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CORPORATE PARTICIPANTS

Gary R. Maharaj *Surmodics, Inc. - CEO, President & Director*
Timothy J. Arens *Surmodics, Inc. - VP of Corporate Development & Strategy, Interim VP of Finance and CFO*

CONFERENCE CALL PARTICIPANTS

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

PRESENTATION

Operator

Good day, and welcome to the Surmodics' Fourth Quarter 2018 Earnings Conference Call. Today's conference is being recorded.

At this time, I would like to turn the conference over to Tim Arens. Please go ahead, sir.

Timothy J. Arens *Surmodics, Inc. - VP of Corporate Development & Strategy, Interim VP of Finance and CFO*

Thank you, Chantel. Good morning, and welcome to Surmodics' Fiscal 2018 Fourth Quarter Earnings Call.

Before we begin, I would like to remind you that during this call, we will make forward-looking statements. These forward-looking statements are covered under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and includes 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 our forward-looking statements, resulting from certain risks and uncertainties, including those described in our SEC filings. Surmodics disclaims any duty to update or revise our forward-looking statements as a result of new information, future events, developments or otherwise.

We'll also refer to non-GAAP measures because we believe they provide useful information for our investors. Today's news release contains a reconciliation table to our GAAP results.

This conference call is being webcast and is accessible through the Investor Relations section of the Surmodics' website, where the audio recording of the webcast will also be archived for future reference. A press release disclosing our quarterly results was issued earlier this morning and is available on our website at surmodics.com.

I will now turn the call over to Gary Maharaj. Gary?

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

Thank you, Tim, and good morning, and thank you for joining us. Fiscal 2018 has been an exciting year for Surmodics with many significant accomplishments by our team. First and foremost, we're fully ahead of our schedule on our previously stated goal to achieve consistent double-digit revenue growth by the end of fiscal 2019. Not only did we accomplish this goal by growing revenue 11% year-over-year in fiscal 2018, we believe that Surmodics is now positioned for sustained double-digit revenue growth into the future.

We also accomplished several key strategic initiatives that position us for this growth. We signed an agreement with Abbott as our worldwide commercialization partner for our SurVeil drug-coated balloon. We strengthened our innovative product pipeline with acquisition of a novel and differentiated thrombectomy platform. We executed 3 510(k) submissions for unique medical devices developed in-house. And we initiated 59 U.S. clinical sites for the TRANSCEND clinical trial and substantially accelerated study enrollment. And in the fourth quarter, we submitted for regulatory approval for the first in-human study for AVess, our arteriovenous access drug-coated balloon.

Moving on to our fourth quarter operating results, we are pleased to report another quarter of solid top line and operational performance, including additional investments in our new product pipeline. We generated revenue of $23 million, growing 15% over the

fourth quarter of fiscal 2017. This included $2.2 million of revenue from our SurVeil agreement with Abbott.

We also reported a diluted GAAP loss per share of $0.13 in the fourth quarter. Looking ahead, we're well positioned to build on our momentum, and we are issuing our fiscal 2019 revenue expectations to $92 million to $97 million, reflecting growth of between 13% to 19% year-over-year.

We have 3 core objectives to guide us, and we continue to execute on our strategic initiatives in fiscal '19. These are: first, to ensure the success of SurVeil, specifically to complete the TRANSCEND study enrollment and to make substantial progress towards achieving the CE Mark; second, to continue to make meaningful advances with our DCB pipeline and our nondrug delivery device portfolio, including the acceleration of our thrombectomy platform development; third, to continue to drive revenue growth and cash flow from our existing Medical Device coatings and IVD offerings. While these offerings generate moderate revenue growth, they do provide significant and ongoing return on invested capital and continue to grow in intrinsic value even while they provide investment funding to fuel our strategic growth initiatives.

