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PRESENTATION

Operator

Welcome, everyone, to Surmodics' Second Quarter of Fiscal Year 2024 Earnings Call. Please note that this call is being webcast. The webcast is accessible through Investor Relations section of the Surmodics website at www.surmodics.com, where an audio replay will be archived for future reference. An earnings press release disclosing Surmodics' quarterly and full year results was issued earlier today and is available on the company website as well.

Before we begin, I would like to remind everyone that remarks in response to your questions on today's call may contain 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 Surmodics' forward-looking statements resulting from certain risks and uncertainties, including those described in the company's SEC filings. Surmodics disclaims any duty to update or revise these forward-looking statements as a result of new information, future events, developments or otherwise. This call will also include references to non-GAAP measures because Surmodics believes they provide useful information for investors.

Today's earnings release contains reconciliation tables to GAAP results.

I would now like to turn the call over to Mr. Gary Maharaj, Surmodics' President and Chief Executive Officer. Please go ahead, sir.

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

Thank you, Kat, and welcome, everyone, to our second quarter fiscal year 2024 earnings call. Let me provide you with a brief overview of what we plan to cover today. I will review our quarterly financial performance at a high level and discuss the operational progress we've made with respect to our key strategic objectives for fiscal 2024. Tim will then walk through our financial results in further detail and review our financial guidance, which we updated in our earnings press release earlier this morning. I'll then share some concluding thoughts on our outlook before opening the call for questions.

With that as a backdrop, let's begin with a review of our quarterly financial results. Our team achieved impressive revenue performance in our second fiscal quarter, culminating in total revenue growth of 18% year-over-year to $32 million. We grew 19%, excluding license fee revenue related to our SurVeil drug-coated balloon, which represented a headwind of approximately 240,000 year-over-year.

Our team's performance handily exceeded our expectations for the quarter, coming in $2.5 million above the range of expectations that we shared on our last earnings call. Looking at the revenue year-over-year performance of our 2 business segments. Revenue from our in Vitro Diagnostics

or IVD segment decreased 5% to $7.1 million, which was consistent with our expectations given the high comparable of the prior year quarter. Our revenue growth in the second quarter was exclusively driven by the Medical Device segment revenue, which increased 26% to $24.8 million and 29% excluding the headwind I mentioned related to the SurVeil DCB license fee revenue.

Within our Medical Device segment, our year-over-year performance was fueled primarily by product sales, which increased by 40% year-over-year generating $3.2 million of growth. I'm pleased to report that nearly all of the $3.2 million in medical device product sales growth was driven by sales of our Vascular Interventions portfolio, which includes our SurVeil DCB, Pounce thrombectomy and Sublime radial access products. We were pleased with the performance of each of these 3 product platforms that I'll discuss in detail later.

We also saw impressive contributions from royalties and license fee revenue related to our medical device performance coatings, which increased 27% year-over-year, generating $2.2 million of growth driven in part by a $1.4 million in catch-up payments reported to us by our customers. Importantly, both of these areas of our Medical Device segment exceeded our expectations driving the $2.5 million of total revenue outperformance that we saw relative to our stated range of expectations for the quarter.

In addition to our strong revenue performance, we achieved notable year-over-year improvements in our profitability profile, including an $8 million improvement from a GAAP net loss to GAAP net income and a $6.3 million increase in our adjusted EBITDA. And we generated significantly $7.4 million in cash flow from operations in the quarter to further strengthen our balance sheet. Our cash flow performance exceeded our expectations this quarter, driven in part by the royalty catch-up payments I just mentioned as well as a $3.4 million cash tax refund that we secured from the IRS during the second quarter, which Tim will discuss. All in all, we were quite pleased with our second quarter financial results across the Board.

Shifting to a discussion of our recent operational performance. I'm excited to report that our team's achievements in recent months enabled us to deliver strong progress with respect to each of our 3 stated strategic objectives for fiscal '24. Let's begin with our first objective. To capitalize on the key near-term growth catalysts in our vascular interventions portfolio. By facilitating the adoption and utilization of our SurVeil DCB, Pounce thrombectomy and Sublime radial access products. Our success with respect to this initiative is reflected in part by the strong product revenue growth in the Medical Device segment.

As I mentioned earlier, growth in sales of these products fueled the 40% increase in product revenue and accounted for nearly all of the $3.2 million of product sales growth in the segment. Most notably, we saw consistent demand for our SurVeil drug-coated balloon from our commercial partner, Abbott, following the initial stocking order placed in our fiscal first quarter. As we shared on our last earnings call, we were pleased to see Abbott initiate the commercialization of our SurVeil DCB in late January. As (inaudible) has progressed through the initial months of commercialization, we have been focused on satisfying their demand for product and providing technical information to support their sales, marketing and clinical training activities.

Since the fulfillment of the initial SurVeil stocking order during the first quarter, we have received orders and updated forecasts from Abbott on a monthly basis, and our team has been continuously building and shipping products to meet these monthly orders. From a manufacturing standpoint, I'm pleased with our successful transition to a steady state of operations following the initial stocking order. As I've said before, drug portable is some of the most difficult interventional devices to make in the industry, and we take pride in our ability to efficiently manufacture the SurVeil DCB to an exacting standard.

While our commercial partner remains in the first few months of commercialization, the initial feedback garnered from physician users has been positive. Based on this feedback, we believe SurVeil's ability to achieve uniform targeted transfer and retention of paclitaxel at the treatment area with a highly deliverable balloon platform and ultimately achieved clinical outcomes consistent with the market-leading IN.PACT Admiral device which carries a 75% higher drug load of the cytotoxic drug.

