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PRESENTATION

Operator

Good day, and welcome to the Surmodics Third Quarter 2017 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. - CFO, Principal Accounting Officer and VP of Finance & Information Systems*

Thank you, Jenny. Good morning, and welcome to Surmodics 2017 Third 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. - CEO, President and Director*

Thank you, Andy. Good morning, everyone, and thank you for joining. On today's call, I'll provide an overview for our key achievements and an update on this execution of our strategy and plans for fiscal 2017. And then I will turn it over to Andy to provide a review of our third quarter financial results and our fiscal 2017 guidance. We'll then open the call to take your questions.

We are pleased to report our third quarter results, which reflect continued operational performance in our 2 core businesses as well as tangible progress in our clinical programs. We're driving our innovative pipeline of whole-product solutions with considerable progress to date to achieve several upcoming milestones, both from a regulatory and development standpoint.

In the third quarter, we continue to demonstrate meaningful progress in our 3 major fiscal 2017 objectives. Recall that these are: one, to meet our overall revenue and profitability goals in our core businesses, even as we manage the o U.S. expiration of significant royalty-generating patents in our medical coatings business; two, to invest in and achieve significant milestones in our drug-coated balloon programs and secure regulatory approvals in our catheter and balloon R&D pipeline; and third, to expand our manufacturing capacity for high-quality and cost-efficient manufacturing through continued investment.

At a high level, revenue declined 11% in the third quarter versus the third quarter last year, and we achieved GAAP diluted earnings of $0.05 per share. 2 main factors caused this decline: first, in the third quarter of fiscal 2016, we received a onetime $2.6 million coatings royalty catch-up payment; and second, the noted expiration of our third-generation hydrophilic patents. Including the prior year net catch-up payments, revenue actually grew 2.5% in the current year third quarter. Given these results, we are raising our revenue guidance for fiscal 2017 to an expected range of $70 million to $72 million and GAAP earnings to a range of $0.15 to $0.25 per share. Andy will provide more details regarding revenue and profitability in the third quarter.

The most important achievement that I want to highlight today is that we received IDE approval from the U.S. FDA to begin our pivotal trial for SurVeil, our paclitaxel drug-coated balloon for the treatment of femoral-popliteal disease. The study named TRANSCEND is expected to enroll approximately 446 patients at more than 60 clinical sites in the U.S. and European Union. The randomized control trial will evaluate SurVeil drug-coated balloon for treatment of peripheral artery disease in the upper leg compared to the Medtronic IN.PACT Admiral drug-coated balloon. This trial is amongst the first studies to compare next-generation drug-coated balloon with one that is commercially available.

As many of you may recall, we intend to evaluate clinical results to show continued safety and efficacy of the SurVeil DCB that can be used for both regulatory approvals and reimbursement. The regulatory path that we are undertaking for SurVeil to move directly into a major clinical trial is both positive and unprecedented and marks a major milestone for the company. The primary efficacy endpoint of TRANSCEND is patency, defined as a compositive freedom from restenosis and clinically driven target lesion revascularization, TLR, through 12 months post-index procedure. All randomized subjects will be followed through 36 months post-index procedure. The principal investigators in the U.S. are Dr. Ken Rosenfield, Section Head of Vascular Medicine and Intervention at Massachusetts General Hospital and the Chair of the Surmodics Clinical Advisory Board; and Dr. Gary Ansel, System Medical Chief of the Vascular Program at OhioHealth; Dr. Marianne Brodmann, Substitute Head of the Division of Angiology and the Department of Internal Medicine at the Medical University of Graz in Graz, Austria, is the European principal investigator. All 3 highly skilled at drug-coated balloon investigators. We expect to begin enrollment in the fourth calendar quarter of this year.

To provide some background, the design of SurVeil reflects our strength in developing surface technology for vascular devices, in this case, specifically drug delivery. The device includes a proprietary drug-excipient formulation for the balloon coating and is manufactured using an automated proprietary process to dramatically improve coating uniformity. Preclinical data have shown a 3 to 5x higher target tissue concentration, a more evenly distributed and durable drug effect and lower incidence of downstream drug concentrations compared to controlled drug-coated balloons. The SurVeil drug-coated balloon early feasibility study conducted in the United States met its primary endpoint by demonstrating peak paclitaxel concentrations post-index procedure. Consistent with our preclinical data, the systemic levels were low and cleared rapidly. No safety issues were reported with the product. We are confident in our prospects and look forward to beginning enrollment in our pivotal study as we move into the next phase of clinical development.