Let me provide some more perspective regarding these core objectives. Starting with SurVeil. We're very pleased with enrollment progress in TRANSCEND, our pivotal trial for SurVeil. The fourth quarter saw the highest quarterly enrollments since the trial was initiated. 59 of the 60 U.S. clinical sites have been initiated, and we are actively getting our 18 OUS sites up and running. As planned, we expect to complete TRANSCEND enrollment by September of 2019. Furthermore, discussions with our European Notified Body have provided more clarity on a regulatory path necessary to attain the CE Mark, which we are targeting to receive before the end of calendar 2019. In parallel to obtaining the CE mark, we are ensuring our production engine is ready to support the product demand resulting from commercialization by our partner Abbott in their approved geographies. The 12-month data from our PREVEIL early feasibility study for SurVeil was presented at the VIVA Conference earlier this week. Recall that the PREVEIL trial enrolled 13 subjects in the U.S. with a primary endpoint of plasma pharmacokinetics and safety. I am pleased that the data for primary and secondary performance and safety endpoints were all excellent. There was an absence of any safety issues, including 100% freedom from clinically driven target lesion revascularization. In other words, at up to 12 months, no patient had to be readmitted to retreat the target lesion nor the target vessel. We're quite pleased with these results. In addition, these patients continue to experience ongoing significant clinical improvement in ankle brachial index, walking distance, walking speed and stair-climbing scores. We are also unaware of any early feasibility trial of a combination product that is drug device that has been successfully performed in the United States to date.

Turning to some of our other products in our burgeoning pipeline. We have made significant progress developing our AV fistula access drug-coated balloon, AVess. I mentioned at the top of the call that we have recently submitted for the first in-human study for AVess. And in our innovative below-the-knee program, we're in the process of optimizing the coding and drug delivery formulation based on the results from our preclinical investigations. In 2019, we're aiming to both initiate and complete the first in-human trial of AVess and initiate the first in-human study for our BTK balloon, now called Sundance.

We continue to make progress on our nondelivery pipeline -- drug delivery pipeline as well. And we are committed to continually work on the next wave of product innovations that solve real and meaningful problems. This will help us build differentiated platforms and create additional shareholder value. During fiscal 2019, we expect to submit 3 to 4 more 510(k) clearances to the U.S. FDA. As part of these efforts, we're committed to accelerate the development of our thrombectomy platform. As a reminder, our thrombectomy platform has broad potential to treat thrombosis in multiple muscular beds, including arterial and venous thrombosis, pulmonary embolism and neurovascular applications. Our team is working on the test methods and initial prototypes with an aggressive aim to complete design freeze by the end of fiscal 2019 and to submit our first application for regulatory clearance for vascular thrombosis in the first half of calendar 2020.

Moving on to our commercially approved devices. We're making progress towards a distribution agreement with several interested parties who are in the process of clinically evaluating each of these products. As we did with SurVeil, we continue to exercise the appropriate patience to sign the right deal with the right partner in order to maximize the commercial potential for each of these devices.

Finally, our Medical Device and IVD business segments continue to drive commercial excellence. While our Medical Device business segment is expected to contribute significantly to our expected double-digit revenue growth in fiscal '19, our coating derived revenue is

expected to remain relatively flat as we get closer to exhausting our third-generation patent expiration headwinds. Meanwhile, revenue from our IVD business continues to outperform the broader immunoassay market growth rate of 3%. By accomplishing these 3 important core objectives in fiscal '19, we will have built on our fiscal 2018 successes and position Surmodics for continued, consistent double-digit revenue growth and generating EBITDA margins at or above 30% by fiscal 2021.

I'll now turn the call over to Tim to provide more details on our fourth quarter fiscal '18 results as well as our outlook for fiscal '19. Tim?

Timothy J. Arens ***Surmodics, Inc. - VP of Corporate Development & Strategy, Interim VP of Finance and CFO***

Thank you, Gary. Revenue for the fourth quarter of fiscal 2018 was $23 million as compared with $20.1 million in the fourth quarter of 2017, which, as a reminder, included a onetime license fee of $1.1 million.

