REFINITIV STREETEVENTS

EDITED TRANSCRIPT

Q3 2023 Surmodics Inc Earnings Call

EVENT DATE/TIME: AUGUST 02, 2023 / 12:00PM GMT

CORPORATE PARTICIPANTS

Gary R. Maharaj *Surmodics, Inc. - CEO, President & Director*
Timothy J. Arens *Surmodics, Inc. - Senior VP of Finance & Information Technology and CFO*

CONFERENCE CALL PARTICIPANTS

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

PRESENTATION

Operator

Welcome, everyone, to Surmodics third quarter of fiscal year 2023 earnings call. Please note that this call is being webcast. The webcast is accessible through the 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 results was issued earlier today and is available on the company's website as well. Before we begin, I would like to remind everyone that remarks and responses 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, operator, and welcome, everyone, to our earnings call for the third quarter of fiscal year 2023. Let me begin with a quick overview of what we plan to cover on today's call. I'll begin my remarks with a brief overview of our quarterly revenue results and the key drivers of our performance, followed by a discussion of our recent operational progress and thoughts on our outlook for the remainder of the fiscal year. Tim will then discuss our third quarter financial performance in detail and review our fiscal 2023 guidance, which we updated in our earnings press release today. We'll then open the call for questions. With that, let's get started with a review of our revenue performance.

In the third quarter of fiscal 2023, we reported total revenue of $52.5 million, representing growth of 111% on a year-over-year basis. Our total revenue performance was driven by exceptionally strong growth in our Medical Device segment, which increased 163% year-over-year, more than offsetting a 12% decrease in revenue from our In Vitro Diagnostics or "IVD" segment.

Our total revenue and medical device revenue growth benefited from the achievement of FDA premarket approval for our SurVeil™ drug-coated balloon. As a result of this achievement, we received $27 million of a milestone payment during the quarter from our commercial partner, Abbott, of which $24.6 million was recognized as revenue. I'll discuss this important accomplishment in further detail later in my remarks. I'm pleased to report that we delivered strong performance during the quarter on an underlying basis as well. Excluding the PMA milestone, we achieved total revenue growth of 12% year-over-year, driven by the Medical Device segment total revenue growth of 22% year-over-year.

This impressive performance in our Medical Device segment was largely driven by product sales. The Medical Device segment product sales increased 38% year-over-year, fueled primarily by our sales of our Pounce and Sublime products, along with strength across our product portfolio, including sales of our performance coating reagents. In our IVD business, the year-over-year softness was driven primarily by decreased sales across our core product lines as we saw several customers taking steps to manage elevated inventory levels

during the quarter. All in all, we were pleased with our revenue performance in the third quarter.

Shifting to an update on our recent operational highlights. During the third quarter, our team made important progress with respect to each of our three key strategic objectives for fiscal 2023, while continuing to advance our pipeline of vascular intervention products towards commercialization. I'll start by discussing our recent progress with respect to each of these objectives, which as a reminder are: one, to achieve FDA premarket approval or PMA for the SurVeil™ drug-coated balloon and then support our partner, Abbott, as they prepare to commercialize the product. Two, to advance the initial commercialization of our Sublime radial and Pounce arterial thrombectomy platforms; and three, to drive revenue and cash flow growth from our medical device performance coatings offerings and IVD businesses.

Beginning with our first strategic objective, securing the PMA for SurVeil DCB. We entered the third quarter fiscal '23 with strong momentum on the regulatory front, having secured formal feedback from the FDA's review team that provided the additional clarity in the process and content required to successfully amend our application for the PMA. As we shared by a press release on March 28, we believe the additional clarity to be obtained would enable us to prepare an amended PMA application for submission in the third quarter and secure the PMA in the fourth quarter of fiscal 2023.

We submitted this PMA application to the FDA in May, consistent with our stated expectations. In the months leading up to and following submission, our team continue to engage with FDA's review team to discuss and clarify aspects of our submission and to facilitate their review process. On June 20, we were proud to announce the receipt of the FDA premarket approval for our SurVeil drug-coated balloon. With this approval, our SurVeil DCB may now be marketed and sold in the U.S. to physicians for "percutaneous transluminal angioplasty after appropriate vessel preparation, of de novo or restenotic lesions less than or equal to 180 millimeters in length in femoral and popliteal lotteries, having reference vessel diameters of 4 to 7 millimeters."

Securing the PMA for SurVeil represents one of the most significant achievements in our 44-year history as an organization. It will enable us to provide physicians and patients with a next-generation option for the treatment of peripheral artery disease, one that leverages the culmination of our decades of expertise as an organization in developing and applying drug-eluting coating technologies.

