REFINITIV STREETEVENTS

EDITED TRANSCRIPT

SRDX.OQ - Q1 2023 Surmodics Inc Earnings Call

EVENT DATE/TIME: FEBRUARY 06, 2023 / 10:00PM GMT

REFINITIV

CORPORATE PARTICIPANTS

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

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

CONFERENCE CALL PARTICIPANTS

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

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

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

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

PRESENTATION

Operator

Welcome, everyone, to Surmodics' First Quarter of Fiscal Year 2023 Earnings Call. Please note that this call is being webcast. The webcast is accessible through the Investor Relations section of the Surmodics website at www.surmodics.com where an audio replay will be archived for future reference.

An earnings press release disclosing Surmodics quarterly results was issued earlier today and is available on the company's website as well.

Before we begin, I would like to remind everyone that remarks and responses to your questions today 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 Surmodics' SEC filings. Surmodics disclaims any duty to update or revise these forward-looking statements as a result of new information, future events, developments or otherwise.

This call will also include references to non-GAAP measures because Surmodics believes they provide useful information for investors. Today's earnings release contains reconciliation tables to GAAP results.

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

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

Thank you, operator. Hello, everyone, and thank you for joining us for our first quarter fiscal year 2023 Earnings Call. I'll start my remarks today with a brief review of our first quarter revenue performance.

In the first quarter of fiscal 2023, we achieved total revenue of $24.9 million, representing 8% growth on a year-over-year basis. Importantly, our total revenue performance exceeded our expectations for the first quarter, which we shared on our earnings call in November. Our higher-than-anticipated total revenue growth was driven exclusively by our Medical Device revenue, which increased 12% year-over-year, more than offsetting a 3% decrease in our In Vitro Diagnostics, or IVD, revenue.

Within our Medical Device business, our year-over-year sales growth was driven primarily by strong sales of our performance coating reagents and device products, including important contribution from sales of our Pounce and supplying products. We also saw higher royalty and license fee revenue.

In summary, we were largely pleased with our revenue results in the first quarter.

Tim will talk through our revenue and other financial performance, including our updated fiscal 2023 guidance in further detail during his prepared remarks. But first, let me discuss some of the key operational developments during our first fiscal quarter and in recent weeks, beginning with an update on our SurVeil drug-coated balloon.

As we shared on our November earnings call, our regulatory and clinical team finalized our complete response to the FDA's comments on our SurVeil PMA application, and we submitted our response to the agency on October 13. On January 19, we issued a press release announcing the receipt of a letter from the FDA related to our PMA application for SurVeil. In the letter, the FDA indicated that our PMA application was not approvable in its current form. We're understandably disappointed to receive this letter given the hard work and dedication of our team who have been focused on working collaboratively with the FDA to address their requests and provide additional clarification, data and testing, as necessary, as well as our numerous interactions with the agency in recent months.

It is important to understand that a not-approval letter is not a permanent denial decision. The agency provided specific guidance in terms of the information that must be added to our PMA application in order to place it in an approvable form. The information the agency requested was within 2 general categories: labeling and biocompatibility.

With respect to labeling, the agency requested revisions to some of the language related to the devices, patient labeling and instructions for use and shared revised language incorporating these revisions. We view the FDA's labeling questions as generally routine and believe that it can be easily addressed.

And with respect to biocompatibility, the agency raised additional questions related to our nonclinical testing and requested additional data to address these questions.

First, let me say that we continue to believe that SurVeil is both safe and effective with clinical outcomes for patients that are equivalent to the current market-leading device while using a substantially lower dose of a known cytotoxic drug, paclitaxel. These outcomes are reflected in the 24-month data from our SurVeil TRANSCEND clinical trial, which were presented at the VIVA Conference on November 1 and most recently at the ISET Conference on January 18, which demonstrated the sustained durability of SurVeil's safety and efficacy outcomes. Specifically, these data demonstrated comparable sustained clinical outcomes between the SurVeil DCB and the IN.PACT Admiral DCB cohorts through 24 months in both the primary and safety and efficacy endpoints despite the In.PACT having 75% more paclitaxel.

As it relates to the FDA letter specifically, I want to stress that the letter did not question the human clinical data that we submitted, including the data from the TRANSCEND clinical trial. Moreover, the letter did not request any further human clinical data. And there were also no concerns cited with our large-animal studies, or our engineering. With that said, the questions and requests received with respect to biocompatibility do require additional nonhuman testing and analysis to address.

