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SRDX - Q1 2018 Surmodics Inc Earnings Call

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CORPORATE PARTICIPANTS

Andrew D. C. LaFrence *Surmodics, Inc. - VP of Finance & Information Systems, CFO and Principal Accounting Officer*

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

CONFERENCE CALL PARTICIPANTS

Benjamin Charles Haynor *Aegis Capital Corporation, Research Division - Equity Research Analyst*

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*

PRESENTATION

Operator

Good day, and welcome to the Surmodics First Quarter 2018 Earnings Call. Today's conference is being recorded. At this time, I would like to turn the conference over to Andy LaFrence, Vice President of Finance and Chief Financial Officer. Please go ahead, sir.

Andrew D. C. LaFrence - *Surmodics, Inc. - VP of Finance & Information Systems, CFO and Principal Accounting Officer*

Thank you Siobhan. Good morning, and welcome to Surmodics' Fiscal 2018 First 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 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 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 will 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 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 www.surmodics.com.

I'll now turn the call over to Gary Maharaj. Gary?

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

Thank you, Andy, and good morning, everyone, and thank you for joining us. We had a busy and productive first quarter, and our results reflect both solid top line performance and operational results, even as we invest in our new products pipeline. We generated revenue of $17 million and diluted GAAP loss per share of $0.12 in the quarter, and we are reiterating our expectations for fiscal 2018 revenue to be in the range of $72 million to $75 million for the year.

On today's call, I will provide an overview of our quarterly achievements and progress towards our strategic objectives, and then I'll turn the call over to Andy to provide a more detailed review of our first quarter financial results and updates to our fiscal 2018 guidance. We will then open the call to take your questions.

In the first quarter, we were pleased at the progress on each of our 3 major strategic objectives that we previously described for fiscal 2018. As a reminder, these are to execute the TRANSCEND trial in a high-quality, rigorous and efficient manner. We plan to have a full complement of clinical

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sites initiated and up and running by the end of fiscal 2018. Two, to advance our R&D whole product solutions pipeline by securing regulatory clearances for at least 4 new products in fiscal 2018 and file for the first-in-human use of either our below-the-knee or AV fistula access drug-coated balloon programs. And three, finalize and further delineate our commercialization strategy with potential distribution partners for our proprietary products.

Starting with TRANSCEND, we have started our pivotal trial comparing our SurVeil drug-coated balloon to the U.S. market-leading Medtronic IN.PACT Admiral drug-coated balloon. We're actually getting sites up and running and beginning to enroll patients, and we are on track for continued progress throughout this year. As a reminder, TRANSCEND is expected to enroll approximately 446 patients at up to 60 clinical sites in the U.S. and 18 clinical sites in Europe. The randomized trial will evaluate the SurVeil drug-coated balloon for the treatment of peripheral artery disease in the upper leg compared to the Medtronic IN.PACT Admiral drug-coated balloon. This trial is amongst first level-one studies to compare a next-generation DCB with one that is commercially available.

In Europe, we are still in the process of evaluating our strategy and timing for our assumptions to get the CE mark, taking into consideration evolving EU regulations. We look forward to further progress in both the U.S. and Europe as we move through this year.

Switching gears to our R&D efforts around our whole product solutions pipeline, starting with our sirolimus-based below-the-knee DCB program. We're making progress using our internally developed 014 balloon platform, working through the preclinical studies for the data package that will be used to determine our readiness for first-in-human clinical trial. We remain on track with this program and expect to make continued progress throughout the remainder of fiscal 2018.

We've also made dramatic progress developing our AV fistula drug-coated balloon. As discussed previously, we believe we have the technology to address access and maintenance of fistula patency, which are major frustrations for patients undergoing renal dialysis and that can add dramatically to the cost of care. We are moving forward developing our preclinical data set that will determine the possibility to further accelerate this DCB program even in this fiscal year. We're working to gathering the preclinical data and clarity to file for regulatory clearances to conduct the first-in-human study in either of these drug-coated programs.