Moving on to our sirolimus-based, below-the-knee drug-coated balloon program. We're continuing to make progress using our own internally developed 014 balloon platform. As announced last quarter, we have completed a major dosing study that has helped us freeze the dose to determine the optimal amount of drug to provide the desired biological effect with maximum safety. Recall that sirolimus is a different drug with different characteristics than paclitaxel, which is why we had to repeat these dosing studies. We have confirmed this dose and are preparing for formal preclinical studies and are fast-tracking this program to try to move into clinical evaluation quickly. We'll provide more updates in the coming months.

We've also made excellent progress in developing our AV fistula drug-coated balloon. As discussed previously, 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. Our early preclinical data are quite encouraging. If we continue to see positive data from these early studies, we may choose to further accelerate this drug-coated balloon program in fiscal 2018.

Now turning our focus to our non-drug delivery research and development pipeline. We are making significant progress, moving forward at our 3 products in development using advanced coating versions of our coating chemistry. In the fiscal third quarter, we completed regulatory submissions for 2 of these 3 products: our 014 peripheral balloon catheter, which incorporates a version of our Serene hydrophilic coating; and our microcatheter, which actually uses the Surmodics PRISTYNE advanced hydrophilic coating. Given our current discussions and the status of these submissions, we believe that we can receive regulatory clearances for these products sometime in the fourth quarter of calendar 2017. Furthermore, we expect a regulatory submission for our 018 peripheral balloon catheter, incorporating our Serene hydrophilic coating within the next several months. Approval of this catheter is expected in the first several months of calendar 2018.

We have also begun work on the next wave of product innovations for which we are targeting regulatory filings and clearance in calendar 2018. These will continue to build momentum on our non-drug delivery portfolio to accelerate top line growth.

And finally, with respect to manufacturing capabilities, our Ballinasloe, Ireland facility is both ready and capable of handling both drug delivery and non-drug delivery devices. We continue to invest in the coating equipment to increase our hydrophilic coating services to many of our key customers who also have manufacturing facilities in Ireland. We have effectively doubled our footprint in Ireland, and we have installed and validated the new processes which provide important scale and ability to quickly ramp up production, in line with our whole-product solution strategy.

Our progress in each of these areas continues to guide our capital allocation choices in fiscal 2017 and as we think about fiscal 2018. We believe that the best way for Surmodics to maximize long-term shareholder value is to accelerate these investments in core R&D programs that enable us to capitalize on some key strategic assets to develop unique whole-product solutions. This investment is critical to our long-term success. Our objective remains the same: to generate consistent, double-digit revenue growth on a constant currency basis within 3 years and to generate EBITDA margins greater than 30% within 5 years.

It's an exciting time at Surmodics. Given the robustness of our current R&D programs, we are on track to becoming a valuable and enduring medical device innovator by combining our key technology assets with our existing medical device customer relationships to develop best-in-class creative solutions for vascular disease. We are encouraged by our clinical, regulatory and development achievements within our R&D pipeline and coupled with our ongoing top line performance and operational progress. Rest assured, again, that our capital allocation will be accomplished in a characteristically disciplined fashion that our track record demonstrates and that you have come to expect from us.

I'll now turn the call over to Andy to provide more details on our third quarter fiscal 2017 results as well as our outlook for the remainder of 2017. Andy?