Looking at our 2 business units, Medical Device delivered solid 15.4% growth, increasing $2.3 million to $17 million in the fourth quarter. For In Vitro Diagnostics business, fourth quarter fiscal 2018 revenue, which is predominantly comprised of product sales, totaled $6.1 million, up 13.4% compared with the year ago period.

Looking at specific areas within Medical Device, fourth quarter royalty and license fee revenue totaled $10.3 million, up $1.1 million from the comparable prior year quarter. The increase in royalty and license fee revenue reflects $2.2 million of license fee revenue recognized from the SurVeil distribution and development agreement with Abbott.

As previously noted, revenue in the fourth quarter of fiscal 2017 included a onetime $1.1 million license fee.

Product sales increased $1.2 million or 33%. Driving this growth was a substantial increase in balloon catheter unit volume as a result of recent customer product launches as well as increased reagent sales.

The Medical Device unit reported a $2.1 million operating loss in the fourth quarter versus operating income of $300,000 in the prior year quarter. Medical Device operating results were impacted by $2.4 million of increased R&D spend, reflecting progress with our TRANSCEND clinical study and continued investment in our innovative product development pipeline to support our future growth as well as a $1 million increase in contingent consideration expense. These expense increases were partially offset by the revenue gains in the quarter.

IVD revenue in the fourth quarter reflected strong growth in antigen and DNA slide sales. IVD operating income of $2.4 million in the fourth quarter was essentially flat compared to the year ago period.

Operating margin in the fourth quarter of fiscal 2018 was 39% compared to 44% in the comparable prior year quarter. Impacting IVD operating margin was product revenue mix, which was skewed towards lower-margin products.

Product gross margins for the quarter were 61.8% of product sales as compared with 62.4% in the prior year quarter. Impacting our fourth quarter product gross margins was an increase in sales of distributed diagnostic products and continued scale-up costs in our Irish facility as we prepare for future growth.

As a percentage of revenue, fourth quarter fiscal 2018 R&D expenses, including costs of clinical and regulatory activities, totaled 54.6% compared with 48.4% in the year ago period. R&D expense was $12.6 million for the quarter, up $2.9 million from the fourth quarter of fiscal 2017. The increase in R&D expense was driven by increased spending associated with our TRANSCEND clinical study as well as continued progress on the development of our whole-product solutions pipeline, including preclinical studies supporting our AV access and below-the-knee drug-coated balloons.

As Gary mentioned, we expect to complete TRANSCEND enrollment during fiscal 2019 and also fund the first in-human clinical study for our AV access drug-coated balloon and preclinical and clinical activities for our below-the-knee drug-coated balloon. We also expect to submit for 510(k) clearances on 3 to 4 uniquely differentiated peripheral vascular products during fiscal 2019. As a result, we expect R&D expense to range in the low to mid-50s as a percentage of revenue in fiscal 2019.

Turning to SG&A expenses. In the fourth quarter of fiscal 2018, SG&A expenses were 28.2% of revenue versus 26.5% in the prior year period. On a dollar basis, SG&A in the fourth quarter of fiscal 2018 totaled $6.5 million as compared with $5.3 million a year ago. Impacting the increase in SG&A expense during the quarter were higher incentive and stock-based compensation expenses.

We also recorded a $1.6 million expense as we marked our contingent consideration obligations to fair market value, based on the anticipated achievement of strategic milestones.

We recorded an income tax benefit of $300,000 in the fourth quarter of fiscal 2018 as compared with income tax benefit of $200,000 in the prior year period. The current quarter benefit reflects a $600,000 discrete benefit from stock award exercise activity. Both periods reflect the impact of nontax-benefited amortization, accretion, contingent consideration gains and expenses, foreign currency gains or losses and the operating losses in Ireland.

On a GAAP basis, our diluted loss totaled $0.13 per share in the current year quarter as compared with earnings of $0.03 per share in the fourth quarter of fiscal 2017. On a non-GAAP basis, quarterly earnings per share were $0.05 in the fourth quarter of fiscal 2018 versus $0.18 in the prior year quarter.

