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PRESENTATION

Operator

Good day, and welcome to the Surmodics Fourth 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, Senior Vice President of Finance and Chief Financial Officer. Please go ahead, sir.

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

Thank you, Corey. Good afternoon, and welcome to Surmodics Fiscal 2020 Fourth Quarter Earnings Call. Before we begin, I would like to remind you that during this call, we will make forward-looking statements. These forward-looking statements are covered under the Safe Harbor Provisions of the Private Securities Litigation Reform Act of 1995 and include statements regarding Surmodics' future financial and operating results or other statements that are not historical facts.

Please be advised that actual results could differ materially from those stated or implied by our forward-looking statements, resulting from certain risks and uncertainties, including those described in our SEC filings. Surmodics disclaims any duty to update or revise our forward-looking statements as a result of new information, future events, developments or otherwise.

We'll also refer to non-GAAP measures because we believe they provide useful information for our investors. Today's news release contains 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*

Thank you, Tim. Good afternoon, and thank you for joining us. We hope you and your loved ones are healthy and safe.

We're quite pleased with our performance in fiscal 2020. We achieved all the value-creating strategic objectives we set out to accomplish even while facing multiple environmental challenges due to the COVID-19 pandemic.

In addition, our full year financial performance was excellent despite the COVID-19-related drop in procedures on our Medical Device revenue, and that led to headwinds of the expiration of our Gen4 coating patents. Importantly, we ensure the adequate allocation of capital to our long-term growth and value creation.

Total fiscal year revenue was $94.9 million as compared with $100.1 million in the prior year. Medical Device total fiscal year revenue declined 9% to $71.4 million as compared with the prior fiscal year, while In Vitro Diagnostics revenue increased 8% to $23.5 million as compared with the prior fiscal year.

These accomplishments would not have been possible without our amazing team at Surmodics. Our team has rallied together to overcome these challenges posed by this pandemic and demonstrated resilience through these difficult times. This fiscal year's success is the product of our team's dedication to patients, customers and caregivers.

Last fiscal year, we had 3 primary areas of focus: The first was to ensure the continued success of SurVeil; the second was to continue to advance our product pipeline; and the third was to drive the legacy offerings in our Medical Device and In Vitro Diagnostic businesses. We made tremendous progress and delivered on these goals, a few of which I'll briefly highlight.

Starting with SurVeil. We received CE Mark certification for our SurVeil drug-coated balloon, moving us forward in our mission to pioneer offerings that increase the treatment of peripheral artery disease.

We made meaningful progress with our TRANSCEND clinical study follow-up despite the difficulties of patients returning for their follow-up visits as a result of COVID-19.

We successfully initiated our first-in-human study for Sundance, our below-the-knee drug-coated balloon, notwithstanding a 3-month delay due to COVID-19.

We successfully completed the first-in-human clinical study of Avess, our arteriovenous fistula drug-coated balloon.

Earlier this year, we also received CE Mark certification for our Telemark coronary support microcatheter.

We achieved significant advancements in our product pipeline, attaining 510(k) clearance for Sublime .014 radial balloon catheter.

And as a capstone to the year, we received 510(k) clearance for Pounce Thrombus Retrieval System.

These are remarkable achievements for a company of any size in the vascular space within the last 12 months.

As we look ahead to fiscal '21, I'm confident in our team's ability to execute on our strategy. I'm excited about what we have on tap for fiscal '21, especially its potential to set us up for achieving consistent double-digit revenue growth in fiscal '22 and beyond.

The objectives for fiscal '21 are:

First, to continue building traction with SurVeil, marching towards PMA approval, beginning with our final submission to the FDA;

Second, to accelerate the advancement of our robust product pipeline through product development, regulatory clearances, clinical evaluation and feedback;

Third, to optimize cash flow from our In Vitro Diagnostics and Medical Device coatings offerings to support our strategic growth initiatives.

