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PRESENTATION

Operator

Good day and welcome to the Surmodics third-quarter 2018 conference call. Today's call is being recorded.

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

Tim Arens - *Surmodics, Inc. - VP, Corporate Development and Strategy and Interim VP, Finance and CFO*

Thank you, Katie. Good morning and welcome to Surmodics' fiscal 2018 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 surmodics.com.

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

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

Thank you, Tim. Good morning and thank you for joining us. Before we get into the quarter, I'd like to take a moment to introduce Tim Arens, our Vice President of Strategy and Corporate Development and our interim CFO.

Some of you may recall Tim acted as our interim CFO for six quarters from 2011 through 2013. Prior to that, Tim was both the general manager of our in vitro diagnostics business unit and the head of our FP&A process.

Tim was also the internal quarterback of the three seminal acquisitions we performed in the last three years and also led the DCB commercialization deal we recently completed with Abbott earlier this year. We are glad to have Tim's business acumen and key contributions to our corporate strategy to act as our interim CFO. Thank you, Tim.

Moving on to our third-quarter performance, we are pleased to report strong operating performance and meaningful advances on our strategic objectives. Our results reflect solid top-line performance and operational results as we continue to invest in our new product pipeline.

We generated revenue of $22.2 million, growing 25% over the third quarter of fiscal 2017. This included $1.7 million of revenue from our SurVeil agreement with Abbott. We also reported diluted non-GAAP earnings of $0.27 per share in the third quarter.

Our underlying core business performed well as we continue to execute our core commercial opportunities. As a result, we are updating our expectations for fiscal 2018 revenue to be in the range of $79 million to $81 million, up from the previous range of $75 million to $79 million for the year. We have also revised our expected diluted loss in the range of negative $0.25 to negative $0.30 per share as compared with the prior guidance of negative $0.20 to negative $0.35 per share.

The updated guidance reflects a $0.47 per-share charge during the quarter related to the acquisition of in-process research and development assets from Embolitech as well as better-than-expected revenue performance. Non-GAAP diluted earnings per share guidance has now been substantially increased to $0.39 to $0.44 as compared with prior guidance of a loss of $0.06 to positive $0.09 per share.

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

As many of you will recall, in late February, we announced an agreement with Abbott for worldwide commercialization rights for our SurVeil drug-coated balloon. As part of the agreement, we will supply the SurVeil drug-coated balloon to Abbott and collaborate with Abbott on product development, clinical trials, and regulatory activities to obtain marketing approval in the US and outside of the US, including Europe.

Separately, Abbott also received options and negotiated agreements for our below the knee and AV fistula drug-coated balloon programs, which are currently in preclinical development. As a reminder, SurVeil is built on a next-generation technology which includes a proprietary drug excipient formulation for a durable balloon coating and is manufactured using a unique process to improve coating uniformity.

Preclinical data have shown a three to five times higher target tissue drug concentration, a more evenly distributed and durable drug effect, and a lower incidence of downstream drug particulates as compared to earlier generations of drug-coated balloons. The design of the SurVeil drug-coated balloon reflects our industry leadership in the development of surface technology for vascular medical devices.

With Abbott arrangement in place, we are prioritizing resources to support this project. Our collaboration with the Abbott team on ongoing development for SurVeil and the partnership itself is going exceptionally well. We are excited by the partnership, given their deep expertise in vascular care products and their worldwide market coverage. And we look forward to working together with Abbott to realize the full potential of our SurVeil drug-coated balloon to treat people with peripheral artery disease.

Now I will turn to the three strategic objectives that we outlined in the beginning of the year. As a reminder, these are to: one, execute the TRANSCEND clinical trial in a high-quality rigorous and efficient manner; two, to advance our R&D whole product solutions pipeline by securing the regulatory clearances for at least four new products in fiscal 2018; and to file for the first in-human use of either our below the knee or AV access -- AV fistula drug-coated balloon programs; and three, to finalize and further delineate our commercialization strategy with potential distribution partners for our proprietary products.

For the TRANSCEND program, our pivotal trial for SurVeil, it progressed nicely throughout the quarter. We're well on our way to having all US clinical sites initiated by the end of fiscal 2018 as planned. We are actively getting sites up and running and enrollment is progressing, including at some clinical sites in Europe.