This represents a compelling clinical advantage for physicians seeking to optimize treatment of peripheral artery disease. Our TRANSCEND randomized controlled trial, which demonstrated excellent safety and effectiveness of our SurVeil DCB at 12, 24 and 36 months post procedure represents important clinical evidence for the Abbott team that can leverage these to articulate the compelling advantages while engaging potential physician users.

We look forward to Abbott's continued efforts in the market as they work to facilitate adoption of the SurVeil DCB by raising awareness among key accounts, education and navigating the approval and contracting process associated (inaudible). Aside from the strong demand for our SurVeil DCB from our commercial partner, direct sales of our Pounce thrombectomy products were the most important driver of the 40% or $3.2 million of product sales growth we achieved in the Medical Device segment in the second quarter.

The size of our direct sales team has remained consistent throughout the first half of the year with 23 territory managers at the end of the second quarter. As a result of our team's efforts to develop existing accounts expand our active customer base, our Pounce thrombectomy and Sublime radial access products both continue to gain traction in the marketplace. Sales of both products exceeded our expectations during the quarter, driven by strong commercial uptake from new and existing customers.

Specifically, we saw strong growth in both of our active customer base and in the average revenue per existing customer. In addition, we also saw contributions from our new products, which I'll discuss now. In addition to driving adoption and utilization of our existing Pounce and Sublime products, our team continued to advance the limited market valuations for new additions to our vascular interventions portfolio, including both Pounce Venous for the venous vasculature and Pounce Low Profile for the arterial vasculature. These efforts enable us to achieve considerable progress with respect to our second strategic objective for fiscal '24, which is to facilitate our long-term growth by developing and introducing new products and line extensions to enhance our existing Pounce, Sublime and medical device performance coatings portfolio. Let's begin with an update on Pounce Venous.

During our second quarter, we completed our limited market evaluation or LME for the Pounce Venous device. Pounce Venus is a 10-French mechanical thrombectomy system designed for mechanical declotting in the peripheral vasculature without the need for capital equipment. During the LME, we were able to evaluate clinical performance in over 75 venous procedures, representing a considerable variety of clinical cases across a broad range of clot morphologies with a large number of physician operators. Pounce Venous has been used throughout the peripheral anatomy ranging from iliac, iliofemoral, femoral popliteal, and subclavian veins. The devices low profile has enabled flexibility in access sites ranging from popliteal, internal jugular brachial veins to as far as the patient's calf.

Clinically, the dual action design of Pounce Venous has shown the ability to remove large volumes of acute and subacute thrombus via its Archimedes Screw technology while the device basket is designed to remove chronic clot. Physician feedback has been invaluable as we work to better understand a broad array of clinical user and product dynamics. Our LME physician users have highlighted some key differentiating features, which make this product unique in the venous thrombectomy space. For example, the device's dynamically adjustable basket automatically adapts to changes in vessel size while applying consistent radial force even within smaller vessels.

Given the goal of minimizing vessel trauma, physicians have appreciated the ability to expand and retract the basket to spot treat only the areas of need versus repeatedly dragging a mechanical device through the entire vasculature between every pass. Pounce can be resheated, readvanced and deployed within the Clark region if the physician decides and the basket is retracted during removal in non-target treatment zones.

In addition to this positive feedback on March 4th, we are pleased to see the publication of a multicenter study in the Journal of Vascular Surgery by Dr. Stephen Black at AL, which evaluated the safety and performance of Pounce Venous in 19 patients with acute iliofemoral deep vein thrombosis. The study met its primary endpoint of complete or near complete thrombus removal achieved in all patients with a median treatment time of 23 minutes. All safety endpoints were achieved as well with no major bleeding nor device-related events.

Based on these findings, the research has concluded that Pounce Venus is both safe and effective for the removal of thrombus in patients with acute iliofemoral deep vein thrombosis. While our FDA 510(k) clearance for Pounce Venous currently does not include a specific clinical indication for the treatment of deep vein thrombosis, we are pleased to see the results of this study.

More broadly, the study in our LME further demonstrated Pounce Venous is safe and effective for removing a variety of different types of thrombus, including chronic clots in a single treatment session, one that can enable physicians to enhance the efficiency and vesatility while minimizing vessel trauma during use.

The devices low-profile dual action technology, combined with the physician controllable basket, ease of use and incredibly low learning curve are likely to be key drivers of product adoption. Like the rest of the Pounce Thrombectomy platform, Pounce Venous also provides additional compelling advantages for physician, and that requires no capital equipment and helps to minimize the need for overnight thrombolytic therapy. On the heels of this important progress, we are excited to announce in our earnings release this morning, the Pounce Venous has now transitioned to a full commercial launch in March.

Given the attractive features and advantages I just outlined, our team is energized and ready to bring this new treatment option to our physician customers, providing with the new tools to enhance the capabilities and outcomes for these patients. Tuning to a Pounce Low Profile Thrombectomy System. As a reminder, Pounce Low Profile or LP features the same mechanism of action as our original Pounce Mid Profile Thrombectomy System. Pounce LP expands the capabilities of our existing offering with a specific clinical indication to treat smaller diameter peripheral arterial vessels, ranging from 2 to 4 millimeters such as those found below the knee.

On our earnings call in February, I mentioned that the clinical outcomes and feedback from our initial 10 LME cases have been overwhelmingly positive. I'm now pleased to report that the LME continued to surpass our expectations with simply impressive clinical and product performance as we progress through the quarter, and we were equally pleased with the strong positive feedback we obtained. As a reminder, vasculature below the knee tends to be narrow and delicate. Physicians currently have really limited options for removing clot and debris in below-the-knee vessels, which greatly heightens the level of concern for embolic events that can occur during any endovascular procedure.