Our balance sheet reflects the strength of our operating performance even as we make significant investments to support our strategic initiatives. Cash and investments totaled $65 million at quarter-end, and we generated cash from operating activities of $4.8 million in the fourth quarter, bringing us to $34.1 million for fiscal 2018. We also invested $9 million in plant and equipment during fiscal 2018. Our current cash and investment balances and operating cash flows provide adequate capacity to support our corporate strategic growth initiatives.

Turning now to our 2019 revenue and earnings performance guidance. We expect fiscal year 2019 revenue to range from $92 million to $97 million, an increase of between 13% to 19% as compared with fiscal 2018 revenue. This outlook includes between $14 million and $15 million of revenue from our SurVeil distribution agreement with Abbott and keeps us on track with our stated goal of delivering double-digit revenue growth. Included in our revenue outlook is revenue recognized both from the $25 million upfront license fee received in Q2 of fiscal 2018 as well as a $10 million milestone payment associated with the completion of the TRANSCEND clinical study enrollment, which we expect to occur during fiscal 2019.

We expect a fiscal 2019 diluted loss in the range of $0.32 to a loss of $0.02 per share. We expect non-GAAP diluted earnings per share to range from a loss of $0.07 to a gain of $0.23.

Operator, this concludes our prepared remarks. We would now like to open the call to questions.

QUESTIONS AND ANSWERS

Operator

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

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

I have a few questions. First off, I was hoping you might just review what you believe are going to be the key milestones for SurVeil in 2019. And maybe you could just extend it all the way to the end of the calendar year, not just the fiscal year. But I think I heard you say, you think you might get CE mark approval for that product during 2019?

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

Yes. So the SurVeil objectives are pretty straightforward. Get the trial completely enrolled by the end of the fiscal year, and that's quite important to us and we're on track for that. The second one is to obtain the CE mark so that we can get into commercialization revenue of the product. Now Brooks, as you know, the European -- I was just at the VIVA Conference and there was a lot of discussion. The European regulatory environment is changing dramatically. And as many of these notified bodies are trying to adopt and adapt to the new

regulations that are about to change, clarity was the biggest issue for us. What is the hurdle and how do we get over it? I feel much better about the clarity we've received from our notified body of the pathway to get CE mark. And so we believe we can get this by the end of calendar 2019. Now there's a little bit of variance on that because clearly, we would like to beat that, and earlier we can get to commercialization revenue, the better. But on the back end, it certainly seems achievable by the end of calendar 2019. Now we'll keep you updated on that. And of course, we wouldn't really know if we can beat it until sometime in the second half of fiscal '19. So the more we get information, the more -- the quicker we will share. The third aspect is preparing for commercialization and scale. I can tell you, Abbott is our commercialization partner, and the time I've spent with their European sales and marketing team, they are eager to get going. And so the other commitment we have to them as our commercialization partner is to have the production engine ripe and ready to produce the quantities that they believe they can drive through to European market and subsequent markets that will follow the CE mark. And so making sure our Irish production facility is really ready to go is another key objective. So we get those 3 things run: complete enrollment, get and clear the CE mark and get clarity of the actual achievement dataset and get the production and system ready.

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

That's great. So if I was listening correctly, and I might have misunderstood, but it sounds like you're making big progress with the AV fistula product. Maybe you could just comment a little further on that as well as it sounded like you're going to go through a process very similar to what you did with DCB, have some discussions with potential partners. I think I remember maybe Abbott has the right of first refusal on that product. And maybe you could just talk about the process you're going to go through.

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

Sure. We completed our preclinical GLP studies and felt really good with the AV product, and so we filed that in our fourth quarter. I wouldn't give clarity in which regulatory environment we filed it in yet. But -- because I'm hopeful and watchfully waiting for an approval from that regulatory body to get the first in-human trial accomplished. And so we feel really good about that. We'd like to be able to finish that first in-human trial within the fiscal year. And the data -- now finishing enrollment of the trial doesn't mean finishing the primary endpoint. So as an example, if we finish enrollment of anywhere from 10 to 20 patients, the primary endpoint might be 3 to 6 months out. And so the view of that data is what Abbott will be looking at. And they have the first right to look at it in a very short window to exercise a form of an option on it. And so that is not necessary tied to the completion of enrollment. It'll be tied to the completion of the dataset, which could be 3 to 6 months out. And so feel really good. I'd like to get going early. I mean, we -- while we could hear as early as our first quarter, it's more than likely we will hear from the regulatory bodies in the second quarter whether we've gotten the approval to start the trial or not.