We expect to complete TRANSCEND enrollment by the end of fiscal 2019. And as a reminder, TRANSCEND is expected to enroll approximately 446 patients at up to 60 clinical sites in the US and 18 sites outside of the US.

This randomized trial will evaluate the SurVeil drug-coated balloon for treatment of peripheral artery disease in the upper leg compared to the Medtronic IN. PACT Admiral DCB, the market leader. This trial is among the first Level I studies to compare next-generation DCB with one that is commercially available. We continue to work with the respective regulatory agencies in multiple countries to secure approval for site initiation and have to date received clearance to initiate sites in several countries.

However, our assumptions on timing will depend on the feedback we obtain from initial filings, especially taking into consideration regulatory requirements in each country. We look forward to reporting further progress in our clinical sites, both the US and internationally, in upcoming calls.

We continue to expect a filing for the first human use of our below the knee and AV fistula access drug-coated balloons in fiscal 2018. Further, we anticipate initiating a first-in-human study for at least one of these products in fiscal 2019. And we are making progress with our 014 sirolimus-coated balloon for below the knee drug-coated balloons.

We are currently working through the preclinical studies for the data package that will be used to determine our readiness for a first-in-human trial. We remain on track with this program and expect to make continued progress throughout the remainder of fiscal 2018.

Turning briefly to our IVD business, we recently launched the MatrixGuard diluent, which provides assay developers unsurpassed blocking of matrix interferences while the intended assay signal is maintained. MatrixGuard diluent significantly reduces the risk of false positives and has excellent three-year stability. With the launch of the MatrixGuard diluent, we continue our commitment to be a premier provider of diagnostic assay components that improve performance and manufacturability of immunoassays.

Switching gears now to our further R&D efforts around our whole product solutions pipeline, in May, we announced the acquisition of an innovative thrombectomy platform technology and the related intellectual property from Embolitech. Thrombectomy is a $400 million global market growing in the high-single digits.

However, there are significant limitations with currently available technologies and the ability to treat especially organized thrombus. The Embolitech technology is an innovative platform with broad potential peripheral vascular applications, including arterial thrombosis, pulmonary embolism, neuroendovascular embolism, and deep vein thrombosis.

The technology offers next-generation innovation that eliminates the need for the use of thrombolytics, reducing the likelihood of ICU time and bleeding complications that significantly affect patient recovery and outcomes. In addition, this technology is anticipated to reduce procedure time and the need for multiple procedures. And it does not require any additional external capital equipment, thereby providing an on-the-table solution for the patient in the cath lab.

We are excited to add to this portfolio a technology that offers significant advantages over the current treatment of complex peripheral thrombosis. The addition of this technology strengthens our pipeline of highly differentiated whole product solutions. We will use our design and development capabilities, our hydrophilic-coating technology and our manufacturing operations as we absorb this technology into our whole product solution pipeline.

Our team is quite excited to be working on the technology and is already working on initial prototypes and test methods. And we are currently executing at a very aggressive timeline with expectations to submit our first application for regulatory approval in the first half of calendar 2020.

Turning now to our pipeline of commercially approved products, we are progressing towards commercial agreements with several interested parties who are in the process of reviewing each of our products that have received regulatory approval. We continue to exercise the appropriate patience in order to maximize the commercial potential for each of these devices and sign the appropriate deal for our shareholders.

As you may recall, the Telemark 014 coronary and peripheral support microcatheter received FDA clearance in the second quarter of fiscal 2018. Early clinician feedback in cases treating patients continues to be overwhelmingly positive.

As a reminder, the Telemark support microcatheter offers excellent cross-ability for complex coronary and peripheral lesions. This microcatheter combines Surmodics' extreme composite shaft technology with the high-performance PRISTYNE hydrophilic coating that together provide exceptional deliverability, kink resistance, and lesion crossing. Surmodics' PRISTYNE hydrophilic coating offers a best-in-class lubricity and low particulates.

The Telemark microcatheter's tapered profile has an outer diameter ranging from 2.6 down to 1.4 French for effective penetration of especially tough calcified lesions. And it has performed very well in the hands of key opinion leaders going through very tough lesions.