Now turning our focus to our nondrug delivery R&D pipeline. We're quite pleased with the recent FDA clearance of our Telemark support microcatheter. The Telemark support microcatheter offers superior crossability for complex coronary and peripheral lesions. This microcatheter combines Surmodics' Xtreme composite shaft technology with a high-performance Pristyne hydrophilic coating, that together, provide exceptional deliverability, kink resistance and complex lesion crossing. Surmodics' Pristyne hydrophilic coating offers best-in-class lubricity and low particulates and is available only on Surmodics' proprietary products. The Telemark microcatheter's tapered profile design has an outer diameter ranging from 2.6 French to 1.4 French for effective penetration of very tough, calcified lesions.

We continue to make headway with products in developing using advanced versions of our coating chemistry. As you recall, in late 2017, we received both FDA clearance and CE mark for our 014 balloon catheter, which incorporates our Serene hydrophilic coating for use in below-the-knee angioplasty. We're confident that our highly deliverable, low-profile PTA catheter will provide clinicians an effective tool for accessing and crossing even the most complex peripheral lesions. For the 018 peripheral balloon catheter incorporating our Serene hydrophilic coating, we have finalized our design specifications and have submitted our data package to the agency for 510(k) clearance.

Looking ahead, we have also begun work on the next wave of product innovations for which we are targeting regulatory filings and clearances in calendar 2018. These will help us further build on our platform and achieve significant top line growth. We will discuss these R&D programs in future calls as we get closer to these regulatory filings.

Now turning to our third strategic objective regarding the whole product solutions product commercialization strategy. Our 014 PTA balloon catheter is currently undergoing clinical evaluation in actual patient use, both by Surmodics and interested partners. We are targeting revenue to be generated from this product in the latter part of fiscal 2018. We'll also be gaining clinical user experience with the Telemark 014 support microcatheter in the coming several quarters.

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It's an exciting time at Surmodics, and we are investing in and making great progress in our R&D programs. 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 and highly innovative product solutions for vascular disease. We are excited by our clinical, regulatory and development achievements, coupled with ongoing top line performance and operational progress. Our long-term goals of generating double-digit top line growth by the end of calendar 2019 and generating EBITDA margins at or above 30% by fiscal 2021 are in our sights and, we believe, are very attainable.

I'll now turn the call back to Andy to provide more details on our first quarter fiscal 2018 results as well as our outlook for 2018. Andy?

Andrew D. C. LaFrence - *Surmodics, Inc. - VP of Finance & Information Systems, CFO and Principal Accounting Officer*

Thank you, Gary. We are pleased to report that revenue for the first quarter of fiscal 2018 was $17 million as compared with $17.8 million in the first quarter of last year. As a result of our significant investments in our whole products solutions strategy, we delivered an operating loss of $0.6 million in the first quarter of fiscal 2018 as compared with operating income of $3.3 million in the comparable prior year period.

On a GAAP basis, our diluted loss totaled $0.12 per share in the current year quarter as compared with earnings of $0.17 per share in the first quarter of fiscal 2017. On a non-GAAP basis, quarterly earnings per share were $0.10 per share in the first quarter of fiscal 2018 versus $0.19 in the prior year quarter.

Turning now to our 2 business units. Medical Device reported revenue of $12.8 million, a decrease of $1 million as compared with the year-ago period. Looking at specific areas within Medical Device, first quarter royalty and license fee revenue totaled $7.1 million, down $0.9 million from the comparable prior year quarter. The decrease in royalty and license fee revenue was anticipated and is attributable to lower royalties resulting from expiration of patents covering our third-generation hydrophilic coatings.

Product sales increased $0.1 million from the comparable prior year quarter due to increased reagent shipments. Medical Device customer research, development and other revenue decreased $0.2 million from the current quarter as compared with the first quarter of fiscal 2017. This unit generated a $0.4 million operating loss in the first quarter versus operating income of $3.7 million in the prior year quarter. The Medical Device operating income change was impacted by planned increased investments related to our whole products solution strategy, anticipated reductions in royalty revenue as well as a $0.7 million increase in our contingent consideration expense.

