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PRESENTATION

Operator

Welcome, everyone, to Surmodics Fourth Quarter and 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 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 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 also includes reference 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 Gary Maharaj, Surmodics' President and Chief Executive Officer. Please go ahead, sir.

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

Thank you, operator. Welcome, everyone, to our fourth quarter and fiscal year 2023 earnings call.

First, let me provide you with a brief overview of what we plan to cover today. I'll start off by discussing our financial performance for the quarter and the full year, followed by an update on our recent operational progress and thoughts on our outlook for fiscal 2024. Tim will then cover our fourth quarter financial performance in greater detail and review our fiscal '24 guidance, which we introduced in our earnings press release today. We'll then open the call for questions.

With that, let's begin with a discussion of our financial performance. In the fourth quarter, we generated total revenue of $28 million, representing 8% year-over-year growth. Our revenue performance exceeded the high end of our guidance range, which implied year-over-year growth of 5% for the fourth quarter due to strong performance in both of our business segments. Importantly, our total revenue performance in the fourth quarter was impacted by a $1 million headwind related to the year-over-year decline in the SurVeil DCB license fee revenue. Excluding the SurVeil DCB license revenue, we achieved total revenue growth of 12% year-over-year.

Revenue from our Medical Device segment grew 8% year-over-year to $21 million. This again, despite the $1 million headwind from the year-over-year decline in SurVeil license fee revenue. Excluding this license fee revenue, our Medical Device segment delivered 15% revenue growth year-over-year, fueled by increased royalties and license fee revenue from our Performance Coatings, product sales, including major contributions from our Pounce Arterial Thrombectomy platform and R&D services revenue.

We're also quite pleased to see robust contributions from our In Vitro Diagnostics or "IVD" segment as well. As we had anticipated in our last earnings call, our IVD segment returned to growth in the fourth quarter, increasing 7% year-over-year to $6.9 million, with customers returning to more normalized purchasing patterns after taking steps in recent quarters to manage COVID era elevated inventory levels.

In addition to our revenue performance in the fourth quarter, we achieved notable year-over-year improvements in our operating results, delivering adjusted EBITDA of $1.7 million, a $4.2 million improvement compared to the fourth quarter of last year. Importantly, we generated $1.3 million of cash flow from operations during the quarter as well.

Now it's important to note that our fourth quarter performance was favorably impacted by the delay of certain product development activities and investments in our commercial organization that we had contemplated in our full year guidance. We did this while we focused on executing against the SurVeil stocking orders, which I will describe shortly. We expect to resume these activities and investments in fiscal 2024.

Our financial performance in the fourth quarter culminated in a strong year overall. We delivered total revenue of $133 million in fiscal 2023, representing growth of 33%. Our fiscal 2023 revenue included $29.6 million of license fee revenue related to our SurVeil DCB, including $25 million recognized in connection with our achievement of the PMA approval compared to $5.7 million in fiscal 2022. Excluding SurVeil DCB license fee revenue, we grew total revenue by 9% year-over-year in fiscal 2023, driven by 14% growth in our Medical Device business, which more than offset a 3% decrease in our IVD business.

We also closed out the year strong from a capital standpoint. Cash provided by operations in fiscal 2023 totaled $10.5 million, and we ended the year with over $45 million of cash and investments to support our future operations.

Turning now to our operational progress in the fourth quarter. We are pleased to bring fiscal 2023 to a strong close by delivering on the three strategic objectives that we laid out at the beginning of the year, which, as a reminder, were as follows: first, to achieve FDA premarket approval or "PMA" for our SurVeil DCB and support our partner, Abbott, as they prepare to commercialize the product; second, advance the initial commercialization of our Pounce Arterial Thrombectomy and Sublime Radial platforms; and third, drive revenue and cash flow growth of our Medical Device Performance Coatings offerings and IVD businesses.

With each objective as our context, I'll discuss our progress during the fourth quarter with respect to each one, beginning with SurVeil. After securing the FDA PMA for SurVeil, which we announced on June 20, our team has been intently focused on supporting Abbott, our commercial partner, as they prepare for U.S. commercialization. As we shared in our last earnings call, our top priority during the fourth quarter was to ensure we added capacity, materials and processes in place to manufacture and efficiently supply Abbott, the product, and address their anticipated demand. With respect to each of these key areas, we believe we are well positioned to support Abbott's future launch and initial commercialization of the SurVeil DCB.

With this as a backdrop, I'm pleased to report that we received Abbott's initial stocking order in mid-August, consistent with our stated expectations. Our team began manufacturing products through the remaining weeks of the fourth quarter, and the production process has been running smoothly. In October, we made the first of our shipments for the initial stocking order, generating our first commercial revenue related to the SurVeil DCB in the first quarter of fiscal 2024.

As a reminder, when shipping SurVeil orders to our commercial partner, we recognized two revenue streams under the terms of our agreement and agreed upon transfer price per unit and an estimate of the profit sharing, both of which will be reported as product revenue upon shipments within our Medical Device segment. As we have shared previously, we expect to fulfill Abbott's initial stocking order through multiple shipments following that initial shipment made in October, with additional shipments in the remaining months of our first fiscal quarter.

In tandem with this effort, we've continued to engage with Abbott's vascular team as they plan to commercialize the product. While we are limited in terms of what we are able to communicate publicly about Abbott's commercialization plans, I'm pleased to share that we expect the commercial launch of the SurVeil DCB will commence in the first half of calendar 2024.