I'll start with our first initiative, our goal to obtain FDA approval of SurVeil. We are focusing our efforts on completing our fourth and final PMA module submission to the FDA in Q2 to fulfill the PMA requirements for approval of SurVeil. This module incorporates the primary end point clinical report and other product-related technical data. To that end, we have successfully conducted 12-month follow-up visits with more than 70% of the patients in the pivotal TRANSCEND trial. We have also been engaged in active dialogue with the FDA to address any missing data that we encountered due to the impacts of COVID-19 on this process. We have successfully gained alignment with the FDA on the best course of action to take with this subset of patients and have made the necessary adjustments to the protocol. In addition, we have been in discussions with the FDA on the amount of long-term vital status data that will be needed for the PMA. Vital status information is whether the subject is alive, deceased or unknown. These data are an emerging requirement for new PMAs of vascular devices that use Paclitaxel in order to ascertain long-term safety and appear to be a direct result of the ongoing discussions surrounding paclitaxel-containing vascular devices, which is the active drug in the SurVeil drug-coated balloon. We have been encouraged by our discussions with the FDA on this and expect to have clarity on additional requirements by Q2.

There are substantial financial outcomes from these efforts that I'll further clarify. As we have previously acknowledged, we have $45

million of remaining milestones under our commercialization agreement with Abbott. The first component of this is a $15 million milestone based on the successful completion of the clinical study report of the TRANSCEND pivotal trial demonstrating safety and clinical noninferiority with the control device. While we will not know the answer to these questions until the clinical and statistical analysis of data has been completed, which we expect in Q2, this milestone will be an important achievement for us on the path to premarket approval by the FDA. The remaining $30 million would be achieved upon approval of SurVeil by the FDA and the PMA. Our goal is to secure FDA approval as early as possible. However, we are unable to predict the precise timing because of the need for vital status data, as I previously discussed.

Switching to our second objective, expanding our product portfolio. Our product innovations aim to improve patients' outcomes and quality of life while reducing healthcare costs. As a reminder, we have three main platforms within our pipeline. The first is vascular drug delivery via drug-coated balloons underscored by SurVeil, as we just discussed; as well as Avess, our AV fistula DCB; and Sundance, our below-the-knee DCB. The second platform is our thrombectomy platform focused on removing thrombus in multiple vascular beds, including arterial and venous, and pulmonary embolism. The third is in the treatment of vascular disease via radial artery access, which has the potential to redefine patient care.

Let's start with our of DCB programs and turned to Sundance, our sirolimus-coated balloon for below-the-knee disease. We continue to make progress in patient enrollment in our first-in-human trial, SWING, with more than 1/3 of the patients already enrolled. We are targeting completion of enrollment by the second half of fiscal '21. Sundance has the potential to improve the treatment of arterial blockage below the knee, which can lead to amputation and death.

With respect to the Avess drug-coated balloon, as we previously announced, we successfully completed data collection in our first-in-human study. As a recap, these results provided vital safety data on Avess and directional data on its effectiveness. Importantly, freedom from revascularization at 6 months was greater than 90%. These results will be presented as part of a presentation by one of our principal investigators, Dr. Andrew Holden, at the VIVA meeting later this week. We are quite pleased with the first-in-human trial results, and we'll be discussing more specific plans for Avess in subsequent earnings calls.

Next, turning to our radial platform. With FDA clearances obtained for our Sublime Radial Guide Sheath and our 0.014" radial balloon catheter, our focus continues to be on getting these products into clinical use in Q2 with our field team of clinical specialists. Our team is also continuing to make progress on filing a 510(k) submission, FDA clearance for 0.018" peripheral balloon catheter to treat more proximal vessels behind and above the knee via radial access in Q2. As a reminder, both of these balloon catheters will help patients who are suffering from peripheral artery disease in the low vasculature. We have several other products in the pipeline, and we will share as we complete the concept development of these.

Moving to our nondrug delivery pipeline and Pounce. As we discussed earlier, we successfully achieved 510(k) clearance for this device. Our teams continue to work diligently on the validations and manufacturing builds to start evaluations of this system in the clinic to remove clots in the peripheral arteries. Given the critical nature of this product and the thoroughness of the validations we require, we expect product for clinical use to be available towards the end of the fiscal year. We are also scoping the programs for the next targeted vascular bed for thrombus removal, including deep vein thrombosis and pulmonary embolism.

Finally, turning to our In Vitro Diagnostics and Medical Device businesses. Our IVD business is expected to continue to outperform the immunoassay market growth of 3% while generating excellent operating margins. We are pleased to support several customer-related efforts for COVID-19 research and serology tests with our chemical components.