In the days since we received the letter, our regulatory and clinical teams, in conjunction with our external advisers, have been focused on evaluating its contents and preparing to formally engage with the FDA. Specifically, our team has had an informal call with the agency representatives and is now preparing a request to obtain feedback from the FDA review team through the FDA's Q-submission process. The goal of this request is to see clarification and obtain feedback on the specific requirements for the additional testing and analysis to address the items outlined in the FDA letter. Assuming normal timelines, we anticipate receiving the FDA's formal feedback on our proposed approach via this process in May.

In tandem, following the receipt of the FDA letter, we informed our commercial partner, Abbott, and provided them with a copy of the communication. Our interactions with Abbott remain continuously productive as we pursue the next steps with the FDA that I just outlined.

Our overarching goal in pursuing these steps is to obtain additional clarity from the agency on what is required for this amended application to receive an approval decision. Based upon the feedback we received from the agency during this process, our team and external advisers will determine the appropriate path forward, and we look forward to sharing additional details.

While we work to obtain additional clarity and evaluate the path forward, we believe it is important for the investment community to appreciate some of the important considerations as we continue to navigate the regulatory process. First, while we are optimistic we'll be able to address the FDA's questions through our engagement with the agency, we could learn that it may not be practical for us to pursue the level of evidence or request. While unlikely, if this were to occur, we would need to evaluate -- reevaluate our regulatory and commercial strategy for the product.

Second, as we have shared in the past, if we obtain PMA approval for SurVeil before December 31 of this year, we are entitled to a final milestone payment of at least $24 million under our development and distribution agreement with our commercial partner, Abbott. After December 31, we remain entitled to the $24 million milestone payment following the receipt of the PMA approval provided that Abbott chooses to commercialize the product and does not exercise the right to terminate the agreement.

Ultimately, despite this unfortunate development in our path to commercialization of the SurVeil DCB, our team remains focused and productive. We will continue to engage with the agency and our commercial partner, Abbott, as we navigate the next steps in the regulatory process that I have outlined with the goal of bringing this innovative product to physicians and patients as efficiently as possible. We look forward to providing the investment community with additional details on our strategy as we obtain additional information from the FDA and determine our path forward.

Now let me provide you with an update on our progress related to our other strategic objectives for fiscal 2023, beginning with our second strategic objective: to advance the initial commercialization of our Sublime radial and Pounce arterial thrombectomy platform.

During the first quarter of 2023, our recently established direct sales force of 28 territory managers continue to focus on building our customer base and drive repeat orders across our expanded account base. Our market development team has successfully raised national product and brand awareness of our Sublime and Pounce platforms, with 2 dedicated supplements published in an Endovascular Today, which is viewed as one of the most recognized publications in endovascular medicine.

The Sublime radial access "Wrist to Foot" supplement was published in November of 2022 and outlines a compelling case for why the radial revolution spearheaded by the Sublime line of products in the peripheral space is gaining momentum. With the shift of endovascular procedures moving from hospitals to ambulatory centers and office-based labs, the benefits of radial access approach will be strategically important for owners and operators while having a positive impact on patients.

In December of 2022, the Pounce thrombectomy supplement was published and reinforces the importance and success of our grab-and-go device that offers on-the-table results. The risk of arterial clot has increased significantly in the post-COVID era, which exemplifies the need for a simple, efficient endovascular solution versus the more complex capital-intensive devices that exist today and a traditional surgical Fogarty procedure. I highly recommend for you to read each of these if you want to understand more about our mission and why we remain committed to bringing these incredible technologies to market.

Our team has made strong progress in engaging with potential new customers and working with them to get our products approved through their hospitals or clinics value analysis committee. I'm pleased to report that we ended the quarter with over 135 total customers for Pounce and Sublime compared to over 100 at the end of fiscal 2022.

And lastly, our pipeline of prospective customers has continued to expand at a healthy pace. At the end of the first quarter, the number of value analysis committees that are considering our products increased by more than 20% compared to the end of fiscal '22. We are beginning to see the impact of our brand awareness and market education programs, which continue to drive new customer interest.

Ultimately, we remain in the initial months of commercialization with a small but growing customer base and an average sales force tenure for approximately 9 months at quarter end. Looking ahead, we remain focused on building our recent progress through the next 9 months of fiscal 2023 as we progress through our first full year of commercialization and continue to lay the foundation for strong future growth. I am excited about the ongoing clinical performance of our commercial offering, and we'll continue to find ways to accelerate growth in these areas.

