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PRESENTATION

Operator

Welcome, everyone, to Surmodics' Second 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 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 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 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 second quarter of fiscal year 2023. I'll start my remarks today with a brief overview of our second quarter revenue performance.

We generated total revenue of $27.2 million in the second quarter of fiscal 2023, representing growth of 4% year-over-year. Our total revenue growth was driven by our revenue in medical devices, which increased 7% year-over-year, offsetting a 2% decrease in In Vitro Diagnostics, or IVD revenue. Looking at these two areas of our businesses more closely, in our Medical Device segment, our performance was almost exclusively driven by product sales, which increased 23% year-over-year with significant contributions from sales of our Pounce and Sublime products as well as from our performance coating reagents. Specifically, sales of our Pounce and Sublime products contributed more than half of the medical device revenue product sales growth we saw in this quarter.

And in our IVD segment, we were pleased with our year-over-year sales performance in the second quarter, given the prior year comparison. As a reminder, we generated record quarterly IVD revenue in the second quarter of fiscal 2022. In short, we reported solid revenue performance across the key areas of our business in the second quarter.

Tim will walk through our second quarter financial performance and updated fiscal 2023 guidance in further detail. But let me now shift to an update of our recent operational performance, beginning with an update of each of our three strategic objectives for fiscal 2023. As a reminder, our strategic objectives for fiscal 2023 that we outlined at the beginning of the fiscal year are as follows. First, to achieve FDA pre-market approval, or PMA, for our SurVeil drug-coated balloon and then support Abbott's commercialization efforts. Second, to advance initial commercialization of our Sublime radial and Pounce arterial thrombectomy platforms. And third, to drive revenue and cash flow growth from our medical device coatings offerings and IVD businesses.

With these three objectives in mind, I'll now discuss our project -- progress with respect to each. We began the second quarter having to navigate unexpected challenges along our path to securing the PMA for our SurVeil drug-coated balloon and ultimately made important progress and exceeded expectations we shared on our earnings call in early February. As a reminder, on January 19, we announced that we received a letter from the FDA which indicated that our PMA application was not approvable in its current form and provided guidance and information that must be added to amend our PMA application.

The information the FDA requested was within two general categories: labeling, including language revisions related to some of the device's patient labeling and instructions for use; and biocompatibility, including additional questions and data requests related to our non-clinical testing. While this was an unfortunate and disappointing development, we were pleased to see that the letter did not question our engineering, large animal studies, and most importantly, the human clinical data that we submitted, including the safety and efficacy data from our 446-patient TRANSCEND clinical trial.

During February and March, our regulatory and clinical teams focused on engaging with the FDA to inform our SurVeil regulatory strategy and were able to make meaningful progress during this quarter. Our team's primary goal over this period was to obtain additional clarity in the pathway and specific requirements to address the agency's questions and data requests in order to position us to prepare and submit an amended PMA application in an approvable form.

Working closely with our external regulatory advisors, our team engaged in informal discussions with FDA representatives, then prepared a submission issues request intended to obtain formal feedback on our proposed approach for addressing the items in the FDA letter from the FDA's review team. This was done via agency's Q-submission process. As we shared on our last earnings call, we anticipated receiving the FDA's formal feedback on our proposed approach via this process in May, based on normal timelines. With this as a backdrop, our team was ultimately able to prepare and submit our submission issue request ahead of our expectations, obtain FDA's formal written feedback and response, and then complete the submission issue meeting with the agency to discuss the details of both the request and the FDA's written feedback, all occurring before the end of our second fiscal quarter.

In addition to this impressive level of interaction, we were pleased with both the level and content of the feedback obtained from the agency in response to our submission issue request. With this additional feedback, we have now have the additional clarity in the process and content required to successfully amend our PMA application. Moreover, in the FDA's written and verbal feedback on our submission issue request, we were pleased to see that the additional clarification requested by the FDA to amend our PMA application was focused on existing biocompatibility studies that we have previously completed as well as revisions to our proposed labeling. Based on this feedback, we do not currently anticipate the need for additional biocompatibility studies. With this additional clarity, our team has been focused on preparing our amended PMA application, which we expect to submit during our fiscal third quarter.