While our Medical Device coatings revenue continues to face headwinds this year due to the expiration of our fourth-generation hydrophilic coating patents, we believe that despite the uncertainty related to the pandemic, the strength of our coating technologies and diversified customer base position us well to operate through these unpredictable times.

While fiscal '21 has several facets of external uncertainty, including COVID-19 and the worldwide economic and geopolitical stresses, our goals are clear. And we have the talent, the capabilities and the financial resources to successfully execute our fiscal '21 objectives.

From a strategic point of view, fiscal 2021 ultimately is about setting the stage for revenue growth from our product investments in development, clinical research, manufacturing, and commercial readiness. I'm excited about this year and our ongoing commitment to the long-term strategic transformation of Surmodics. I believe that these are the right moves and that the success derived from them will position Surmodics for strong long-term growth and shareholder value creation.

I'll now turn the call over to Tim to provide more details on our fourth quarter fiscal 2020 results, including some perspective that COVID-19 is having on our company's results as well as some thoughts on how we are thinking about certain fiscal '21 revenue impacts and operating expenses. 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 fourth quarter operating performance. While we are not providing fiscal 2021 financial guidance at this time, I will provide comments on how we are thinking about operating expenses and the revenue impacts associated with our fourth-generation hydrophilic coating patent expiration and our SurVeil drug-coated balloon distribution and development agreement with Abbott Vascular.

Fourth quarter revenue was $22.5 million as compared with $30.8 million in the prior year. Both business segments saw year-over-year declines in the quarter as they faced several headwinds, including the prior year impact of the achievement of a SurVeil milestone, the expiration of our Gen4 coating patents and COVID-19.

I'll start with the impacts of COVID-19 to our business during the fourth quarter. First, our fourth quarter Medical Device coating royalties include approximately $2 million associated with a true-up from our third quarter royalty revenue as the actual royalties reported by our customers during the April through June period exceeded our estimate. As a reminder, U.S. GAAP requires that we recognize quarterly royalty revenue based upon an estimate of our customers' sales during the period. Prior to the pandemic, these estimates have been relatively predictable.

Actual royalty payments received from our customers' Q3 sales suggest that the COVID impact in our Q3 royalty revenue was approximately 10% below pre-COVID levels, which was much more favorable than the 30% decline that we had estimated, resulting in a favorable true-up to our fourth quarter royalty revenue. Partially offsetting the royalty revenue true-up is an estimated 10% decline below pre-COVID levels or approximately $500,000 in royalty revenue associated with procedure declines due to the pandemic in Q4.

Second, we continue to see impacts to our Medical Device product and R&D revenue, with demand reduced for our wound catheters and coating service offerings based in part on customers that are managing their inventory levels in response to reduced procedure volume.

Third, our In Vitro Diagnostics business saw a revenue decline from the prior year period by approximately $600,000. Lower sales of our distributed antigen products accounted for the majority of the decline, although we have also seen declines in our chemical component offerings as customers are working through inventory levels that had been previously increased to minimize potential supply chain disruptions due to COVID. Since the COVID-19 pandemic began, we have experienced a modest increase in sales of our chemical components and microarray DNA slides to support COVID-19-related research and testing. Today, we have several customers utilizing our enabling technologies and the recently commercialized serology tests.

Although COVID continues to have a net unfavorable impact on our business, we have been pleased to see the resilience of both our Medical Device and In Vitro Diagnostics business during a highly uncertain year.

Moving to financial results for the quarter. Revenue for the fourth quarter of fiscal 2020 declined 27% to $22.5 million as compared with $30.8 million in the fourth quarter of 2019. Let me remind you that last year's fourth quarter benefited from the achievement of the $10 million SurVeil TRANSCEND study enrollment completion milestone, of which $5.1 million was recognized in the year-ago period. Looking at our 2 business units. Medical Device revenue declined 31% to $17.2 million, and In Vitro Diagnostics revenue declined 10% to $5.4 million in the fourth quarter as compared with the prior year quarter.

Our fourth quarter royalty and license fee revenue totaled $9.9 million, down $6.9 million or 41% from the prior year period, primarily as

a result of revenue recognized in the fourth quarter of fiscal 2019 from the achievement of the SurVeil full enrollment milestone. Our SurVeil distribution and development agreement with Abbott Vascular generated revenue of $1.6 million in the fourth quarter, a decline of $6 million compared to the year-ago period.