For our In Vitro Diagnostics segment, first quarter fiscal 2018 revenue, which consists of product sales, totaled $4.2 million as compared with $4 million in the comparable prior year period, an increase of 5.9%. IVD revenue in the current year first quarter reflected strong growth in BioFX substrates and microarray slides. IVD operating income was $1.7 million in the current quarter as compared with $1.5 million in the first quarter of fiscal 2017.

Operating margin in the first quarter of fiscal 2018 increased to 39.4% versus 36.4% in the comparable prior year quarter due to improved gross margins due to a casualty loss incurred in the first quarter of fiscal 2017 related to a damaged shipment from our vendor, which reduced product gross margins.

Product gross margins for the first quarter were 64.3% of product sales as compared with 65.9% in the prior year quarter. The current year period gross margins benefited from higher Medical Device reagent and IVD sales, lower scrap from a prior year damaged shipment from a vendor, which was more than offset by our Irish facility infrastructure and scale-up costs in anticipation of future growth, resulting in lower Medical Device product gross margins.

As a percent of revenue, first quarter fiscal 2018 R&D expenses were 46% versus 33.6% in the comparable year-ago period. R&D expense of $7.8 million for the current quarter was up $1.9 million from the first quarter of fiscal 2017. As we have stated before, we anticipate R&D expense would increase in fiscal 2018 as we accelerate our whole products solution strategy investments, including advancing our TRANSCEND drug-coated balloon human clinical trial and other proprietary products, including preclinical work on below-the-knee and AV fistula drug-coated balloon projects.

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SG&A expenses in the first quarter of fiscal 2018 were 30.5% of revenue versus 27.4% in the prior year period. On a dollar basis, SG&A in the first quarter of fiscal 2018 totaled $5.2 million as compared with $4.9 million a year ago. The increase in SG&A expenses reflects continued infrastructure investments to support our whole products solution strategy. Additionally, stock-based compensation expenses for the quarter -- for the first quarter of fiscal 2018 increased by $0.1 million as compared with the same fiscal 2017 quarter.

During the quarter, the U.S. dollar continued to weaken as compared with the euro. As a result, we realized a $0.2 million foreign exchange loss on our euro-denominated contingent consideration obligation related to the Creagh Medical acquisition. We recorded -- we also recorded an income tax expense of $1 million in the first quarter of fiscal 2018 as compared with income tax expense of $1.7 million or 42.9% of pretax income in the prior year period.

The current quarter included a onetime tax expense of $1.2 million from our net deferred tax assets revaluation as a result of the Tax Cuts and Jobs Act's enactment in December 2017. Both periods reflect the impact of nontax-benefited amortization, accretion, contingent consideration gains and losses, foreign currency losses and operating losses in Ireland. We realize that it may be difficult to model our income tax expense for fiscal 2018 given all the moving pieces, from tax reform and impacts of nontax-benefited items. We expect income tax expense, including the impact of tax reform, for fiscal 2018 to be in the range of $0.3 million to $0.8 million.

Looking at our balance sheet, which continues to be strong, cash and investments totaled $46.7 million at quarter-end. We generated cash from operating activities of $0.6 million in the first quarter of fiscal 2018. We invested $1.3 million in plant and equipment during the first quarter as well. Our current cash and investments balances and operating cash flows provide adequate capacity to support our corporate strategic growth initiatives.

As for our outlook, we continue to expect revenue in the range of $72 million to $75 million for fiscal 2018. GAAP diluted loss is expected to be in the range of $0.45 to $0.70 per share as compared with the prior guidance of $0.50 to $0.75 per share. We expect non-GAAP to range from a loss of $0.20 to earnings of $0.05 per share as compared with the prior guidance of a $0.16 to $0.41 per share diluted loss. As previously noted, the guidance per share includes a $3 million or $0.15 per share estimated R&D expense variability as a result of our estimated range of patient enrollment rates in our TRANSCEND study.