Lastly, an update on our Pounce venous thrombectomy device. We have recently begun to conduct limited market evaluations to gain experience across a wide variety of cases and clinical conditions and evaluate the feedback from numerous physicians. The real-world feedback obtained through these renewed evaluations will help inform potential future design enhancements that benefit physicians and patients while optimizing its commercial viability.

With respect to our third strategic objective: to drive revenue and cash flow growth from our Medical Device Coatings offerings and diagnostic businesses. Broadly speaking, we were pleased with the overall performance of our core businesses during the first quarter. Revenue from our Medical Device Performance Coatings offerings grew 10%, while revenue from our IVD business decreased 3% year-over-year in the first quarter. Now the decrease in IVD revenue was driven primarily by the completion of a customer development program. Together, these businesses generated significant cash flow to support our growth initiatives, including the year-over-year increase in operating expenses related to the expansion of our direct sales force.

So with this as an operational update as a backdrop, I'd like to turn now to discuss the spending reduction plan we have recently implemented. As we indicated in our press release on January 19, the FDA's response to our SurVeil PMA application, which means that we will not receive the related Abbott milestone payment in our second fiscal quarter as anticipated, this prompted us to evaluate options and take action in order to preserve capital as we prioritize investment in our key strategic growth initiatives. As a result, we have recently implemented a spending reduction plan designed to reduce our planned use of cash by approximately $10 million to $11 million for the remainder of fiscal 2023 prior to the restructuring charges.

Approximately 48% of the spending reduction is from SG&A, 27% from capital expenditures and 25% from R&D. Importantly, this plan was created and implemented after careful evaluation. We do not expect it to impact our ability to serve our customers, nor our ability to respond to the FDA. The spending reduction plan includes 2 primary components: a workforce restructuring and additional cash saving measures.

Let me take a minute to cover both of these components in some more detail. The workforce restructuring involves a 13% reduction in our employee head count. These workforce reductions are intended to streamline and refocus the teams in several areas of our business, including manufacturing and operations, R&D and clinical, sales operations and our direct sales force, so that we can continue to execute our growth strategy more efficiently in fiscal '23.

On the manufacturing and operations front, we have reduced the number of positions that support the manufacture of our SurVeil drug-coated balloon while retaining our core team that supports SurVeil, including key manufacturing, technical, regulatory and clinical personnel.

On the R&D and clinical front, we have aligned our head count to support our current R&D priorities from a product development standpoint, which I'll discuss in a minute. And finally, we've reduced the size of the our -- the commercial organization supporting our Pounce thrombectomy and Sublime radial access products to optimize our investment in sales operations. Our direct sales force consists now of 21 territory managers as of today's call and remains focused and committed to driving growth in these product platforms.

The additional cash saving measures that I mentioned, including a reduction in our planned CapEx, a reduction of our hiring plan for the remainder of fiscal 2023 and a refocusing of our investments in product development to prioritize progress primarily on our near-term commercialization opportunities. In terms of our priorities from a product development standpoint, we'll focus our product efforts on areas including Pounce arterial, Pounce venous, and the Sublime radial product platforms. Several of our pipeline projects with a longer path to commercialization, including our Sundance and Avess drug-coated programs, have been placed on hold.

As it relates to our Sundance and Avess drug-coated balloons, we continue to be proud of the compelling first-in-human clinical data we have generated for these products to date and the ongoing follow-up of our first-in-human studies that is ongoing. More recently, we were pleased to see the 12-month data from our 35-patient SWING trial for Sundance presented at the International Symposium on Endovascular Therapy or ISET Conference on January 19.

These data clearly show that the use of Sundance was associated with a primary patency maintained at 12 months and 80% of the per protocol analysis population. Based on the 12-month data, our co-lead investigator for the trial, Professor Ramon Varcoe, concluded that Sundance holds

significant promise for treating real-world patients for peripheral vascular artery disease. Given that Sundance and Avess DCBs use the same similar drug delivery technology to that of SurVeil, we'll use the experience we gained from the SurVeil product PMA application process to develop the commercial and regulatory strategies for these drug-coated balloons.

So stepping back. Implementing the spending reduction plan and the related adjustment in our staffing levels was a very difficult decision for us and in no way is it a reflection of the incredible talent and hard work of our team members during their time at Surmodics. We value every employee of Surmodics and have taken careful measures to ease the burden of those impacted, including severance and outplacement services. Ultimately, this is a decision that we believe was both appropriate and necessary for the longer-term success of our company and the benefit of all of its stakeholders. These steps will re-focus the organization to better align our spending with our near-term strategic priorities and growth opportunities.

