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PRESENTATION

Operator

Good day, and welcome to the Surmodics First Quarter 2019 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, Todd. Good afternoon, and welcome to Surmodics fiscal 2019 first quarter earnings call. Before we begin, I would like to remind you that during this call, we may 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 afternoon 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***

Thanks, Tim, and good afternoon, everyone, and thank you for joining us from Minnesota where the temperature outside is negative 15 degrees.

We're off to a great start in the execution of our fiscal 2019 strategic initiatives, including substantial progress in our drug-coated balloon programs as well as our Medical Device coatings and IVD offerings. Our results reflect excellent top and bottom line performance, and we're quite proud of the accomplishments of our entire team at Surmodics. They have been and continue to be instrumental in our growing momentum and success. In the first quarter, we generated revenue of $22.2 million, growing 31% over the first quarter of fiscal 2018. This included $2.4 million of revenue from our SurVeil agreement with Abbott. We also reported diluted GAAP earnings of $0.09 per share and non-GAAP earnings of positive $0.12 per share in the first quarter. Looking ahead, we're well positioned to build on our momentum and have updated our fiscal 2019 revenue expectations, which Tim will discuss later in the call.

In the first quarter of our fiscal year, we were very pleased with the progress made in each of our 3 major strategic objectives, that we previously described for fiscal 2019. As a reminder, these are: first, to ensure the success of SurVeil, specifically to complete the TRANSCEND pivotal study enrollment and to make substantial progress towards achieving CE Mark; second, to continue to make meaningful advances with our drug-coated balloon pipeline and our nondrug delivery service -- device portfolio, including the acceleration of our thrombectomy platform development; and finally, to continue to drive revenue growth and cash flow from our existing Medical Device coatings and IVD offerings. These offerings provide significant ongoing return on invested capital and cash flow to fuel our strategic growth initiatives. Let me provide some color on each of these core objectives.

Starting with SurVeil. We are pleased with the enrollment progress in TRANSCEND, our pivotal trial for SurVeil. The acceleration seen in enrollment this quarter takes us well beyond the half-way point for total enrollment. All U.S. and almost all of the outside of United States clinical sites have been initiated. As planned, we expect to complete TRANSCEND enrollment by the end of fiscal 2019. Further, we have submitted key elements of our regulatory filings to our European Notified Body as part of our efforts to obtain the CE Mark for SurVeil. While the timing of receiving the CE Mark is difficult to predict, given the changing European regulations, we are targeting no later than the end of calendar 2019. Many of you are aware of the recent clinical debate on the safety of intravascular devices that use paclitaxel as a active pharmaceutical agent. This was triggered by a publication in December by Dr. Konstantinos Katsanos of Greece. The paper described a meta-analysis of vascular devices, including drug-coated balloons and drug-eluting stents and highlighted a signal of increased mortality in devices containing paclitaxel versus nondrug controls after 3 to 5 years. This has created much debate in the industry and we are following it closely. Much of the feedback on the paper involved significant limitations of such analysis as a category and a specific limitations as applied to this particular study. Meta-analysis requires significant sophisticated assumptions in how to treat and pool data from multiple disparate sources and device categories. There is some disagreement on whether the correct statistical methods and assumptions were made in the analysis. In addition, patient level data was not available to Dr. Katsanos and his colleagues. These data contained a specific and relevant information relating to mortality. At last week's LINC conference in Germany, the patient level data were presented on each of the devices in question and demonstrated no significant increase nor difference in mortality rates. The clinical discussion continued at the ISET meeting earlier this week in Florida and will again be vigorously discussed at the upcoming Vascular Leaders Forum sponsored by the VIVA Physicians group at the end of February, where Surmodics has been invited to participate. In addition, the FDA recently issued a notice that included a statement that the current benefit to risk data supports the use of these devices and encouraged continued surveillance and reporting of any adverse events, as they continue to reduce and look at this data. It is important to note that the steering committee of the TRANSCEND trial has recommended continuing with the trial. Our steering committee is comprised of the world's leading clinicians with expertise in this specific area. TRANSCEND is a highly independently monitored trial with 5-year follow up and will add important rigorously reviewed clinical efficacy and safety data to this field. We have not seen an impact on enrollment as a result of this clinical debate and will continue to monitor it and contribute to it, where relevant.