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

Thank you, Gary. We are happy to report that revenue for the third quarter of fiscal 2017 was $17.8 million as compared with $20 million in the third quarter last year. The prior year quarter included hydrophilic royalty catch-up payments that netted to $2.6 million of incremental revenue. Excluding the impact of these items, the prior year quarter -- in prior year quarter, revenue grew 2.5%. On a GAAP basis, our diluted earnings totaled $0.05 per share as compared with $0.03 per share in the prior year quarter. We delivered operating income of $1.7 million in the third quarter of fiscal 2017, down from $6.6 million in the prior year period. Operating margin decreased from 33% to 9.8% in the current year quarter. The declines in GAAP earnings per share, operating income and margin in the current year quarter as compared with the prior year quarter reflected planned increases in R&D spend to support our whole-product solutions product development and regulatory submissions as well as the previously mentioned net hydrophilic royalty revenue catch-up payments in the third quarter of fiscal 2016, offset by a $0.6 million or $0.05 per share net gain related to fair value adjustments to contingent consideration obligations in the current year quarter. On a non-GAAP basis, quarterly earnings per share were $0.09 per share in the third quarter of fiscal 2017 versus $0.41 last year.

Turning now to our 2 business units. Medical Device reported revenue of $12.8 million, a decrease of $2.9 million as compared with the year-ago period as a result of lower hydrophilic royalty revenue. Looking at specific areas within Medical Device, third quarter royalty and license fee revenue totaled $7.2 million, down $3.3 million from the prior year quarter. The change in royalty and license fee revenue is attributable to the impact of the $2.6 million net catch-up royalty payments in the prior year and, to a lesser extent, the expiration of our third-generation hydrophilic coatings patents. Product sales increased $0.1 million from the prior year quarter due to increased reagent shipments. Medical Device customer research

and development revenue rose $0.3 million for the quarter as a result of higher demand for contract coating services to support customer clinical trials in select product launches. This unit generated $1.4 million of operating income in the third quarter versus $6.7 million in the prior year quarter. The Medical Device operating income change was impacted by the previously described planned increased investments related to our whole-products strategy and reduced royalty revenue, offset by net contingent consideration fair value gains.

For our In Vitro Diagnostics segment, third quarter fiscal 2017 revenue, which consists of product sales, totaled $5 million, an increase of 16.1% from the year-ago period. IVD revenue in the third quarter reflected strong growth and stabilization, BioFX, microarray and antigen product sales, which more than offset the previously disclosed decline from a significant microarray customer that was acquired by one of its competitors. We are updating our expectations for fiscal 2017 IVD revenue to grow in the low single digits as compared with the prior year. This growth is despite the loss of the microarray customer, which is expected to negatively impact revenue by up to $1.2 million in fiscal 2017 as compared with fiscal 2016. Long term, we believe IVD revenue growth will be in the mid-single digits.

IVD operating income was $2.2 million as compared with $1.7 million in the third quarter of fiscal 2016. Operating margin increased to 44.5% versus 38.8% in the prior year quarter due to improved gross margin resulting from favorable product mix and increased operating leverage from higher revenue.

Product gross margins for the quarter were 65% of product sales as compared with 63% in the prior year quarter. Gross margins benefited from manufacturing leverage and favorable sales mix.

As a percentage of revenue, third quarter R&D expenses were 44.6% versus 23.5% in the year-ago period. R&D expense of $7.9 million for the quarter was up $3.2 million from last year. As we have stated before, we anticipate R&D expense will increase in the second half of fiscal 2017 as we accelerate our whole-product solutions strategy, including advancing our SurVeil drug-coated balloon human clinical trials and other proprietary products. We anticipate R&D expense will range between 40% to 44% of fiscal 2017 revenue.

SG&A expenses in the third quarter of fiscal 2017 were 29.4% of revenue versus 22.4% in the prior year period. On a dollar basis, SG&A in the third quarter of fiscal 2017 totaled $5.2 million as compared with $4.5 million a year ago. The planned SG&A expense increase reflects infrastructure needed to support our whole-products strategy.

During the quarter, the U.S. dollar continued to weaken as compared with the euro. As a result, we realized a $0.6 million foreign exchange loss on our euro-denominated contingent consideration obligation related to the Creagh Medical acquisition. During the quarter, we also made adjustments to our contingent consideration obligations related to NorMedix and Creagh Medical acquisitions and record a $1.2 million gain.

Income tax expense was 42.5% of pretax income in the third quarter, down from 42.8% in the prior year period. The effective tax rate reflects an impact of nontax-benefited amortization, accretion, contingent consideration gains, foreign currency gains and losses as well as operating losses in Ireland.