As we look ahead, we remain focused on our 3 strategic priorities. First, we will continue to make progress with respect to our regulatory strategy for the SurVeil drug-coated balloon as we prepare to engage with the FDA and evaluate the appropriate path forward. Second, we will continue to advance initial commercialization of our Sublime radial and Pounce arterial platforms, turning the corner from market entry eventually to rapid growth. And third, we will drive revenue and cash flow growth from our Medical Device performance coatings offerings and IVD businesses.

Despite the challenges we have faced in recent weeks, we believe that pursuing these 3 objectives represents the best path to achieving strong sustainable growth and creating long-term shareholder value. With a recently enhanced balance sheet and access to approximately $60 million in incremental debt financing, a disciplined approach to spending and capital allocation, strong and stable core businesses and a portfolio of innovative technologies, we believe we are well positioned for the future and remain committed to executing our strategic initiatives efficiently.

I'll now turn the call over to Tim Arens, our Chief Financial Officer, to provide more details on our first quarter fiscal '23 and our updated fiscal '23 guidance. Tim?

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

Thank you, Gary. Total revenue for the first quarter of fiscal 2023 increased $1.9 million or 8% year-over-year to $24.9 million compared to $23 million in the prior year period. Product revenue increased $1.9 million or 15% year-over-year to $14.2 million in the first quarter of fiscal 2023. The year-over-year increase in product revenue was primarily driven by Medical Device product revenue, which increased $1.6 million or 23% year-over-year due to strong sales of our performance coating reagents and medical devices, including contributions from sales of our Pounce arterial thrombectomy and Sublime radial platforms.

We also saw contributions from growth in IVD product revenue, which increased $300,000 or 5% year-over-year, driven by growth across several IVD product lines, which more than offset some unfavorable order timing for distributed antigen products, which fluctuates quarter-to-quarter.

Royalty and license fee revenue increased $670,000 or 8% year-over-year to $8.8 million. Royalty revenue from our performance coatings increased $520,000 or 8% year-over-year. Compared to the first quarter of fiscal 2022, royalty revenue was less impacted by pressures on procedure volumes related to hospital capacity constraints and customer supply chain disruptions. License fee revenue increased $140,000 or 12% year-over-year related to our SurVeil agreement with Abbott.

R&D services revenue decreased $630,000 or 24% year-over-year to $1.9 million. The year-over-year decrease in R&D services revenue was primarily due to the completion of a customer development program in our In Vitro Diagnostics business and the timing of customer development programs in our Medical Device business.

Product gross margin in the first quarter of fiscal 2023 was 63% compared to 63.6% 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 partly offset by the favorable impact of product mix.

R&D expense includes cost of clinical and regulatory activities increased $1.1 million or 9% year-over-year to $12.7 million in the first quarter. The year-over-year increase in R&D expense was primarily driven by increased product development investments in our Pounce thrombectomy portfolio and costs associated with our SurVeil drug-coated balloon.

SG&A expense increased $4 million or 44% year-over-year to $13.2 million in the first quarter of fiscal 2023, primarily driven by a year-over-year increase in head count 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.

Our Medical Device business reported an operating loss of $7.2 million in the first quarter of fiscal 2023 compared to a loss of $3.8 million in the prior year period. The year-over-year change was driven primarily by the investments in our direct sales force. Our IVD business reported an operating income of $2.9 million in the first quarter or 50% of revenue compared to $3.2 million or 52% of revenue in the prior year period.

Turning to income taxes. In the first quarter of fiscal 2023, we recorded an income tax benefit of $170,000 compared to a benefit of $710,000 in the prior year period. As we discussed in our fourth quarter earnings call, we are no longer recording tax benefits on U.S. net operating losses as a result of having established a full valuation allowance against our U.S. deferred tax assets.

GAAP net loss in the first quarter of fiscal 2023 was $7.8 million or a loss of $0.56 per diluted share compared to a loss of $2.8 million or a loss of $0.20 per diluted share in the prior year period. Non-GAAP net loss in the first quarter of fiscal 2023 was $7 million or a loss of $0.50 per diluted share compared to a loss of $1.8 million or a loss of $0.13 per diluted share in the prior year period.

Adjusted EBITDA loss in the first quarter of fiscal 2023 was $3.3 million compared to adjusted EBITDA of $650,000 in the prior year period. Note, our adjusted EBITDA in both periods includes an adjustment for stock-based compensation expense. For your reference, we've included a detailed reconciliation in our earnings press release.