While hospitalized treatment likely will include overnight thrombolytic therapy, and it may have some usefulness in treating soft acute clots, it's a costly option. Thrombolytic therapy is also often contraindicated in patients with elevated risk of bleeding. Similarly, the performance of aspiration-based technology is quite limited given that aspiration can be less effective, especially in the smaller diameter harder-to-reach vessels.

In addition, aspiration technology runs the risk of inadvertently driving costs further down the vessel, further complicating the procedure. The stakes are quite high and vascular interventions often have struggled to address harder, subacute and chronic clots in this area without resorting to open surgery. Performing surgery on tibial arteries is typically quite challenging and often season as an approach to avoid for patients in poor health. With this in mind, a single session on the table and the vascular approach like Pounce LP can completely transform how below the knee and small arterial vessel clot is viewed and treated.

I'd like to repeat that, it can completely transform how below-the-knee vessels are treated. With this as a backdrop, it's difficult to overstate the level of positive feedback to Pounce LP has received from physicians involved in our LME. In contrast to the challenges I just described with expensive overnight thrombolytic therapy, aspiration and open surgery, our early physician users have found that Pounce LP can be deployed past clots all the way down into the ankle with relative ease. Pounce LP's baskets that have expanded and the devices retracted to quickly pull out clots regardless of their morphology restoring fluid to the patient's limb with the entire process taking just a few minutes.

In view of the success of these cases and the consistency of the feedback received, I'm excited to announce today that we have also initiated the full commercial Pounce LP, which began in April. We began -- we're looking forward to providing physicians this new nonsurgical solution that fills an important critical gap in existing thrombectomy toolkits.

In addition to this progress with respect to our thrombectomy platform, we continue to be pleased with the market's response to Preside the latest and most advanced hydrophilic coating technology in our Medical Device Performance Coatings business. As we discussed in detail on our last earnings call, Preside hydrophilic coatings impact both industry-leading lubricity and enhanced coating durability to coat the devices. After securing early 510(k) clearances and initiating the commercial launch of Preside hydrophilic coatings during our first quarter, we have seen significant interest from both new and existing customers interested in integrating Preside into their next generation of neurovascular, coronary and peripheral vascular devices.

Per our typical process, we are actively working with our customers to conduct feasibility studies for each device and the coating application so they can proceed to securing necessary regulatory approvals. With both our Preside and Serene hydrophilic coatings in the market, we will continue to enhance and strengthen our position as the industry-leading provider of performance coating technologies.

Lastly, we continue to deliver on our third and final strategic objective by driving durable revenue growth and cash flow generation across our core medical device, Performance Coatings offerings and IVD businesses. Revenue from these 2 areas of our business increased 8% year-over-year on a combined basis. This performance is driven by strong growth in Medical Device Performance Coatings, where we saw a lot of royalty and license fee revenue that exceeded our expectations benefiting from the $1.4 million in catch-up payments reported by our customers and continued growth in customer utilization of our Serene hydrophilic coatings.

This performance more than offset the performance in our Diagnostics business, where we saw revenue decreased 5% against our largest fiscal quarter of 2023 driven primarily by lower sales of substrate products. As I mentioned earlier, the performance of IVD business was consistent with our expectations for the quarter. The incremental revenue generated by these 2 core business on a combined basis yielded significant contributions to our adjusted EBITDA growth on a year-over-year basis enhancing our profitability profile.

So stepping back. We're quite proud of our recent piece of execution in fiscal 2024. And this has translated to strong financial performance in the first half of the year and meaningful progress with respect to all of our stated objectives. Looking at our year-over-year results in the first half of our fiscal year, our team's execution has enabled us to achieve product sales growth of 41% in our Medical Device segment.

In combination with the strong contribution from our core businesses, this performance accelerated our total revenue growth to 20% on a year-over-year basis in the first half of fiscal '24, 22% growth excluding the SurVeil licensee revenue. In combination with our continued focus on controlling our expenses, our strong revenue performance enabled us to achieve significant year-over-year enhancements to our profitability profile. In the first half of fiscal 2024, we will essentially breakeven on a GAAP net income basis. We generated $8.7 million of adjusted EBITDA and reported $1.4 million in cash used in operating activities.

With $41 million in cash and investments on our balance sheet and access to approximately $65 million of additional debt capital at quarter end, we are well capitalized to support our operations and future growth objectives.

Lastly, let me thank every Surmodics' team member for what you have made possible in the first half of this fiscal year. The commercialization of 4 new products to date, our SurVeil DCB, Pounce Venous, Pounce LP, and our Preside coating. It is your dedication, perseverance and belief that makes a difference in lives of patients with the commercial availability of these innovative devices and technologies.

We look forward to capitalizing on these important growth catalysts as we tap the significant incremental cost opportunity that they collectively address.

With that said, I'll turn it over to Tim. I know you've been excited to wait for what Tim has to say here. He will discuss our second quarter financial results and fiscal '24 guidance in detail. Tim?

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

Thank you, Gary. Unless noted, all references to second quarter results are on a GAAP and year-over-year basis. Total revenue for the second quarter of fiscal 2024 increased $4.8 million or 18% to $32 million. Excluding SurVeil DCB license fee revenue, total revenue increased $5 million or 19% to $30.9 million. Our earnings press release includes detailed reconciliations of total revenue, excluding SurVeil DCB license fee revenue. Product revenue increased $2.7 million or 18% to $18.1 million. Medical Device product revenue increased $3.2 million or 40% to $11.1 million, the second consecutive quarter of 40% or higher growth in our Medical Device business.

Medical Device product revenue growth was primarily driven by monthly shipments of our SurVeil drug-coated balloon to Abbott and increased sales of our Pounce Thrombectomy device platform. IVD product revenue decreased $440,000 or 6% to $7 million, primarily driven by lower sales of our substrate products. We were pleased with this performance as the prior year quarter was the highest revenue quarter during fiscal 2023 for our IVD business.