Looking at our balance sheet, which continues to be strong, cash and investments totaled $43.7 million at quarter end. We generated cash from operations of $7.7 million in the first 9 months of fiscal 2017. We repurchased 169,868 common shares for $4 million during the current quarter under the company's share repurchase program. We also invested $4.9 million in plant and equipment during that period.

Our current cash and investment balances and operating cash flows, combined with Surmodics' $30 million line of credit, provide adequate capacity to support our corporate strategic growth initiatives.

We are updating our revenue and EPS guidance for fiscal 2017. Based on the strength of revenue, we now expect revenue to range between $70 million and $72 million, up from our previous range of $65 million to $68 million. GAAP diluted earnings guidance is now expected to be in the range of $0.15 to $0.25 per share as compared with the previous range of a loss of $0.02 to a net income of $0.08 per share. Therefore, we now also expect non-GAAP earnings of $0.29 per share to $0.39 per share as compared with our prior year guidance of $0.15 to $0.25 per share.

Gary and I continue to be very impressed with the performance of the Surmodics team as we optimize our core business revenues and cash flows while we execute our whole-products solutions strategy. Thank you to the entire team for their hard work and outstanding results.

And finally, for those of you who'll be attending the TCT conference in late October, we are planning to host an analyst meeting on the morning of October 31 to discuss in more detail whole-products solutions strategy, the particulars and status of our TRANSCEND pivotal study for SurVeil and to have presentations from leading clinicians offering their perspectives on the market opportunity and their experiences to date with our unique solutions. Details will be forthcoming, and we hope you can join us.

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

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And we'll go to our first question from Ben Haynor of Aegis Capital.

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

First off, congrats on the IDE clearance. And I was just kind of wondering, can you talk about how you secured such high-profile principal investigators? I know initially that they are on your clinical scientific adviser roster, but how did they come to you? Was it after seeing some of the early data on the drug-coated balloon? Was it existing rolodexes (inaudible) other relationships? I guess, how did that happen?

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

Sure. And, Ben, before, I wanted to clarify, I said something incorrect in the script. The follow-up for the patient is not 36 months, it's actually 60 months, so 5 years. I just want to make sure everybody got that. It's a 5-year follow-up. To answer your question, they actually saw our preclinical data, and Dr. Rosenfield was the first one we have spoken with. And I don't want to put words in his mouth to speak for him, but needless to say, he was very excited, both with the data and the caliber of the technology. And he reached out to the -- his comrades, like Dr. Ansel, Dr. Brodmann, and they actually were equally as excited. Dr. Ansel will be presenting the clinical data. I believe it may be in late-breaking clinical at the VIVA meeting in September. So stay tuned for that. I believe the abstract in the presentation was accepted recently for our presentation. So Dr. Ansel himself actually treated some of these patients in the early feasibility trial. But I would say, for them, each of these PIs have substantial experience with the prior studies, specifically, the LEVANT 2 and the IN.PACT study. So the question is, is there room for improvement with some really good data that comes from these drug-coated balloons? And I believe they're working with us because they believe so, that there is room for improvement.

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

Okay, great. And then it sounds like one of your fellow med tech firms in the Twin Cities area just received FDA approval for radial access peripheral atherectomy device just the other day. And I know a part of your strategy is being able to enable radial access with some of these -- or expanded radial access with some of these 510(k) products and other things you're doing. Do you think that the recent approval from your fellow firm helps grow the radial access market and ultimately winds up aiding your strategy?

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

We actually like approvals in the radial access domain for one big reason. The weak limiting thing for any company breaking ice in this area is going to be clinical adoption from the [transdermalists] or radialists. And I think that's a critical part of developing the market. I don't think -- Surmodics, given the size and scale of our company, breaking that ice in terms of adoption from a [transdermal] to radial is we take all the help that we can,

and, in fact, it's an atherectomy device. And by the way, Ben, I'm not aware of that particular one. I may be confusing which one you're talking about, but I'll certainly check after this. But that's terrific. Market development is great for competition, and it opens a door for us and the suite of devices that we have. My son just started his cardiology fellowship, and I'm encouraging him to learn radial from the start. So hopefully, he listens.