The SurVeil DCB leverages our proprietary technologies and capabilities with a design that promotes more uniform drug distribution, more efficient drug transfer to the target region while reducing particulates and downstream emboli. This approval also represents further validation of the strong safety and efficacy profile of our SurVeil DCB, and the results of our 446 patient TRANSCEND clinical trial. As the two-year results of this trial demonstrated, the SurVeil DCB achieves clinical and safety outcomes that are consistent with the market-leading device. These results are despite the competitive device having 75% more paclitaxel compared to the SurVeil DCB.

Given the numerous challenges that had to be navigated in order to secure this approval, including the FDA has heightened concerns of whether use of paclitaxel for the treatment of peripheral artery disease beginning in 2019, it also represents a herculean accomplishment by our product development, regulatory and clinical teams made possible through their years of hard work, dedication and commitment to working in partnership with the agency to satisfy their questions. With the PMA now in hand, our team has been squarely focused on supporting our commercial partner, Abbott, as they prepare for U.S. commercialization.

We've been actively engaged with Abbott's commercial and operations team to refine the plan for SurVeil's commercial launch. As a reminder, under the terms of our agreement, we are responsible for manufacturing and supplying Abbott with product as they commercialize the SurVeil DCB. While we are limited in terms of what we can say publicly at this time with respect to the commercialization, we expect to receive Abbott's initial stocking order during the fourth quarter of fiscal 2023, with commercialization anticipated in fiscal 2024. We look forward to sharing more details in the future earnings call.

Since receiving the PMA, our team has been focused on all the pre-commercial activities to ensure our readiness to satisfy Abbott's initial stocking order as well as subsequent orders. We've started up the manufacturing engine for the SurVeil DCB with successful initial test runs of our production and quality processes. With respect to raw materials, we are well positioned to support the commercial launch. From a people standpoint, throughout this year, we have continued to retain experienced manufacturing team members focused on SurVeil production.

Teams who have been responsible for building thousands of SurVeil units in recent years to satisfy the clinical and regulatory needs. We've also hired several additional team members to provide future support as we scale. In short, we are well positioned with the capacity, materials and processes in place to meet the needs of our commercial partners.

Given Abbott's commercial distribution infrastructure, their market presence and expertise in vascular care, we're excited to be entering this pivotal stage of our partnership. We believe our next-generation drug coated balloon will complement and enhance their existing product portfolio, and we look forward to our continued collaboration with Abbott as we provide physicians and patients with a safe, effective and innovative solution that leverages our best-in-class technology to address the challenges presented by peripheral artery disease. On a related note, we were excited to see the FDA published a letter to health care providers on July 11 that summarize the agency's latest use of or the potential risk to paclitaxel-coated medical devices.

As I mentioned earlier in my remarks, paclitaxel has been an area of increased focus on regulatory scrutiny for the past five years since the FDA posted a letter to health care providers on January 17, 2019, sharing their concerns. The FDA follow-up letter published in July is titled "Paclitaxel-Coated Devices to Treat Peripheral Artery Disease Unlikely to Increase the Risk of Mortality." It states that the agency has reached a conclusion that the totality of available data and analysis does not support an excess mortality risk for paclitaxel-coated devices. It goes on to summarize the key data and analyses that supported this conclusion and clarify that the decision applies to all paclitaxel-coated devices.

We were also pleased to see the FDA state and the letter that they will work with device manufacturers to update product labeling based on the current available data. In terms of its implications, we believe this letter provides important closure with respect to the concerns that were initially raised by the agency in 2019. Like other devices in the market, the product labeling for SurVeil DCB does currently include a standard warning related to paclitaxel. The FDA noted in the July letter that they will work with device manufacturers to update the product leading based on the current data. We look forward to working with agency to make the needed updates to our SurVeil DCB labeling and expect this to be a fairly straightforward process.

Moving to our second strategic objective, advancing the initial commercialization of Sublime Radial and our Pounce Arterial Thrombectomy platforms. As I mentioned earlier, sales of our Pounce and Sublime products were an important contributor to the 38% medical device business product sales growth that we achieved in the third quarter. From a commercial standpoint, we are pleased with the execution of our direct sales team as they work with physicians at potential new accounts to navigate our products through value analysis committees. As a result of their efforts, we continue to make progress in expanding our base of customers, ending the third quarter with more than 215 customers for our Pounce and Sublime platforms compared to over 170 at the end of the second quarter, and we achieved our stated target for fiscal 2023 ahead of our expectations.

Given that we entered fiscal 2022 with just over 100 customers, we're pleased with the strong progress made over the first nine months of the fiscal year, especially considering the workforce reduction that we implemented during the second quarter. Our sales team continued to make progress in expanding our pipeline of prospective customers with a number of value analysis committees considering our products remaining in line with the March quarter despite the growth in new customer conversions, and we remain pleased with the reordering we're seeing from existing users as well.