We're energized by our recent pace of progress and the prospect of bringing SurVeil DCB to physicians and patients, and we're equally excited of its potential as a key growth catalyst for the following reasons. From a product standpoint, SurVeil reflects our industry-leading expertise in developing drug delivery and drug coating technologies. Its patented coating technology provides unmatched uniformity and consistency of drug distribution, along with lower particulate generation and downstream emboli. Its design and features enable it to achieve therapeutic outcomes consistent with the most prominent drug-coated balloon in the market, a device which uses 75% more paclitaxel. And as the 2-year results of a full 446-patient head-to-head TRANSCEND trial demonstrated, as we look forward to sharing a 3-year results of this trial, which will be presented at VEITH Symposium on November 15.

From a market standpoint, we believe that SurVeil DCB addresses a $1 billion market opportunity in peripheral artery disease based on estimated 500,000 above-the-knee procedures performed in the U.S. each year. Of these 500,000 procedures, approximately 1/4 of them are currently being addressed using drug-coated balloons, which provides a significant opportunity for SurVeil DCB.

We're also pleased to see the resolution in the marketplace about potential risks posed by paclitaxel-coated devices. In its letter to health care providers on July 11, the FDA communicated that the risk of mortality associated with these devices is no longer supported based on the totality of the available data and analysis. We believe that this may be favorable to increasing paclitaxel drug-coated balloon market adoption. Importantly, the product labeling for our SurVeil DCB is consistent with the FDAs updated view.

Lastly, from a partnership standpoint, we believe Abbott is well positioned to take advantage of these attractive market dynamics in 2024 and the years to come with a significant sales and marketing presence in the vascular space and a complementary suite of existing products, including sense and atherectomy devices. Our SurVeil DCB fills an important gap in their portfolio for peripheral artery disease, providing them with a complete and comprehensive offering for their existing and potential customers. We look forward to future progress in this market and remain committed to supporting them.

Moving to our second strategic objective: advancing initial commercialization for Pounce Arterial Thrombectomy and Sublime Radial platforms. We ended the fourth quarter with 23 territory managers at quarter end compared to 22 at the beginning of the quarter. With an average rep tenure of 16 months at quarter end, our team continued to make progress through what we have referred to as the early market development stage of our commercialization effort. Specifically, we continue to lay our foundation for growth by raising awareness of our Pounce and Sublime products, working through the value analysis committees at new accounts and driving repeat orders from existing customers.

From a new account perspective, we expanded our base to over 235 customers at the end of fiscal 2023 compared to more than 215 at the end of the third quarter and just over 100 at the end of fiscal 2022. From a utilization standpoint, we continue to see attractive reorder rates from our existing customers, along with a notable uptick year-over-year in average revenue per customer. And we signed our first integrated delivery network or IDN contract with a major health system operating across more than a dozen states for all 3 products. We're excited about the expanded access that this contract will provide as our reps continue to expand their pipeline of prospective customers.

The feedback we received from new and existing physician customers this past quarter clearly demonstrates advantages of our Pounce and Sublime products, and they are resonating in the market. Many of our new users have adopted the Pounce Arterial Thrombectomy platform after using it during a case where other interventional products and approaches that they traditional employ fails. This unique ability of the Pounce device to quickly and easily redeploy in situations like this even with first-time physicians and without the need for capital equipment and minimal need for lytic drugs, combined with the results that physicians are actually experiencing on the table, instantly helps them recognize the value it brings.

Likewise, our Sublime Radial Access platform's ability to treat patients from the wrist to the foot, reducing their length of stay, blood-loss, complications and pain continues to build awareness among dedicated radialists across the industry, and we look forward to further penetrating this market.

And lastly, from a revenue contribution standpoint, I'm pleased to report that we continued our recent momentum with quarterly Pounce and Sublime sales exceeding $1 million in revenue for the third consecutive quarter now. Our performance in the fourth quarter ultimately enabled us to generate growth in sales of these products in excess of 250% for the full year fiscal 2023, fueling the 22% growth in the Medical Device segment product sales that we achieved this year. In a relatively short amount of time, our small sales force has established a solid foundation for future growth, positioning us to drive performance in the years ahead. And we look forward to building on their achievements in fiscal 2024.

Third, turning to our third strategic objective, which is driving revenue and cash flow from our Medical Device Performance Coatings offerings and IVD business. For full year 2023, our combined revenue from these 2 areas of our business increased 5%, near the end of our long-term goal of generating low-to-mid single-digit growth on an annualized basis.

Our Medical Device Performance Coatings team delivered an exceptional year with growth of 9% in fiscal '23, driven primarily by strong sales of our performance coating reagents, coupled with high royalty revenue from broad-based growth across applications as procedure volumes in the medical device industry returned to more normalized levels as compared to fiscal '22.

Revenue from our IVD business decreased 3% in fiscal 2023 as customers focused on reducing safety stock levels due to lower demand across the industry for COVID testing products and the normalization of the supply chain. With that said, as we shared on our Q3 earnings call, we believe this macro-related industry headwind is largely behind us, and we are pleased to see return to growth that we anticipated in the fourth quarter with IVD revenue increasing 7% on a year-over-year basis.

In addition to delivering 5% revenue growth on a combined basis in fiscal 2023, our Medical Device Performance Coatings offerings and IVD businesses generated significant cash to support commercialization and enhancement of our vascular interventions portfolio.