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

And then lastly from me, I think, initially, you had thought that there might be some potential for these 510(k) products to see approval, the first 3, prior to the end of the current quarter, but it sounds like that might have moved back a little bit. We have heard that in some areas, the FDA might be a little bit short-staffed with the change in administration. Is it a function of that? Is it feedback that you've gotten from the FDA or just general time line?

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

Yes, that's a good question. We -- you're never in control. You're only in control of when you file or you submit for these clearances. And so we met our targets of the submissions and then you add the time period. As it is with any regulatory agency, depending on the level of interactive questions you get, you can be on and off the clock in terms of these statutory requirements. And so if you have 1 round of questions, it adds a certain period of time. So I don't know and I can't comment whether the agency is short-staffed or not, but we've gotten questions back on the submissions. At least one of these is a pretty dug-on unique product. So we got more questions than we would have anticipated. And on things like the 014, the questions -- I won't go into the detail of the questions, but we believe that there have been some market issues with current products in the market, that the agency is asking for more test data. And so we hear them, we debated with them and we're prepared to generate that data and then submit that extra data package. So that's what's going on. It's sort of an interactive thing, but it's taking a bit longer than we expected. The 018 product platform, given the questions we had on the 014, it didn't really make sense just because we told TheStreet we were going to submit it -- to just submit it and go through the same type of questions. So we did not -- have not submitted that yet because we anticipate the same questions, so we might as well have that complete data package at the time of submission. So that explains the third(inaudible) product.

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

Okay, that makes sense. And then just following up on that. I mean, it doesn't sound like any of the questions is kind of profiled as "deal breakers or showstoppers."

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

No, no, nothing like that.

Operator

And we'll hear next from Brooks O'Neill, Lake Street Capital Markets.

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

I have just a couple of questions, and I'm probably going to delve into an area you may be somewhat reluctant to talk about. But I'm trying to think about the forward fiscal year and the impact of R&D spending. As you look out, obviously, all the work you're doing is strategically attractive and critically important for the company, but I'm curious how you might think about -- I'm not asking for specific guidance on the amount of R&D spending, but talk to us a little bit about your outlook for the spending and the cost related to the trials and the work you're doing to develop these products.

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

Brooks, thanks for the question. You're correct, we're not going to be providing guidance really. In 2018, we're planning to do that. I think we've got -- early November, we'll have our year-end call and give guidance for '18. But what I can tell you is that as we look at the TRANSCEND study, it is expected to cost us in the low $30 million range, maybe up to $40 million, and that spend will be concentrated largely over the first 2 to 3 years of the study as we enroll patients in that study. And we'll provide more guidance on that in terms of that enrollment process on October 31 product-only analyst meeting at TCT. But for the rest of the spend for 2018, as Gary mentioned in his prepared remarks, we are evaluating our capital allocation related to both the AV fistula and below-the-knee products, and we will be working with the team here to determine what is in the best interest of shareholders to accelerate or allocate capital to those projects as well as to other proprietary products in 2018. I think all along, we've said that '17 was going to be a very strong R&D spend, and we still anticipate kind of being in that $31 million range in terms of R&D spend for this year. And you can anticipate that given the fact that we have achieved our goal of receiving approval to move forward with the pivotal study, that we will have a robust rate of R&D spend in 2018 as well.

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

Cool. That's helpful. And then recognizing that you had some patent expirations that impacted the business, do you anticipate any significant near-term patent expirations or things that might impact the existing business that we should be thinking about?