Royalty and license fee revenue increased $2 million or 21% to $11.4 million. Performance coating royalty and license fee revenue increased $2.2 million or 27% to $10.3 million. Royalty revenue benefited from $1.4 million in catch-up payments in the normal course of our customers reporting

sales-based royalties. Royalty revenue growth was also driven by customer reported royalties in excess of estimated royalty as well as continued growth in customer utilization of our Serene hydrophilic coating.

SurVeil DCB license fee revenue decreased $240,000 or 18% to $1.1 million, corresponding to the decrease in transient clinical study costs incurred. R&D services revenue was $2.4 million and was consistent with the prior year period.

Moving down the P&L. Product gross margin was 60.8% compared to 62.6% in the prior year period. As we shared last quarter, sales of our near-term growth catalysts, our SurVeil drug-coated balloon, Pounce and Sublime products are increasing as a proportion of total company product sales. These device products are not yet at scale and product gross margins are impacted by the associated under absorption and production inefficiencies.

R&D expense decreased $2.7 million or 21% to $10.2 million. This was primarily driven by lower SurVeil DCB related costs, the timing of development and commercialization of our thrombectomy devices and the benefits from the spending reduction plan we implemented during the second quarter of fiscal 2023. SG&A expense increased $130,000 or 1% to $13.1 million. Lastly, in the prior year quarter, we reported $1.3 million in severance-related restructuring expense from the workforce restructuring implemented last year.

We were pleased to generate GAAP operating income in both our Medical Device and IVD businesses during the quarter. Our Medical Device business reported operating income of $300,000 compared to a loss of $7.1 million in the prior year period, primarily reflecting our strong revenue growth and lower R&D expenses. Two items I discussed earlier, the $1.4 million in royalty revenue catch-up payments recognized this quarter and the $1.3 million restructuring expense in the prior year provided tailwinds to our performance as well.

Our IVD business reported operating income of $3.4 million or 47% of IVD revenue compared to $3.6 million or 49% of IVD revenue in the prior year period reflecting the decrease in IVD revenue.

Turning to income taxes. We reported income tax benefit of $80,000 compared to income tax expense of $370,000 in the prior year period. GAAP net income was $250,000 or $0.02 per diluted share compared to a net loss of $7.7 million or a loss of $0.55 per diluted share in the prior year period.

Non-GAAP net income was $1.1 million or $0.07 per diluted share compared to a net loss of $5.6 million or a loss of $0.40 per diluted share in the prior year period. Non-GAAP adjusted EBITDA was $4.8 million compared to adjusted EBITDA loss of $1.5 million in the prior year period. Our earnings press release includes detailed reconciliations of GAAP to non-GAAP measures.

Moving to the balance sheet. During the second quarter, we reported cash provided by operating activities of $7.4 million and capital expenditures of $1.3 million. Cash provided by operating activities in the second quarter benefited from the receipt of a $3.4 million cash tax refund from the IRS associated with the Cares Act employee retention credit which we have discussed in our prior earnings calls and which we were pleased to receive during this period.

We ended the second quarter with $40.9 million in total cash and cash equivalents and investments and available for security investments, an increase of $5.8 million during the quarter. Long-term debt of $29.5 million was unchanged during the quarter. At quarter end, we had access to approximately $65 million in additional borrowing capacity under our existing credit agreement.

Turning now to fiscal 2024 guidance, which we updated in our earnings release today to reflect both our outperformance in the second quarter as well as our improved outlook for the remainder of fiscal 2024. We now expect fiscal 2024 total revenue to range from $122 million to $124 million, representing a decrease of 8% to 6%. Excluding SurVeil DCB license fee revenue, we expect revenue to range from $118 million to $120 million, representing an increase of 15% to 17%. This compares to our prior range of $113 million to $117 million or an increase of 10% to 14% over the prior year.

SurVeil DCB license fee revenue is expected to be approximately $4 million in fiscal 2024 compared to $29.6 million in fiscal 2023. We now expect fiscal 2024 GAAP loss per diluted share to range from a loss of $0.90 to a loss of $0.70 compared to our prior range of a loss of $1.40 to a loss of

$1.10. Non-GAAP loss per diluted share is expected to range from a loss of $0.67 to $0.47 per share compared to our prior range of a loss of $1.17 to a loss of $0.87 per share.

I'll now share a few additional considerations for modeling purposes. With respect to our fiscal 2024 total revenue guidance, product revenue is expected to be approximately 60% of total revenue, driven largely by contributions from our product growth catalysts. Specifically, we now expect combined product revenue from our SurVeil, Pounce and Sublime products of at least $15.5 million, an increase from the $14 million we communicated last quarter. Revenue associated with our Medical Device performance coating offerings and IVD business is expected to grow in the low to mid-single digits from the $88.3 million of combined revenue generated in fiscal 2023.

Our fiscal 2024 diluted loss per share guidance reflects the following assumptions for the full fiscal year. Product gross margin is expected to be in the mid- to high 50s, we expect operating expenses, excluding product costs to decrease in the mid-single digits. We expect R&D expense to range from $39.5 million to $40.5 million, representing a decrease of 15% to 13%. We expect SG&A expense to range from $53 million to $54 million, representing an increase of 2% to 4% as we invest in our commercial organization. Interest expense is expected to be approximately $3.5 million, consistent with the prior year.