Gary and I are pleased with the performance of the entire Surmodics team in our fiscal first quarter. Thank you for your hard work and outstanding results.

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

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And we will take our first question from Jim Sidoti from Sidoti & Company.

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

Sorry if you covered this. I'm actually trying to listen to 2 calls at once. But R&D spending is down at a little under $8 million. That's the lowest it's been in the last 3 quarters. Is that just a timing issue? And where do we -- where do you expect that to be over the next 2 to 3 quarters?

Andrew D. C. LaFrence - *Surmodics, Inc. - VP of Finance & Information Systems, CFO and Principal Accounting Officer*

Yes. There's a couple pieces there, Jim, regarding the R&D expense. First of all, if you recall, we do have R&D revenues, which are down slightly this year, and so part of the customer R&D expense is down by, in the first quarter, about $900,000 from where we thought it would be. And a lot of that has to do with our customer-focused R&D expenditures. And if you look at where we're at from our internal R&D expense, we're probably

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about $1 million light on that, and that's just timing. So in the aggregate, if you look at where we're going to be, we're still going to be in that 55% to 60% of revenue for the year. And we would expect to see acceleration in the back half of the year, so that -- I would say that if you think about it as a percentage of revenue, that will be ramping up to closer to 60%, in that 55% to 60% in each of the next 2 quarters -- next 3 quarters, I should say.

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

Okay. All right. And then you indicated that the tax rate's going to be difficult to model this year. But as we look ahead out into the next 2 or 3 years, when you get back to being a profitable company, what do you think the right tax rate will be for Surmodics?

Andrew D. C. LaFrence - *Surmodics, Inc. - VP of Finance & Information Systems, CFO and Principal Accounting Officer*

Well, part of that, Jim, has to do with the timing of our run-through of our NOLs in Ireland. As you know, the Irish tax effect is about 12.5%. And with the new model here in the U.S. at 21%, we'd expect a blended range probably to be in the high teens once we get to the point where we've gone through the NOLs. And then our state rates right now are running about 1% to 2%, so that will give you a pretty high teens, maybe 20% rate going forward once we get through those NOLs.

Operator

And we will take our next question from Brooks O'Neil from Lake Street Capital Markets.

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

I want to be sure I understand a little bit about this tax charge. I'm thinking you said the loss of $0.12 on a GAAP basis includes the $1.2 million charge. So the -- excluding that charge, you'd be quite a bit lower loss. Is that correct?

Andrew D. C. LaFrence - *Surmodics, Inc. - VP of Finance & Information Systems, CFO and Principal Accounting Officer*

Brooks, that's correct. If you look at our press release, there's actually a reconciliation between our GAAP numbers and our non-GAAP numbers. And tax reform's impact is $0.09 a share. So to be specific, what happened there is that we have deferred tax assets that are on the books, and those are valued at 35%. And as a result of tax reform, the benefit we'll actually receive from those when we can deduct those expenses will now be 21%. So the difference between that is -- was a charge to earnings for deferred taxes of $1.2 million.

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

Okay. I got that. Appreciate that. Secondly, could you guys comment about the level of interest you're seeing in 014 catheter? I think you said you're doing some testing with that product as well as customers or potential partners. Just give us some...

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

Yes. Our strategy is, for both us and the strategic partners now that we have the regulatory clearances, and on the 014, it's both in Europe and the U.S., is to get it into clinical evaluation with some of the world's top below-the-knee interventionalists. I think our team was in Europe and Australia last week with one of these top interventionalists using the device. And for Surmodics to get a good deal or the best deal for our shareholders, we also want to have our independent data on how the product performs in patients. And that, sometimes, is the best -- certainly, the strategics will be doing the evaluations in patients as well. But we want to have direct knowledge of how this device performs as well so that when we sit down to talk about potential distribution agreements, the data and the feedback from the physicians is critical, and we -- by the way, we feel very positive.

