a share repurchase, but as we kind of continue to look out over the next few years and continue to be in a position where we could grow the cash balance, that certainly could be on the table. Our team is pretty well set in terms of the activities that we are engaging on to help to grow the business. And I made a comment earlier in the call with regard to the potential of clinical studies to support approvals for some real important products in our portfolio, namely AVess and Sundance. It's possible that you could be seeing capital allocated to support pivotal studies, especially if we think that there could be a really nice and solid investment creation thesis behind doing that. And Gary highlighted something, it's taken us 5 years or so to kind of build this strategy, the transformation. We continue to execute on it. We're looking to put more points on the board. But we got to today by doing some pretty strategic I would say somewhat modest size transactions relative to what our market cap is. I would expect that if there's -- if we're going to be opportunistic, if there are things that really can help support the value creation that we have in front of us and complement these platforms that we're driving, don't be surprised if we do something like that. So the one thing that I will say is Gary is pretty clear in terms of capital allocation and return on invested capital. We won't do anything that we don't think has real strong likelihood of succeeding and is highly complementary to what we're doing. The vision, the mission is really clear around here, and you won't see us going off after things that are shiny. We'll be sticking closer to the knitting around here. Operator

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

Well, thank you all for joining our second fiscal quarter earnings call. And everyone, have a good day. Thanks.

Operator

Thank you. Ladies and gentlemen, this concludes today's presentation. You may now disconnect.