Royalty revenue declined to $8.3 million in the fourth quarter as compared with $9.2 million in the prior year quarter. The expiration of our fourth-generation hydrophilic coating patents created an expected headwind of approximately $2 million compared to the prior year quarter. For the full year, the impact of this patent expiration was approximately $5.5 million, which was in line with expectations. In addition to the fourth-generation hydrophilic coating patent expiration, fourth quarter revenue was impacted by lower procedure volumes as a result of COVID. As I discussed earlier, this was more than offset by the favorable impact of the fourth quarter royalty revenue from stronger-than-estimated third quarter reported royalties by customers.

Product revenue of $10.6 million in the fourth quarter was essentially flat when compared to prior year revenue. In our Medical Device business, product revenue was up 8% to $5.4 million, with growth in legacy Ireland medical device revenue offsetting a modest decline in reagent sales. In Vitro Diagnostics product revenue declined 9% to $5.2 million. Continued growth in our microarray DNA slide products was more than offset by a decline in antigen product sales due to order timing as well as overall softness in orders as customers are working off recent inventory builds related to COVID.

R&D services revenue of $2.1 million was down $1.2 million as compared with the prior year period. Our coating services customers have reduced demand in response to the pandemic, and the timing of customer R&D projects has also been impacted.

The Medical Device business reported an operating loss of $1.9 million in the fourth quarter compared to operating income of $3.7 million in the year-ago period, which benefited from the previously mentioned revenue recognized on the fiscal 2019 SurVeil full enrollment milestone. Medical Device operating results were also impacted by COVID-19 and the Gen4 patent expiration as royalty and R&D revenue declined compared to the prior year period. Partially offsetting the decline in revenue was a $2.4 million decline in operating costs and expenses, which included the effect of an $890,000 onetime charge to R&D in the prior year from acquired in-process research and development.

IVD revenue of $5.4 million in the fourth quarter was down $600,000 or 10% compared to the prior year quarter. As mentioned previously, we saw continued demand for our microarray DNA slide products, offset by a decline in antigen product sales and softness in orders from certain customers who are managing inventory levels that had been built as a response to the pandemic. IVD operating margins remained relatively stable at 46% as compared with 47% in the prior year quarter.

Product gross margins were down in the quarter at 63% as compared with 66% in the prior year. Product gross margins reflect negative impacts from both product mix and leverage on volume from the COVID-related decline in Medical Device reagent sales.

R&D expense, including costs of clinical and regulatory activities, was 57% of revenue for the fourth quarter as compared with 47% in the year-ago period. R&D expense was $12.8 million for the fourth quarter, down 12% or $1.7 million as compared with the year-ago period. In the fourth quarter, TRANSCEND clinical study costs declined, partially offset by increased product development investments and costs associated with manufacturing readiness activities for our Sublime radial access platform.

SG&A expense in the fourth quarter of fiscal 2020 was $7.3 million or 32% of revenue compared to 23% of revenue in the prior year period. SG&A expenses were essentially flat with the year-ago period.

Now turning to income taxes. We recorded income tax expense of $870,000 in the fourth quarter as compared with income tax expense of $560,000 in the prior year period. 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 loss per share was $0.22 in the fourth quarter as compared with earnings of $0.26 in the prior year quarter. On a non-GAAP basis, diluted EPS was a loss of $0.18 in the fourth quarter versus earnings of $0.37 in the prior year quarter.

Moving to the balance sheet. We continue to have strong cash position and no debt. In the fourth quarter, we began with $60.6 million of cash and short-term investments and generated $1.3 million of cash from operating activities. During the quarter, we paid $1 million for capital expenditures. As of September 30, 2020, we had cash and short-term investments totaling $61.1 million. Our current cash and investment balances provide adequate capacity to support our strategic growth initiatives.

Turning now to fiscal 2021. As noted in our press release issued this afternoon, due to the continued uncertainty created by the pandemic, we are not currently providing fiscal 2021 guidance. However, I will provide some comments related to our royalty and license fee revenue as well as our operating expenses that may be beneficial to understanding our operating performance.