Finally, our EPS guidance reflects full year tax expense of $3.5 million to $4.5 million. With respect to our revenue growth in the third quarter, we expect third quarter total revenue to range from approximately $29.5 million to $30.5 million, representing a decrease of approximately 44% to 42%. Excluding SurVeil drug-coated balloon license fee revenue, we expect third quarter revenue to range from $28.5 million to $29.5 million, representing an increase of 7% to 11%. As a reminder, in the third quarter of fiscal 2023, we recognized $25.9 million of SurVeil drug-coated balloon license fee revenue, the majority of which was related to the PMA milestone payment achieved in the period.

Lastly, with respect to cash utilization. At the end of fiscal 2023, we had $45.4 million of cash and investments, which included $3.9 million of available-for-sale securities. We now expect to finish fiscal 2024 with approximately $35 million to $38 million in cash and investments, representing a year-over-year decrease of $10 million to $7 million. Our updated expectation represents an improvement of $6 million to $7 million compared to the expectation shared on our first quarter earnings call, driven by improved operating performance.

As we have discussed in detail on recent earnings calls during fiscal 2023, cash and investments increased $26 million, reflecting an influx of cash from the $27 million milestone payment on receiving PMA for the SurVeil drug-coated balloon as well as $19.3 million in net debt proceeds from our term loan and revolving credit facility. Setting aside these items, cash and investments decreased by approximately $20 million in fiscal 2023. With this in mind, our updated expectations for fiscal 2024 year in cash and investments reflects an improvement in cash use of $10 million to $13 million compared to the $20 million in fiscal 2023 I just mentioned.

Our expectations for fiscal 2024 year-end cash and investments continue to reflect the following assumptions. Capital expenditures of up to $5 million compared to $2.9 million in fiscal 2023, which includes certain investments postponed last year as part of our spending reduction plan and payments totaling $2.7 million to satisfy obligations related to previous acquisitions, of which $930,000 was paid during the second quarter.

We remain focused on disciplined expense management and optimization of working capital and importantly, our fiscal 2024 guidance continues to assume no borrowings under our credit agreement.

With that, I'll turn the call back to Gary for closing remarks.

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

Thanks, Tim. As Tim mentioned, we're pleased to reach our financial guidance today for the second time this year, which reflects both our recent outperformance and our increased outlook for the balance of the year. Importantly, I want to emphasize that the low end of our guidance range now calls for total revenue growth of at least 15% year-over-year, excluding the headwinds related to the SurVeil DCB license fee revenue.

We expect this growth to be fueled by revenue from our vascular interventional products of at least $15.5 million compared with our initial expectation of $15.5 million. Looking ahead, our team is energized by our recent success and remains focused on executing our growth strategy

to continue our recent momentum as we enter the second half of fiscal 2024. With steady growth and cash flow generation from our core businesses, demonstrated commercial traction from our existing products and an expanded portfolio of innovative vascular interventional devices addressing large and underpenetrated markets, we believe Surmodics is exceptionally well positioned to deliver strong, sustained revenue growth.

By accelerating our growth while continuing to control our expenses, and allocate capital dynamically and strategically, we remain committed to delivering sustained improvements in our underlying profitability profile. Surmodics is focused on delivering value for the benefit of our patients, our customers, our employees and investors. And it's important that you know we have the courage and the commitment to continue to pursue our mission to improve the detection and treatment of disease.

I'd like to conclude my prepared remarks today by thanking all of these important stakeholders for their support of our company and our continued pursuit of this mission. We really need more companies like Surmodics.

Operator, we will now open the call for questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question will come from Brooks O'Neil from Lake Street Capital Markets.

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

As usual, you guys operate a very thorough and complete overview. But I think it's offensive that you talk about all this detail, and then you say we can ask 1 question and 1 follow-up, but I'll try my best to stick to your requirements here. So first, I'm just curious, if you could help us to calibrate the TAM for SurVeil today and the second part of question one, could you give us a sense for whether the level of revenue the product is beginning to generate is sufficient to maintain Abbott's long-term interest in this product in this market?

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

Yes. Brook, I'll start with the second part there. We -- I don't want to speculate about what Abbott needs, but I can tell you that the partnership is strong, and they're excited about getting going in its very early innings. As far as their portfolio and their strategy and numbers and stuff, I don't have the information to speculate now what I want to. I'll turn over some of the TAM component to Tim here. But think of it -- it's a bit of a dynamic TAM. Since the FDA unwounded the label warning on paclitaxel a year ago, I guess, it was last year.

Every patient who is going to be treated with balloon angioplasty procedure in the periphery, in my opinion, is a candidate for a drug-coated balloon. I mean with so many randomized, I don't know, we have 7 randomized controlled trials culminating with the TRANSCEND trial, which I will say is the best one -- the best ever run trial in this space because it was head-to-head, but really clearly demonstrates the durability and impartment of anti-restenotic drug on a balloon. And that durability, as I said, the data is quite compelling.

So if you want to prevent restenosis rates on plain old balloon, the mandate should be you always use a drug-coated balloon, not just for difficult lesions. So I would say the TAM is much, much larger than the current market. But I know, Tim, we've been tracking the IMS data and seeing the rebound of the market. So I'll turn that over to Tim.

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

That's right. TAM really hasn't changed, Brooks. There's over 500,000 above-the-knee cases that are performed in the U.S. annually. Given kind of the cases leverage multiple balloons, I've heard anywhere from 1.3 north of 1.3 balloons per procedure, you're looking at ASPs from a list perspective

that are greater than 1,500, obviously, there's some discounts, but that gets you to about $1 billion TAM. I think 1 of the reasons Abbott was interested in negotiating an agreement for distribution rights back in 2018 was because of the TAM and how they viewed it, as Gary mentioned, a technology that could really provide a lot of benefit to patients that were suffering from peripheral vascular disease.