Turning to some other products that are promising in our pipeline. We received approval to initiate the first-in-human study for our AVess, arteriovenous access drug-coated balloon. This is exciting, and we have already treated successfully the first patient. We're on track to complete the first in-man trial of AVess by the end of calendar 2019.

Moving on to our innovative below-the-knee sirolimus drug-coated balloon. We're in the process of refining the coating and drug delivery formulations based on the results from our earlier preclinical evaluations. In short, we were not satisfied with some of the data we observed in the last set of preclinical studies and believe that we can improve on this. Below-the-knee disease is complex and multifactorial. And we intend to develop a device that has the most significant favorable impact for these patients and that further optimization will help us achieve this. We anticipate submitting for regulatory approval to initiate the first-in-human trial by the end of fiscal 2019. We also continue to make progress on our nondrug delivery pipeline and we're committed to working on the next wave of product innovations to solve unmet clinical needs. These innovations will help us build highly differentiated platforms and create additional shareholder value.

During fiscal 2019, we remain on track to file submissions for regulatory approval on 3 to 4 new devices. As part of these efforts, we have committed to accelerate the development of the thrombectomy platform. Physician evaluation of our first design iteration for arterial thrombosis has been excellent. The device was capable of removing organized thrombus in a simulated arterial model. Organized thrombi are very difficult to remove, often requiring surgery and resulting in significant blood loss and patient hospitalization. We believe, our design represents an on-the-table solution without requiring the use of capital equipment, while potentially minimizing patient blood loss and reducing the likelihood of hospitalization. As a reminder, our thrombectomy platform has broad potential to treat thrombosis in multiple vascular beds, including arterial and venous thrombosis, pulmonary embolism and neurovascular applications. We are targeting completion of design activities by the end of fiscal 2019 and to submit our first application for regulatory approval for vascular thrombosis, sometime in the first quarter of fiscal 2020.

In December, we convened a group of the world's top radialists for a discussion of device needs for radial access to the peripheral arteries

and to seek feedback on our early ideas and prototypes in this area. Radialists are interventional physicians (cardiologists, vascular surgeons and interventional radiologists) who prefer practice interventions via the radial artery versus the femoral artery for access. It is well known that radial access to the coronary vessels generally results in better safety outcomes for patients. Radial access to coronary vessels is used more than 70% of the time in Europe and we believe, approximately 35% to 40% of the time in the U.S. Radial access to the peripheral vasculature, however, is in its infancy. The lack of devices for both access and treatment is a limiting factor. This physician group was able to test drive some of our early prototypes of peripheral radial access in simulated anatomical models and were, to a person, visibly impressed. We intend to seek and develop -- develop and seek regulatory approval for multiple devices that are able to access and treat peripheral vascular disease using a radial approach within the next 18 months. The benefits will not only be to patients but also to health care economics, given the potential for low risk of bleeding complications and much faster patient discharge following the procedure.

Finally, superb execution by our Medical Device and IVD businesses has continued to produce strong performance with growth seen across all product revenue categories. We expect our Medical Device business segment to continue to contribute significantly to our expected double-digit revenue growth in fiscal 2019, including modest growth in our coatings derived revenue compared with the prior year. It is a credit to the strength of our coatings team that they have managed such excellent execution in continuing to grow the coatings business in the mid-single digits, in spite of recent patent expirations. Our IVD team also delivered exceptional performance this past quarter, growing revenue by over 17%. This performance was the result of strength across the customer base, although, against a weaker comparison quarter relative to the second half performance of last year. Nevertheless, the business continues to handily outperform the immunoassay market growth rates of 2% to 3%.

In sum, we are encouraged by the significant accomplishments this quarter, which continue to enhance the foundational elements needed to drive our near-and long-term growth. And looking at our current trajectory, our fundamentals and business outlook are stronger than they have ever been before. With a great team assembled as well as a breadth of intellectual property, we are well positioned for continued topline growth and operational performance.