In terms of the size of our team, we're pleased to see continued stability during the third quarter with 22 territory managers at quarter end with an average tenure of 13 months compared to 21 territory managers at the beginning of Q3. From a market education standpoint, we continue to make progress with respect to our PROWL registry study, which we initiated during the third quarter. We believe this study will further underscore the compelling therapeutic benefits of our Pounce Arterial Thrombectomy System as used in real-world settings. We are enrolling patients at two sites at quarter end, and we continue to anticipate sharing interim data with current and prospective customers as part of our efforts to educate the market and raise awareness.

Based on the progress made over the first nine months of our fiscal year, we believe we are squarely in the process of graduating from initial market entry to what we referred to previously as the early market development stage for our commercialization effort. As we look ahead to the remainder of fiscal '23, we expect our customer base to grow to more than 250 accounts at year-end and generate Pounce

and Sublime sales growth in excess of 250% year-over-year as we continue to focus on raising awareness of the capabilities and advantages of these platforms, crossing the chasm, so to speak, by converting mainstream users as well as early adopters and facilitating strong utilization across the entire user base.

In addition to driving adoption and commercial traction with respect to our Pounce and Sublime portfolio, we are continuing to expand this portfolio with our new product pipeline. I will discuss this progress on this front in a moment. Let me give you a nugget here about Pounce and Sublime revenue. They have now contributed more than $1 million of revenue per quarter for two consecutive quarters now. This, while small and a relative scale is fantastic news. It demonstrates the power of developing and commercializing devices that can change the standard of care and we're doing this with a sales team that is still in the early innings and less than 1/10 the size of larger medical companies. As you've heard me say in the past, the future has already been created. It's just not evenly distributed yet, here in lies the potential of Surmodics' vascular intention strategy.

Turning to our third strategic objective, driving revenue and cash flow growth from our Medical Device performance coating offerings and IVD businesses. We're pleased to see revenue from Medical Device Performance Coatings offerings in our third quarter increased 11% on a year-over-year basis, driven primarily by strong sales of performance coating reagents. This was moderated partially by the 12% decrease in our IVD business that I discussed earlier. The decrease does not appear to be driven by market competition but by multiple macroeconomic factors impacting the entire IVD industry, including the decrease in demand for COVID-testing products and stabilization in supply chains, reducing the need for elevated safety stock.

These together, revenue from these categories increased 4% year-over-year in the third quarter, consistent with our long-term expectations of low to mid-single-digit growth, generating cash flow to support our strategy. Lastly, in addition to our progress with these key objectives, we continue to advance our new product pipeline. With respect to Pounce Arterial Thrombectomy Platform, we're continuing to enhance the capabilities of this portfolio to expand the addressable market with new product introductions and clinical indications.

Most notably, on June 14, we announced the receipt of FDA 510(k) clearance for Pounce Low Profile or LP Thrombectomy System with a clinical indication for use in vessels ranging from 2 to 4 millimeters diameter. The addition of Pounce LP will expand the range of the Pounce Arterial system by providing systems to physicians with a product designed to facilitate efficient removal of organized clots in smaller vessels, such as those found in the peripheral arteries below the knee.

Securing regulatory clearance for Pounce LP, takes us one step closer to our commitment to providing patients and physicians with a comprehensive suite of mechanical thrombectomy solutions to address acute limb ischemia across the entire peripheral vasculature, helping to reduce amputations. We look forward to commencing this limited market evaluation of our Pounce LP Thrombectomy System by the end of the first quarter of fiscal 2024 and entering full commercialization following its completion. With respect to our Pounce Venous Thrombectomy System, we continue to make progress through our limited market evaluation, which we initiated during the second quarter to collect physician feedback on the systems used across a variety of cases.

Our progress is initially paced by limited product availability, but we were able to work through this constraint during the quarter and accelerate the pace of evaluations. We've been pleased to find physician users emphasizing their appreciation for the system's simplicity, ease of use steering cases. And the feedback we've been obtained so far has been nicely informative as we prepare for commercialization. We'll continue to progress through this limited market evaluation during the fourth quarter with the goal of entering commercialization in fiscal 2024.

And lastly, at the end of April, we commenced limited market evaluation of our .035 Sublime Radial Access mMicrocatheter. This is part of what will be the industry's first suite of torqueable, high-performance microcatheters designed for peripheral interventions and available in both radial and femoral lengths. We believe these Sublime microcatheters will enhance our existing Sublime Radial access platform by empowering physicians with tools specifically designed to cross difficult lesions, helping to facilitate the adoption of peripheral treatment via radial approach. The feedback was obtained in the .035 microcatheters, to date has been positive, and we look forward to initiating limited market valuations of our .018 and .014 microcatheters, the remaining products in this microcatheter portfolio.