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

Okay, that's good. And then I'll just ask one more and then turn it over. You commented, or maybe Tim did, about flatness in the core coatings business, and you alluded to patent expiration, particularly third-generation patents. Can you just give us a quick overview of where you're at with your core coatings business? And I think you're on Generation 4 or beyond. But just tell us sort of the outlook, particularly related to patent and where you stand.

Timothy J. Arens ***Surmodics, Inc. - VP of Corporate Development & Strategy, Interim VP of Finance and CFO***

Sure. Brooks, this is Tim. Thank you for the question. Yes, in terms of 2018 an impact from the Gen 3 coatings, it's under $2.5 million a headwind that we experienced in the quarter. And that's tapering in fiscal 2019. We're looking at somewhere in the vicinity of maybe $0.5 million of impact in headwinds. And then we should be pretty much through the Generation 3 headwinds with regard to patent expiration. We have -- most of the customers who are evaluating and utilizing Surmodics' coatings for their development initiatives, are leveraging our Generation 5 Serene coding. And as we think through the next 5 years, we're probably looking at flattish growth overall in the coatings revenue. We feel that once we work through some of the headwind issues with regard to future generation coatings, we should be growing at a rate probably more in the mid-single digits, but that's several years out.

Operator

Our next question will come from Mike Matson, Needham & Company.

David Joshua Saxon ***Needham & Company, LLC, Research Division - Associate***

Gary and Tim, this is David on for Mike. So just wanted to ask one about guidance. Does it include any contribution from the 510(k) products or any OUS survey revenue?

Timothy J. Arens ***Surmodics, Inc. - VP of Corporate Development & Strategy, Interim VP of Finance and CFO***

It's a great question, David. The outlook for 2019 includes revenue associated with the cleared 510(k) proprietary products, but does not include revenue associated with the sale of SurVeil drug-coated balloons in Europe.

David Joshua Saxon ***Needham & Company, LLC, Research Division - Associate***

Okay, that's helpful. And then, I guess, I mean, backed into a concern just came out with some data at VIVA, so there were Lutonix, BTK balloons. Just wanted to hear your thoughts on that.

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

Yes. I mean, I thought Dr. Mustapha presented a very nice outcome. We are happy to see that there was an efficacy effect between the drug-coated balloon and deployable arm. As you know, BTK disease is so hard to derive a primary endpoint. I think Lutonix did a -- and Dr. Mustapha and that team did a remarkable job of simplifying a very complex endpoint, but definitely saw at least a 10% improvement for these patients. And keep in mind you could take 2 views of it. You could say the data doesn't look like a huge improvement. But for these patients, any improvement of that magnitude is actually huge because they're at the point of last resort from a critical limit limb ischemia viewpoint. So we were quite happy to see that drug-coated balloons as a category demonstrated a positive impact for these patients.

David Joshua Saxon ***Needham & Company, LLC, Research Division - Associate***

Okay, that's helpful. And then just one last one. I mean, I guess, it was last week or so, you hired Terry Sides as CMO. But I mean, I guess, just since you're not selling direct to the end customers, I guess, can you give some more color on what her role is going to be and maybe if this kind of signals the shift in strategy?