We continue to develop our clinical experience to assess its performance and guard the clinician feedback in the coming months. And we continue to have active and ongoing strategies in this product from multiple parties who are conducting their own clinical evaluation.

Our 014 PTA balloon catheter is also undergoing clinical evaluation, both by Surmodics and interested parties. During the quarter, we continued collecting user experience with 014 PTA balloon catheter with extremely encouraging clinician feedback from these initial cases. We are pleased and are still targeting revenue generation for this product in fiscal 2019.

We are also continuing to make measurable headway in products in development using advanced versions of our coating chemistry and our design capabilities. In April of this year, we received FDA 510(k) clearance for our 018 peripheral balloon catheter, which incorporates our Serene hydrophilic coating.

As you recall in late calendar 2017, we also received both FDA clearance and CE Mark for the 014 balloon catheter, which also uses Serene hydrophilic coating. Both catheters, the 014 and 018, offer best-in-class deliverability and lesion crossing by leveraging our proprietary hydrophilic coating for unmatched friction and particulates.

These proprietary technologies, combined with Surmodics' advanced processes, ensure ultralow tip entry and crossing profile for smooth transitions to achieve best-in-class product solutions. And these new products demonstrate our focus for improving on and providing next-generation devices to address the growing need for minimally invasive peripheral artery disease treatment. We are confident that these devices will provide clinicians an effective tool for accessing and crossing the most complex lesion.

Looking ahead, we continue to work on the next wave of product innovations for which we are targeting regulatory filings and clearance in calendar 2018. These will help us further build on our platform and achieve top-line growth.

It is an exciting time at Surmodics and I will highlight these exciting products after their respective breakthrough clearances have been achieved. However, we are on track to become a leading and enduring medical device innovator by combining our key technology assets, our medical device customer relationships to deliver best-in-class innovative product solutions.

We are also encouraged by our clinical regulatory achievements combined with the ongoing top-line performance and operational progress. Our goals of generating consistent 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 very attainable.

I will now turn the call over to Tim to provide some more details on our third-quarter fiscal 2018 results as well as our outlook for the remainder of fiscal 2018. Tim?

Tim Arens - *Surmodics, Inc. - VP, Corporate Development and Strategy and Interim VP, Finance and CFO*

Thank you, Gary. We are pleased to report that revenue for the third quarter of fiscal 2018 was $22.2 million as compared with $17.8 million in the third quarter of last year. We reported an operating loss of $6.3 million in the third quarter of fiscal 2018 as compared with operating income of $1.7 million in the comparable prior-year quarter.

Our third-quarter financial results reflect the $7.9 million acquired in-process research and development charge associated with our acquisition of Embolitech's thrombectomy platform technology and its related intellectual property.

On a GAAP basis, our diluted loss totaled $0.20 per share in the current-year quarter as compared with earnings of $0.05 per share in the third quarter of fiscal 2017. On a non-GAAP basis, quarterly earnings per share were $0.27 in the third quarter of fiscal 2018 versus $0.09 in the prior-year quarter.

Turning now to our two business units, medical device delivered an impressive 31% or $3.9 million increase with revenue of $16.7 million in the current quarter. Looking at specific areas within medical device, third-quarter royalty and license fee revenue totaled $9.6 million, up $2.4 million from the comparable prior-year quarter.

The increase in royalty and license fee revenue reflects broad strength in our hydrophilic coatings royalties and $1.7 million of license fee revenue recognized from the SurVeil distribution and development agreement signed with Abbott during the second quarter of this fiscal year.

Product sales increased $1.6 million or 49%. Driving this growth was a substantial increase in balloon catheter unit volume as a result of recent customer product launches as well as increased reagent sales.

The medical device business unit reported a $6.2 million operating loss in the third quarter versus operating income of $1.4 million in the prior-year quarter. The medical device operating results were impacted by the $7.9 million IPR&D charge associated with the acquisition of the Embolitech thrombectomy technology and also $1.5 million of increased R&D spend. These expense increases were partially offset by the revenue gains in the quarter.

For our in vitro diagnostics business, third-quarter fiscal 2018 revenue, which is predominantly comprised of product sales, totaled $5.5 million, up 10% or $500,000 compared with the year-ago period. IVD revenue in the third quarter reflected strong growth in antigen and stabilizer sales.