Looking ahead, the FDA guides to a 180-day period to review and render a decision on an amended PME. While the process and timing of the FDA's review is ultimately under their purview, we are currently anticipating the receipt of pre-market approval in the fourth quarter of fiscal 2023, and we look forward to providing future updates on our progress.

Turning to our second strategic objective, advancing the initial commercialization of our Pounce radial and Pounce arterial thrombectomy platforms. From a market education standpoint, during the second quarter, our team continued to leverage the 2 dedicated supplements that were recently published in Endovascular Today to raise awareness and educate prospective customers. As a reminder, these publications articulated the capabilities and advantage of our Pounce arterial thrombectomy and Sublime radial in terms of their simplicity, efficiency and potentially lifesaving benefits

they bring to endovascular procedures relative to the existing devices and procedures on the market and regardless of whether these procedures are performed at hospitals, ASCs or office-based labs.

Throughout the second quarter, we continued to see evidence that these recent publications, along with our product awareness initiatives, are resonating with prospective customers. From a commercial standpoint, as I mentioned earlier, we saw impressive contributions from direct sales of these products during the second quarter, fueling more than half of our medical device product sales growth year-over-year in this period. Our direct sales team continued to make impressive headway driving adoption of these technologies and expanding our base of clinical users in part by helping prospective customers navigate the value analysis committee process with their respective institutions.

We succeeded in expanding our customer base to over 170 total customers for Pounce and Sublime platforms compared to more than 135 at the end of the first quarter and just over 100 at the end of fiscal 2022. Given the strong sequential growth in new accounts we've seen in fiscal 2023 to date, it's important to note that our pipeline of prospective customers has continued to increase sequentially as well. In the second quarter, the number of value analysis committees evaluating our products saw modest sequential quarterly growth, despite the recent reduction in the number of territory managers in the field. And we remain pleased with our customer reorder rate, which continues to track in line with our expectations for fiscal 2023.

While we are still in the early innings of our commercial efforts for Pounce and Sublime, with an average tenure now of 12 months across our team of 21 territory managers, we're excited by the recent progress made and the resulting contributions to our revenue growth in the second quarter. Based on our recent progress, we continue to see significant growth and contribution potential from our Pounce arterial and Sublime radial platforms. And we remain on track to drive growth in combined sales from these platforms for approximately 300% year-over-year for the full fiscal year 2023 as we begin to move from initial market entry into the early stage of market development and ultimately our commercialization efforts.

Subsequent to quarter end, we were also pleased to announce the beginning of patient enrollment in PROWL, a new U.S. registry study. The PROWL registry is designed to enroll up to 500 patients across 30 sites, collecting real-world efficacy and safety outcomes for our Pounce arterial thrombectomy system when used in a variety of endovascular interventions for the non-surgical removal of clots in the peripheral arterial vasculature. When a patient's peripheral artery becomes blocked, the clot needs to be addressed as quickly and as effectively as possible to prevent limb loss and patient mortality due to acute limb ischemia. With this in mind, our Pounce radial thrombectomy system was designed to consistently remove clots in a single treatment session while also reducing the need for thrombolytic drugs and subsequent ICU stays.

We believe the PROWL registry will continue to highlight these compelling therapeutic benefits, along with a strong safety profile, of our Pounce technology. And as this registry progresses, we look forward to sharing the interim data with clinicians to support our market education and awareness initiatives.

Now with respect to our third strategic objective to drive revenue and cash flow growth from our Medical Device performance coatings offerings and IVD businesses. Revenue from our Medical Device performance coating offering increased 3% year-over-year, more than offsetting the 2% decrease that we saw in our IVD business, and the performance of our core businesses overall exceeded our expectations. As I mentioned earlier, we were pleased with the year-over-year sales performance in our IVD business against a challenging year-over-year comparison as our IVD business generated all-time record quarterly revenue in the second quarter fiscal 2022. In addition to the revenue performance in the quarter, these businesses continue to generate significant cash flow to support our other strategic growth initiatives.