I'm incredibly proud of our operational and financial accomplishments this past quarter. Our team drove important progress on each of our strategic objectives that we prioritize for fiscal '23. This progress enabled us to deliver impressive financial results, including $52.5 million of total revenue, $21.4 million of operating income and $24.6 million of adjusted EBITDA. Excluding the $24.6 million of revenue related to the SurVeil PMA milestone, we delivered total revenue growth in the third quarter of 12% year-over-year, and we were essentially breakeven on an adjusted EBITDA basis. As I mentioned in our last earnings call, cash flow remains a priority for organization. From a cash flow perspective, we generated $25.4 million of cash during the quarter to further strengthen our balance sheet, ending the quarter with $44.6 million of cash and equivalents and approximately $61 million in incremental debt financing available under our existing credit facility.

Excluding the $27 million milestone payment, we were also pleased to reduce our quarterly cash burden to $1.6 million of cash use, exceeding our stated objective of $3.5 million to $4.4 million of used cash for the quarter as we continue to control our expenses and allocate capital thoughtfully following the implementation of our spending reduction plan implemented earlier this year. And lastly, as we continue to advance multiple key products in our pipeline, positioning Surmodics to drive future growth and value creation through innovation in the years to come.

As Tim will discuss, we are raising our guidance today to reflect our impressive financial and operational performance in the third quarter as well as our updated expectations for the balance of the fiscal year. We remain committed to perpetuating our recent momentum and bringing fiscal '23 to a strong conclusion. I'd like to conclude my remarks today by congratulating the entire Surmodics team on the many achievements made during this past quarter that would not have been possible without their hard work and dedication. With that, I'll now turn the call over to Timothy Arens, our Chief Financial Officer, to discuss our third quarter fiscal 2023 results and updated guidance. Tim?

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

Thank you, Gary. Unless noted, all references to third quarter results are on a GAAP and year-over-year basis. Total revenue for the third quarter of fiscal 2023 increased $27.6 million or 111% to $52.5 million. As Gary mentioned, our total revenue in the third quarter of this year included $24.6 million of revenue recognized from the $27 million milestone payment received for obtaining premarket approval of our SurVeil drug-coated balloon. Excluding the impact of this milestone payment, third quarter total revenue grew 12%. Product revenue increased $1.7 million or 13% to $15.7 million in the third quarter of fiscal 2023. The increase was driven by broad-based product sales growth in our Medical Device business, which increased $2.6 million or 38%, driven primarily by increased sales of our Pounce Arterial Thrombectomy and Sublime Radial platforms as well as our performance coating reagents.

IVD product revenue decreased $810,000 or 11% to $6.4 million. The decrease was driven primarily by several customers actively managing their inventory levels. The IVD industry is adapting to respond to multiple macroeconomic factors, including the decrease in demand for COVID testing products as well as stabilization and supply chains, which are reducing the need for elevated safety stock. Royalty and license fee revenue increased $25.4 million or 288% to $34.2 million. Excluding $24.6 million of license fee revenue recognized in the third quarter of fiscal 2023 from the SurVeil PMA milestone payment, royalty and license fee revenue increased 8%. Royalty revenue from our Performance Coatings increased $450,000 or 6%. R&D services revenue increased $520,000 or 24% to $2.7 million. The increase was primarily due to higher customer demand for our Performance Coating Services in our Medical Device business, which was impacted in the prior year period by our customer supply chain challenges.

Moving down the P&L. Product gross margin in the third quarter of fiscal 2023 was 55.8% compared to 63.1% in the prior year period. The decline in product gross margin was driven by the adverse mix impact from increased device product sales, which have lower product gross margins due to low production volumes during the scale-up phase following initial commercialization. R&D expense, including costs related to clinical and regulatory activities, decreased $1.7 million or 13% to $11.2 million in the third quarter of fiscal 2023.

The decrease in R&D expense reflects the benefits from the spending reduction plan we implemented during the second quarter of 2023. SG&A expense was $12.9 million and was unchanged compared to the prior year period. Contingent consideration gain of $830,000 resulted from a noncash fair value adjustment to acquisition-related contingent consideration liabilities. Our Medical Device business reported operating income of $21.8 million compared to an operating loss of $7.3 million in the prior year period.

The year-over-year change reflects the $24.6 million in license fee revenue recognized on the SurVeil PMA milestone payment in the third quarter along with disciplined expense management, broad-based revenue growth and the aforementioned contingent consideration gain. Our IVD business reported operating income of $2.9 million compared to $3.4 million in the prior year period. IVD operating income was 44% of IVD revenue compared to 46% in the prior year period.

Turning to income taxes, in the third quarter of fiscal 2023, we reported income tax expense of $13.3 million compared to an income tax benefit of $1.5 million in the prior year period. Given the magnitude of income taxes this quarter, I'd like to take a moment to outline the key drivers, starting with the $24.6 million in revenue recognized on the PMA milestone payment. In the third quarter, as a result of the milestone payment, we shifted from a taxable loss to a taxable income position, resulting in significant tax expense. Also contributing to our income tax expense was a recently effective IRS requirement to spread the deduction of U.S. R&D expense over a 5-year period. As a reminder, we are no longer recording tax benefits for deferred deductions or net operating losses as a result of having established a full valuation allowance against U.S. deferred tax assets at the end of fiscal 2022.