Moving to the balance sheet. We began the first quarter of fiscal 2023 with $19 million in cash and $10 million in debt outstanding in our revolving credit facility with Bridgewater Bank. Cash used by operations during the first quarter was $10.8 million, and capital expenditures totaled $1.0 million. It is important to note that our first quarter historically requires a higher use of cash to fund our working capital needs such as annual employee bonus payments and our annual prepaid insurance premiums.

In mid-October, we entered into a new 5-year credit agreement with MidCap Financial, comprised of up to $100 million in term loans and a $25 million revolving credit facility. We drew on the term loan and revolving credit facility at close and received net proceeds of $19.3 million. A portion of gross proceeds were used to retire our prior revolving credit facility with Bridgewater Bank.

As of December 31, 2022, we ended the quarter with $26.4 million in cash and $29.4 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 December 31, 2022, we have approximately $60 million in debt capital available consisting of $50 million on our term loan availability as well as incremental availability on our revolving credit facility, which is subject to borrowing base requirements.

Turning now to fiscal 2023 guidance. We have updated our fiscal 2023 revenue guidance to reflect our performance in the first quarter as well as our revised expectations for the remainder of fiscal 2023. We now expect fiscal 2023 total revenue to range from $102 million to $106 million, representing an increase of 2% to 6% compared to the prior year. This compares to our prior range of $103 million to $107 million or an increase of 3% to 7% compared to the prior year.

Our updated total revenue guidance incorporates revised fiscal 2023 revenue expectations for our Pounce and Sublime products, including changes to reflect our updated sales head count, which Gary mentioned. We now expect fiscal 2023 GAAP loss per share to range from a loss of $2.40 to a loss of $2, compared to our prior range of a loss of $2.80 to a loss of $2.40.

Non-GAAP loss per diluted share in fiscal 2023 is expected to range from a loss of $2.09 to a loss of $1.69 compared to our prior range of a loss of $2.54 to a loss of $2.14. Our updated fiscal 2023 loss per diluted share guidance reflects the revisions made to our total revenue guidance that I just mentioned as well as a net favorable impact of our spending reduction measures.

It is important to note that guidance does not include any incremental expense that may be incurred to potentially conduct any animal studies or other expenses that may be required to address the FDA's biocompatibility concerns related to SurVeil. In addition, our guidance excludes revenue associated with any potential future Abbott milestone payment on receipt of 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. As a reminder, we continue to expect margins to be impacted by product mix and inflationary pressures. In addition, we expect higher absorption of fixed overhead costs and our cost of sales as commercialized products are allocated in the increased share of our overhead expenses due to reductions in drug-coated balloon production.

With regard to operating expenses, excluding onetime severance costs, we expect rest of the 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. We expect a nominal amount of tax benefit 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 in cash. We expect our cash use for the full year fiscal 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 the following items and assumptions: our updated revenue guidance and active management of working capital; our spending reduction plan, which, as Gary discussed, is expected to reduce cash use by $10 million to $11 million, excluding severance costs; we expect onetime severance costs of $1 million to $1.2 million, which we expect will be mostly incurred in the second quarter; and lastly, we expect to incur no further borrowings on our revolving credit facility and term loans. 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 come from Brooks O'Neil with Lake Street Capital Markets.

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

I appreciate the substantial amount of detail and, clearly, thoughtful comments about all aspects of the business. I guess one thing I didn't hear you discuss that I think investors would like a little color on is whether you considered kind of the [do-it-alone] versus partner approach for Sublime and Pounce. And if you did, which I assume you did, perhaps you could just give us a little color about your thinking in that regard.

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

Yes. I mean, we evaluated this a long time ago and continuously scan the environment on this issue. It was clear that the best way to create long-term shareholder value creation was in the hands of our direct sales force. As you know, we have some experience with the partnership of whole products. Given these -- the unique capability of these products at this point, nothing has changed there.

We, like, what we see. The cost is going to take some time to produce ongoing "milk" production, but early development in the first 9 months of -- and sorry, that's an analogy of use of, "You don't measure milk production from a cost. You measure it from a cow, right?" Just to remind everybody. But with 9 months of average tenure into this, it's early innings. And we're seeing the uptake and growth of these products as this begin to develop and it is best in our direct hands.

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

Very good. Let me ask a second question, which is -- I appreciate Tim's comments on the guidance and, Gary, your comment on the outlook forward for Sublime. I'm just curious, given that the FDA has given you some guidance about the path forward, why did you guys decide not to include the potential cost of the animal testing in the forward guidance?