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

Well, let me, first of all, give you some thoughts around the third-generation patent expiration. You might recall earlier in the year that we started talking about potentially a headwind of $5 million to $6 million related to the patent expiration. Now we kind of look at that today and think that third-generation patent expiration headwind is going to be more in the $3.5 million to $4 million range. And we've benefited from the fact that we have had some transition of our customers to future generation technologies, and the mix is more towards international versus domestic sales. So that's helped us. So we do expect, from that standpoint a third-generation coating patent expiration, that we will continue to have some headwinds into, really, I think, the first half of 2018. And then we should be, year-over-year, in pretty good shape in terms of the royalties. Looking forward, our next patent expiration is in fiscal '22 related to our fourth-generation coating technology. And the guidance that we've given long-term for the collective Medical Device core business, which includes not only the royalties but also the reagent sales as well as our coatings business, where we're doing contract coating and optimization work for our customers who we expect that business to grow in the mid-single digits, probably on the lower end of that. So that's really -- the benefits we get in 2020 with the expiration of that patent is that our Serene coating will be on a lot more products, and a lot more of those products will have launched, which will help to significantly mitigate any headwinds we might have from that expiration.

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

That's very, very helpful. And then last question from me, I just want to confirm. I think you've talked about the fact that SurVeil might use your seventh-generation coating. Do I have that right?

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

No, SurVeil is actually using...

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

Is that a proprietary coating?

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

It's a proprietary coating, so it -- while there is a hydrophilic coating embedded on the balloon, the coating that we're using is actually a coating that includes a proprietary excipient and the paclitaxel. So it's not a hydrophilic coating itself, it actually is a drug delivery coating technology. So I would not put that in kind of the sequential of the hydrophilic coatings sequences but is a separate asset, similar to our Bravo coating we used back in the day with the Cypher stent.

Operator

(Operator Instructions) We will hear next from Mike Petusky of Barrington Research.

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

A couple of questions. I guess, Andy, I -- and I -- I fully understand you're not giving specific guidance for '18, but I just wanted to, I guess, clarify something. When you talk about R&D spend for '17 being around $31 million, then you sort of characterized '18 as also being heavy, it's not going to be comparable to '17. I mean, it's going to be materially higher between the SurVeil and whatever you do on below-the-knee and AV fistula, right? I mean, it's fair to say it's going to be meaningfully higher in '18 in terms of R&D spend versus '17, right?

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

Mike, if we determine that we're going to go into a first-in-human, for example, for below-the-knee or AV fistula and continue to move those programs forward, you would expect that there would be a significant increase in R&D, and that's the process we're going through right now, as you can imagine, with annual operating plan being pulled together. And we're meeting with the board, quite frankly, next month to kind of review that. So it's premature to say that we actually will execute that strategy. But if we choose to do that, you would expect that R&D spend would be up next year. And just with the SurVeil-TRANSCEND program itself, we would expect the spend to be up. So overall, what I can guide you to is that we do expect R&D spending to be more than $31 million next year.

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

Yes. And just one comment. A part of it -- our decision depends on if we see continued positive results in our AV fistula program, the question remains on the table, can Surmodics have 3 drug delivery programs with concurrent clinicals over the next 1 to 3 to 5 years? And so that will be a decision we take on. Below-the-knee is a very difficult disease, enrollments rates are very slow. And it is possible -- and I'm not saying we have gotten to a decision or internal point of view on this, but it's possible that an AV fistula drug-coated balloon can compete from a time and market attainability and size-of-market viewpoint, given the type of clinical and the device that we are developing. So that's a trade-off. We need time and information. It's not we're holding back from -- we internally need time and information to make the best capital allocation decision there, yes.

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

Okay. All right. Great. And then, Gary, I may have sort of got lost in the explanation here, but on the 510(k) products, I think I understand that the 018, you didn't even make a submission package there because, essentially, you expected the same questions that you got on the 014. But, I guess, what I'm wondering is, in the...

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

And we're a little bit behind on that one as well because it was after the 014. So -- but keep going.

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

Okay. Yes. So maybe just to answer my question, but I was going to ask then, why the several months delay in terms of when you expect potential approvals on that product versus the others, if it was just essentially the same questions, but it sounds like you may have just answered that.