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And the data, even last week, is very positive about the device's ability to go below the knee, to actually treat the lesion and things like that. So that's the idea. The microcatheter will go through the same paces, and I'm not sure if people quite get the degree of technology in this microcatheter. I mean, this thing is a 1.5 meter long. It starts off at one end at less than 1 millimeter in diameter and tapers over that 1.5 meters to less than 0.5 millimeter in diameter. And it's surrounding a guide wire that's about 0.33 millimeter. And so there aren't really products like that in the market across complex coronary and peripheral lesions. The only 2 that come to mind, really, in that category are the Terumo Finecross, which was sort of the granddaddy of that genre of devices, and then in June of '16, ASAHI launched what we call ASAHI Caravel. And so we're building on the capabilities of those products with the Telemark. So it's a pretty unique product, and we can't wait to put it through its paces in these very complex lesions.

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

That's very helpful, Gary. And could you just comment about any surprises you have found as it relates to the interest in strategics picking up a product like that? Obviously, it's sort of your first shot at trying to negotiate with potential partners.

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

This is purely anecdotal, but I'll share it anyway, but I'll protect the names of those involved. One of the heads of R&D of a very large strategic basically said, "I've got dozens of people working on this for many years. How do you guys come up with this so quickly based on the microcatheter?" So there is strategic interest, and as I said, some of the Japanese multinationals have had a really good head start on the U.S. multinationals in this genre of technology. And so Surmodics is bringing that to the next level. And so yes, the interest is high. The 014 as well, the interest is high. It's probably a smaller pool of strategics, but it's still a key level of interest in that. So no surprises. Yes. It also reflects, for us at least, the Pristyne coating, which -- the only way to get that is on our devices that we have now secured an FDA clearance using that Pristyne coating for the first time in our devices.

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

That's good. You had earlier, I think in prior conference calls, suggested that if you saw favorable things from your additional products, particularly the AV fistula product and I think the microcatheter as well, that you might actually increase your R&D investment this year. And if I'm looking at your guidance appropriately, it looks like, at least so far, you have not made a decision to do that. Could you comment on that just so I have clarification on how you're thinking about it?

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

It depends on what Andy lets me do. We have planned the year to accommodate what we believe are R&D spendings. But what I ask of Andy is -- sometimes, things are opportunistic, and so we feel good about our range in R&D that he just described earlier. But if we see an opportunity, if the preclinical data on AV is so dramatic and there's an opportunity to accelerate, we always believe it's in the best interest of our shareholders to do that. Now our -- the way we do it is not by just increasing our R&D budget. We look at the trade-offs and what we're doing first, so we can reallocate the investment from one area to another. After we optimize that, if there is still a need, only then will we consider increasing the budget. Is that close, Andy?

Andrew D. C. LaFrence - *Surmodics, Inc. - VP of Finance & Information Systems, CFO and Principal Accounting Officer*

That is correct.

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

He controls that flow.

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

I'm going to ask Andy about this tomorrow, so when you're not in the room, I'll get the real scoop.

Andrew D. C. LaFrence - *Surmodics, Inc. - VP of Finance & Information Systems, CFO and Principal Accounting Officer*

It will be the same scoop.

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

I'm sure that's true. So last question for me, and it's a 2-part question, I guess. Number one, any early surprises in the SurVeil work you're doing? And then I continue to have in the back of my mind that you're comparing that product to a product from your largest customer. And I'm curious if your prodding the bear has resulted in any reaction from it.