We have the potential to receive a $15 million milestone payment during fiscal 2021 related to the successful achievement of the TRANSCEND written clinical report milestone under the terms of our SurVeil distribution and development agreement with Abbott Vascular. The potential revenue associated with this milestone would range between $11.3 million and $11.6 million. Furthermore, full year fiscal 2021 license fee and milestone revenue associated with the SurVeil agreement, including the written clinical report milestone, could range between $16 million and $17 million.

During fiscal 2020, we generated $28.6 million in royalty revenue. We estimate that the expiration of our fourth-generation hydrophilic coating patents reduced our fiscal 2020 royalty revenue by approximately $5.5 million compared to fiscal 2019. In addition, we estimate that COVID further reduced our fiscal 2020 royalty revenue by approximately $2 million.

During fiscal 2021, we estimate that the expiration of our fourth-generation hydrophilic coating patents will further reduce our royalty revenue by approximately $3 million. We see no further Gen4 patent expiration headwinds beyond fiscal 2021.

As Gary mentioned, in fiscal 2021, we expect to complete our submission to the FDA for the approval of our SurVeil drug-coated balloon, complete enrollment in our Sundance below-the-knee sirolimus drug-coated balloon first-in-human trial and initiate clinical evaluations for our recently cleared Sublime radial access and Pounce Thrombus Retrieval System products. As a result, we expect fiscal 2021 R&D expense to be similar to our Q3 and Q4 fiscal 2020 levels or approximately $13 million per quarter.

To continue to support our strategy, we expect to grow SG&A in the low double digits during fiscal 2021 to increase the talent and capabilities necessary to support product development activities and accelerate the development and management of our existing product platforms, including receiving physician feedback and performing clinical evaluations.

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

QUESTIONS AND ANSWERS

Operator

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

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

I have a few questions. I guess the first one, my sense is BSX recently got approval for a paclitaxel-coated balloon catheter for peripheral arteries. Can you give us any feel for how you believe SurVeil might compare with the characteristics of their new product?

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

I can't speculate too much about it. We do know the technology fairly well even prior to the acquisition of this technology by Boston Scientific. I think the -- from the outside looking in, what's interesting is that the data was presented a year ago, I think November 5 at the VIVA Meeting, the 12-month data from the pivotal study. And so almost to the day 1 year later, they would secure their approval. So we are quite happy to see them get the approval because the paclitaxel-containing device is going through the FDA. Now clearly, there are some additional requirements. So it bodes well for us that they secured it, although it did take -- and again, I can't speculate what it was. But it appears to take close to a year from the time they presented the 12-month data publicly.

On the other hand, I would say the data looks in range with the drug-coated balloon's impact. I know there's a physician or a site-sponsored, investigator-sponsored study head-to-head with Medtronic. So it clearly does look in line with what we've seen. I would say that what we look at is not necessary the Kaplan-Meier 365. We'll try to look at when all the patients have been assessed for binary patency. 365, really any patient who has not come in for the duplex is counted as patent. So you really have to wait for all of them. And I think Boston has reported that data as well, and that's the data we look at.

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

Okay. Given what you just said about the BSX device, would you expect it to take a year to get through FDA for SurVeil?

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

It's hard. We -- of course, we would like it as quickly as possible because it's a commercialization revenue. That's a critical path. But as I said, Brooks, the FDA has informed us that -- the paclitaxel issue, they're kind of on the hook now for long-term mortality data as an agency looking out for public health. So they are looking for data sets of PMA that were -- we are not aware that was ever a component of securing approvals. Really, the 1-year safety and efficacy data.

Now they would like to see some longer-term data. And so that really, in our opinion, is what sets the critical path to get the approval depending on the amount and which cohort of time, is it 2-year and 3-year data and -- or more. But the 3-year data, how many patients do you need to get at that to satisfy the agency's requirements? Now recall, 3 years sounds like a scary long time, but we already have patients at the 3-year mark because the patients enrolled over a period of time. So I believe the first patients in the SurVeil TRANSCEND study are now beginning to hit their 3-year end point. So it doesn't mean we have to wait 3 years. It just means we have to look at the 3-year data from an initial cohort of patients. Is what we believe. So I know I haven't answered your questions because I really can't predict if it will take less or more than a year, except to say we will do everything we can to clearly meet the FDA's requirements, but to expedite any additional data sets they need.

