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PRESENTATION

Operator

Ladies and gentlemen, good day, and welcome to the Surmodics' Second Quarter Fiscal 2018 Earnings Call. Today's conference is being recorded.

At this time, I would like to turn the conference over to Mr. 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, David. Good morning, and welcome to Surmodics' Fiscal 2018 Second Quarter Earnings Call.

Before we begin, I would like to remind you that during the course of this call, we will make forward-looking statements. These forward-looking statements are covered under the provisions of the safe harbor act and the Private Securities Litigation Reform Act of 1995, and includes statements regarding Surmodics' future financial and operating results or other statements that are not historical facts. Please be advised that actual results could differ materially from those stated or implied by our forward-looking statements resulting from certain risks and uncertainties, including those described in our SEC filings. Surmodics disclaims any duty to update or revise our forward-looking statements as a result of new information, future events, developments or otherwise.

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

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

Thank you, Andy. Good morning, and thank you for joining us. During the second quarter, we made excellent progress on our strategic objectives. And our results reflects solid top line growth and operational performance, even as we continue to invest in our new product pipeline. We're proud of the accomplishments of the Surmodics team. Our strong performance is a result of their considerable talents and hard work.

In the second quarter, we generated revenue of $19.1 million and diluted GAAP earnings of $0.11 per share. And we are updating our expectations for fiscal 2018 revenue to be in the range of $75 million to $79 million, up from the previous range of $72 million to $75 million.

Based on our strong financial performance and the signing of the Abbott transaction, we have also improved our expected diluted loss in the range of negative $0.20 to negative $0.35 per share as compared with the prior guidance of $0.45 to $0.70 per share loss.

Non-GAAP diluted loss guidance range is now negative $0.06 to negative $0.09 per share, as compared with prior guidance of a loss of $0.20 to $0.05 per share.

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 second quarter financial results and updates to our fiscal 2018 guidance. We'll then open the call to take your questions.

As you may recall, in late February we announced an agreement with Abbott for the exclusive worldwide commercialization rights of 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 approvals in the United States and Europe. Separately, Abbott also received options to negotiate agreements for below-the-knee on AV fistula drug-coated balloon products, which are currently in preclinical development.

As part of this collaboration, Surmodics received an initial payment of $25 million and may receive an initial $67 million upon the successful completion of certain pre-commercialization clinical and regulatory milestones that lead to U.S. and European approvals, more important, at a potential for post commercialization cash flows from the long-term strategic relationship with Abbott.

In particular, Surmodics will realize revenue based on initial product sales to Abbott as well as a share of profits resulting from Abbott's sales to third parties. We will continue to prioritize and support the ongoing development of SurVeil drug-coated balloon, with a view towards meeting the requirements of the partnership with Abbott and the transaction.

As a reminder, SurVeil is built on the next-generation technology, which includes a proprietary drug excipient formulation for quite durable drug-coated balloon that is manufactured using a unique process to improve the coating uniformity. Pre-clinical data have shown a 3 to 5x 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 generation drug-coated balloons. The design of the SurVeil drug-coated balloon reflects our industry leadership and the development of surface technology for vascular medical devices.

We are excited with the Abbott partnership given their deep expertise in vascular care products and their worldwide sales and marketing strength. During the past 2 months, we have begun to collaborate with Abbott team on the ongoing development for SurVeil. And the partnership is going exceptionally well.

Now I'll turn to the 3 strategic objectives that we outlined at the beginning of the year. As a reminder, these are to: execute the TRANSCEND trial in a rigorous, high-quality and efficient manner; two, to advance our R&D whole-product solutions pipeline by securing regulatory clearances for these 4 new products in fiscal 2018, and file for the first human use of our below-the-knee or AV fistula drug-coated balloons; and third, to finalize and further delineate our commercialization strategy with potential distribution partners for our proprietary products.

Starting with the TRANSCEND trial, our pivotal trial for SurVeil, it progressed nicely through the quarter. We expect to have all U.S. clinical sites up and running by the end of fiscal 2018. We're actively getting sites up and running currently, and patient enrollment is progressing as a result.

As a reminder, TRANSCEND is expected to enroll approximately 446 patients at up to 60 clinical sites in United States and 18 sites in Europe. The 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 drug-coated balloon. This trial is amongst the first Level I studies to compare next-generation DCB with one that is commercially available.

In Europe, we have started a process of formal submissions to the regulatory agencies for our CE Mark. However, our assumptions on timing will depend on the feedback we obtain from these initial filings, especially taking into account the new and evolving regulations in the European Union. We look forward to further progress in both the U.S. and Europe as we move throughout the year.

We continue to advance our other drug-coated balloon programs as well, with a goal of commencing an early feasibility study of at least one of these programs in fiscal 2019. We are making progress with our sirolimus-based below-the-knee DCB platform and we're continuing to work through the preclinical studies, the data package, the data analysis and other things that will be used to determine our readiness for first-in-human clinical trial.

We remain on track for this program and expect to make continued progress through the remainder of fiscal 2018. We've also made progress developing our AV fistula drug-coated balloon. As discussed previously, we have the technology, we believe, 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're moving forward developing these preclinical data sets and will determine their feasibility to further accelerate this program later in the fiscal year.