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

Sure. No surprises with the performance of SurVeil. Clearly, we don't see the endpoint data, and it is blinded. But getting sites, the budgeting and the contracting, it's a process. I mean, you have to get a contract and budget, and lawyers have to talk to lawyers for every single site. But that's ongoing, and as I said, we expect to have the sites up and running by the end of the fiscal year. As far as the head-to-head trial, no. Medtronic is our largest customer. We have good relationships with the team there, and it's really about the clinical question, not about the competitive question. It is a non-inferiority trial, but there's been this debate -- I was just at the LINC meeting in Leipzig about whether there's a class effect of drug-coated balloons or are there really differences in the technology. And so we believe for the clinical community versus the competitive devices, it's a very relevant question to answer about drug-coated balloons. So the outcomes of the trial is really about that. And for us, the outcome is really we'll secure the CME approval. And so no, I certainly don't sense or believe that -- both companies are very high class act companies, and there's no bad blood at all.

Operator

We will take our next question from Ben Haynor from Aegis Capital.

Benjamin Charles Haynor - *Aegis Capital Corporation, Research Division - Equity Research Analyst*

First off for me, kind of falling on Brooks' last question. Just when it comes to adding the sites and enrolling patients, I know there's still a lot that needs to take place before they get up and running and the patients are enrolled. But do you feel that you're on track with what your internal expectations were for having sites up and running and patients being enrolled?

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

I think we're on track in terms of selecting the highest-quality sites. We could take the approach of just grab a bunch of sites and hope for the best. And so we're being very selective. In terms of our -- I always have my expectations, and the clinical team just groans when they hear what my expectations are. But if you look -- I mean, the most recent trial was the Stellarex device, and they had, and don't hold me to this, about 350 patients, about 90 to 100 less than us. And it took from June of '15 to June of '17, I believe, to enroll that trial. So that's the nature of what we're working in. We clearly are trying to beat that, but we have more patients. But we also think the fact that a head-to-head trial should give us more interest from

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the clinical community. So it's hard to tell because it's so early. I continue to push. The next quarter, I'll have a better read to see the 2 curves of sites up and running. There's 2 curves that we look at, 2 sets of data: how many sites are we getting up and running and what is the enrollment rate of the sites that are up and running. And what I'm looking forward to is getting all of the sites up and running so that you can get the maximum contribution by having a big denominator.

Benjamin Charles Haynor - *Aegis Capital Corporation, Research Division - Equity Research Analyst*

Okay. That makes sense. And then just out of curiosity, are you planning on disclosing, "Okay, we've got X number of sites up and running, which is all that we're going to do," and if you plan on disclosing enrollment figures as the trial goes on maybe every conference call or when you hit like 25% or 30% or milestones like that?

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

Yes. Frankly, we want to stay away from the latter. We don't want to be the first company putting ourselves on the hook on an enrollment rate chart. That's -- there's also reasons that, for some of our strategic partners, they want to -- we'd all want to keep that (inaudible). I believe that we can't say, and Andy will give me the kick under the table here, but we can't say when we've gotten the full complement of sites up and running because we have said what our target is on that.

Andrew D. C. LaFrence - *Surmodics, Inc. - VP of Finance & Information Systems, CFO and Principal Accounting Officer*

And Ben, one of the realizations of that will be through our guidance around R&D expense, so that's where we'll -- you'll be able to think about where we're at with the study. We've already disclosed the study is going to be $32 million to $40 million over the next several years. So that's really where you'll have a sense of being on track.

Benjamin Charles Haynor - *Aegis Capital Corporation, Research Division - Equity Research Analyst*

Okay. That's helpful. And then it's nice to hear some of the comments you're getting on the microcatheter. With those types of comments coming your way, are you getting maybe internal suggestions on the pipeline on where to go next? Or is there any back and forth in that fashion with the strategics?

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

Yes. We'll lay out more of the details of the pipeline, but clearly, we are very excited about the microcatheter. And now, the 018, hopefully, in the latter part of this year, we can get a clearance on that as well. So the 014 is below the knee. The 018 sort of goes into the vessels behind the knee, and it's a very tortuous pathway. But we actually have the pipeline set for the next year. The things that we're working on, typically, you have to have been working on them before. So we are getting suggestions, but we also are very clearly what we need to deliver on that. So there's no lack of clarity in our end of what's going on in the early pipeline right now. But because -- for some competitive reasons and for some disclosure reasons, we want to keep that tight until we feel we were able to solve the clinical problem. We don't want to say what we're trying to solve and then we can't solve it. So later in this year, I hope as the teams get through their first challenge testing, then we can -- we'll share more.