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

Great. All that's helpful. I really appreciate it. I'm curious if there's any time frame that you anticipate anyone sharing data on the success or lack thereof of SurVeil in the TRANSCEND trial. I mean are we going to see any data from that trial anytime soon?

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

Well, a couple of things. We -- and I know I said we followed up 70% of patients. What I really mean is that's patients within window with all completed data set. We have followed up close to 90% of the patients. So just to make that clear. That means the full 12-month clinical follow-up, some of them with the duplex, some of them without. But what we -- the first agreement we had to have with the agency was how to treat the missing data and how to do a statistical analysis of the missing data, and I'm happy to say we have alignment with the agency on that.

In the future, we'll be getting alignment on the long-term mortality data. So what we did is we waited for -- I don't want to use this word. It's not the right word. We waited for the stragglers to come in.

If you lock the database too soon, you miss data of patients who probably are at their 14th month. And it is important data. As an example, say, if a patient missed the 12-month window and they are patent at 14th month, that patency still counts. So what our team did is we made sure we got as much of that data that was relevant as possible. And the locking of the database is the next critical point, which I am confident will happen before the end of the calendar year. And what that means is all the case report forms, everything has been -- all the data and the database has been checked. The query is completed and the principal investigators have all signed off on all the [CRFs] for each site.

Subsequent to that, you run the statistical analysis right the clinical study report and such. And our colleagues at Abbott will be helping us with that, reviewing that and such. But as far as public release of the data, it's not prudent to release this data publicly until the FDA has it. So the first public release of this data, will be subsequent in our opinion will be after the agency has the data in hand. And so we

are looking at clearly most of these meetings, all of them are virtual, for the virtual meetings in the first and second quarter of calendar 2021, with the emphasis on being early is better for all of us. We'd like to get the data out as quickly as possible. But the critical thing is the FDA need to have a clinical study report for us first.

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

Right. And then one last one, and I appreciate all of this color. If I remember, TRANSCEND, the basic milestone is clinical equivalent with the Admiral product, I think. And I also think I remember that you will try to get enough patients enrolled so that you might demonstrate superiority. And can you share any thoughts or impressions on that?

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

Yes. The primary efficacy end point is clinical noninferiority to the INPACT device. If there is sufficient power to conduct and demonstrate clinical superiority, that will be done, but that's a secondary outcome.

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

Okay. I guess I'll just ask you one more, and this is a little speculation but I'm curious. So if you're fortunate enough to receive the balance in the milestone payments from Abbott, I think you said $45 million probably over the next year or something, how might you think about using that money? You obviously have a lot of cash on the balance sheet now and you're managing your spending prudently and all of that. How do you think about that?

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

Yes. Brooks, thank you for the question. I think Gary and I, our thinking about the milestone payments, clearly, we expect that we will see the balance of the $45 million in terms of any significant changes with regard to the organization and capital allocation. Really don't have a whole lot to share with you today. I think what you can expect is the color that I provided in terms of operating expenses is probably the way I want you to think about the near-term future and perhaps maybe even moving a bit into 2022. But if anything should change, we'll be the first to let folks know. But that's kind of what we're working toward right now, is making sure we're advancing the 3 platforms.

That being said, I think Gary and I will be talking more, as he mentioned in his prepared remarks, with regard to what we might be looking to do with Avess, our paclitaxel-coated drug-coated balloon used for stenos AV grafts. Depending on what may happen there, that clearly would require a pivotal study, and that wouldn't be reflected in the operating expense color that I provided for 2021 and beyond. So until we have a better understanding of what we might do with Avess, there may be a need -- the need for allocating capital to Avess because we think there could be a good shareholder return associated with that level of investment. But we still need to do some work there.

Operator

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

David Joshua Saxon ***Needham & Company, LLC, Research Division - Analyst***

This is David Saxon on for Mike. Thanks for taking the question and I'm hopping between calls so I'm sorry if I'm repeating anything. But first, during the quarter, you got the Pounce approval. So just can you talk about how you're thinking about the market size? And have you had any conversations with any strategics about distribution?

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

It's premature on the strategic conversation yet, especially as we are quite excited about arterial thrombectomy in terms of the market size. I mean there's a lot of discussions about DVT and PE, especially since Inari went public early in the summer.