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

Yes. It's a matter of -- developing a balloon is anything but trivial, and they use a lot of the same equipment in the R&D stage. So we prioritized the 014 ahead of the 018 balloon. And so we knew that was always going to be a later filing. Then one of the other things is, as we develop these products, keep in mind, our key strategic customers, we would somewhat interactively with them. And so when we have the -- before design freeze, we'd get feedback from different strategics because they have specific targets they need for their arsenal. And so I believe the 018, we also -- and in addition to that, we got some feedback that said we may want to tweak some things here and there before the design freeze. So that, plus understanding the testing, plus it started behind because of the same resources that it uses -- the same equipment, is really the cause of that delay. And I don't want to gild a lily here. That is a delay. It's not something we knew beforehand and we're saying that we're going to be good. It is a delay and it's for a number of reasons. On the other hand, I would say none of them are fatal flaw reasons. When you're trying to develop the world's best 018, it takes some time and you want to make sure the strategics themselves see it is the world's best 018 peripheral balloon platform (inaudible).

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

Okay. And then, I guess, just last question. So in terms of, obviously, the -- somewhat delayed approvals, in terms of partnerships, I mean, when would you expect we might hear something in terms of partnerships with the first 2 products? I mean, would that be hopefully first half of '18? Or can you talk about that?

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

Right. We -- here's the thing, we can sign -- we believe we can sign deals earlier, but I think our shareholders want us to sign the right deals. So 2 things we contemplated is, a, getting -- upon getting approvals, we want to get these products in clinical usage because we will have the clearances, I should say, and then -- and get clinical usage from the high-profile, high-volume users to also demonstrate its clinical viability. It's no longer preclinical testing and really get a nice track record here. That could take up to a quarter. We may do that in conjunction with some of our strategic partners who have the reach for some of these clinicians. And so to get the right deal signed, we would like to give it at least a 1-quarter lag, because we think in the second quarter after these approvals, we will get that clinical utility. It will also create some competitive tensions among some of the strategics who would want these products to get the best deals signed. So while we could sign an early deal, we don't believe that's the best interest of us and our shareholders. So I would say if we get approvals, let's say, early first quarter or late first quarter, I would look into giving it at least 1-quarter lag before you see a deal happen or announced.

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

Okay. Let me -- great. Let me think -- one more quick one out, and then I'll get back into the queue. In terms of -- obviously, these first few products are just the beginning of what you hope will be multiple years of developing products. Does the delay in these products -- does that, in any way, impact your hopes for what you can develop and submit in fiscal '18?

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

No. The delay -- actually, we have several products currently in development, and those are moving ahead on their own regulatory -- sorry, product development and regulatory time line. I believe we would learn a lot from the interactive mode with the FDA in terms of some of these new type of products, what they're looking for, and that will help us accelerate the submissions and, hopefully, the clearances that we would get on these

new products. But right now, there's not a bottleneck on the catheter or things like guide sheets, those type of platforms. If we have multiple balloons coming down the pipeline, there is a chance that there may be some resource overlap there. But currently, our 2 contemplated balloon devices are actually in play, the 014 and 018. So the backup is not necessarily causing a backup in the early pipeline.

Operator

And our next question comes from Jim Sidoti of Sidoti & Company.

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

So start with the quarter that just ended, revenue definitely came in, I think, a little better than I thought you're taking your guidance up. Can you just give us a little more color on where the upside was in the quarter that ended?

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

Jim, clearly, to look at IBD, with the revenues up 16.1%, they just -- they performed extremely well, and that was a big improvement in the quarter. And some of that, as you recall, they had some really tough comps in the first 2 quarters to deal with. But a number of things have -- in terms of some market share wins that we have and just some of the timing of the orders. And so we're seeing, really, I think, good growth overall. It's broad-based, all the products there. And -- so that's really one of the places. And then the second area is that we talked about the hydrophilic coatings royalties being -- actually being better than anticipated in terms of the impact of the patent expiration. And I think last quarter, we were kind of $4 million to $5 million sort of impact for the year, and we're now at $3.5 million to $4 million. So we've seen that a couple of things have really driven that, and that's been the mix, U.S. mix versus o U.S. mix. And then, quite frankly, there's been some customers -- if you look at, I think we've signed this year 8 new licenses and 5 of them have been for Serene and 3 of them actually have been know-how extensions for the third-generation coatings. And those have been helpful as well in terms of giving clarity, in terms of the expectations of the royalty. So those are the 2 big drivers that are out there right now.