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

Yes. Here's the issue. We don't want to speculate publicly when -- after we come out of the submission issue meeting, which we expect in the next couple of months and we have alignment to the agency, only then will we have what we call much firmer data to share with our shareholders. Right now, it would be subject to speculation.

I'll give one caveat, however. This is not $10 million. This could be $1 million or $2 million. And again, I'm speculating here, but I want to be clear, this is not in the large number of millions of dollars, which is why we said in the script, if it appears to be that, we will pause and reconsider the best options for our shareholders. But I don't want to speculate without having the agency, basically, get to alignment with us. And then if I speculate now, I'll be updating that, and I prefer to hold that in reserve at this point.

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

Okay. Just a quick follow-up. You do think it's likely the FDA will want additional small animal testing, right?

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

So in the letter, they laid out in specific but not directly detailed terms what type of data they'd like to see to cover any gaps that they believe exists. So -- and much of this really deals with small animals, not the large animal testing.

Operator

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

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

I guess just start with SurVeil. So I think you said you expect to hear back from them in May. So if you hear back from them in May and then you have to do some additional testing, maybe you can resubmit something in kind of like, the fall. So I mean, is it possible we could get another -- an answer from the amendment in calendar '23? Like, does it sound right? Yes.

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

Yes. I appreciate the question. And it -- the timing -- I can lay out just briefly the process. So to get the feedback, it's like filing a brief in front of a judge. You can't secure the meeting until your brief is complete. So our team is working around the clock to complete our view and our brief and our point of view on the requirements. Only then do you send that and you secure a meeting, which takes, in a matter of, not months, but it's a matter of weeks. So it could be a month. And so this process is really important for us to get it right with our brief, then get that meeting. So all of that, as we said, on the normal time lines, we would expect to happen by May.

If animals, small animal testing is required, depending on the numbers, the type of species, et cetera, this will then be scheduled with the -- our partners at animal labs that conduct these preclinical labs so they're independent that were conducted. So if you're asking us if we would like this done by the end of fiscal year -- by the end of the calendar year, absolutely.

But -- and I appreciate the question, but until I have more appropriate information, again, I'd prefer to get in front of the agency and get some level of detail before speculating openly, with one caveat again. Clearly, we are working as fast as we can. And if there's a way to get this before the end of the calendar year or earlier, we would be using every angle.

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

Okay. I understand you don't really know what's going to need to be done on the testing aspect, but let's just say that you're able to do that. And then I guess my question would be, once you complete -- let's say, there are some additional testing you completed and submit that back to the FDA in this amendment, is there some kind of time requirement for them to -- what's the clock there? How much time do they have to respond to that when you resubmit that amendment once it's -- whatever testing is done?

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

Sure. They are not on what we call the "MDUFA" clock right now. And 180 days is typical, but we don't expect it to take that long. This is not a whole application. It's a subset of a subset of biocompatibility. And so the early indications, they recognize that, and they don't -- I don't want to quote them. But until I have this in a committed written document from the FDA, I don't want to speculate again, but 180 is typical. We don't expect it to take that long.

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

Okay. All right. And then just maybe, can you explain this whole process? They just seem to have some kind of hang up on whatever you're using in your coatings. And what is it in the coating? And why are they so worried about this? I mean, the drug is the same, right? It's a lower dose. So it's got to be some other ingredient, right?

(technical difficulty)

Operator

Ladies and gentlemen, thank you for standing by. Please continue to hold as we reconnect the speakers. Thank you.

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

The call dropped for some reason. So thanks, we're back.

Operator

(Operator Instructions)

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

Yes. So I guess I don't know what point I got cut off, but I was asking a question about just kind of what the concerns are at the FDA about biocompatibility. I mean, I guess I thought that's why you've done the kind of round of tests that you did last fall to address those concerns. So I mean what -- I don't know if you can comment, but I mean what is it about the product that they're still hung up on? Is it like -- I mean it's the same drug. It's a lower dose. It doesn't seem like that's the issue, but is there some other sort of ingredient that you're using that's unique to your balloon versus some of the others?

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

So certainly, we use some -- what I'd call, exciting technology. And I'll just say this, none of this, going back to it, relates to human clinical data, large animals or the engineering. And if you think about it, we have the only, and I mean the only pivotal worldwide trial of a low dose versus high dose.

No other company has that in the industry, so approaching 4-year human safety data now. And so we feel that clearly, our technology has a dramatic benefit because no one else has demonstrated it in a level 3 evidence randomized controlled trial like we have. So we were confident doing it because we're confident in the technology.