GAAP net income in the third quarter of fiscal 2023 was $7.3 million or $0.52 per diluted share compared to a net loss of $5.7 million or a loss of $0.41 per diluted share in the prior year period. Non-GAAP net income in the third quarter of fiscal 2023 was $7.3 million or $0.52 per diluted share compared to non-GAAP net loss of $4.7 million or a loss of $0.34 per diluted share in the prior year period. Non-GAAP adjusted EBITDA in the third quarter of fiscal 2023 was $24.6 million compared to adjusted EBITDA loss of $3.1 million in the prior year period. Adjusted EBITDA includes adjustments for contingent consideration gain in the third quarter of fiscal 2023 and for stock-based compensation expense in both periods. Our earnings press release includes detailed reconciliations of GAAP to non-GAAP measures.

Moving to the balance sheet, we began the third quarter of fiscal 2023 with $19.2 million in cash and $29.3 million in long-term debt. Cash provided by operations during the third quarter was $25.9 million, reflecting the $27 million PMA milestone payment from Abbott. Capital expenditures totaled $470,000. We ended the quarter with $44.6 million in cash and $29.4 million in long-term debt as of June 30, 2023. Long-term debt includes $5 million in borrowings on our $25 million revolving credit facility and $25 million in borrowings on our $100 million term loan facility. As of June 30, 2023, we had approximately $61 million in debt capital available, consisting of $50 million on our term loan availability and approximately $11 million of incremental availability on our revolving credit facility, which is subject to borrowing base requirements.

Turning now to fiscal 2023 guidance. We updated our fiscal 2023 revenue guidance today to reflect our performance in the third quarter as well as our revised expectations for the remainder of fiscal 2023. We now expect fiscal 2023 total revenue to range from $130 million to $132 million, representing an increase of 30% to 32% over the prior year. Excluding the estimated revenue recognized on the PMA milestone payment, we expect total revenue to range from $105 million to $107 million. This compares to our prior range of $103 million to $106 million or an increase of 3% to 6% over the prior year. We now expect fiscal 2023 GAAP diluted loss per share to range from a loss of $0.55 to a loss of $0.40 compared to our prior range of a loss of $2.30 to a loss of $2.

Non-GAAP diluted loss per share in fiscal 2023 is expected to range from a loss of $0.29 to a loss of $0.14 compared to our prior range of a loss of $1.98 to a loss of $1.68. I'll now share a few additional considerations for modeling purposes. Our updated total revenue guidance reflects the following assumptions for the full fiscal year. Revenue for our 2 businesses, Medical Device and IVD is expected to be approximately 80% and 20% of revenue, respectively. Product revenue is expected to be approximately 46% of total revenue. Our guidance for product revenue does not include any sales of the SurVeil(TM) DCB product in our fourth quarter. Revenue associated with our legacy medical device performance coating offerings is expected to grow in the mid- to high single digits. IVD revenue is expected to decline in the low single digits.

Abbott SurVeil license fee revenue is expected to range from $29.5 million to $30 million, which includes approximately $25 million in revenue recognized in fiscal 2023 on the $27 million PMA milestone payment. This assumes fourth quarter revenue associated with the PMA milestone of $400,000. In the prior year, total Abbott SurVeil license fee revenue was $5.7 million. Our updated diluted loss per share guidance reflects the following full year assumptions: Product gross margin in the high 50s, reflecting continuing mix impact from growth in device sales during the manufacturing scale-up phase. R&D expense in the range of $48.5 million to $49 million and SG&A expense of $52.5 million to $53 million. Interest expense of approximately $3.4 million.

Finally, our updated EPS guidance reflects full year tax expense of $4 million to $5 million. This assumes a sizable tax benefit in the fourth quarter of approximately $8.5 million to $9.5 million. Lastly, with respect to cash utilization, we anticipate that we will finish the fiscal year with approximately $37.5 million to $38 million of cash, with cash used in the fourth quarter of approximately $6.5 million to $7 million, which includes approximately $3 million in estimated cash tax obligations as a result of the PMA milestone payment. This reflects our disciplined expense management, the spending reduction plan implemented in the second quarter and our active management of working capital. With that, operator, we would like now to open the call to questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) One moment, please, while we poll for questions. Our first question is from Brooks O'Neil with Lake Street Capital Markets, please go ahead.

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

Good morning, since I have about 10 questions, I'm going to have to queue up multiple times here, but I'll try to follow your guidance. The first question I have is, how do you think the FDA declaration that there is no negative effect from paclitaxel to impact the ultimate success of SurVeil?