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

I will say I'll give great credit to our commercial teams, both in Diagnostics and Medical Device. I mean, the IVD team is just commercial execution and excellence of new products across the range, things that they're doing with new customers with current products. And the Medical Coatings team, to be able to swing know-how extensions on expired patents and the way we manage those customers that are on the patent expiration really gave us a lot of that lift, too. So...

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

Okay. And then with respect to the guidance, you've done $0.26 so far this year. You're guiding for $0.15 to $0.25. So, obviously, the R&D spend is going to impact profitability. But, I guess, my question is, why such a big range, $0.15 to $0.25, with only 1 quarter left?

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

No, that's a fair question, Jim. And if you look at the revenue guidance of being between $70 million and $72 million, a lot of that flex that we have there has to do with license and royalty fees. And there is a number of things that are in play there, and as you recall, those go straight to the operating income line one for one. So if you have a $2 million swing between the two of them, after tax, it's about $1,300,000, which is $0.10 a share. So there's some of the variability right there, just what will the execution look like, and many of our customers haven't reported at this point in time. So that -- we're extrapolating with what we have reported, and that gives you, I think, the big variability there in terms of the revenue guidance drives that.

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

All right. And for the trial that you're about to start, can you remind me how many patients are going to be in that trial?

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

It's 446 patients, so one-to-one enrollment. And that's -- you may have some loss to follow up, so -- in that order, 446.

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

All right. And for the other trials that you mentioned, would they be similar size? Would they be smaller?

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

They were all in the same range. The 3 RCTs that we conducted that led to approvals were all versus plain old balloon angioplasty. So you design, you power the study based on the statistics, based on the difference between the control arm and the study arm. And so, yes, they were pretty much in that range. I don't know what the more recent ones are -- what the ranges are for them. I think Boston and QT Vascular have several -- have different types of clinical design.

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

And total cost for a trial like this, I think you said -- can you just repeat where you think that will be?

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

Jim, we anticipate that the cost of trial to be in the low $30 millions and up to maybe $40 million.

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

Okay. And that's just for one. So there would be similar costs for the other ones as well?

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

It's hard to tell -- the BTK, maybe, it may be spread out. Enrollment rates and below-the-knee disease are very different. Remember, this is spread over 5 years. It's certainly front-loaded, but you follow up the patient for 5 years. And so the heavy-lifting will be in the first 2 to 3 years. AV access, we don't believe it will be in that range because the trial is a very -- it's a different type of trial for a different amount of time. But that's -- $30 million to $40 million is a good way to think of the SurVeil trial.

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

Okay. But looking at your balance sheet, you obviously -- you can afford to do the first one on your own, but as you look towards numbers 2 and 3, either you need to find a new source of capital or sign a partner. Can you just give us what -- some sense of what you're thinking for trials 2 and 3?

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

A couple of things. We clearly can't comment on anything with the partners or anything at this point. But as we look forward in the capital allocations for '18, we have to make some strategic choices, and that's what we are -- as I said earlier, the AV access continues with really good preclinical results. We may have some ways to accelerate that not at the full freight charge to do that. The question is, it comes down to really, can we have both BTK and AV fistula in the same clinical development at the same time? Because we're committed to SurVeil already, okay? So that's the decision that we have to really think through for fiscal '18. Clearly, if there's a strategic partner who would want to contribute to this, those things are clearly not off the table, but we don't make it a habit of commenting of whether those are viable or not at this point.

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

One thing I would mention, Jim, is we still have 2 businesses that are generating a lot of cash. So if you look at where our expectations are for -- for example, for this year, our EBITDA, we're anticipating, probably will be $11.5 million to $12-plus million for this year, and our CapEx is in the $7 million to $8 million range for the year. So we're still generating a significant amount of cash, which will continue to fund any of these clinical trials.

Operator

And it appears there are no further questions at this time. I'd now like to turn the conference back to management for closing comments.

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

Thank you for all of your questions. And we are pleased with our third quarter results and progress in our whole-products solutions strategy. And I look forward to speaking with you in our fourth quarter earnings call. And those of you who can attend our analyst meeting on October 31, we will speak then as well. Thanks, everyone.

Operator

And, again, that does conclude the call. We would like to thank everyone for their participation. You may now disconnect.