It is highly unusual to be going back after you have hundreds of patients out to 4 years in -- with sort of a pristine safety and efficacy record. So what I would say, Mike, is I don't want to divulge some of the unique components of Surmodics technology at this point. But yet, needless to say, these technologies that we believe mitigate the risk of using very powerful drugs by being able to use a lot less. And we believe we have actually put our money where our mouth is and conducted, once again, the only pivotal trial in the industry versus a high-dose device. Nobody else has done it.

So we'll work through this with the agency. I think it's just a matter of us getting in front of them and getting alignment. And until I get that alignment, I prefer to just stick to what we know now. We're still, in fact, finding more with them.

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

Okay. I understand. And then I think on the prior call, maybe it was the last quarter, I don't remember, but you talked about building up some SurVeil inventory. So is that the case? And I mean maybe that's why you had the manufacturing reduction, I don't know. But what's the shelf life? Is that stuff going to have to -- is there a risk that, that stuff has to be written off if this doesn't end up being approved or it takes longer than expected?

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

Thank you, Mike. This is Tim and I appreciate the question. Yes, there are obviously some moving parts here. You -- you're addressing an important aspect of what's impacting the product gross margins for Q2, 3 and 4. This basically speaks to our expectation that we would have been in a position to have received the PMA and begin to support the Abbott commercialization engine, and you see that in our inventory build this most recent quarter versus Q4.

But it also affects us because the folks that would be working in the production line, all of that, that would have been hitting some inventory for Q2, 3 and 4 is now being absorbed into our product sales. So it does have an impact there. You can probably do the math. It's $1.5 million to $2 million. And those costs are going to be hitting the P&L.

In terms of scrap and how to think about, are there things in terms of our raw materials inventory on the balance sheet, it's important to know that we really don't have final finished products on the balance sheet. It's all raw materials or components that are on the balance sheet. There are a few things that will probably have some potential for reserving against, sort of scrapping.

But again, it really is going to be dependent upon how we think about the timing of a potential FDA decision based upon the process that Gary described with the Q submission. And we should hopefully have greater insight and perspectives on that as we kind of get into the May earnings call, but I don't know that there would be anything other than probably something nominal for the fiscal '23.

Operator

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

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

So you talked about the $10 million to $11 million in cash spending for the remainder of the year. How much of that carries over into fiscal 2024 assuming that you don't bring back Sundance and Avess?

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

Thank you for the question, Jim. It's Tim. And I would tell you that, obviously, this is a 9-month view. Actually, it's closer to 8 months given the timing of the decision. And it's fair that you can run rate a good portion of that. One thing to be mindful of, the $10 million to $11 million that's reflected in the reduction, the spend reduction efforts would actually be probably greater because there are things that are more likely to be a cash impact that would occur in our Q1, for example, the annual incentive plan or payment. So it probably is not incorrect to get you a pretty good view on the dart board at least, taking the $10 million to $11 million and run rating that out.

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

Okay. Right. And then you mentioned that Abbott would have the option to not commercialize the product if you don't get approval by the end of calendar 2023. If that were to happen, would you have to refund the many of the milestone payments they've given you so far?

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

We would not.

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

Okay. And so if they've already invested $60-plus million into the product, it's probably unlikely that they would opt to not commercialize it if it takes a few months into 2024. That's an even...

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

Understood. We're limited in what we can say about Abbott, but I have found them to be highly constructive and engaged throughout this entire regulatory process. So that partnership, as we continue to interact with them, is strong, and it continues. However they decide months from now, I think that'll be, however -- it's really up to them. So I'm limited to what I can say on their behalf, obviously.

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

All right. And then just one more on Sundance and Avess. If you don't decide to go ahead with commercializing those products, are there any options -- any other options for you to monetize that? Are those assets that you can sell?

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

Go ahead.

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

Go ahead. I was going to say with a PMA approval for SurVeil, the value is nonlinearly increased for those. So bookending them now, meaning taking them off the [shelf] and putting them in a form where we can pick it back up more efficiently is the best to preserve the value there.

And given our cash burn, we don't want to continue with parallelism. Even though we believe that, that results in an opportunity. We simply want to get through this issue with SurVeil, and we can pick it up. Those technologies would not be losing value as we book ended it. I remain quite excited about them, but let's deal with SurVeil first. That's how we feel.

Operator

(Operator Instructions) Our next question comes from Mike Petusky with Barrington Research.

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

I guess, Gary, you described Abbott as engaged and highly constructive. I'm just curious given their wealth of experience and all the rest. Have they given you any input on anything based on their experience that's similar or any advice or any, essentially, guidance as how they would sort of try to approach this?