In addition to our continued progress with respect to these 3 strategic objectives, early during the second quarter, we implemented a spending reduction plan to preserve capital in response to the delay in our anticipated SurVeil PMA timing. As I discussed in detail on our last earnings call, this spending reduction plan was implemented after careful evaluation and was designed to reduce our planned cash use by approximately $10 million to $11 million for the remainder of fiscal 2023 prior to the restructuring charges. The spending reduction plan included a workforce restructuring to streamline and refocus the teams in several areas of our business. It also featured several additional cash-saving measures, namely a reduction in our planned capital expenditures, a reduction of our hiring plan for fiscal 2023 and the refocusing of our investments in product development to prioritize progress primarily in our nearer term commercialization opportunities, including our Pounce arterial and Pounce venous thrombectomy systems as well as our Sublime radial product platform.

As a result of the spending reduction plan and keeping in mind our guidance expectations for the full year, we continue to expect our quarterly cash use in the third and the fourth quarters of fiscal 2023 to be approximately $3.5 million to $4 million each quarter.

I want to emphasize; cash flow remains an important priority for our organization. We remain committed to reducing our use of cash over time through a combination of disciplined expense management, as evidenced by the implementation of our spending reduction plan, along with a continued focus and execution with respect to our stated strategic priorities, which we believe represents the best path to driving enhanced sustainable long-term value and growth.

Before I turn the call over to Tim, I'd also like to provide a quick update on some of our recent progress related to our new product pipeline. From a new product perspective, our team continues to advance our existing pipeline of products within the Pounce and Sublime platforms with the goal of expanding and enhancing this portfolio managed by our direct sales force. In the second quarter, we began limited market evaluations for our Pounce venous thrombectomy system. We are excited to continue this effort and to obtain and evaluate real-world feedback from numerous physicians across a wide variety of therapeutic cases.

With respect to our Sublime radial platform, last week we were pleased to announce that we have also commenced limited market evaluations for our Sublime radial access microcatheter. This device is part of what will be the industry's first suite of torqueable, high-performance peripheral microcatheters available in both radial and the transfemoral lengths. Torqueable microcatheters have been an important innovation in complex coronary artery disease, enabling clinicians to cross difficult lesions and overcome some of the most challenging cases. We are excited by the potential to bring this level of innovation and performance to the peripheral intervention community with a suite of microcatheter products designed to provide clinicians with torque control, push transmission and deliverability to distal target lesions in the periphery from any access site.

Our Sublime microcatheter portfolio will also include 014, 018 and 035 microcatheters, which can be telescoped through the 035 microcatheter to provide additional backup support when navigating extreme tortuosity or heavily stenosed lesions. We look forward to gaining important physician feedback on these devices and progressing towards the limited market introductions of these remaining products in the portfolio over the coming months.

And lastly, with respect to our Pounce arterial thrombectomy system, it is important to bear in mind that we estimate the U.S. market for peripheral arterial occlusions to represent an approximately $800 million market opportunity for Surmodics. We believe our Pounce arterial thrombectomy system is uniquely positioned to penetrate this market, given multiple factors, including its advantages for the treatment of acute limb ischemia, the procedural results it continues to demonstrate as well as its limited commercial competition at present.

In addition to our commercial and market development efforts, from a pipeline perspective, we are focused on further enhancing this Pounce arterial system by expanding our existing clinical indications and new development of new products to add to this portfolio, including Pounce LP, Pounce Low Profile, Pounce XL, and towards establishing Pounce arterial as the preferred solution for cases across the entire lower limb vasculature.

So stepping back, I'm incredibly proud of our team's performance, focus and execution during the second quarter. Together, we navigated a challenging environment, which saw us quickly respond to the FDA's letter related to our PMA application for SurVeil and implement difficult but important actions to reduce our planned use of cash through the remainder of fiscal 2023. We did so while delivering solid commercial performance and with respect to our vascular intervention, performance coatings and IVD products. And we continue to advance our pipeline of new products towards commercial introduction, including our SurVeil drug-coated balloon, Pounce venous thrombectomy device and new products within our Pounce arterial and Sublime platform.