Before discussing our priorities in fiscal 2024, let me take a minute to highlight some of the recent progress with respect to our new product pipeline. Notably, our regulatory team engaged the FDA to secure the 510(k) clearance for the Preside solutions, our latest and most advanced hydrophilic coating technology ever created. Preside is designed to be easily applied and covalently bonded to medical devices in the neurovascular, coronary and peripheral vascular spaces using our patented Photolink curing processes. It's specifically formulated to provide industry-leading lubricity, reducing friction for these devices to access and navigate the most tortuous vascular pathways. These benefits will enable physicians to -- ultimately to reach distal treatment sites and deliver improved therapeutic outcomes.

Preside is also formulated to deliver enhanced coating durability, resulting in a reduction of particulates, which will promote compliance with today's increasingly more rigorous regulatory requirements. This is a critical requirement for our customers, especially in the neuro-market segment, but there's other market segments as well. This development and regulatory clearance of Preside, our new coating technology, reflects our continued commitment to innovation and industry leadership in the medical device coatings industry, which has been a defining area of differentiation and a core competency for Surmodics throughout much of our history.

We were pleased to announce the commercial launch of Preside in October and believe it will raise the standard of performance for hydrophilic coatings and facilitate the use and functionality of catheters across many complex applications and secure our leadership and competitive position.

And lastly, with respect to our Pounce Venous Thrombectomy System, after working through the limited product availability we experienced in the third quarter, which paced the initial months of our limited market evaluation, we are pleased to have completed 45 cases through the end of October. The feedback we have garnered from physician users in this limited market evaluation has highlighted the device's ability to effectively address a variety of different clot morphologies, extracting these clots and utilizing its architecture of a screw to macerate acute and subacute clots. And our physicians also appreciate the unique ability to adjust the diameter of the basket, allowing them to reduce the stress on the interior of the vein and avoid damage to the valves and the vein wall itself, and it also allows them to meet multiple pathways with a single device.

This and other feedback we've garnered to date has been invaluable, enhancing our appreciation for the device's primary clinical advantage when used in a real-world setting and informing our approach for training new clinicians on the device to maximize its effectiveness in the multiple scenarios that they'll encounter with patients. We look forward to gaining insight through some additional LME cases as we prepare for commercialization in the first half of fiscal '24 on a limited basis before commencing a full launch in the second half of the year.

Stepping back, fiscal '23 was a year of pivotal success in the face of major challenges. In response to a very significant regulatory setback with the receipt of a not-approvable letter in the second quarter for the SurVeil DCB, we quickly engaged and proactively engaged with the FDA to amend our PMA application, ultimately resubmitting and securing the PMA from the FDA ahead of our expectations. In tandem, we took important steps to control the use of capital beginning in the second quarter, executing superbly against this plan to reduce our average quarterly cash in the second half of the fiscal year. And then despite these spending reductions, we continued to advance initial commercialization of Pounce Arterial and Sublime Radial products, fueling the Medical Device segment growth in product sales of 22% for the fiscal year. And we drove strong revenue and cash flow from our Medical Device coatings offerings and IVD businesses on a combined basis.

And lastly, we significantly enhanced our cash balance by achieving a $27 million milestone payment related to the SurVeil PMA approval and raising $19.3 million in net proceeds under our new 5-year credit agreement. With durable and profitable core businesses, a portfolio and pipeline of key catalysts and more than $45 million of cash and investments to support our operations and access to approximately $61 million in available debt capital to provide additional financial flexibility, we believe we are strategically positioned for future success.

As we look ahead to fiscal 2024, our team is focused on executing the following strategic objectives: first, to drive our near-term growth catalyst in our vascular interventions portfolio, namely SurVeil, Pounce and Sublime, including the launch of our Pounce Venous products platform; two, to drive durable growth and cash flow generation across our core Medical Device Performance Coatings and IVD businesses; and three, to enhance our Pounce, Sublime and Medical Device Performance Coatings portfolios by developing new products and line extensions to facilitate our long-term growth.

As our guidance range implies, we expect to accelerate our total revenue growth profile in fiscal 2024, driving growth of 9% or higher, excluding license fee revenue related to our SurVeil DCB. I also want to stress that cash efficiency remains a top priority for our organization despite our influx of capital and even in light of the large number of projects we have. Tim will provide more detail in his commentary.

As we pursue these three strategic objectives, we are focused on executing efficiently as possible to maintain a healthy balance sheet and position Surmodics' strong, sustainable long-term growth and value creation going forward.

I'd like to thank my colleagues across the entire organization for their contributions to our success this past year and their commitment to our mission of helping humanity by improving the detection and treatment of disease. Thank you as well to our customers and shareholders for their ongoing support.

With that, I'll turn the call over to Tim Arens, our Chief Financial Officer, to discuss our fourth quarter results and fiscal 2024 guidance. Tim?

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

Thank you, Gary. Unless noted, all references to fourth quarter results are on a GAAP and year-over-year basis.

Total revenue for the fourth quarter of fiscal 2023 increased $2 million or 8% to $28 million. Excluding SurVeil DCB license fee revenue, total revenue increased $3 million or 12% to $26.9 million. Our earnings press release includes detailed reconciliations of total revenue, excluding SurVeil DCB license fee revenue.