I'll now turn the call over to Tim to provide more details on the first quarter of fiscal 2019 results as well as our outlook for fiscal 2019. Tim?

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

Thank you, Gary. Revenue for the first quarter of fiscal 2019 saw growth, as Gary mentioned, across all revenue categories in both of our business segments. Total revenue for the quarter was $22.2 million as compared with $17 million in the first quarter of 2018. Looking at our 2 business units, Medical Device delivered an impressive 35% revenue growth, increasing $4.6 million to $17.3 million in the first quarter. For In Vitro Diagnostics business, first quarter fiscal 2019 revenue, which is predominantly comprised of product sales, totaled $5 million, up nearly 18% compared with a year-ago period.

Looking at specific areas within Medical Device, first quarter royalty and license fee revenue totaled $10.1 million, up $3 million from the comparable prior year quarter. The increase in royalty and license fee revenue reflects $2.4 million of license fee revenue recognized from the SurVeil distribution and development agreement with Abbott. Product sales increased $900,000 or 24%. Medical Device product sales benefited from an increase in balloon catheter unit volume as a result of recent customer product launches. R&D revenues associated with customer feasibility projects in coatings services increased $500,000 from the prior year quarter. The Medical Device business unit reported $357,000 of operating income in the first quarter versus an operating loss of $389,000 in the prior year quarter. Medical Device operating results benefited from our strong revenue performance and were impacted by $3.7 million of increased R&D spend, reflecting continued progress with our drug-coated balloon programs, including the TRANSCEND clinical study and continued investment in our innovative product development pipeline to support our future growth. IVD revenue in the first quarter reflected strong growth in sales of our chemical components used in diagnostic tests and microarray slides. IVD operating income of $2.5 million in the first quarter increased $785,000 or 47% compared to the year-ago period. Operating margin in the first quarter of fiscal 2019 was 49% compared to 39% in the prior year quarter. Impacting IVD operating margin was product revenue mix, which was skewed toward higher margin products.

Product gross margins for the quarter were 63.9% of product sales as compared with 64.3% in the prior year quarter. Impacting our first

quarter product gross margins was product mix, as we continue to see an increase in balloon catheter product sales and continued scale-up costs in our Irish facility as we prepare for future growth. As a percentage of revenue, first quarter of fiscal 2019 R&D expenses, including costs of clinical and regulatory activities, totaled 51.6% compared with 46% in the year-ago period.

Our Q1 R&D spend, as a percentage of revenue, was in line with our full year R&D expense guidance range, which I'll remind you, remains in the low to mid-50s. Although, the full year is expected to fall within this range, we may see some quarters that fall outside of this range. R&D expense was $11.5 million for the quarter, up $3.7 million from the first quarter of fiscal 2018. 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 spending to support our AV access and below-the-knee drug-coated balloon programs.

SG&A expenses in the first quarter of fiscal 2019 were 26.7% of revenue versus 30.4% in the prior year period. On a dollar basis, SG&A in the first quarter of fiscal 2019 totaled $5.9 million as compared with $5.2 million 1 year ago. Impacting the increase in SG&A expense during the quarter were higher compensation and benefit expenses associated with staffing to support our strategic initiatives. We recorded an income tax benefit of $176,000 in the first quarter of fiscal 2019 as compared with income tax expense of $1 million in the prior year period. If you recall, the prior year period included a $1.2 million charge associated with the impacts of tax reform. On a GAAP basis, our diluted earnings totaled $0.09 per share in the current year quarter as compared with the loss of $0.12 per share in the first quarter of fiscal 2018. On a non-GAAP basis, quarterly earnings per share were $0.12 in the first quarter of fiscal 2019 versus $0.10 in the prior year quarter.