But the arterial side is as important, and it's really for critical issues when a patient's on the table and you can't get a clot out and it's blocking the lower limb. So we'll talk a little bit more on market size because it also depends on the future commercialization plan for that. What I will say is the device -- we'll share more of this in future calls. The device is quite unique to what's out there. It requires no capital equipment. So either the market is defined by a lot of devices that require capital equipment, require suction, require blood loss.

We see this as operating beyond the market sizes of those because it's quite simple to use. It can, we believe, remove or to organized thrombus, not just fresh thrombus and -- with minimal blood loss. And again, without having a need for capital equipment and really easy to use and operate, we think it has a significant impact on the market.

That being said, the reason it has been -- we have a lot to do to -- it's a complete therapeutic unit. And we want to make sure the validations, the manufacturing readiness and our own time to evaluate the clinical use of the device before we get too far into any discussions. If what we believe is true, the clinical use of this device will be incredibly easy and fairly significant impact in -- competitively in the market. So we'd like to take the time to prove that out before going much further.

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

David, I'll just offer a little color. I understand that clot removal in the arterial system, peripheral arterial system, about 100,000 cases in the U.S. performed annually. How it's been framed up, for me at least, is -- on a global perspective, it looks like the arterial clot removal space is about a $400 million market opportunity today.

David Joshua Saxon ***Needham & Company, LLC, Research Division - Analyst***

Okay. That's helpful. And then, I mean, it seems like concerns over paclitaxel devices are just easing. So maybe can you update us on how you're thinking about that debate and at [TCT], the VOYAGER trial showed no mortality difference between the drug-coated devices and noncoated devices. So any thoughts on how meaningful that is from a utilization perspective?

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

We think -- yes. We were happy to see that data. And I'm trying to remember now, I guess, it was propensity-matched. It is comparable to the current data set. It really is up, at least in the U.S., to the FDA. And there is an industry collaboration that works quite actively with the U.S. FDA and with physicians. And I haven't -- I'll put it this way. The movement has been positive, but I haven't been made aware of any significant shift by the FDA yet.

Clearly, the data is coming down. But I do believe for practicing physicians, it continues to demonstrate the safety of the entire range of therapy. So we're quite happy to see that. And eventually, that will, I believe, help the market creep back to where it should have been.

But as this hazard ratio comes down, I believe that the lower limit of the confidence interval becomes less than 1. This is just my personal opinion. You really then have to say the probability of this being a nonissue has gone up dramatically. So we'll wait for that, and then we'll wait to see how the FDA specifically responds.

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

And Gary, I might offer a few comments for David and for others as well. I know with regard to the FDA and kind of their thinking with regard to the paclitaxel matter, there has been, I think, an interview with the FDA that was published in the September Endovascular Today, where the FDA answered several questions with regard to the current status, and it might be helpful for folks maybe to take a look at that.

I think the other comment I'll make is, I know prior to the COVID pandemic, it looked like we were seeing some improvement in terms of U.S. utilization based upon the IMS Health data. We'll still need to take a look at that here for Q3. I'm not sure that you'll get a lot out of the Q2 data because of the pandemic, but it looked like we started to see increased utilization for the use of paclitaxel-coated devices to treat SFA. So I would encourage people to take a look at that article and hear in the article what the FDA is directly commenting on the matter.

David Joshua Saxon ***Needham & Company, LLC, Research Division - Analyst***

Okay. That's helpful. And just a quick follow-up on the same topic. So if and when the FDA does shift, do you expect them to provide an update on the recommendations? Or kind of in what form would their shift take?

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

Well, really, the shift takes -- took place in terms of the labeling of the devices and when to use them and when to consider not using them. So I don't actually notice, but I would imagine it would be then a change on easing of the label restrictions on this category of devices. Right now, physicians are being encouraged to use alternative devices, except if they believe a patient is at high-risk of restenosis. If that label is eased up, what a physician is then allowed to use the [sub patients] according to their clinical judgment. That will be a big thing because that's how it was before. When you talk to clinicians, the high risk of restenosis applies to pretty much a majority of patients, but it still has that limiting factor for them.

Operator

(Operator Instructions) And at this time, there are no further questions in queue. I would like to turn the call back over to management for closing remarks.

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

Well, thank you. We want to close by expressing our appreciation to our employees for their incredible dedication and commitment this past fiscal year through unprecedented circumstances. Stay safe, everyone, and be well. Thank you.

Operator

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