IVD operating income of $2.2 million in the third quarter was down slightly compared to the year-ago period. Operating margin in the third quarter of fiscal 2018 was 39% compared to 44% in the comparable prior-year quarter. Product revenue mix was skewed toward lower-margin products.

Product gross margins for the quarter were 60.8% of product sales as compared with 65% in the prior-year quarter. Our third-quarter product gross margins were negatively impacted as product revenue mix was skewed towards lower-margin products. Driving the margin declines were an increase in sales of distributed diagnostic products as well as the infrastructure and scale-up costs in our Irish facility as we prepare for future growth.

As a percentage of revenue, third-quarter fiscal 2018 R&D expenses were relatively unchanged at 44% compared with the year-ago period. R&D expense, excluding IPR&D associated with the Embolitech asset acquisition, was $9.8 million for the quarter, up $1.9 million for the third quarter of fiscal 2017.

R&D expenses totaled 44% of revenue for the quarter due to increases in product and royalty revenue as well as favorable impact from a change in the scope of work to be performed by an external partner involved in our TRANSCEND clinical study.

We continue to track towards completing enrollment in the trial by the end of fiscal 2019 and anticipate R&D expense will accelerate in Q4 fiscal 2018. We expect Q4 fiscal 2018 R&D to be in the mid to high 50%s as a percentage of revenue. Related to the May 2018 Embolitech technology acquisition, $7.9 million of IPR&D was charged to operating expenses in the third quarter of fiscal 2018.

SG&A expenses in the third quarter of fiscal 2018 were 26.9% of revenue versus 29.4% in the prior-year period. On a dollar basis, SG&A in the third quarter of fiscal 2018 totaled $6 million as compared with $5.2 million a year ago. Impacting the increase in SG&A expense during the quarter were higher stock-based compensation expenses and higher payroll taxes associated with stock option exercises.

During the quarter, the US dollar strengthened as compared with the euro. As a result, we realized $600,000 of foreign exchange gain on our euro-denominated contingent consideration obligation related to the Creagh Medical acquisition.

We recorded an income tax benefit of $2.6 million in the third quarter of fiscal 2018 as compared with income tax expense of $0.5 million in the prior-year period. The current-year benefit reflects a deferred tax impact of the $7.9 million IP and R&D charge from Embolitech as well as a $1 million discrete benefit from stock award exercise activity.

Both periods reflect the impact of non-tax benefited amortization, accretion, contingent consideration gains and expenses, foreign currency gains or losses, and operating losses in Ireland. We expect income tax benefit, including the impact of tax reform, for fiscal 2018 to be in the range of $2.5 million to $2.9 million.

Our balance sheet reflects the strength of our operating performance, even as we make significant investments to support our strategic initiatives. Cash and investments totaled $62.4 million at quarter end and we generated cash from operating activities of $1.8 million in the third quarter, bringing us to $29.2 million year to date.

Our cash and investment balances were impacted by the $4.5 million paid in the current quarter for the acquisition of the IP and R&D assets from Embolitech. We also invested $6.9 million in plant and equipment during the first nine months of fiscal 2018. Our current cash and investment balances and operating cash flows provide adequate capacity to meet our corporate strategic growth initiatives.

As a result of our operating performance in the recent quarter and over the first nine months of fiscal 2018, and to reflect the IPR&D charge related to the thrombectomy technology acquisition, Surmodics has revised its fiscal 2018 revenue and earnings performance guidance. We expect fiscal-year 2018 revenue to range from $79 million to $81 million, up from the previous expectation in the range of $75 million to $79 million.

This outlook includes between $4 million and $4.5 million of revenue from our SurVeil distribution agreement with Abbott for fiscal 2018. This is up from our previous expectation of $3 million to $4 million.

The Company now expects diluted loss in the range of $0.25 to a loss of $0.30 per share as compared with prior guidance of a loss of $0.20 to a loss of $0.35 per share. The current guidance also includes a $0.47 loss per diluted share related to the thrombectomy technology acquisition.

Non-GAAP diluted earnings per share guidance range is now $0.39 to $0.44 as compared with the prior guidance of a loss of $0.06 to an earnings of $0.09 per share. Gary and I are extremely pleased with the performance of the entire Surmodics team in our fiscal third quarter. Thank you for your hard work and outstanding results.