We continue to maintain a strong balance sheet. Cash and investments totaled $45.9 million at the quarter end. During the quarter, we paid $11 million to satisfy all remaining contingent earn out obligations associated with our November 2015 acquisition of Creagh Medical as well as $7 million of net impact from plan changes in operating assets and liabilities in the quarter. In addition, we invested $2.1 million in productive plant and equipment during our first fiscal quarter of 2019. Our current cash and investment balances and expected operating cash flows provide adequate capacity to support our corporate strategic growth initiatives. As for our 2019 revenue and earnings performance guidance, we are increasing the lower end of our fiscal 2019 revenue expectations to $94 million from $92 million, while maintaining the upper end of our fiscal 2019 revenue expectations of $97 million. Representing an increase ranging from 16% to 19% as compared with fiscal 2018 revenue. We now expect a fiscal 2019 diluted loss in the range of $0.22 to a loss of $0.02 per share compared with our previous expectation of a loss at the low end of our range of $0.32 per share. We now expect non-GAAP diluted earnings per share to range from $0.02 to $0.22 per share compared with our previous expectations of a loss at the lower end of our range of $0.07 per share to a non-GAAP earnings of $0.23 per share. Non-GAAP EPS was impacted by a gain of $0.01 share related to the foreign currency exchange rate effect on our contingent consideration obligations, which were paid in the first quarter.

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

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) We'll take our first question from Mike Matson with Needham & Company.

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

This is David Saxon on for Mike this afternoon. Been hopping between some calls, so I apologize if you answered some of these questions. First, just wanted to start off with the paclitaxel meta-analysis. I know there's been a lot of buzz. Just wanted to get your thoughts on that?

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

Yes, first of all, I have been impressed with all the stakeholders in this debate where patient safety is primal for everyone. I know Dr. Katsanos personally and spoke with him as recently as last week. He has a step through the limitations in any of these. Meta-analysis are very difficult analysis to conduct, because you're pooling multiple data sources that may or may not have the same type of distributions, and you're pooling separate categories of devices, and Dr. Katsanos acknowledges the limitations of it. He is pointing to a signal. The other thing is -- and there is some debate whether the right assumptions were used, and that goes over my head, so I will limit it to this,

I'm observing the debate on the statistical method. On the other hand, patient-level data is often, and in this case, missing because the authors and -- the publication authors don't have access to the patient-level data. So I was quite impressed with the industry and the physicians at the LINC meeting, every device -- they must have been scrambling -- as Dr. Schneider said this is how we spent this Christmas holidays, where they actually scrubbed the patient-level data, which does exist, to search for a signal of statistical significance and mortality, and indeed, did not find that. This was presented for the Medtronic device, the Bard Lutonix device. I believe Stellarex had some presentation there as well as those of (inaudible) and one of the drug-eluting stent. And clearly, the patient-level data where you can actually see what was the cause of mortality for the patient, indicated no statistical difference. The date isn't over because the test for mortality -- these trials, including TRANSCEND, designed for binary patency significance at one year, test for mortality is the specific safety outcome, literally requires thousands of patients over 5 years. So I believe -- I don't know this, but I believe there will now potentially be a pooling of the patient-level data in independent meta-analytical method to see if there's any further signal from this. This is not a small endeavor, and I think this could take -- from a layperson's viewpoint, I think it'll take several months. The FDA is also weighing in on this, and I think you have seen that the [adapter] letter where -- in some form, it was mischaracterized as a warning. It was, I believe, good judgment by the FDA to reinforce the systematic surveillance of any adverse events reporting the appropriate consenting of patients, who are being treated with these devices, and also the -- to ensure that the FDA was going to be following up and doing, I believe, their own analysis. But they reminded everyone that thus far, the benefits to risks of these devices remain in favor of using the devices. And so I believe FDA will have a major plot to play in the ongoing debate. The next setup for this will be the VIVA leadership forum in D.C. at the end of February, and I think I said we've been invited to participate in that as well. So it's hard to make a decision on whether it's true. I think no one wants to make, what I call it -- what is known as a type 1 error, which is basically concluding that there is a safety signal, when in fact there is none, given the dramatic efficacy of these devices. So I think the industry and the clinical community will be very busy cranking this data to find out whether there is a signal or not.

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

Yes, that's very helpful. And then, just can you touch on the status of the -- any distribution agreements for your 510(k) products you may have signed this quarter?

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

Yes. We -- Tim and I keep saying, we want the right agreement for shareholders. And yes, we are -- if you talk to the parties who we negotiate with, they would say we're tough. And that -- and so the issue isn't the lack of interest, it really is -- we believe in these devices and our team is -- I'd say fairly sophisticated financial models of what we need from our distribution partners. And so we continue to ferret that out. I don't want to say we've never been closer, but I think patients is key here as we continue to be very active in these, so...