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

I'll say we have an excellent regulatory and technical connection with the Abbott team on this. And so they know what we're filing. They know the idiosyncrasies of the FDA interaction. And I will say I've only high respect for their technical experts that they gave us on loan to comment or give advice on this. So yes, that interaction clearly has been always a part of the partnership through each of these stages. And I believe it will continue in that way.

That said, we -- and I believe they understand our technologies well enough. This comes down to a matter of perspective, matter of, to me, at least, using the totality of data versus dissecting small data sets and then using that to guide the whole.

We have a plethora of evidence from humans to all the way down to small animals. So I think it's really making sure the FDA understands that perspective and narrative at a high level versus just a mere drill down into a specific small component data set. So I'll say Abbott has been constructive, and they know I don't expect that constructive interaction amongst the peers on Abbott team and our technical and regulatory view has to change.

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

I guess probably for Tim. The -- I guess the maybe $2.5 million or so of R&D expense reduction, is most of that around Sundance and Avess? Or are there other things there that make up a meaningful amount?

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

Yes. No, it's a good question. It's obviously impacting more than just Sundance and Avess. We do have -- we've made some decisions to delay some of the longer-term activities in some of the R&D programs and, of course, some of the personnel. So there is a number of factors, but you're picking up on a key one there, which is the drug-coated balloon aspect of this.

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

Right. Would that be the majority of the $2.5 million or $3 million?

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

It's a fair amount of it, yes.

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

All right. And then jumping over to Sublime and Pounce. Any -- I didn't catch it. If you said it, I missed it. Anything to say on reorder rates? And any anything to share there even anecdotal?

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

I think I'll say when dealing with small data and small numbers of time, you can draw many conclusions. When we have looked at the reorder rates, they are exactly where we expect them to be, and that's not a negative statement. That's a positive statement. I think what's really interesting and frankly, quite exciting to us, if you look at LinkedIn and you see physicians unprompted, saying things like, "I just did my first Pounce case, and I've got to tell the world about it." I really -- and I know I don't want to sound like an advertisement for endovascular today, but the best way to get a sense, just a small, "tip of the iceberg," sense of the power of these products is to read those supplements. There are physicians and cases that talk about the power of these products, so.

With reorder rates, we're happy with the reorder rates. I'll let you know that. Growth, we're happy with the growth. Clearly, we'll take a bit of a trim on revenue given that we have eliminated some of these territories, but we're still going to have very efficient growth. It was clearly an optimization of cash versus growth and value creation that way.

Tim and I made the right choice of how to get that revenue growth, but to also ensure cash burn is within reasonable disciplined limits for the corporation. I'm -- I'll say this one more time, I'm quite excited about the evolution of those products.

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

Right. Your comments -- just jumping back real quick, just last one. Your comments today that you got the notification from FDA. You sort of talked about possibly we're having to go back and do some animal testing. Is there anything in your learnings since that day that would indicate it could possibly be expanded beyond animal testing in terms of additional data that would need to be captured for some reason? Or are you pretty confident that, that would be the extent of it, although you don't know exactly how involved the animal testing would be?

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

It's a very good question. What I'll say is my risk adjustment for dealing with the agency from the lessons learned here has clearly gone up. However, the way to mitigate that risk is to get assurance from senior management of the agency of the integrity of the process, the timing and the exchange of scientific information. I -- life as an FDA review has got to be hard. They have to go wide and also deep. However, sponsors know the technology, just by nature, much deeper than an FDA review can.

Without the right level of interaction, if we are not able to demonstrate to these reviewers the levels of detail that are relevant to their decision, we think you'll always get a deficiency. And so part of it, for me, is the process doesn't lend itself to the engagement and dissemination of scientific judgment and understanding when it comes to technologies with the new and different.

So I'll leave it as that. I don't -- so with that being said, I'd be quite surprised if there is something to come up about human clinical data. I can't see that happening, but allow me to risk-adjust it a little bit again. I don't see it happening. While highly improbable, I'll say it could be possible, but I don't mean to scare you with that. Just giving you the risk that I see until we get full alignment of the agency.

Our data is -- I'll say we run the best trial that's ever been conducted in the industry. And again, the only head-to-head randomized pivotal trial worldwide. And so I feel really positive about the clinical data. And I think what's stuck in my craw is that this device can be having a huge beneficial impact, to me, on U.S. patients. But we'll work through this with the agency.

Operator

Thank you. And that does conclude our conference for today.