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

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Brooks O'Neil, Lake Street Capital Markets.

Brooks O'Neil - *Lake Street Capital Markets - Analyst*

Good morning and congratulations on another terrific quarter and progress you are making. I was hoping that I could ask you guys just a little bit about the BTK and AV fistula programs.

I had some sense from comments in prior quarters that it was possible you might increase your spending against those two programs if you saw encouraging results. Obviously, the raised guidance today does not appear like that is coming to pass.

Can you just comment on how you feel about the development in those two areas in particular? And whether we should expect to see increased spending behind them as we move forward over the next few quarters?

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

Sure, Brooks. I will take the first part and Tim can talk about how it relates to R&D spending. First of all, I feel really good about the results we have seen in both those programs.

I think the BTK is, as you know, a very difficult disease and it's a very challenging product to develop. However, we have completed the preclinical studies and we are in the data assessment component of that right now. And so any implied impact on our R&D spending is not at all connected to the actual data we are seeing.

And I was just out of the country talking to the clinicians who agreed to participate in those below the knee studies as we get -- as we file for regulatory approval. So continues to be good news there.

The AV program in a similar vein, and I believe it's probably lagging a little bit right now the BTK. The prime reason for that is the AV requires more balloon development. We have to upsize balloons all the way up to 12 millimeters in diameter, but the drug delivery capability continues to meet all of our expectations internally. The BTK is on our 014 balloon platform, so that's I should say a straighter shot for us in terms of the underlying device.

Tim, any comments on the R&D?

Tim Arens - *Surmodics, Inc. - VP, Corporate Development and Strategy and Interim VP, Finance and CFO*

Yes. Brooks, I would imagine that you will see a ramp in below the knee and AV fistula spend in the coming quarters. I would say one of the things that we are probably really pleased with is the teams have been, to a large extent, able to leverage the existing platform technology, which has helped us maybe to get a little further along than perhaps maybe what we had thought.

It wasn't all green lights go. But as Gary mentioned in his prepared remarks, we expect that we have an opportunity here for a regulatory filing for a first-in-human in one or both of these programs. So I think we are really pleased with the progress on both of these programs.

Brooks O'Neil - *Lake Street Capital Markets - Analyst*

Great. Let me just ask one follow-up. I'm curious; if I was listening correctly, it sounds like you are entertaining conversations with multiple potential partners on the products -- whole products you are developing. I'm just curious how all of this plays with the various children you are engaged with, including obviously Medtronic, your largest customer; Abbott, your newest large partner; and potential engagements with other companies as well?

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

Well, I will say first of all, remember that Abbott has options on the drug delivery portfolio. So they will certainly be quite interested in reviewing the first-in-human data for both of those -- for one or both of those programs at a time.

As far as the whole products -- the 014, 018, and the microcatheter as an example -- those fill different holes in different strategics portfolio. And so we are not generating -- I hope we are not generating any bad blood with anyone strategic because the customers who need a 014 balloon platform refresh are not necessarily the same ones who need a 018 balloon -- a new state-of-the-art 018 balloon. And also the same with the microcatheter.

So just like in the case with the Abbott deal, these are all our customers. And we are basically offering them fully derisked, clinically technically, and regulatory derisked clinical solutions to fit their portfolio. So as a result, there is not -- I don't sense any friction with our customers. I think those who are evaluating it are happy to be evaluating it.

Tim?

Tim Arens - *Surmodics, Inc. - VP, Corporate Development and Strategy and Interim VP, Finance and CFO*

And Brooks, Gary is spot on with that. It probably isn't a surprise, but I would imagine probably not too far of a stretch for you to think that those organizations that you've mentioned are aware of the cleared products and may have expressed interest in them. We will get into more detail on that at a later date once agreements are signed.

But as Gary did describe, we have conducted clinical evaluations on these technologies and now we've got these strategic partners who are doing the same. So stay tuned. We are excited about these products and we look forward to talking more about them in the coming quarters.

Brooks O'Neil - *Lake Street Capital Markets - Analyst*

Fantastic. Thank you very much and congratulations.

Operator

Jim Sidoti, Sidoti & Company.