As a result of these efforts, we believe we are well positioned to drive strong commercial and operational progress as we enter the second half of fiscal 2023. Our core businesses, including our Medical Device performance coatings offerings and our IVD businesses, are generating significant cash flow. The initial commercialization of Pounce arterial and Sublime radial platforms is yielding significant contributions to our revenue growth as we drive progress in these large and underpenetrated markets. Our product pipeline of innovative vascular intervention devices, including our SurVeil DCB and Pounce venous thrombectomy device, represent important future catalysts with the potential to further accelerate our future growth and financial performance.

We remain committed to demonstrating prudent expense management and disciplined capital allocation as we pursue long-term revenue growth and value creation. And lastly, we remain well capitalized with $19 million of cash on our balance sheet at quarter end and access to approximately $61 million in incremental debt financing under our existing credit facility.

With that, I'll now turn the call over to Tim Arens, our Chief Financial Officer, to discuss our second quarter fiscal 2023 results and updated guidance for fiscal 2023. Tim?

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

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

Total revenue for the second quarter of fiscal 2023 increased $1.1 million or 4% to $27.2 million compared to $26.1 million in the prior year period. Product revenue increased $1.4 million, or 10%, to $15.4 million in the second quarter of fiscal 2023. The increase in product revenue was driven by Medical Device product revenue, which increased $1.5 million, or 23%, due to increased sales of our device products, including significant contributions from our Pounce arterial thrombectomy and Sublime radial platforms as well as increased sales of our performance coating reagents.

IVD product revenue decreased 1%, driven in part by active management of inventory levels by certain customers. Our IVD business saw a decrease in sales of protein stabilization products, which was partly offset by growth in sales of microarray slide products and favorable order timing for distributed antigen products.

Royalty and license fee revenue decreased $420,000, or 4%, to $9.4 million. Royalty revenue from our performance coatings decreased $290,000, or 3%. The prior year quarter provides a challenging comparable as the period benefited from stronger than expected customer reported royalties relative to our estimate. License fee revenue decreased $130,000, or 9%, due to the timing of revenue recognition from our SurVeil agreement with Abbott.

R&D revenue increased $120,000, or 5%, to $2.4 million. The increase in R&D services revenue was primarily due to higher customer demand for performance coating services in our Medical Device business, which was impacted in the prior year by our customer supply chain challenges.

Product gross margin in the second quarter of fiscal 2023 was 62.6% compared to 63.4% in the prior year period. Product gross margin was adversely impacted relative to the prior year by certain manufacturing inefficiencies associated with ramp-up of production of new products, which was partially offset by the favorable impact of product mix.

R&D expense, including cost of clinical and regulatory activities, decreased $790,000, or 6%, to $12.9 million in the second quarter of fiscal 2023. The decrease in R&D expense reflects the initial benefits from the spending reduction plan implemented during the second quarter of 2023.

SG&A expense increased $1.9 million, or 17%, to $13 million in the second quarter of fiscal 2023, primarily driven by a year-over-year increase in headcount related to the expansion of our direct sales force in fiscal 2022 and related investments to support the commercialization of our Pounce and Sublime products.

We reported $1.3 million in restructuring expense in the second quarter of fiscal 2023 for severance-related costs related to the workforce restructuring implemented during the quarter as part of our spending reduction plan. The majority of these costs were paid during the quarter.

Our Medical Device business reported an operating loss of $7.1 million in the second quarter of fiscal 2023 compared to a loss of $5.6 million in the prior year period. The change in operating loss was driven primarily by the aforementioned investment in our direct sales force as well as by the $1.3 million in restructuring expense recorded in the second quarter.

Our IVD business reported operating income of $3.6 million in the second quarter of fiscal 2023 compared to $3.7 million in the prior year period. IVD operating income was 49% of IVD revenue in both periods.

Turning to income taxes. In the second quarter of fiscal 2023, we reported income tax expense of $370,000 compared to income tax benefit of $920,000 in the prior year period. As a reminder, we are no longer recording tax benefits on U.S. 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 loss in the second quarter of fiscal 2023 was $7.7 million, or a loss of $0.55 per diluted share, compared to a loss of $4.1 million, or a loss of $0.29 per diluted share in the prior year period. Non-GAAP net loss in the second quarter of fiscal 2023 was $5.6 million, or a loss of $0.40 per diluted share, compared to a loss of $3.1 million, or a loss of $0.22 per diluted share in the prior year period.