Product revenue increased $1 million or 7% to $15.4 million. Medical Device product revenue increased $570,000 or 7% to $8.5 million, driven primarily by increased sales of our Pounce thrombectomy device platform as well as our Performance Coating reagents. This growth was offset in part by a decrease in proprietary specialty catheter product sales due to the completion of a customer development program. IVD product revenue increased $400,000 or 6% to $6.8 million. Our diagnostics business benefited from strength in our microarray slide and antigen offerings.

Royalty and license fee revenue increased $540,000 or 6% to $10.1 million. Royalty and license fee revenue from our Performance Coatings increased $1.5 million or 21% to $9 million compared to the prior year period. The fourth quarter benefited from improved U.S. procedure volumes. In addition, we continue to see growth from customer devices using our Serene coating as well as growth from recent customer product launches. SurVeil

Drug Coated Balloon license fee revenue declined $1 million or 48% to $1.1 million, corresponding with the decrease in TRANSCEND clinical trial costs.

R&D services revenue increased $470,000 or 23% to $2.6 million. The increase was primarily due to higher customer demand for Performance Coating Services in our Medical Device business, which was impacted in the prior year period by our customers' supply chain challenges.

Moving down to P&L. Product gross margin was 54.2% compared to 61.1% in the prior year period. As we discussed on last quarter's call, the decrease was expected and was driven by the adverse mix impact from increased device product sales, which have lowered product gross margins from under-absorption and production inefficiencies, including expiration of inventory associated with low production volumes during the scale-up phase following our initial commercialization.

R&D expense, including costs related to clinical and regulatory activities, decreased $2.6 million or 21% to $9.7 million, reflecting the benefits of the spending reduction plan we implemented during the second quarter of fiscal 2023. R&D expenditures were favorable to our expectations as a result of timing for certain projects in our pipeline.

SG&A expense decreased $1 million or 7% due to lower direct sales headcount compared to the prior year period related to the aforementioned spending reduction plan. SG&A expenditures were favorable to our expectations as a result of the timing of investments in our commercial organization.

Our Medical Device business reported an operating loss of $(2.4) million compared to $(6.2) million in the prior year period, reflecting our disciplined expense management, favorability and timing of operating expenditures and broad-based revenue growth. Our IVD business reported operating income of $3.2 million or 46% of IVD revenue compared to $2.8 million or 43% of revenue in the prior year period, reflecting our return to revenue growth this quarter.

Turning to income taxes. We reported an income tax benefit of $9.5 million compared to an income tax expense of $(7.9) million in the prior year period. As we discussed on last quarter's call, the substantial tax benefit was expected and offset the substantial tax expense recorded in the third quarter of fiscal '23 as a result of the $27 million SurVeil PMA milestone. As a result, the $7.9 million tax expense in the fourth quarter of fiscal 2022 included a noncash charge of $10.2 million to establish a full valuation allowance against U.S. deferred tax assets.

GAAP net income was $6.7 million or $0.47 per diluted share compared to a net loss of $(14.7) million or a loss of $(1.06) per diluted share in the prior year period. Non-GAAP net income was $7.5 million or $0.53 per diluted share compared to a non-GAAP net loss of $3.7 million or a loss of $(0.26) per diluted share in the prior year period.

Non-GAAP adjusted EBITDA was $1.7 million compared to adjusted EBITDA loss of $(2.5) million in the prior year period. Adjusted EBITDA includes adjustments 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 fourth quarter of fiscal 2023 with $44.6 million in cash and $29.4 million in long-term debt. Cash provided by operations during the fourth quarter was $1.3 million and capital expenditures totaled $750,000. As of September 30, 2023, we had $45.4 million in cash and investments, $29.4 million in long-term debt and approximately $61 million in additional borrowing capacity under our existing credit agreement.

Turning now to fiscal 2024 guidance. We expect fiscal 2024 total revenue to range from $116 million to $121 million, representing a decrease of (13)% to (9)%. Excluding SurVeil DCB license fee revenue, we expect revenue to range from $112 million to $117 million, representing an increase of 9% to 14%. SurVeil DCB license fee revenue is expected to be approximately $4 million in fiscal 2024. This compares to $29.6 million received or earned in fiscal 2023.

We expect fiscal 2024 GAAP loss per diluted share to range from a loss of $(1.55) to a loss of $(1.20). Non-GAAP loss per diluted share is expected to range from a loss of $(1.32) to a loss of $(0.97) 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 expect combined product revenue from our SurVeil, Pounce and Sublime products of at least $13.5 million.

Our guidance includes SurVeil DCB product sales to Abbott for the initial stocking order in the first quarter of fiscal 2024 and subsequent orders throughout the remainder of the year. Note, SurVeil DCB product revenue consists of revenue from both the transfer price and estimated profit sharing; the two revenue streams under our development and distribution agreement with Abbott. Revenue associated with our Medical Device Performance Coatings 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 full year assumptions. Product gross margin is expected to be in the mid-50s. We expect operating expenses, excluding product costs, to be flat to slightly down. We expect R&D expense to range from $43 million to $44 million, representing a decrease of 8% to 6%. We expect SG&A expense to range from $54 million to $55 million, representing an increase of 4% to 6% 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 $1.5 million to $2.5 million.

With respect to our revenue growth in the first quarter of fiscal 2024, we expect first quarter total revenue to range from approximately $29.5 million to $30.5 million, representing an increase of approximately 18% to 22%.