But to be clear, it's very early in Abbott's launch. They launched in late January. We're here on May 1. We're 3 months into it. I'll just refer you back to our prepared remarks. Every month, we've been receiving orders from Abbott -- every month Brooks. As Gary mentioned, they've been consistent. We're pleased with the orders. We're manufacturing, we're shifting. We're recognizing revenue. So let's make sure we don't forget to ask the question again next quarter or maybe even the quarter after. But we're pleased with what we're seeing right now.

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

Just the 1 question, though.

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

So just as a follow-up, sorted to that related to Abbott, I saw an announcement the other day that they got approval for dissolving drug-coated stent for below-the-knee (inaudible) that they probably put that in, unless they have a catheter to open the vessel a little bit. Are they showing any new or renewed interest in your products that are developed for below the knee?

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

We haven't had any discussions with them about that, but the (inaudible) standards by resorbable -- and I believe it specifically got PMA approval this week. It's specifically for below-the-knee vessels. So as far as our Sundance, we have -- we continue to make progress in looking for parties of interest, and we have conversations with multiple parties there. Sundance requires some investment and allocation of capital to get it to an IDE level.

At this point, we would choose not to move much more on that without a partner helping the funding of that. But we are in that...

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

Okay. You are in discussions Okay? I'm just going to ask 1 more, which is, obviously, over the past 5 years, R&D spending has been in the range of 50% of revenue. It's been a very productive investment, and it shows tremendous promise. Do you expect to continue spending at that dollar level or that percent of revenue level now that we're, let's say breaking into the clear here?

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

Right. And I'll give you a little bit of the strategy and Tim will follow up with some of the actual hot edges. So if you don't have a pipeline, you have to develop a pipeline, right? And so pipeline stuffing requires, as you know, accelerated R&D investments. Eventually, the pipeline gets into equilibrium. What's going in and what's coming out, generating cash in an equilibrium and those help offset each other.

So the clinical trial costs are coming out. We have multiple year follow-up. We have a couple more years of follow-up in some of them. Revenue is going up, but the level of R&D spending that we are contemplating right now are really A, on the vascular inventions portfolio, making sure the platforms we have, thrombectomy and radial access -- venous and arterial thrombectomy and radial access, that we fill out those platforms with the complete product line so that we could be compellingly -- compelling competitive advantage. That's still in process. We still have Pounce Excel. We still have things like Pounce Over The Wire. We have many things in that pipeline within that box of current platforms.

We also want to make sure on the Performance Coatings business. We have Preside and our teams just a remarkably sounded chemical engineering team of how we further advance that technology. So we can make the game over. I mean, Surmodics is going to lead this field and we're not seeding that leadership advantage in our Performance Coatings business.

Apart from that, Tim, I'll turn it over to you. I would expect some (inaudible).

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

Thank you, Brooks. We're really pleased that we're starting to see the product revenue grow the way it's been growing as -- as Gary and I have mentioned in the prepared remarks, we're expecting at least $15.5 million of revenue this year, and we keep increasing our guidance every quarter with regard to these products. This is a combination of that -- those investments in R&D over several years.

As you mentioned, 50% of our revenue in the past had been invested in R&D. There's -- clearly, this year, you heard in my remarks in terms of some of the modeling considerations, we're having a lower spend in R&D this fiscal year versus the prior fiscal year, that's really attributable to the R&D spend that had gone into SurVeil and other drug-coated balloon platforms. That's really what the driver is. We've continued to invest, obviously, in some of the vascular intervention products with regard to Pounce and Sublime of which notably we've launched a few and commercialized if you hear just within the last quarter. So I wouldn't drive you or guide you to thinking that we'd get back to 50% of revenue would be spent on R&D.

At least we don't see that in the near and intermediate term by any means. And certainly, as our revenue continues to jump and Brooks, you go back several years ago, we were in the mid-70s in terms of millions of dollars of revenue generated annually, here we are talking about $122 million to $124 million. So there is -- it would be very unlikely that we'd get back to 50%. But we feel very confident that we're making the appropriate level of investments in R&D at this point.

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

Perfect. That's very helpful. Congratulations on all you've accomplished.

Operator

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

Joseph Scott Conway - *Needham & Company, LLC, Research Division - Research Analyst*

This is Joseph on for Mike. Just from us. The 14 -- or I guess, $15.5 million guide for Pounce, SurVeil, Sublime, I was just wondering if we could maybe get a little bit more color on those numbers, not necessarily asking for a split, but if there is any more upside to that, any raises, wondering if you could call out where you think those would come from? Whether it be a specific product? And then I don't know if you said that in the prepared remarks, but the raise today, is that driven by the launches of LP and -- in Pounce LP and Pounce Venous? Or just a little bit more color on that would be great.

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

Sure. It's a great question, and I'm sure a lot of people are thinking and wanting to ask the same question. So thanks for putting it out there. Yes, I would tell you that our view today on the at least $15.5 million is at least $15.5 million. Justin, let's be really clear on the question with regard to the raise and what's coming -- what's coming from Pounce LP and Pounce Venous, we're very measured on that. It's very early stages. We've completed the limited market evaluations, they went very well. But as you can imagine, we're going to be appropriately conservative in terms of including in our guidance any real significant revenue increases until we validate and get traction. So the $15.5 million, although it does include some revenue from these recent product launches, it's not what's driving it entirely. It's a portion of the increase.

You had asked about could we provide a bit more context and color between the products. And we're not in a position here and nor do we believe it's all that helpful for investors to be getting a lot of product level detail on revenue at the current stage of these products, they're pretty modest still, even though we're guiding to $15.5 million, there is noise. And I don't think it is very helpful from a modeling perspective or helping provide any real perspective that will be of use.