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

Yes, that's helpful. And then just a quick one for Tim. How much of -- from the Abbott milestone did you recognize this quarter?

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

David, it was $2.4 million.

Operator

We'll take our next question from Brooks O'Neil with Lake Street Capital Markets.

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

I too was jumping a little bit between calls, so if I ask a question that you've already addressed, just say so, and I'll read the transcript. But my sense is, SurVeil is the device that uses paclitaxel and Medtronic Admiral does as well. Do you see the discussion in the ongoing, let's call it, minor uncertainty related to it, having any impact on that trial?

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

No. We have seen the same rate of enrollment. Between Thanksgiving and New Year's day, we had an expected drop in enrollment just because patient senses a number of procedures of this type are down. But it rebounded back to January where we are at the levels that we predicted in January. So I have not seen an impact in enrollment, we've had several webinars with the clinician and research coordinated community who conduct this trial, and they continue to be very active. We have had one site withdraw of the 69 sites, just

saying they want to wait this out and see how this debate comes out. But that's -- that being said, that site has not had a negative influence on us. So clearly, we feel confident we're on track for September -- end of September completion of the trial.

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

Great. Secondly, I'm curious as you think about your core business -- device business, let's say, do you see this having a potentially positive effect as device manufacturers think about other drugs, other ways to put them into the body and use them to treat patients?

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

It's hard to tell. I think it's quite early. The first thing that has to be resolved here, it's very difficult to find a mortality signal with limited number of patients. And in fact, the -- Dr. Schneider and his team recently published the Medtronic data, I think it was last week, it was published. I believe almost 2,000 patients in the Medtronic arm. And when they looked at it in every which way from the amount of the size of the balloon the patient got in terms of the dose of paclitaxel, could not find any signal relative to dose or mortality versus the PTA control group. And in fact, on an absolute basis, the PTA control group was actually high, but on a statistical basis, there was no difference. So hard to predict, I -- we use sirolimus for below-the-knee for different reasons because we have a hypothesis that it's a better drug for smaller friable vessels in the tibial artery area. It's just must like in the coronary, (inaudible) are really the prevalent drug of choice. So -- I hate to cop out, but don't know or naturally don't believe there'll be much impact, one way or another.

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

Cool. And Gary, just you mentioned the sirolimus, do you see that as a drug that has wide application beyond the BTK work you're doing right now? Or how are you viewing it today?

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

Right now, we're really focused on BTK. Is there a (inaudible) in the superficial femoral artery in the (inaudible)? Possibly, that's not really been well demonstrated yet. The thing that's hot is -- and we've talked to all experts, and I don't know if anyone really knows whether vascular biology acts the same in different vascular beds. Clearly, sirolimus can be made to work. There may be some advantages to that in other tissue beds as well. So whatever we learned in our BTK program even though, it's taking a little bit longer, will be very good learning for us to that same question you are asking, in the future.

Operator

(Operator Instructions) We'll take our next question from Jim Sidoti with Sidoti & Company.

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

Can you hear me?

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

We hear you just -- loud and clear, Jim.

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

Great, great. On the Medical Device revenue, even if you were to exclude the $2.4 million you got from Abbott, your royalty revenue is up about $500,000. Is that related to new particle entries?

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

Well, no. It's really a portfolio affect. We've -- we have certain customers who have -- and I'm looking at Gary here but -- and talking with the BD team, really it's broad-based. We're seeing customers outperform. It's not just 1 product, it's not just 1 customer, so just real strong performance by our customers here this past quarter.

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

And do you still have a headwind from patent expirations?

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

Yes, Jim. I think we talked about this back in the November call. It's really -- maybe about $0.5 million is what kind of we're expecting this year in terms of the patent headwinds from the gen-3 coating, which really suggests that the other coating families and generations are really picking up the pace.

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

Right, right. Then on R&D spending, you're down about $1 million from the quarter that ended in September. Is that timing of enrollment? Anything else there?