Jim Sidoti - *Sidoti & Company - Analyst*

Good morning. Just first, accounting type question. You booked $1.7 million from Abbott royalty revenue in the quarter. Should we expect similar type revenue from Abbott being booked in the next several quarters?

Tim Arens - *Surmodics, Inc. - VP, Corporate Development and Strategy and Interim VP, Finance and CFO*

Jim, I think it will be higher. In our guidance, I think we highlighted between $4 million to $4.5 million for the year. I think if you were to back out the $2.2 million that we have already generated would imply, what, $1.8 million to $2.3 million for Q4.

If you look at the balance sheet, we do have a deferred revenue item that you will see in the release of about $10.3 million. So the way I would kind of tell folks to think about it is in any of the next four quarters we could probably be looking at anywhere from $1.8 million to $2.8 million per quarter.

Now, be mindful: these are some significant management estimates. A lot of this is tied to the costs that are going on with the SurVeil study, the TRANSCEND study. And I think we've talked previously about a $32 million to $40 million study.

As we progress through this, we get more clarity. So there are updates to this as we go through. But this is our current thinking, and really just to kind of answer your question, we think it will be higher.

Jim Sidoti - *Sidoti & Company - Analyst*

Okay. And then next question. The fact that R&D spending was down from the March quarter, should we think that as a negative or is that just a temporary timing issue?

Tim Arens - *Surmodics, Inc. - VP, Corporate Development and Strategy and Interim VP, Finance and CFO*

It really is a timing issue. I think we had mentioned in the script there is a couple things -- actually revenue's up -- or expenses are up in an aggregate dollar amount. But as a percentage, it's really down on a sequential basis, but it's equivalent to what we saw the prior-year quarter. Remember: the revenue was much, much stronger than what we had anticipated and forecast. And so that had an impact in terms of the percent.

But one of the things that we mentioned in the prepared remarks here was that we had an impact from a change in some of the work that was to be completed by one of the CROs. Again, that just comes back to gaining greater clarity and understanding of what absolutely needs to be done, who is doing it, and how much it's going to cost.

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

Yes. And in fact, we got some discounts. That helped us a lot.

Jim Sidoti - *Sidoti & Company - Analyst*

Okay. And then last question. We hardly hear anybody talk about the diagnostic business, even though it is funding the other side of the Company. You had a new product approved in that business. You had 10% growth, which is the best growth I've seen in several quarters. Should we expect similar type performance going forward?

Tim Arens - *Surmodics, Inc. - VP, Corporate Development and Strategy and Interim VP, Finance and CFO*

I think the diagnostics business should be really proud of what they accomplished this quarter. And I would caution against thinking that the business will be delivering double-digit revenue growth. We are always very happy when they do this.

Probably the best way to think about the revenue performance going forward is mid-single-digit growth. And yes, we are really pleased with the MatrixGuard diluent launch here that just happened at AACC. That will take some time for that to really kind of work its way through the financials, but we do anticipate that will be a nice solid base hit for the business over time.

Jim Sidoti - *Sidoti & Company - Analyst*

All right, thank you.

Operator

(Operator Instructions) Mike Matson, Needham & Company.

Mike Matson - *Needham & Company - Analyst*

Morning. Thanks for taking my questions. Just wanted to go back to the revenue that you are booking from the Abbott deal. I think you said there is about around $10 million of deferred revenue.

So I guess my question is once that runs out, what happens? Is there any additional revenue from that deal as it currently stands in total products launched? Or is that going to create some kind of a drag or a hole in your revenues once that runs out?

Tim Arens - *Surmodics, Inc. - VP, Corporate Development and Strategy and Interim VP, Finance and CFO*

Well, it's a really good question. So let me see if I can help with the jigsaw puzzle pieces here. The total upfront license fee that was received from Abbott was $25 million.

And so if you take a look at the balance sheet, you will also see there's a deferred revenue, which is predominantly Abbott. We have already recognized about $2.2 million and there is about $10 million of current deferred revenue -- $10.3 million to be exact -- on the balance sheet.

Mike, another important part of this puzzle is think through what we've described in terms of our enrollment completion. So these timings don't completely align, but we expect that we will have enrollment completed by the end of fiscal 2019.