Non-GAAP adjusted EBITDA loss in the second quarter of fiscal 2023 was $1.5 million compared to adjusted EBITDA loss of $860,000 in the prior year period. Adjusted EBITDA includes an adjustment for restructuring expense in the second quarter of fiscal 2023 and 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 second quarter of fiscal 2023 with $26.4 million in cash and $29.5 million in long-term debt. Cash used by operations during the second quarter was $5.8 million, and capital expenditures totaled $720,000. As of March 31, 2023, we ended the quarter with $19.2 million in cash and $29.3 million in long-term debt. 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 March 31, 2023, we have approximately $61 million in debt capital available, consisting of $50 million on our term loan availability and $11 million of incremental availability in our revolving credit facility, which is subject to borrowing base requirements.

Finally, a housekeeping note. We have a $200 million shelf registration statement in place, which is set to expire in May. As a part of good corporate governance, we plan to file a replacement Form S-3 with the SEC to keep the shelf registration active.

Turning now to fiscal 2023 guidance. We have updated our fiscal 2023 revenue guidance to reflect our performance in the second quarter as well as our revised expectations for the remainder of fiscal 2023. We now expect fiscal 2023 total revenue to range from $103 million to $106 million, representing an increase of 3% to 6% compared to the prior year, compared to our prior range of $102 million to $106 million or an increase of 2% to 6% compared to the prior year.

We now expect fiscal 2023 GAAP loss per diluted share to range from a loss of $2.30 to a loss of $2.00 compared to our prior range of a loss of $2.40 to a loss of $2.00.

Non-GAAP loss per diluted share in fiscal 2023 is expected to range from a loss of $1.98 to $1.68 per share compared to our prior range of a loss of $2.09 to a loss of $1.69 per share.

As a reminder, our guidance excludes revenue associated with the potential future added milestone payment on receipt of the PMA from the FDA, which has been our practice with previous regulatory milestones.

I'll now share a few additional considerations for modeling purposes. Our fiscal 2023 total revenue guidance assumes revenue for our 2 businesses, Medical Device and IVD, is expected to be approximately 73% and 27% of revenue, respectively. Product revenue is expected to be approximately 58% of total revenue. Revenue associated with our legacy Medical Device coating offerings and IVD business is expected to grow modestly. Abbott SurVeil license fee revenue is expected to range from $4 million to $4.5 million. This compares to $5.7 million in fiscal 2022.

Turning to the rest of the P&L. Our updated fiscal 2023 guidance reflects the following expectations. Product gross margins are expected to be in the mid-50s for the remainder of fiscal 2023. In the second half of fiscal 2023, we expect higher absorption of fixed overhead costs in cost of sales as commercialized products are allocated in an increased share of overhead expenses due to reductions to drug-coated balloon production. With regard to operating expenses, we expect rest of year quarterly expense of $12 million to $12.5 million in R&D expense and $13 million to $13.5 million in SG&A expense. Interest expense is expected to be $3.4 million for the full year, and we expect a nominal amount of tax expense for the full year.

Lastly, with respect to our fiscal 2023 cash utilization, we anticipate that we will finish the year with approximately $11 million to $13 million of cash. We expect our cash use for full fiscal year 2023 to be approximately $26 million, which consists of the total change in cash, excluding the net proceeds from long-term debt in the first quarter of $19.3 million. Further, we expect our Q3 and Q4 cash use to be approximately $3.5 million to $4 million each quarter. This reflects our recently implemented spending reduction plan and active management of working capital. We expect to continually evaluate and assess capital allocation decisions throughout the year to ensure effective and efficient use of our cash and resources to support our business needs.

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

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And our first question will be from Mike Matson with Needham & Company.

Unidentified Analyst

This is Joseph on for Mike. I guess for the first one, for the venous version of Pounce, we're wondering when you expect to start the trials for PE and DVT. Maybe if you have estimations on how much these will cost and when that could lead to FDA approval.