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

I'm sorry, Jim. We're up on a year-on-year basis. Are you asking me about sequential?

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

Sequential, right. Compared to the quarter that ended in September?

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

Oh, sorry, sorry. Yes. No, it's basically just -- it's a lot of the timing related aspects of running multiple programs, clinical studies. As we've discussed here over the last couple of calls, we anticipate the R&D expenditures as a percentage of revenue will fall between that 50% to 55%, low-to-mid 50s. We're right in that range this quarter. We'll see some quarters where we might be below or above that, I wouldn't read anything into it on a sequential basis.

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

All right. And then on the balance sheet. You have a new entry for contract assets. Is that related -- what is that related to?

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

Yes, great catch on that. Yes, it's a -- it's related to the new accounting standards and how we have to recognize the royalty revenue in the period in which our customers actually sell in. So that's our estimate of what the royalty revenues would be from the coatings business for the most part. So that's what that is.

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

Okay. And then last thing from me is cash flow. You invested a lot this quarter, you did some capital expansion in Ireland, you also paid off the -- I guess the contingency payments for the acquisitions you did a couple of years ago. What should we think about free cash flow for the year so far?

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

Yes, so for the year, we'll be positive, that's how we're thinking about it. Q1 had a couple of unique things as you've described here. Going forward, Q2, 3 and 4, one shouldn't be expecting that we're going to be positive from an operating cash flow perspective.

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

How about for free cash?

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

Yes. Over the course of the year, the free cash, I think we're going to be -- it's going to be pretty good, I'd say we're probably looking at something that's going to be just slightly -- a slight increase here.

Operator

We'll take our next question from Mike Petusky with Barrington Research.

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

A couple of questions. Gary, I just want to clarify, the one site that dropped out, that was a U.S. site? Is that right?

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

Yes. Yes.

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

Okay. And then you also said that most of the OUS sites have, at this point, been activated. Is that -- did I get that correctly?

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

Yes. We have a -- we got German approval. I think it was late last quarter, and so a lot of these sites are in Germany. So we're just marching through -- I believe there is one in Austria and one in Germany that's left, so it's probably all but 2.

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

All but 2, okay, great. And then just moving on to the 510(k) products. Obviously you commented about ongoing negotiations and hopefully, your close. Is there any backing away from -- I think you guys had said, hey, look, while we're not putting a lot of revenue into our guidance for '19 associated with the 510(k) products that are approved. We do think that we'll generate revenue from -- I believe you said from all 3 products in fiscal '19. Any backing off that? Or maybe just a note of caution around that at this point or no?

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

Yes, you know we -- as far as commercial -- getting commercial agreements here, the one thing we are consider, and Tim, I don't believe we're backing off the revenues from 510(k) products.

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

We're not.

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

Oh, yes. But the -- in this we believe we have to also do our part to set the tone with our strategic partners, and if we don't sign the right agreements in the first quiver of these agreements it sets us up negatively for the products that follow. So yes, we're not backing off and we believe we can get a right agreement signed.

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

Okay, great. And there's still an expectation that you guys will file for another 3 or 4 510(k) clearances in fiscal '19?

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

Yes, yes. Our nondrug delivery team are very busy as well and we believe we can get those 3 or 4 filed in this fiscal year, yes.

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

Okay, great. And then just last one, and forgive if you've mentioned this, I just never quite caught on but how many patients are in the AV trial?

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

It's up to 50 patients in the first in human, and given these are essentially first-in-human trials is a little -- the differences in enrollment criteria for them, so we're targeting to be finished with enrollment in that by the end of our fiscal year. And we're very excited to get -- to be able to quickly get into the first patient and we have several more on tap. So 50 patients, up to 50 patients.

Operator

At this time, we have no further questions. I'll turn it back to management for closing remarks.

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

Well, thank you all for your questions. We're excited that we're making progress in our SurVeil program with the TRANSCEND trial. We're very excited to have started our AV fistula drug-coated balloon first in-human trial. And just hats off to our core business execution that continues to perform incredibly well even as we transform this business. Thanks, everyone, and have a great afternoon.

Operator

Thank you, ladies and gentlemen. This concludes today's conference. You may now disconnect.