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 securities. In fiscal 2024, we expect to finish the fiscal year with approximately $27 million to $31 million of cash and investments.

Let me take a minute to walk through what this means for our anticipated cash use in fiscal 2024 compared to 2023. In fiscal 2023, our cash and investments increased by $26 million year-over-year. Importantly, this $26 million increase included an influx of cash from both a milestone payment for obtaining SurVeil PMA approval as well as the net proceeds drawn from our term loan and revolving credit facility. Setting aside the $27 million from the SurVeil PMA milestone payment and the $19.3 million in net proceeds from our mid-cap credit agreement, cash and investments decreased approximately $20 million in fiscal 2023. By comparison, in fiscal 2024, we expect a year-over-year decrease in cash and investments to range from approximately $18 million to $14 million, reflecting an improvement in the use of cash and investments of approximately $2 million to $6 million compared to the $20 million in fiscal '23 that I just mentioned.

Our expectations for cash use in fiscal 2024 reflect the following assumptions: the receipt of a $3.6 million cash tax refund from the IRS associated with the CARES Act Employee Retention Credit; 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 approximately $2.7 million to satisfy obligations related to previous acquisitions.

Lastly, it's important to note that our first quarter historically requires a higher use of cash to fund our working capital needs, such as our annual employee bonus payments and our annual prepaid insurance premiums. As Gary mentioned, despite our recent influx of capital, cash efficiency remains a top priority for the organization. We remain focused on disciplined expense management and optimization of working capital. And importantly, our guidance assumes no further borrowings during fiscal 2024 under our credit agreement.

With that, operator, we would now like to open the call to questions.

QUESTIONS AND ANSWERS

Operator

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

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

A lot to unpack in the various comments you guys just made and to limit myself to 2 questions. I'm going to just try to hit the high points, I guess, as I see them. I'm curious when we contemplate that Abbott has paid you approximately $100 million development fees related to SurVeil, and you've just given us year 1 sort of guidance for SurVeil that includes the revenue you anticipate from Pounce and Sublime and SurVeil of $13.5 million, how should we think about whether this product has the potential to meet the expectations that you have for it and that your partner Abbott might have contemplated when they paid you the $100 million?

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

Thanks, Brooks. First of all, it absolutely is within the confidence limits that we set for ourselves when we started this journey a long time ago. Especially as I would add, in our meetings with Abbott, it reminds me of why we always saw them as a good partner and that continues to be demonstrated in meeting with their commercial team. The other thing is, I'll just offer this, and this is not an Abbott statement, but the recent acquisition of CSI gives them a really nice sales footprint. And they do have the trifecta in this vessel, the superficial femoral artery or the FemPop segment. They have credible stent in Supera. Now they also have the atherectomy devices that came with CSI. And the further missing component to really compete is a drug-coated balloon with an anti-restenotic drug.

So we're excited. My interactions with them have been exciting as well. And now with the sort of removal of this veil of paclitaxel causing a late mortality signal, it's gone. Just at the recent TCT and VIVA meetings, that continue to present how that signal has literally died and these devices are better for patients. So all the momentum, we believe, is stacked positively.

Now when we look at guidance, I'll turn it over to Tim, the estimates we have to make, and they are actuals. And so we have to be cautious on how we make those estimates going forward. I'll turn that over to Tim to...

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

Thank you, Gary. Brooks, thank you for the question. I think the important thing for you and everyone to realize is the most important 3 words that I mentioned in guidance was "of at least" -- of at least $13.5 million. The other thing I think people need to keep in mind too is, we commented about Abbott's expected commercialization timing, which is the first half of calendar year 2024. Please bear in mind, this is 3 to 9 months of potential product revenue for Surmodics from Abbott's commercialization. We'll have a lot more to say on this as we go through the fiscal year. But keep in mind, this does not reflect a full 12 months of revenue from Abbott.

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

The last thing I'll add, Brooks, is Professor Schneider is presenting our 3-year data at the VEITH meeting next week in New York. And I think it's worth paying attention to that. I imagine we'll send a press release summarizing that data afterwards. But the thing you want to look for in these devices is continued durability of the signal, especially as compared to the market-leading device. And so once again, we and Abbott are the only company that has a pivotal head-to-head randomized controlled trial against the device, no one else has it. And so I think, I look forward to that data being presented next week at VEITH.

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

That's great. I appreciate all that color. Let me ask one more. As we think about the world that you've developed here, guys, you have the beginning of significant experience with a partner in Abbott with Sublime. You also have the beginning of essentially a go-it-alone strategy with regard -- I misspoke, with regard to SurVeil and Abbott, but you go it alone with Pounce and Sublime, I have a sense you have a deep and robust pipeline of new products. Share with us just a little bit about how you think about going to market with some of the high-potential products that are still in your pipeline today.

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

Absolutely. We -- to compete in markets, especially in the thrombectomy market, you can't do just the minimum to get the first product iteration out. You have to have the follow-on products. And as I said, we got FDA clearance on the Pounce Low Profile, which will allow us to go down close to the ankles. And so we have other parts of these product expansions. What we're seeing is -- and you've heard me say the future has already been created. It's not evenly distributed. What I mean by that is we're not losing, right? We have 20-something salespeople versus, in some cases, 350, almost 400 or just so to say, a weighted average of 10x our sales force. On the piece-wise basis, we're winning, and I would suggest without hyperbole, we're winning every time. And that's an important thing as we build out this market.