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

It's quite positive actually. If you look at the potential for growth of paclitaxel devices, it's not quite penetrated, and it's been strained because of this 2019 labor warning that's now been removed. And one of the restraints was the marketing and commercial programs to drive market adoption were basically stunted by the FDA's label warning. And so now I believe all companies can get back into demonstrating what paclitaxel can do as an anti-restenotic drug on both stents and drug-coated balloons in the distal peripheral vasculature.

So I think it's going to help drive the market. What it means to us, and I know Tim is closer to some of this market data, but it is about $1 billion potential for this 0.5 million procedures per year. But for us, in particular, with Abbott as a commercial partner, we have the trifecta, I believe, and that momentum. So the timing is great. We have a technically superior product. And we have a clinical trial, the only clinical trial that a pivotal worldwide trial that demonstrates that technical superiority.

This unwinding of the label warning will allow for the market growth opportunity to get back into full ball and then we have the commercial strength of Abbott Vascular. They are really well known for their ability to move the market in terms of drug-eluting devices. So that trifecta, we believe, it's going to give us a multiplicative impact as we grow. Now we'll stay tuned and we'll tell you more about that and what that means for fiscal '24. But the trade winds are blowing favorably because of it.

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

Gary, I would just add for Brooks and other benefits. We have heard from several physicians that there are still hospitals and accounts that have restricted the use of paclitaxel devices. So obviously, with the FDA changing its position, those restrictions should be lifted and should have a greater opportunity in terms of addressing the need to treat patients who are suffering from peripheral vascular disease with the drug coated balloon. So we'll be looking closely to the data on this over the following for the next couple of quarters. So stay tuned.

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

Great. At the risk of being accused of achieving, I'm going to combine questions 2 and 3 and just ask you, can you tell us the key steps and timing that you need to take to prepare for Abbott's launch of the product? And then can you help us begin to think about the impact of SurVeil on Surmodics results in fiscal '24?

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

Sure and Tim is really connected to our operational. So I'll turn part of that over to him pre-commercial activities with Abbott. But really, the first thing was to secure materials, and we're in good shape. It might have increased some inventory balances a little much, especially paclitaxel is not inexpensive drug to acquire. But on the raw materials and supply chain side, we're secure and we're prepared for whatever Abbott has in their plans.

The second thing you've heard me talk about a cold start of a diesel engine in winter.

And so we have started that up. We have been able to retain most of the team members despite the reduction in force we had earlier this year and then we've hired some more people so that we have the ability for future scale here as well. So that's been going well. It takes a while to fulfill these orders that I'll pass it on to Tim.

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

Thank you, Gary. Well said. Brooks, I think the key takeaway for us is that we will be prepared. We have the people, materials and equipment to support Abbott's commercial launch. Notably, our manufacturing team has built thousands and thousands of SurVeil units over the years to satisfy our clinical, regulatory and development efforts. So we've got a lot of experience. We have the experienced team here. They've been in place for years, and we've actually have restarted and have done test manufacturing runs just to ensure that we're ready. And there is still work to be done more on the administrative front, but we're waiting for the (inaudible) and then we'll start manufacturing products.

And the second thought was, what do we expect, I guess, I'll ask you to stay tuned. We have not yet received the final appeal. But what we have discussed in the past, we had talked, I think, previously that Abbott had shared perspective in terms of their forecast. They've done so again. We like what we're seeing. We'll have more to say on this topic probably as early as Q4.

Operator

Thank you. Our next question comes from the line of Michael Matson with Needham & Company. Please go ahead.

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

Thanks, just a few more on SurVeil. So I guess just starting with the DCB market, can you remind us where pricing is, I'm not asking where Abbott is going to price their product, but I seem to remember that the DCB is really launched were kind of in the $1,200 range, I'm remembering correctly, but I think it's come down quite a bit. Do you have a feel for where just kind of the typical pricing is these days?

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

It's a great question, Mike. And what I can tell you is looking at the IMS data, industry data, these are sales into hospital accounts. We still see list prices around $1,400 to $1,500 per device. As you can imagine, every manufacturer is probably having some discount relative to their products. So I can't really speak to what the ultimate pricing is, but the list price has remained constant over the last several years.

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

Okay. And then can you just remind us about what you've said about the economics of the Abbott deal. I know you haven't given specific numbers, but it's kind of convoluted, I guess, in the way that it works from what I remember. And then would it be crazy to assume that Surmodics might be capturing roughly 50% of the kind of end market price in terms of value that you're getting?

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

So I'll walk through great question. I appreciate the question. I know this is a topic on many people's minds. The economics really, I think probably the best way to describe it is that Surmodics will receive 2 revenue streams. The first revenue stream will be for the product shift to Abbott, and we call it a transfer price, and we'll recognize that revenue at the moment the product is shipped out of our docs. And then the second piece is what we call profit sharing. And the profit sharing, obviously, there's a formula, it works somewhat like this. I think we've articulated this a bit in the past, but Abbott will back out the transfer price and they'll have a gross margin.