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

Yes. Thank you, Joseph. So the first component for the Pounce venous is to get through the LME. We've had some limited availability of the product in fiscal Q2, but we're through that constraint right now. And so we just have a whole new lot of the product ready to accelerate the LME for Pounce venous. As you know, the claims for that, there's a difference between a claim of removing clot in a vein versus a claim of being able to treat DVT, which is a disease state. And so our plan release to get the product into the market with the claim of removing venous clot even as we consider the design of an IDE trial that could support a DVT claim. But that is way in our future. I think the first thing is get the LME, get the learnings, understand where the product and the key archetypes where the product works best, and very importantly, get a lot of clinician feedback before what I'll call early commercialization of that, which at this point will be sometime in fiscal 2024.

At that point, as we exercise the product commercially, we'll be considering what an IDE trial could look like and with a focus on efficiency, and also understanding those who went before us, those trial sizes are probably 100 to 120 patients. And then you have to engage with the FDA to actually get the IDE on that. So we're looking at that at some time in fiscal 2024, but it's premature to comment on the actual timing until we complete the LME. And by the way, the Pounce venous device is really for veins, not quite for the pulmonary circulation of PE at this point.

Unidentified Analyst

Okay. Sure. That's very helpful. And then, maybe just assuming SurVeil is approved by the FDA. I don't think you guys have said this in your remarks, but when do you think you could start to see revenue? Would it be an immediate thing after approval, or would there be some type of delay? And how long would this delay be?

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

Joseph, this is Tim. Thank you for the questions. Now with regard to SurVeil, following the PMA approval, there will be a milestone payment that could be received from Abbott, and that could be $24 million or $27 million depending on the timing.

I think you might be asking more specifically about commercialization and commercial product revenue and profit sharing revenue. I think what we've talked about in the past is previous conversations with Abbott suggests that they would want to launch as soon as they can following the PMA approval. However, there still needs to be work to be prepared and implemented, executed to be able to manufacture product and then be able to get it to Abbott. I think in the past, we've characterized this as being several months. So it could be several months following the approval.

But I think it's probably important for folks to appreciate that as important as commercialization of SurVeil is, our attention, focus, energy and effort is 100% on securing the PMA application by submitting an amended application that's an approvable form. So we'll ensure we'll have more to say in commercialization in future quarters, but right now, we're focused on getting the PMA application submitted.

Unidentified Analyst

Absolutely. Okay. Appreciate it.

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

You're welcome.

Operator

Our next question is from Brooks O'Neil with Lake Street Capital Markets.

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

I guess I'm just curious if you could provide any color on any response you've gotten from Abbott with regard to the delay in getting approval for SurVeil.

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

Yes. As we come into the last quarter, we've been updating Abbott on our progress and have had communications with them on the regulatory strategy. But really, based on the restriction of the agreement, I can't go into any specific details in there. I will say Abbott remains excited about the prospects of having this product commercialized and in their portfolio.

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

Good. And then second question, I'm just curious, as you guys look at and think about your scale-up or ramp-up of both Pounce and Sublime, you've been in the market for a while. Do you see any indication that there could be an inflection in the scale or the amount of revenue you can generate from those products in the next, say, year?

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

Well, the inflection is happening. That's a good question. Now we didn't -- directionally, the fact that it's contributed over 50% of our product revenue is a critical component. Our product revenue for Surmodics as a whole is not a -- in the Medical Device segment, it's not a small number. So we're excited to see that beginning.

And Brooks, as I said in the past, I'm glad you asked the question. The first year -- so our sales force very small, 21 field representatives, but they've just hit their average tenure of a year with us. So very early innings. And the first year is what I call that messy market entry. It's lumpy. It's back and

forth -- more forth than back, obviously. And now so we're through what I call that mass market entry. And just to make sure, it's not a bright line, okay? It's a fuzzy line.

Now we're entering what I call really the early market development. So we've gotten through that first messy period, and that early market development, we're beginning to see customer uptake. We're beginning to see very important things like value analysis committees, and including group purchasing contracts being stood up, which are very good things to get to the mainstream market. So that early market development we are now in, which is less messy, a little more predictable and something where you can see growth acceleration.