Now clearly, we have to be cash-efficient. And I recognize that this company had a size of the sales forces of the strategics, for example, we'll be talking about greater than $100 million of revenue next year, right, just on these product lines. But we intend to go and grow as we go and use our cash efficiently, continue to win and continue to supplement that. So I believe that is a very key strategy. When it comes to drug-coated balloons, the competition and the need for a partner like an Abbott really is across multiple product lines, across multiple group contracts and such. And that's something we don't have to compete in an already existing market like drug-coated balloons.

I will say, just getting the first group contract under our belt, which is more than 100 hospitals, it's remarkable to me that we were able to get a group contract for all 3 product lines: Pounce Arterial, Sublime, and we haven't even launched Pounce Venous yet. That's a very significant thing when you think about it. I've not kept up with it, but I don't know any products in mind, maybe something in history, that gets a group contract for a product that's coming. And so that tell you the appetite and signal and our strength of our competitive position. So feel good at where we are.

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

Yes. And I'll just -- I'll add one quick comment here, Brooks, to Gary's remarks here. I think it's important to recognize what Gary described in terms of the '24 strategic objectives, capitalizing on the near-term growth catalysts and the vascular interventions portfolio. And you've heard Gary mention Pounce Venous. There's a few other products that we've described here that are going through limited market evaluations. We anticipate that they'll be in a position for commercialization at some point later in the fiscal year. And we -- our guidance does reflect minimal -- I should say, modest revenue contributions from the commercialization of those products. So again, this year, we'll not be seeing a full 12 months of revenue generation from some of the catalytic products that will be coming to market from Surmodics.

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

Yes. And Brooks, so last thing just to pile on is, if there is any sentiment that Tim and I are not in our legacy business, our core coatings offerings and diagnostics, Preside is -- the Preside coating is a remarkable achievement. It's something we've worked somewhat behind the scenes for the last 2 years, new intellectual property and for many customers in that business, especially in the neurovascular segment, it's unmatchable. So we're not ceding leadership because we're focused on products. Our technology leadership is something we have drawn a line and said, we will maintain technology leadership in all things that we do. So that's just an additional thing on Preside that's happening and even more things we're working on in the future.

Operator

Our next question comes from Mike Petusky with Barrington Research.

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

So Tim, just in terms of the assumption around second half -- I'm sorry, first half calendar commercial launch for SurVeil, obviously, that's -- there's, I guess, 180 days range in there. And your assumption, you have to be assuming something there. I mean, is it fair to say you're assuming somewhere in the middle of that time frame in terms of the $13.5 million or the part of that, the $13.5 million that's the contribution from SurVeil? Are you assuming sort of just that, that's commercialized for essentially the last 3 months of your fiscal? Can you just talk about what you're actually specifically assuming to get to the contribution you're assuming for the -- within the $13.5 million?

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

I'll say one thing and I'll turn it over to Tim for the detailed answer. One of the things in the partnership with Abbott, we recognize the competitive dynamics of a launch and the things that they're trying to set up. And so if there's any implied vagueness, it's because we want to respect our confidentiality as they really gear up for a major launch. So that explains the wide window, even though we know what the window really is. We want to give them every opportunity to compete effectively with their launch planning.

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

Yes. And thank you, Mike, it's a very appropriate question. And as Gary kind of got in front of my answer here, I'm limited in terms of what I can specifically say with regard to Abbott, but I can provide some color and think for folks to probably appreciate is that the first half of the year will reflect the stocking order that we are -- we've been manufacturing and sending to Abbott. And so clearly, the second half of the year is going to be more influenced by Abbott reorders once they're in the market and have commercialized the technology in the product. So I think that's probably the extent of context that I can provide today.

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

Could I just ask, are you assuming any profit share dollars in -- within whatever contribution you're assuming in the $13.5 million?

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

We will, and they're very modest. We'll need some time. Obviously, it is an estimation. It's a judgment and just to probably provide a little clarity for folks, we will need to make assumptions with regard to the units that we ship to Abbott, how many will actually be sold. How many will be used for promotional activities, how much will be expired. We'll have to make assumptions with regard to their selling price. So there is a bit of a number of variables that we need to estimate. And as you can imagine, we'll learn more about how to think about these variables, once Abbott estimates, but know that it's a modest portion of that $13.5 million that I described.

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

Yes. Refining -- first year, we'll refine that model, but you can imagine the first year predictability without those assumptions and history of those assumptions being validated, it's going to be challenging for us.

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

All right. But there is some estimate of that. I'm assuming that's like on a 90-day trail. Is that right?

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

So we'll make the estimate at the time we ship product to Abbott, but there will be a true-up to think of how Surmodics actually goes about estimating our royalty revenue, then we collect the actual royalty payments and there is a true-up or an adjustment based upon our estimate versus what we receive. That will happen over time with Abbott as well.

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

90 days or further out from that?

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

It will be quarterly.

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

Okay. All right. And then last question, I've stretched the boundary of 2 questions, but let me just ask the last question. I guess in terms of the sales effort on Pounce and Sublime, Gary, do you expect that now that you guys are in a better situation in terms of sort of the outlook for the future and sort of the vision there and frankly, the balance sheet, does more investment in the sales team there makes sense at this point?