I think we can appreciate how to get to gross margin. They also can deduct what I would consider a typical multinational strategic sales and selling expense percentage from the revenue. And so then basically what remains is what we call the profit pool, and we've characterized this in the past that it's not quite 50-50, but it's close. And so I would say in terms of thinking about what percentage of the revenue on the sale price of SurVeil, the 50% might be high, but I think we've highlighted in the past that from a whole product solutions or a partnered product solutions perspective, Surmodics is approaching that 50% level. We'll talk more about this, I'm sure, as we kind of get past the initial commercialization, but it is very attractive.

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

Okay. And then when you report your fourth, I understand you're not including any kind of survey revenue in your guidance now. But when you report your fourth quarter, is it safe to assume that you're going to factor something into the '24 guidance, some assumption around SurVeil revenue, continue revenue guidance and earnings guidance?

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

Another great question. Yes, that is the expectation. Gary and I will have more color and context to provide on SurVeil, probably during our November earnings call.

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

Okay. Got it. All right. And then just unrelated to devices or SurVeil on the IVD business, just the decline is a little concerning, I guess, is I mean, how long do you think this is going to last? Is this kind of going to be like a 4-quarter kind of a step down that last 12 months and then you kind of lap it and it starts to grow again or something like that?

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

Tim and I will after the ACC meeting with Joe, our President of that business last week. And if you look, Mike, I don't think you track IVD industry, but it's been whipsawed around and the idea was whipsawed around because of COVID. Now we are a smoothing function on that because we had quite a few reagents and stuff in COVID. And so we didn't get it sold around as much. And 12% is not as much as a lot of the rest of the industry saw. So what we've heard is that the industry hopes to lap that comparable. We don't have enough detailed analysis to know specifically for IVD business, how that lapping is going to work. But we do understand that there were a lot of customers who had geared up for a lot of reagents with high expectations, and they just have to work through that inventory. Tim, I know you have some color as well.

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

Yes. Thank you, Gary. Mike, I think it's really important to recognize that our IVD business has gone through kind of a soft period here over the last several quarters. If you consider and contemplate the guidance that we provided and the percentage of our revenue that's being generated by IVD, you'll come to the conclusion that IVD is going to be returning to growth in our fourth quarter.

We're starting to see some of the customers who have delayed or slowed their purchases. We're seeing some of those come back online. I think we feel pretty confident that this is not going to persist much longer. That's not to say that there could still be some general softness on the business, but we like where we sit today, and we'll have more to say about these macro impacts here in a couple of months.

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

Okay. Got it. So do you feel like you're kind of already several quarters into the slowdown (inaudible).

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

Yes and again, the entire industry in these types of regions have gone through this in a bigger fashion.

Operator

Our next question comes from the line of Michael Petusky with Barrington Research. Please go ahead.

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

So Tim, I guess I wanted to ask on the initial stocking order, you will be able to recognize revenues in Q4 from that initial stocking order. It sounds like you just said that correct?

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

No, that is incorrect. The stocking order. So Mike, just to be clear, let's rewind a bit. We will not recognize revenue on the stocking order until the product leaves our dock. And so you can infer from my comments here that we do not anticipate that we'll be shipping product before the end of September. Just to be clear, the receipt of an Abbott to manufacture SurVeil is a distinct part of the process. Another distinct part of the process is when Abbott wants to receive the product shipment.

So Abbott has to decide when they want to receive the shipment. And as you can imagine, it probably has something to do with when they're thinking about the launch. I will also just let folks know, there's 20-some SKUs. And so it's yet to be determined are we shipping all the SKUs simultaneously? Or does Abbott want to receive certain SKUs. So we'll have a lot more. It's exciting, but we're in a position here of having received the PMA and working with Abbott's commercialization, and we'll have a lot more information over the coming quarters and months.

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

And remember, the initial stocking order, we have up to 120 days, and we might use all of that to produce that product available to be shipped. So it takes us a couple of months. So up to 4 months to actually cool the engine and make sure we can deliver that product when they need.

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

And then just shifting real quick on the side of (inaudible) Gary, you sort of laid out that, hey, the progress we've made, the $1 million revenue each of the past 2 quarters, we've made with a small sales team, a fraction of the size of some competitors out there, given that you now have some breathing room in terms of cash and likely over the next 12 months or so cash generation, I mean, does it make sense to look towards expanding that team and for really putting some muscle to that effort?

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

Yes. I'm glad you picked up on that. And the reason I said it is a lot of investors that says, we have no idea of the scale of this percentages don't mean a whole lot. So I wanted to at least let a little bit out that these products are generating over $1 million per quarter, and we expect that to grow. There are a couple of things. One, we do have to remain disciplined in our allocation of capital. That being said, as these products get more traction of value analysis committees and up to and including group contracts when you have those needs that are pent up from customers, we're going to strategically increase the size of where the territories where we can have territory managers. Right now, we're constrained. But as we look into what we're doing in fiscal '24, we'll strategically do it. I want to stop short of saying we're going hog-wild and just adding dozens of territory managers.