Benjamin Charles Haynor - *Aegis Capital Corporation, Research Division - Equity Research Analyst*

Okay. And then lastly for me. You said that you're going to make the decision on below-the-knee drug-coated balloon or the AV fistula program. Are you leaning one way or another? And I figure I'm probably not going to get an idea which way you're going, but...

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

I am -- the development teams will tell you I'm always leaning one way, and then they actually have data, so I have to shut up and listen to them. But below the knee, certainly, at the LINC meeting, there was a lot of discussion about it and the effect and impact of drug-coated balloons. It still comes down to potentially, how do you deal with calcium. So it's a very complex, multifactorial disease, where everybody understands there's no one interventional approach that works. So that -- we will do our part as far as what a drug-coated balloon can contribute. We will be working on things that also solve the other aspects of the below-the-knee problem. But AV access is such a dramatic, high-volume problem for patients and a very high cost, certainly, in U.S. Medicare. It's probably 1% or 2% of procedures, but it's -- I've been told it's about 7% of Medicare costs. So I'm a fan favorite of that, but really it comes on to the data.

Operator

And our last question comes from Mike Petusky from Barrington Research.

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

So Gary, what do you see as the cadence for the 4 new 510(k) products in fiscal '18? I mean, I'm assuming kind of second half or maybe even very back-end-loaded in terms of regulatory clearances. Is that fair to say?

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

Yes. I think the lessons learned from last year, we're adding -- we had sort of greenlighted our feeling of the timing in terms of getting through with one pass. Now we're adding -- like in a microcatheter, there was a second pass, and some of that had to do with, certainly, the newness of the coating technology we were using and the very intense design of a product like a microcatheter. So we sort of backed up and said realistically, weighted average, this is going to be 1.5 passes, but there's nothing like 1.5 passes, 1.5 duration. So we believe it'll take 2 passes, which will push it probably into the fourth quarter. That doesn't mean we can't have a pleasant surprise in the third quarter. But I think from our viewpoint of submitting these devices -- and this is -- by the way, it's not a knock on the U.S. FDA. We are submitting some devices that really do have some critical aspects for them on how they treat the disease. So that's how we're looking for it. And then later in the calendar year as well, some of these may slip into the first quarter of '19, yes.

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

Okay. And then, I guess, the double-digit revenue growth you guys are projecting to begin in fiscal '19, how much does that hinge on sort of the timing of the 510(k) products that don't yet have clearance? I mean -- I guess essentially, that's the question. How much of that hinges on that timing sort of holding up?

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

Well, first off, we have the clearances on 2, right? One is CE and U.S. and then the microcatheter, and certainly, we'll be looking for -- so we feel quite confident in the contribution from about 3 of them. It really depends on 4, 5 and 6. 5 and 6 may not really contribute in a material way to fiscal '19, but I'll let Andy comment if there's anything.

Andrew D. C. LaFrence - *Surmodics, Inc. - VP of Finance & Information Systems, CFO and Principal Accounting Officer*

I agree with you, Gary.

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

Yes.

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

Okay. So essentially, you have a line of sight on a double-digit revenue growth just sort of based on the 510(k) products that you have gotten clearance on so far but haven't partnered yet and possibly one or 2 others between now and then.

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

Yes.

Operator

As there are no further questions, I would like to hand the call back to Gary Maharaj for any closing remarks.

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

Thanks, Siobhan. Thank you all for your questions. We are pleased with our first quarter results and progress in our whole products solution strategy. I look forward to speaking with you on our second quarter earnings call. Thanks, everyone.

Operator

That will conclude today's conference. Thank you for your participation, ladies and gentlemen. You may now disconnect.

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