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

If we didn't have -- the short answer is yes, but it will be grow as we go. So in other words, as we start generating returns from that business, we'll be investing it in that business. We have drawn a line on what we should be investing on a go-forward basis to show our cash -- so pay attention to our cash forecast, right? Usually, it's revenue and earnings, but cash is an appropriate throttle limiter for where the company is right now. Could we go faster? I believe so, but we don't want to become a balance sheet story as a public company in this macroeconomic condition. So we'll grow as we go. We're not going to double the size of the sales force, I can tell you that. But we will be selectively adding.

Another key thing is, when we do launch the Pounce Venous, right, we'll have to be interpreting whether we can go faster, again, in a very disciplined fashion with some more feet on the street. The one thing we have to say is, as you get GPO contracts, which is -- I don't know how to emphasize this, which is remarkable for a company at this stage, right? Now in GPO contracts and IDN contracts, you have to demonstrate penetration in that contract. So now you're covering an extra 100 hospitals. And so we will be doing an analysis of where the heat maps are to seed our territory managers and field clinical specialists, but we can't overaccelerate there. That's the big discipline we have to put in place this year.

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

Can I just ask a quick follow-up, and this is sort of a big picture longer term? I mean if we're having this conversation 3 years from now and Venous has obviously been commercialized at that point for 2-plus years, I mean it is possible that there could be a doubling of the sales force, isn't it, at that point?

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

I mean typically -- yes, I mean, to really compete well, you eventually need a minimum of 50 people, right? You can go up from there. But getting to that 50 and making sure you have the -- we want to be on the conservative side of sales capacity utilization, right? You always continue to grow, always fund that. And we also have to look at our sources and uses of cash and our debt levels and our senior debt repayment level. So a lot of things come into play there. But yes, 3 years from now, you would -- to be able to support that market growth, you have to have a critical mass to play in that market effectively. So -- and big thing for us continues to be, as we model is, what we call the territory managers' contribution margin. We look at gross margin from a territory offsetting selling costs in that territory. So it's not an operating margin thing, but it's a gross margin, which basically tells us gross margin is paying for the selling efforts and selling expenses. And so that's a nice way to look at how we will look at scaling up over time.

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

Okay. Very good. Well, congratulations, obviously, '23, a huge pivotal year. Congratulations.

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

Thanks, Mike.

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

Thank you.

Operator

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

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

Just to follow up on the sales force. Can you tell us what number or how many sales folks you had at the end of the fiscal year?

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

I think we have it in the remarks. I think it's 23, Jim.

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

You ended with 23. Okay. And so it sounds like you might add a few as the conditions determine now, but you're not expanding it in a big way in fiscal 2024.

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

Not at this point. As I said, we will selectively seed. We have an incredible sales organization. And so when we're adding, we're looking for really first top-tier talent and top-tier talent that's willing to stretch. Our competitors have salespeople for like 5 accounts, right? We have salespeople for 50 to 100. So they have to be able to stretch and they have to come from a great pedigree of success. So we want to keep getting the top-tier talent and seeding them. We'll add as we grow, but again, not intending to double it. And the big thing is when we do launch Pounce Venous and we feel the uptake of that product, we may decide to add some more, but that's later in the year, and clearly, within the constraints of what we're saying in our cash guidance.

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

Okay. All right. Now switching over to Abbott. Can you just lay out what are the milestones that have to happen for Abbott to launch the device? And is there a chance it gets pushed out a little longer? Or maybe is there a chance that it happens a little bit sooner than you indicated so far?

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

Yes. And again, I'll repeat what I just said. Some of the bandwidth we have given the launch there with Abbott is respecting the confidentiality of the contract of when they launch. But as you can imagine, they're professionals at this type of launch, and they're doing all of the appropriate preparation of the ground, fertilization and the appropriate seeding because I suspect when they go, they really go with a very specific launch plan and trajectory. So really, our job is to help them with technical information that they are able to use to train their team and to make sure we have high-quality product delivered on time to their docks. That's really our role in it.

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

Yes. I would say, Jim, too, we're confident in the time frame that Abbott provided in the first half of calendar year 2024. And you can imagine, there could be reasons why they would get out earlier. And you can also imagine that there are reasons why maybe they would kind of move that more towards the second half of that time horizon. So we'll just ask you to stay tuned. There will be more on that. I'm sure everyone will see it when Abbott launches it. And we're here to help support and make sure they have what they need from us so that they can effectively get out into the market with SurVeil.

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

Yes. Basically, we can't talk about it. That's the (inaudible).

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

All right, all right. Can you talk about whether it's strictly limited to the U.S. or if it will be launched worldwide?

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

Yes, we can certainly address that question. I think we've described this over the last several quarters. They are going out U.S. So what we've described in our guidance, what we're talking about in terms of the launch, all pertain to the U.S. market. We have nothing to add OUS at this point, Jim.

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

Okay. And then in terms of Surmodics income statement, if you look, your R&D expense topped out around $50 million in fiscal 2022. It ended this year around $46 million, $47 million. You expect it to tick down to closer to $44 million next year. Do you think it will continue to remain around these levels, maybe come down a little bit? Or are there any major projects you expect to invest in, in the next couple of years?

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

We do have to -- our R&D is really focused on winning in the market segments we have identified. And that does include the venous market. And keep in mind, we're entering several huge markets this year. I mean the Pounce -- the venous market is larger than the arterial market, as a generalized statement. And so to compete with the big guys there and their products, we have to maintain some level of R&D to continue to win and launch those products. We do have some early-stage programs that we're looking at. So some of them involve more venous, [we've got the venous] segment and pulmonary embolism.