That gives you an idea that we recognize a good chunk of the revenue over the enrollment period, but there is a good chunk of the revenue that will be recognized over a longer period. That longer period really ought to be thought of as completing the clinical study, getting approval, and then the post-approval follow-up.

So as you think about Surmodics' obligations under the agreement and the expenses that are incurred over the agreement and to satisfy our obligations, we recognize revenue over that period. And it's really kind of closely tied to those expenses.

So to answer your question: once enrollment is completed, we still will have a fair amount of revenue that will be recognized until we complete the follow-up on TRANSCEND. So there shouldn't be a hole. We should anticipate everything going well, that there will be other revenues streams flowing in as well.

Mike Matson - *Needham & Company - Analyst*

Okay. All right, that makes sense. And then just a few questions on Embolitech. So can you just talk about what remains to really be done there before you can get the 510(k) -- I think it's 510(k) -- for the initial peripheral application? And how long you think that will take and how confident are you in the timing there?

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

Yes, you know, what we have is a very nicely refined concept and IP. For the peripheral bet we are after in arteries and perhaps veins, we believe we could probably get regulatory approval for that vasculature, peripheral vasculature.

It takes about -- and I'm going to channel our head of R&D, Gregg Sutton, here -- 12 to 14 months to really get comfortable and potentially get to what we feel is a post-design free. So looking forward to the first quarter of fiscal 2020.

And those are what I call greenlight -- I have used these expressions in the past, greenlight -- because its product development and you can hit all the speed bumps along the way. But if we greenlight this, really first quarter of fiscal 2020.

And the reason for that is we are changing quite a few paradigms. The first one is you need capital equipment and the thrombolytics. And typically, these patients show up in the cath lab. You didn't see the thrombus before and now you've got to schedule a surgical procedure, which is outside of the cath lab. It is not an on-the-table solution. So that's the first paradigm.

The second one is even in those cases, you have to use products that require capital equipment and can really get fresh thrombus out of there. Organized thrombus becomes a lot more difficult.

So that paradigm of not needing capital equipment and giving the doctor an on-the-table solution is not insubstantial. The product concept looks pretty good, but then the reality of forming clot models and to try doing a whole lot of preclinical evaluation.

So I would say, again, greenlight; I'm looking forward to this design being frozen in that first quarter of 2020, fiscal 2020. And then give or take a quarter, okay. So that's why we said the first half of calendar 2020.

The regulatory approvals on a device like this, we believe it's 510(k)s. And right now, our experience, at least in the US, it's taking a weighted average of like a time and a half or two turns through the 510(k) process. Given the complexity of this product, I think we want to be conservative and give it a fair amount of time.

So the second half of fiscal 2020, I would like to see regulatory clearances on this product. Of course, we are going to try to beat that, but that's the nature of a very complex device. It's all a lot of nitinol, a lot of shape memory alloy, and multiple interacting pieces.

Mike Matson - *Needham & Company - Analyst*

Okay, thanks. And then you quoted a number of about $400 million as the market -- thrombectomy market. So does that include -- I know there is different places it can be used anatomically. So is that just purely peripheral? And when I say peripheral, I just mean I would guess the legs. And then the pulmonary and the neurovascular, would those add to that $400 million or are those included in the $400 million?

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

Clearly, it's a much bigger market. And it's a much bigger market even in the peripheral application. And the reason is there's limitations in the current technology. So now you have to go treat with [lytic], so you have to keep the patient overnight.

Pulmonary embolism continues to be one of the major killers in healthcare around the world. And so that's a huge market in itself. And recall it will take us a couple years to get through all these different vascular bets. And finally, the neurovascular market is resoundingly huge. If we can give an over-the-wire solution for clots [reaching] in the brain, again, think in terms of years, not quarters. The market is all upsized from that. Yes.

Mike Matson - *Needham & Company - Analyst*

All right, thank you.

Operator

Thank you. At this time, I am showing no further questions in the queue. I would now like to turn it back over to management for closing remarks.

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

Well, thank you all for all of your questions. We are pleased with our third-quarter results and excited by the progress on our whole product solution strategy. Tim and I look forward to speaking with you on our year-end quarter earnings call. Thanks, everybody.

Operator

Thank you. Ladies and gentlemen, this concludes today's teleconference. You may now disconnect.