We have a very, very sharp small team now. And what we're looking for are really a player or hungry who can really do justice to the quality and call of these products. And you've heard me wax poetic where I go to conferences and people say these products have had not been created at the end. And so not a single product in our vascular interventions portfolio exists outside of Surmodics. And that's a very important thing. So to answer your question, we'll have a little more color in Q4, but it's a strategic dosing and adding high-caliber sales people, not necessarily doubling the sales force in the next 3 months. There's a limit to how much we can reasonably staff support with the high quality of service that our current sales team does as well. So we'll add us to you, but can't get over the cash barrel too much.

Operator

Our next question comes from the line of Jim Sidoti, with Sidoti & Company. Please go ahead.

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

Gary, how many sales folks does Abbott have that will focus on SurVeil?

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

I don't know the answer, but it's the Abbott vascular sales force, Tim I don't want to guess. It's going to be 100.

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

I remember, Jim, when we think the agreement with Abbott, we had all that information and data honest I have not looked at that.

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

Well, what's changes the acquisition of CSI who had several hundred, but those were coronary and peripheral.

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

So it's large and I would say it's probably, as you think through large Medtech competitors in the space, I would say Abbott's size of their sales force is probably well on the dartboard with everyone.

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

Yes. And look, what I like about the setup. So I would say, Brooks, the question is clearly matches any of the large strategics. And with the acquisition of CSI, I expect that what's nice about it is, at least in my opinion, I'm not speaking on behalf of Abbott here, but in my opinion, Abbott has an incredible stent in (inaudible) I mean you need a trifecta for this vessel, right? You need a sense, you need atherectomy to prepare the vessel and you need a drug-coated balloon. And what I'm excited about is as the Vascular division has all 3 in the arsenal now, and they are formidable sales and marketing organization. So we feel really good about that.

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

And how do you feel about your capacity? Do you think you need to add to ramp up to Abbott's demand? Or do you think that you have enough folks and equipment on hand to meet Abbott's demand?

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

Tim and our operations team have been really carefully monitoring that. As I said, we put the better raw materials component, I don't want any ups there. But Tim, if you're on to chat, I mean we have multiple ships we can go to and stuff.

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

That's right. I think I've addressed this. We're ready, Jim. I think we're ready to support Abbott's commercialization and what their needs are, what we expect there needs to be over the next 12-plus months, not only from an equipment perspective but also from a personnel perspective and raw materials perspective.

We're looking forward to the possibility of the future where we're going to be constrained, and we have to think differently about people and equipment and space. But I think at least for the next 12-plus months, we should be in good shape. And keep in mind one thing, I may have said in the past, but we have proprietary manufacturing technology. I don't know if anybody else has, but I know we have it, which where we use robotic automation to coat the drugs on these devices. These are not trivial low tech components. So in all of the time, we had a mind to when we do have to manufacture these are robotically controlled machines that actually coat the drug on the product. So those manufacturing cells have a lot of scale potential.

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

All right. And then, Tim, can you just talk a little bit about taxes. Why are you going to get the refund in the fourth quarter? Is the $3 million payment, is that all you need to pay on the milestone payment? And when do you think you'll be in a position where you'll be paying cash taxes? Do you think that will happen in fiscal 2024 fiscal 2025?

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

I'll hold off on the second part of your question, James. We still need to do the work to think through fiscal '24 and create our plan, and we'll have a lot more to say about guidance in November. But yes, you're right, the tax bill, the cash tax payment that will be into the IRS, I believe at September 15 will be approximately $3 million. And it's for the entire business, but obviously driven by the SurVeil milestone payment. It is a little wacky that we have a huge tax expense here in Q3, and then we're going to revert to a tax benefit in the fourth

quarter.

That's because we're back in an operating loss position. And you can do the guidance and you will recognize that we will be in an operating loss position. We'll have a tax benefit. That's probably going to put us in a position where it's going to be were you don't see it very often, but we're going to be in a position where I expect that we'll even have a favorable and positive on GAAP EPS and non-GAAP EPS. But if you combine the 2 and the IRS and from a tax perspective, you don't smooth this stuff. But if you combine Q3 and Q4, you actually have about of the $4 million tax expense. And unfortunately, it just makes it really lumpy, and that's probably the best way to describe it. We'll get through the lumpiness here, and we'll have about a $3 million tax payment, as I mentioned. So cash is really the thing we're paying attention to here.

Operator

Thank you, ladies and gentlemen, as there are no further questions, that concludes our conference for today. Thank you for your participation. You may now disconnect your lines.