But what I will say is we have communicated that SurVeil, if you go back to the prepared remarks, was an important contributor, significant contributor, along with Pounce. And as you know, there was no Pounce or no SurVeil product revenue in fiscal '23. So you can imagine that a lot of that growth over $3 million of product revenue growth in med device business. We did see some of that coming from SurVeil and a paramount coming from Pounce. But we're going to provide some color and context but we're just not going to be providing specificity in terms of the numbers at this point. So hopefully, that's helpful. The prepared remarks are intended to help give you what you're looking for. And I'm sure we'll have more to say as we kind of go through the coming quarters in terms of the performance from these recently launched products and the continued performance from SurVeil as well.

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

And Tim has very long legs, so he can kick me under the table, but I'll give you 1 nugget that, that will help. It wasn't too long ago we were talking about the direct sales of vascular interventions product is without SurVeil, we're getting to $1 million -- over $1 million a quarter consistently. What I will share and this is 1 nugget is Pounce Arterial by itself is over $1 million a quarter. So I can't give you any more than that, but I just -- I wanted to make sure people understood the magnitude of the growth we are experiencing in some of these areas.

Joseph Scott Conway - *Needham & Company, LLC, Research Division - Research Analyst*

Okay. Yes. No, all of that is really helpful, much appreciated. I guess maybe let's see. Maybe 1 on Abbott and SurVeil. Just maybe wondering how long maybe rough time line or something when you guys believe you can get to kind of a reasonable medical device gross margin somewhere 60%, 80% with the relationship or I guess -- I guess, how high did the transfer payments seem to get to really realize that -- just I guess, adding 2 kind of subquestions on that. Do you expect any capacity increase in the future? And excluding this milestone payment last year, do you guys expect any gross margin benefit or improvement this year?

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

I'll turn over to Tim for the final point. But just when you -- and this will apply to all of our -- the VI (inaudible) inventions products as well. So when you launch a product, and the first thing you want to know is you get a stable product performing in the marketplace. And any product is small tweaks and engineering change orders. So until we have a stable product, we don't like to commit it to a low-cost environment that makes thousands of them in 1 -- just in a specific operation.

So some of these products are achieving stability right now, like the first portion of Pounce Arterial. Then, when the product is stable and we're satisfied stable, then we can really drive cost out. And there are 2 things helping us there. One is the cost volume profit relationship that helps absorb overhead. That really does that. And then the second 1 is we can lean out those lines specifically because we know we're making it in that exact variance forever more.

As far as SurVeil goes, as Tim has mentioned in the past, and all of these products, we built the fixed infrastructure to scale. So we don't see need for huge capital equipment when we do scale. And so Tim will talk about that. But in the early days, we're just overhead is not our friend. Volume is our friend to overcome that overhead absorption. Tim?

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

I really like the question. And if you go back and take a look at what the product gross margin was for the quarter, it was just under 61%. And I'm quite sure and convinced that it's significantly higher than the consensus estimate. But you'll have heard me comment during the modeling considerations portion of the script that we now expect product gross margins to range from mid-50s to high 50s. If you go back and compare to what we said during the February call, we said mid-50s.

So there's a reason why we're migrating favorably on the product gross margins, and that's because we're seeing the benefits of scale. Clearly, we had a really strong Q2. Product revenue outperformed our expectations and consensus. We're pushing that through the rest of the year. Justin, as you mentioned, you highlighted that there's a couple of new products. Obviously, we've got that reflected in on a modest level, but scale helps. And we're also becoming more efficient in the manufacturing.

As Gary mentioned, it's 1 thing to have a small number of products that you're manufacturing on a monthly basis or a quarterly basis, and that grows. But our teams are becoming more efficient in the manufacturing environment. And so we're getting the benefit of improved yields and being able to manufacture these products more effectively and efficiently. And that's what's driving the guidance there. In terms of when we can get to med tech like gross margins, I would say we've made a substantial step-wise function, higher improvement in product gross margins for the likes of SurVeil and Pounce over the last quarter.

And we continue to have scale. I think we'll continue to do that. We'll continue to be more efficient. But I won't be so bold to tell you precisely when we think we'll get there. But I will tell you that if we continue to grow at the rate that we're growing, it should probably be a couple of years, but if even -- but, again, we're very pleased with the performance and a lot of the credit goes to the ops team.

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

Yes. I mean, there are scenarios where we can get there in calendar '25, but we don't want to give -- we don't want to give the guidance for FY '25 quite yet.

Joseph Scott Conway - *Needham & Company, LLC, Research Division - Research Analyst*

Sure, sure. All right. Well, thank you very much for all the details, super helpful. And congrats on the quarter.

Operator

Our next question comes from Jim Sidoti from Sidoti & Company.

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

First one, a quick one. Other than that $1.4 million of catch-up revenue, was there anything in the quarter you would consider onetime that added to revenue?

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

No. That $1.4 million catch-up payment is really the 1 thing that was unique to the quarter that would -- could be considered to be more of a onetime.

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

Okay. And I know you're reluctant to give any product-specific guidance, but I'm sure you have internal projections for SurVeil. Can you just give us a sense, are you exceeding those internal projections and by approximately how much? on a percentage basis?

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

I like the question, Jim. I'll restrain myself from giving you an answer other than to say it's -- it's -- obviously, we had a really strong quarter in Q2, exceeded our expectations, exceeded consensus. You saw that we raised past the beat, which implies that we have confidence in the second half of the year. We have not changed our guidance with regard to the IVD and Coatings business.

So I think that probably gives you the insight that I want you to take away. We are very pleased with the performance with SurVeil, Pounce, and Sublime.

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

Okay. And then just a question on the sales team. I know you've made some changes to that last year. Is it time to expand again? And can you talk a little bit about international? You don't have any sales there now. Have you considered distribution for sales outside the United States?