And actively, the one thing I would say is, you'll see next week at the VEITH meeting, again, Professor Ramon Varcoe is presenting our 2-year data on Sundance Sirolimus BTK. Now Professor Varcoe presented the LIFE-BTK trial data 2 weeks ago at the TCT meeting in San Francisco, which is an absorbable stent eluting an olimus drug. And so when you look at our 2-year data and I encourage, we will send a press release on that, what I hope is recognized is that we do actually have incredible drug delivery technology in Surmodics.

Our issue again is one of being cash constrained to get ready for an IDE, much less to run a pivotal trial, we will be actively looking for partnership opportunities to help us with that. We can't go that alone as much as you stay tuned for the data being presented. Again, this is a 2-year data, right? Stay tuned for what our 2-year data looks like with any of the BTK device that's been done. So have to be really disciplined, wish we have the capital, but have to maintain that in the public markets.

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

All right. So it sounds like you're going to continue to invest in R&D, but it doesn't sound like you're going to get back to the fiscal 2022 level.

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

Jim, I think what we're providing the guidance here for fiscal 2024, and you noted the reduction in R&D spend over the last few years, there's clearly investments in certain platforms and other platforms are seeing a deceleration in spend, notably SurVeil, which has been less than -- certainly not fully offset by increase in other platforms. But yes, I think we like the trend and we like the investments that we're making and what we think the long-term value creation can be from those investments. Not a whole lot to add for '25 or later. But I'd say, you're probably right to think about the trend.

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

Yes. And one thing, Jim, is R&D includes clinical, right? And so we have the PROWL registry, you have to commit to those registries and the PROWL registry is going just fine, which is for the Pounce Arterial. And eventually, when we do launch the Pounce Venous product line to get the claim expansion to DVT versus removing clot, will require at a minimum registry or very small single arms. So that's more out in the '25 time frame.

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

There's puts and calls, Jim.

Operator

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

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

I wanted to ask one on Pounce versus Sublime. Just reading between the line, but some of the comments, it sounds like Pounce is kind of the bigger growth driver there than Sublime. Is that right? I know you're not going to break out the sales or anything, but can you just qualitatively comment on how the 2 are doing relative to each other?

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

It has been, Mike, and one of the reasons for that, remember in the whole debacle with the PMA not-approvable letter, the VI commercial team took the largest hit in the company. We had to unfortunately reduce the size of the sales team by a lot, right? And so -- and what we had to do at that point because we have to make sure we got to hit our revenue plan, the incentives for the sales team, when you look at a $4,000-plus product in Pounce versus several hundred dollar product in Sublime catheters, we were compelled to redirect the team that we've had towards making sure we're able to hit that revenue. With the new commission plan that goes out -- that went out in October, we have now put Sublime back in its rightful place. So there was a specific conscious decision at that point.

What I would say is that the addressable market for Pounce Arterial is bigger than it is currently for radial devices. And remember, radial is also an adoption curve, not just a competitive [winker]. What I've told our sales team, though, is we'll do well in thrombectomy. I have no doubt. But their grandchildren will remember them for Sublime, right, because that is changing the face of health care towards the positive. I don't know a single other product, and again it's early innings, that has better patient outcomes, right, much better health care economics and a huge impact on patient satisfaction. Hitting that trifecta, we're patient with it, but for the moment, yes, the high ASP of things like Pounce Arterial are outpacing Sublime. And that's okay, by the way, for us right now.

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

Yes. Okay. And then just on the Preside coating, I mean, is that -- I know you're continually iterating on those offerings. So I mean, is this something that could have any sort of impact on the growth? Or is it more just kind of incremental?

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

And you know how that business runs like -- the cycle time -- so we just got the first FDA clearance. I don't think we mentioned that, but we do have an FDA clearance of the first device for Preside. And so what that sets the stage is -- I'm generalizing a little bit here, so the chemistry is on file with the FDA of having seen it now. And it gives our customers an opportunity to leverage that knowledge and working knowledge of that dossier on file with the FDA. The time cycle is you've got to get customers who're interested, help them through their development and their regulatory offerings, right, effort to get clearance for these devices. And only then do we see the royalty when these devices hit the market. So it's a longer offering, but it's significant because we're talking about royalty cash flow here. So I wouldn't expect, Tim, in our guidance, we've put anything for fiscal '24 for any royalty things there, unless people get approvals pretty quickly.

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

Yes. There really isn't. It's -- look, to be clear, Preside is something that is highly complementary to our Serene coating, which has really been growing well over these last few years. And we continue to expect it to grow well. I think we've commented previously that there are 60-plus customer opportunities where we get to dial in our chemistry with our customers' devices. This just -- Preside gives us an opportunity to really claim certain application spaces. I think going distal in the neural, crossing really challenging lesions like total chronic occlusions, it really gives us an advantage with this coating relative to even some of our internal coatings, but more importantly, to competitive coatings. And I think that's why the team has really been focusing on this Preside coding over the last few years is to meet some of the needs where, quite frankly, we felt that we could provide some additional performance enhancements. So as Gary mentioned, it will probably be a few years to grow the trees, but we're planting the seeds today.

Operator

Thank you. And that concludes our conference call for today. Thank you for your participation, and you may disconnect at any time.