A couple things to think through. Every -- we're very disciplined. Every dollar of revenue is not created equal in this period. The dollars of revenue we want are really to go beyond early market adopters. We want to get to mainstream users. They're more pragmatic. They're less prone to move and to switch. But getting them is what secures -- that's where the profit in the market lies. And so the challenge in this market entry period now is really to make sure we're crossing that chasm into mainstream user adoption. And what we don't want to do is try to overdrive revenue by collecting what I call the early adopter models and looking good and not paying attention to the mainstream users. So we continue to see, as we said in the last quarter, maybe at one of the recent conferences, up to a 300% growth in fiscal 2023. And so that should tell you -- it may seem like small numbers, but the revenue growth percentages are large. I'll turn it over to Tim for further color.

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

Gary, well, done. I think just Brooks, for everybody on the line, I think there's just a few things that I might add. Really, we're seeing that expanding customer base. And that's going to be important into that revenue inflection point that you were asking about for the next 12 months. But keep in mind, on the call, Gary did a nice job of explaining and describing what's going on with limited market evaluations. We have a lot of things that have been in product development that are coming through the pipeline or getting into the market, and we expect that they'll be commercialized here over the coming quarters and certainly in 2024, including Pounce venous, Pounce arterial, XL and LP, and of course the Sublime microcatheter. So we'll have more -- we're filling the bay. We'll have more products in the bay, have more customers to sell them to. I think these things bode well to that inflection point that you're asking about.

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

Yes. And Brooks, I'm incredibly proud of our marketing and sales commercial team. Remember, we have much less direct field sales territories than we did 3 months ago. And even that notwithstanding, they drove incredible revenue performance this quarter. So Tim and I appropriately bootstrapped with our financial prudence and how we can accelerate that. But I will tell you, with the small team we've had, they have driven substantial performance beyond my expectations, given the recent cutback in the sales team. So very proud of what they have accomplished.

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

Great. That's very helpful.

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 Gary, I'm wondering, obviously the great update at the end of March on DCB. Has there been, I guess, any learning since then that have made you more confident or just sort of confirmed your confidence in terms of the timing of the potential regulatory clearance in Q4 and your ability to sort of get a PMA submission, amended submission in Q3? I guess, have you learned anything in the last 4 weeks that might be of interest to share in this public forum?

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

You know, first of all, the FDA, I have to say they have responded quickly. I mean this as a compliment. More quickly than Tim and I anticipated in our first quarter earnings call, subsequent to the non-approvable letter. So we want to make sure we can match their speed and readiness. At the same time, we have a lot of work to do in terms of repurposing the narrative and the amended application and so getting that in front of them. I don't want to trivialize that it's like you hit the send button and you're there. And also in terms of discussing and negotiating the appropriate label claims of the product, both with FDA and with our commercial partner, Abbott. So that continues to be a work in progress, which is why we gave ourselves through the third quarter to complete all of that.

And so I think as we said, the FDA usually guides to a 180-day turnaround on an amended PMA. But we're confident with our discussions with them that the reason we can set this as an expectation in our fiscal fourth quarter is that they -- 2 things. They can move quickly on this. And secondarily, the waterfront of things to review is not everything. It's a specific thing to get it to an approvable format. So really, the job right now is to work with Abbott, with agency and get this file submitted in the hopefully third quarter. And so we're really nose to the grindstone, getting it done.

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

All right. Great. A quick one for Tim. I just want to absolutely make sure I understand. The $3.5 million to $4 million of cash utilization, is that sort of cash flow from ops, or is that like free -- in other words, does that include CapEx, or is that before CapEx?

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

That's right. It's free cash flow. It's all in, Mike.

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

Okay. All right. Perfect. Helpful. And then just the last one. Obviously, I think the general view is the Pounce platform over time is maybe much -- hopefully a much bigger opportunity than Sublime. And I'm just wondering, would it at some point make sense to sort of talk about those separately and just sort of talk about Pounce customers and Pounce reorder rate and so forth, even just with arterial and then obviously as you move into venous. To me, it just seems like that's where the massive opportunity is the homerun opportunity potentially. And I guess I'm just wondering, at some point, do you guys start to transition and talk about Pounce separately?

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

Yes. No, Mike, it's a fair question and a good one. At the appropriate time, we will start to tease out more about the vascular invention product portfolio by itself separately. And also at that time, consider then now breaking these apart so we can give more specific information about the growth opportunities there. I think it's a fair question, and in the future, we absolutely are considering that.