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

We -- the short answer is, we have considered all options internationally, but like the Roman Empire, we want to be able to make sure we secure the U.S. market first. And we're trying to be quite disciplined on where we allocate investments on capital, especially given the show returns over the short-term horizon here versus too many long-term deep passes. So the short answer is no, not at this point, but it is not off the table. It will only be on the table if it doesn't impact our cash utilization. We don't want to spend more cash at this point to go to other geographies. But if there's a partner and a capability where we can demonstrate it's not the use of cash, we'll consider it.

And the first part of the question was, was that it I think that was?

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

on the U.S. sales force, are you happy with...

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

Yes. So look, we -- I'll tell you, we have concentrated and curated an amazing sales team here. And they continue to impress me, they're building territories from scratch, and that's never easy. Finally, people are not just saying Surmodics who people realizing us. We made a Morgan Stanley report recently on a KOL (inaudible) Morgan Stanley doesn't even cover us. But the short answer is, we will continue to look for opportunities to grow but it's not just a mass sprinkling of territories. We're really being quite selective with our sales leadership, where the heat maps are and where the opportunities lie.

Now Pounce venous and how that goes in the next couple of quarters could change our allocation of that because to cover territories expenses, which were salaries, commissions and expenses, Pounce Venous is a very high ASP product as is Pounce Arterial as well. And so if that allows us to start covering territory expenses at an accelerated fashion, then we still use the term go as we grow or grow as we go. We can see the territories we want. So we're not too far ahead of cash utilization. Cash is very important to us, as you can tell.

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

Right. Right. And it doesn't appear that you're going to need to raise cash anytime soon that the cash you have on the balance sheet is more than enough to fund the growth.

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

Yes. And I hope investors get the point of what we're seeing in this quarter is how we have managed cash looking forward and also how we've done it in this quarter.

Operator

Our next question comes from Mike Petusky from Barrington Research.

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

Tim, I may have missed this. Did you say whether the profit-sharing piece for SurVeil, like has that started? Are you guys participating in that at this point? Or is that not been calculated yet on these first orders?

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

Yes. Thank you for the question, Mike. Yes, we've communicated on this topic in the past. Probably weren't very clear on it here during our prepared remarks. But yes, the way the profit sharing works, it's not unlike what we have to do with our royalties. For those of you who followed the story for a while, you appreciate that given the accounting standards, we have to make an estimation of what our customers sell and what our royalty will be on the coatings part of the business.

It's not unlike that with regard to the profit sharing with SurVeil. So when we ship product to Abbott, we calculate based upon the unit shift what the profit sharing will be based upon a number of assumptions, including the selling price and including the number of units that are actually sold. So we have to take into consideration units that are used for promotional or samples that aren't charged as well as units that might expire. Recall, we have a 2-year shelf life.

So we're pretty conservative in these assumptions at the moment. We have yet to receive the first profit sharing report from Abbott. We'll have a little bit more insight on the first 1 when we get together for the August call. But there is an amount that's included in the product revenue, which obviously impacts the product gross margins, but we've not made any changes to our assumptions from what we included in Q1 relative to what we booked in Q2 and how we forecast for the full year. So no changes there.

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

Okay. So essentially, you're saying you could come back and say, okay, well, we did a reconciliation with Abbott and there's a disagreement so we have to sort of back off although it sounds like you're being -- you're trying to be conservative with this.

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

Yes. I think the probability of that risk without having perfect clarity would be low. I think that there's -- the probability, in my view would be that it would be favorable versus unfavorable. But I'm sitting here today on May 1st, not having received any reports from Abbott with regard to the key assumptions that we've modeled. We've gotten a little feedback in some insights that we've used in some market data, but I feel comfortable with regard to what we've included in our assumptions to derive or come up with our estimated profit sharing, Mike.

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

Okay. All right. Very good. And then I haven't heard this talked about, I don't think, in a while. In terms of of Abbott's plans for SurVeil OUS, have they communicated anything there as far as timing or even plans to do it?

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

There's no change. What they have communicated is that they want to really make sure they fill out this U.S. market first. And at some point, if they get to that, we'll have that discussion and an appropriate point if it's reportable, we will. But so far, no.

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

Okay. So not even like sort of like, hey, we sort of run this business for 6 quarters in the U.S. and then we start -- like there's nothing on the drawing board in terms of longer-term plan there?

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

Yes. We have not had those discussions yet.

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

We wouldn't have visibility to that at this point, Mike. They've not commented on that, nor have we asked quite frankly. But we're -- I think we're all focused on making sure that we're able to supply not only product, but technical data information that's useful for their marketing and selling and training purposes. We certainly would welcome the opportunity to produce more units for Abbott for sale in other international markets. But that's not what we're manufacturing today. It's only U.S.

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

Okay. And just last question. Obviously, the first couple of quarters of this fiscal have come in really strongly. I think a lot of people -- people we've talked to are sort of interested in what '25 could look like -- and I'm just curious, I mean, is there any chance that you guys may give sort of a little bit of a preview on that, say, before the fourth quarter conference call. Like is there a chance that maybe after the third quarter or something towards the end of this...

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

I want to say more likely not. And not because we're trying to be coy only. We have multiple hypotheses and assumptions that we're validating. And some of those data points, again, we're just launching a couple of products right now. So the way we look at fiscal '25 is we have hypothesis where those products get to. If it's above the low and then we then change our assumptions before that. And given the fact that we're so close to the end of the fiscal year, even then we wouldn't have as many data points as that would typically like to have. So I would say June until the November fourth quarter earnings call.

Operator

We are currently seeing no remaining questions at this time. That does conclude our conference for today. Thank you for your participation.