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

So Terry really -- so I've worked with Terry for almost 23 years. She was the Head of R&D and Marketing at my previous company. But more importantly, over the last 7 years, Terry has been internally one of our architects of our drug-coated balloon programs. So since 2011, she's been working with us in at least a half-time capacity and more so in the last year, she and her team and her company have been working at a full-time capacity. So they run the -- what I call, the operational information technology platforms for our TRANSCEND trial. And as we are really doing that and we're getting our AV fistula, it really made sense for her and actually her team to take the job internally. And then the second real component of that is, Gregg and his team, Gregg also VP of R&D, were really trying to up the ante in all pipeline development, not that our pipeline is paused, but we have strategic choices to make on which of these directions we can go. And a little more color on that is, our technology is applicable in many vascular meds. We talk about thrombectomy. It's applicable to arterial. It's applicable in venous for DVT. It's applicable in the lung vasculature for pulmonary embolism and neurovascular. And so we have to make, what I would call, market-driven choices so that we can have the R&D engine applied in the right direction. So that really -- in my opinion, there's none better in my 30 years in this industry than Terry. And so she is coming to help direct that alignment as she did with the drug-coated balloon portfolio over the last 7 years into the future. And so that's really her job. We do have, as you know, marketing in our business-to-business Medical Device and IVD as well. And those divisions do a nice job of that. So Terry will have some play in that. But her real job is really the drug-coated balloon programs and that pipeline development.

Operator

Our next question will come from Jim Sidoti, Sidoti & Company.

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

I just want to clarify a couple of things. You talked about completing enrollment for the DCB trial in the -- by the end of fiscal 2019. And then you said you expect CE mark by the end of the calendar year, which isn't much time after enrollment. So I just want to be clear, does enrollment -- I mean, does CE mark contingent on completing enrollment? Or could that happen -- or does that happen whether you complete the enrollment in the U.S. trial or not?

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

No. So the U.S. trial primary endpoint. So one would be for the pivotal -- for the PMA approval for the U.S. FDA. So that trial, when we complete enrollment, let's say, the last patient is enrolled September 15 of calendar 2019, the primary endpoint, efficacy endpoint data and part to the primary composite data is not really viewable until that patient is followed up in September 15 within the window in 2020. So that data is where that -- and then you file for your supplement and PMA and clinical data and so forth. So they are not tethered to the completion of enrollment. The CE mark is a completely different dataset that we're working with the European bodies.

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

Okay. So if there's any changes in the enrollment schedule, it shouldn't affect the CE approval then?

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

No. In fact, they completely separate at this point.

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

Okay. Then on the revenue guidance. Tim mentioned it's going to be a $10 million payment that you expect at some point in fiscal '19. Will that be all accrued in 1 quarter? Or will you spread that out over several quarters?

Timothy J. Arens ***Surmodics, Inc. - VP of Corporate Development & Strategy, Interim VP of Finance and CFO***

Jim, great question. And we -- how we will recognize that $10 million is exactly the same way that we recognize the $25 million upfront, which is, we estimate the cost of completion, and then whatever period we're in and reporting, we get the percentage flowing through the P&L. So if I just step back for just one moment, when we received the $10 million payment, I think, in the past, we've previously communicated that about 50% of the expenses associated with the TRANSCEND study will be incurred by the time we get to completion. And quite frankly, it's going to be probably a couple of hundred basis points higher than that. So at the time that we receive the $10 million for completion, we'll be receiving probably 50-some percent of the $10 million. An easy way for you to follow, Jim, is if you think about the guidance we provided in terms of SurVeil, the $14 million to $15 million, if you look at our balance sheet in the release, you'll see that there's deferred revenue of -- I think, it's $9.6 million. So the $9.6 million deferred revenue pertains to the $25 million upfront. Now when we actually receive the $10 million in cash, the -- a portion that isn't recognized as revenue will also show up in that deferred item. But you can do the math. The $14 million to $15 million, minus the $9.6 million, gives you a view of what we're going to be recognizing for the $10 million milestone associated with the completion of TRANSCEND enrollment. It's a bit of a range because, quite frankly, it's really dependent upon kind of what level of expenses we'll be incurring. So that -- it's a concept of revenue-matching expenses. So a lot there to kind of pull apart. But I think, taking a look at the balance sheet and the revenue guidance will help you get there.

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

Okay. And can you give us any sense on when in the year you expect to achieve that $10 million milestone? Is that second half of the year in fact or or could it be...