One thing I will say about the Pounce platform, it's not a sleeper to us. But I'll restate, I don't know another mechanical thrombectomy system that's on the market currently. I mean, there are other devices that are suction-based or break it up based. But Pounce really is clearly something that has this capability. Now as I said, we're bootstrapped by a limited field presence. But even within that, you can do the multiplication of if we had a major field presence -- and I'm not saying we're going to have that, but it gives you an indication of the power of the product with such a limited field presence compared to that. And so very, very happy for that.

As for Sublime, it's a sleeper of a different magnitude, meaning Pounce, a very high ASP, and as you said, thrombectomy is a very hot market and a hot opportunity right now. Sublime is really changing the face of health care. And now that we have -- we'll talk about when we intend to commercialize the microcatheter platform. At this point, it will be sometime in fiscal 2024 after the LME. But that was one of the remaining things, which is how do you get through a tough lesion all the way from the wrist. And taking a cue from the coronary world that faced this maybe a

decade and a half ago and were successfully able to get microcatheter products to go through the coronary vessels, that could really open up the Sublime market. Because now a physician doesn't have to worry about, gosh, I started radially, hit some crud on the way down. I just can't get the guidewire across. And remember, if you can't cross, you can't treat. Now I have to go open up a femoral access point, a pedal access point. Now I can cross.

And so I would stay tuned for Sublime. It is -- while the ASPs may be lower, that product is going to be used in a cath lab many times a day. Pounce is a very high ASP and a lot of opportunity, but that will depend on the cases of thrombectomy coming in. So eventually, Sublime is a product which I have faith in, but it will take some patience to get the market development there. So I hope that answers your question. And we're looking forward to sharing, and as you said, uncovering more in future earnings calls.

Operator

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

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

First one on the revenue guidance, if your revenue stays flat Q3 and Q4 with what you did in Q2, you're already at the high end of that guidance. So does that mean there was something in Q2 that might have been unusually high that you think might come down in the third and fourth quarters?

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

Yes, it's a great question, Jim. Let me help you understand what's going on with the second half of the year. You heard me in my prepared remarks highlight that our SurVeil revenue is going to be about $4 million to $4.5 million, and that compares to about $5.2 million that we generated last year. I think that headwind's about $1.5 million, around the midpoint. That pretty much all is occurring in the second half of the year. And you maybe have $100,000 of it that kind of occurred in Q2, but the vast majority is going to be occurring in the second half of the year. So take that into the calculus.

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

Okay. So royalty and license fee is likely to come down a little in the back half of the year. Is that what I'm hearing?

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

Yes, when you combine the license fees and the milestone, it's probably a good way to think about it.

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

Right. Okay. And then the other question I had is inventory levels are up about $1 million from the previous quarter. Is that finished goods? And is that related to Sublime and Pounce, or is that related to SurVeil or something else?

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

Another great question. It is up about $1 million. It's predominantly raw materials you'll find. You'll see that in the 10-Q, so take a look there. Notably, Q2 product revenue was significantly higher than it was the prior year and significantly higher than what you saw in Q1. I think we had both $1.1 million, $1.2 million of sequential product revenue growth in the quarter.

So yes, of course, we're doing some replenishment in terms of some of the raw materials to support those products that we've been selling. I think there's a little bit of the growth in the inventory this quarter as it relates to some products that were in WIP and finished goods that have yet to be shipped to customers at the end of the quarter, but those I think are going out the door if they haven't already. But you should be thinking about inventory somewhere around the levels that we're currently having them at. A lot of that's going to be dependent upon how we continue to progress with the product sales. But all in all, it's a good sign of what's going on in the revenue line.

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

And have you started to build up inventory for SurVeil?

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

We have raw materials inventory. But Jim, we aren't -- we really don't have any finished goods inventory on the balance sheet here for SurVeil. I think as a reminder, we will build inventory when we start to get POs from Abbott. But there are specific requirements that we have with Abbott in terms of the amount of shelf life that remains on the product. So, not looking to get in front of the curve here and take that risk, but we do have the raw materials to fire up the engine when it's ready.

Operator

That does conclude our conference for today. Thank you for your participation.