Timothy J. Arens ***Surmodics, Inc. - VP of Corporate Development & Strategy, Interim VP of Finance and CFO***

Yes, I think as Gary described in his prepared remarks, we expect it by the end of fiscal 2019. I'd say, it's very fair to be thinking of it as a second half event. In fact, it could be a Q4 event. There's a lot that goes into the completion of enrollment. Obviously, the rate of which we're enrolling the patients is looking really good, as Gary has mentioned. But I would say, it's probably best to think about it as a Q4 event.

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

So should we -- I know you don't want to get too much into the weave and give quarterly guidance, but we should we expect this step up on that royalty line in the back of the year?

Timothy J. Arens ***Surmodics, Inc. - VP of Corporate Development & Strategy, Interim VP of Finance and CFO***

I would say that's a really good way to be thinking about it.

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

Okay. All right, great. And then I see you booked for contingent consideration in the quarter. You booked a little bit higher than you've booked in the past couple of quarters. I think it was about $1.7 million. Is that a positive sign that things are going well with the Creagh and NorMedix acquisitions?

Timothy J. Arens ***Surmodics, Inc. - VP of Corporate Development & Strategy, Interim VP of Finance and CFO***

Yes. Right. So a couple of things. Yes. So basically, the gain, the expense in the contingent consideration, that increase is reflecting what we view as being successful accomplishment of certain milestones and earnouts associated with NorMedix, in particular. I think Gary had made a comment that we're expecting 3 to 4 submissions of highly innovative 510(k) devices in fiscal 2019. I would point you to that as really some of the things in terms of the achievements that are leading to us to book that expense.

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

Okay. And then the last one for me is, some preliminary data required before you sign a partner for the AV balloon, the drug-coated balloon for the AV fistulas? Or could you sign a partner prior to seeing any data on there?

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

No, I highly doubt that. Our agreement with Abbott would require they have the first look. And it's a database look, obviously, to see the results of the first in-human study. Recall, these first in-human studies are really safety studies. They're not design -- powered to show statistical efficacy. But as in the PREVEIL trial, we didn't design it to show efficacy, but a lot of the efficacy data was statistically significant because it was so strong. So no, I believe we'd like to look at the data. And we'd also like to look at the data ourself as part of knowing the strength of our negotiation position in such a deal.

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

Okay. So it seems like you're going to have quite a lot going on in the third and fourth quarter of fiscal '19. You're going to have the completion of the trial, achievement of the milestone payment, possible CE mark and then possible data from this AV fistula balloon. So it seems like things are going to be more weighted -- in terms of announcements, things will be more weighted towards the back of the year for fiscal '19. Is that correct?

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

Yes, that is correct. Yes, that is correct. The stress curve is right now. So it not like the workload goes up. It's a pretty linear workload. But in fact, I would say, a lot of the workload is probably fronted in the first half of the year. But the outputs of -- outcomes are certainly going to be second half.

Operator

(Operator Instructions) Our next question will come from Mike Petusky, Barrington Research.

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

So Tim, I want to get into this top line guidance, just to make sure I understand. So what I think I hear you saying is, $14 million to $15 million of revenue associated with SurVeil/Abbott, about $4 million to $5 million of that associated with the original $25 million that will be recognized and maybe $5 million, $5.5 million or so of this $10 million being recognized. Meaning, essentially, $10 million of recognized revenue in fiscal '19 is what I think I hear you saying.

Timothy J. Arens ***Surmodics, Inc. - VP of Corporate Development & Strategy, Interim VP of Finance and CFO***

Let me really be a little bit more clear on that, Mike. It's $14 million to $15 million of revenue that we expect to recognize in fiscal '19 from SurVeil. Of that, there is $9.6 million on the balance sheet that's deferred revenue associated with the $25 million upfront deal that we received last year. And the remainder is coming from the recognition of the $10 million upfront.

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

Okay. So you're saying $14 million to $15 million of recognized revenue associated with that in fiscal '19?

Timothy J. Arens ***Surmodics, Inc. - VP of Corporate Development & Strategy, Interim VP of Finance and CFO***

That is correct.

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

Okay. Then I really don't understand the revenue guidance. So you finish '18 at $81 million. You're saying, hey, we're going to get $14 million to $15 million just from this piece. We're also going to get revenue from the 510(k). You didn't disclose how much, but some. Are you assuming that product revenue just really backs up this year? Is that what's baked into this?

Timothy J. Arens ***Surmodics, Inc. - VP of Corporate Development & Strategy, Interim VP of Finance and CFO***

Yes, so -- yes, if you back out the SurVeil impact, you're talking about revenue growth in the rest of the business from 1% to 8%, which is really consistent what we have been saying with regard to med device and IVD.

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

All Right. I may have to take this off-line because I'm still not completely tracking. But anyway, let me get onto the next. So Gary, were -- when you said 18 OUS, I think you said something like getting them up and running. Are you saying all those are activated, or some of them are activated, and you're in the process of getting them all activated? Or what was...

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

Yes. So the difference -- so we're pretty much complete in the U.S. I mean, the FDA gives you up to 60 sites. So we have 59. We may add 1 more. Getting a site up and running is not trivial budgeting, contracting and it takes quite a few months. But outside of the U.S., you have to seek regulatory approval in each territory. Even though the FDA is blessed this, they have their own regulatory bodies per country. So it's not a pan-European thing you go to. So we got a -- we're currently enrolling in Australia, Austria, Italy, sites up in Belgium. I believe we just got the German B-Form approval. So getting that -- Germany takes a lot longer than most countries to give you approval. And so we have 5 sites there that we're racing to get up enrolling. So we are enrolling in -- outside of the U.S., but not all the country approvals have come in, or they've -- they all -- they have just come in and now you've got to get the sites initiated. I don't have a count of how many sites have been initiated. I would guess it's at least 7 or 8, but I can't verify that. But the rest should be up and running in the next couple of months.

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

Okay, great. And then, Tim, back to you. What are the assumptions, I may have missed it if you gave it -- what are the assumptions around taxes and share count for fiscal '19?

Timothy J. Arens ***Surmodics, Inc. - VP of Corporate Development & Strategy, Interim VP of Finance and CFO***

Right. So probably the best way to be thinking about taxes would be not to think about it as an effective tax rate, but rather, I think we're talking about a tax benefit somewhere in the range of $0.5 million to $1.5 million.

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

So a benefit?

Timothy J. Arens ***Surmodics, Inc. - VP of Corporate Development & Strategy, Interim VP of Finance and CFO***

Yes. And then in terms of the share count, I think the share count is probably going to be maybe a couple of hundred thousand shares higher than how we finished 2018. So probably somewhere around that 13.5 million shares outstanding. Mike, just on the revenue, just remember, we had $4.3 million of SurVeil revenue in 2018. $14.5 million in '19. And so maybe that might help you with your math.

Operator

Speakers, at this time, we have no further questions. So I'd like to turn it back to management for any closing remarks.

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

Thank you for all of your questions. In closing, we are extremely pleased with our performance during the fiscal fourth quarter and throughout the past fiscal year. We remain committed to generating consistent double-digit top line growth and the providing EBITDA margins at or above 30% by fiscal 2021. We are on track to become a leading and enduring medical device innovator by combining our key strategic technology assets with our Medical Device customer relationships to deliver best-in-class innovative product solutions for vascular disease. We're encouraged by our clinical, regulatory and development achievements, coupled with our ongoing top line performance and operational progress. I'd like to thank our talented team in the U.S. and Ireland for their hard work and perseverance. We'll continue the same spirit of collaboration and courage as we pursue our key objectives in fiscal '19. I'm looking forward to speaking with you again on our first quarter earnings call. Thank you, everyone.

Operator

Thank you very much. Ladies and gentlemen, at this time, this concludes today's conference. You may disconnect your phone lines, and have a great rest of the weekend. Thank you.