Now turning our focus to our nondrug delivery R&D pipeline. As you may recall, our Telemark support microcatheter received FDA clearance in the second quarter of fiscal 2018. Early clinician feedback from using actual interventional procedures is quite positive. The Telemark support microcatheter offers excellent 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 unmatched exceptional deliverability, kink resistant and lesion crossing. The Surmodics Pristyne hydrophilic coating offers best-in-class lubricity with low particulates, and the Telemark microcatheter's tapered profile has a diameter ranging from 2.6 to 1.4 French for quite effective penetration of tough, calcified lesions.

It has performed extremely well to date, but we will continue to develop our clinical experience to assess its performance and continue to gain valuable clinician feedback in the coming months.

As you recall in late 2017, we received both FDA clearance and CE Mark for .014" balloon catheter, which also incorporates our Serene hydrophilic coating for use in below-the-knee angioplasty. Our .014" PTA balloon catheter is undergoing clinical evaluation both by Surmodics and interested strategic parties.

During the quarter we began collecting clinical user experience for the device, and from these initial evaluations, clinicians have been quite impressed with the balloon catheter, and the comments have been quite encouraging.

We're pleased with this initial feedback and are continuing to target revenue to be generated from this product in the late part of fiscal 2018.

We continue to make measurable headway with products in development using advanced versions of our coating chemistry. We recently announced and received FDA 510(k) clearance for our .018" peripheral balloon catheter, which again incorporates our Serene hydrophilic coating. Both the .014" and .018" PTA balloon catheters offer superior deliverability and lesion crossing by leveraging our advanced hydrophilic coatings for unmatched low friction and particulates.

These balloon catheters, combined with our advanced processes, ensure ultra-low-tip entry and crossing profiles, with smooth and exceptional transition to improve performance. Again, these new products demonstrate our focus on next-generation devices to address the growing need for minimally invasive treatment of peripheral artery disease. And we're confident that our highly deliverable low profile PTA balloon catheters will give clinicians an effective tool for accessing or crossing the most complex peripheral lesions.

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 and 2019. We'll discuss these R&D programs in future calls as we get closer to their regulatory filings.

It's an exciting time here at Surmodics. 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 to them highly innovative product solutions for vascular disease. We're encouraged by our clinical, regulatory and development achievements, coupled with our ongoing top line performance and operational progress.

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 quite attainable.

I'll now turn the call over to Andy to give more details on our second quarter fiscal 2018 results as well as our outlook for the remainder of fiscal 2018. Andy?

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

Thank you, Gary. We're pleased to report that revenue for the second quarter of fiscal 2018 was $19.1 million, as compared with $17.5 million in the second quarter of last year. We delivered an operating income of $0.5 million in the second quarter of fiscal 2018, as compared with operating income of $1.7 million in the comparable prior year quarter.

On a GAAP basis, our diluted income totaled $0.11 per share in the current quarter, as compared with $0.04 per share in the second quarter of fiscal 2018. On a non-GAAP basis, quarterly earnings per share were $0.07 per share in the second quarter of fiscal 2018 versus $0.05 in the prior year quarter. The increase in earnings in the current year quarter reflects increased revenue, continued consideration gains and a favorable income tax benefit, partially offset by previously announced increased investments in research and development expenses to support the company's whole-product solutions strategy, including the SurVeil, DCB and other proprietary products as well as increased selling, general and administrative expenses.

Turning now to our 2 business units. Medical Device reported revenue of $14.1 million, an increase of $1.3 million as compared with the year ago period. Looking at the specific areas within Medical Device, second quarter royalty and license fee revenue totaled $8.4 million, increasing $1.1 million from the comparable prior year quarter. The increase in royalty and license fee revenue reflects strength in our hydrophilic coatings royalties as well as $0.5 million of license fee income recognized from our recently announced Abbott relationship.

Product sales increased $0.5 million from the comparable prior year quarter due to increased Medical Device sales. Medical Device customer research and development revenue increased $0.3 million in the current quarter -- excuse me, decreased $0.3 million in the current quarter as compared with the second quarter of fiscal 2017. This unit generated $0.2 million of operating income in the second quarter versus operating income of $1.5 million in the prior year quarter. Reduction in the Medical Device operating income change was impacted by our whole-product solutions strategy R&D investments, a $1 million customer claim accrual and $0.5 million of Abbott-related transaction costs, which were partially offset by benefits from increased revenue and a $2.2 million contingent consideration gain.

For our In Vitro Diagnostics segment, second quarter fiscal 2018 revenue, which consists of product sales, totaled $5 million as compared with $4.8 million in the comparable prior period, an increase of 4.8%. IVD revenue in the second -- in the current year second quarter reflects strong growth in BioFX substrates and microarray slides. IVD operating income was $2.4 million in the current quarter as compared with $2.2 million in the second quarter of fiscal 2017.

Operating margin as a percentage of revenue in second quarter of 2018 increased to 48.4% versus 46.8% in the comparable prior year quarter due to improved gross margins from a combination of higher volumes, reduced scrap rates and a more favorable product mix.

Product gross margins for the quarter were 66.5% of product sales as compared with 67.7% in the prior year quarter. The current year period gross margins benefited from the aforementioned favorable IVD results, which were more than offset by lower Medical Device products' gross margins associated with our Irish facility infrastructure and scale-up costs in anticipation of future growth.

As a percent of revenue, second quarter fiscal 2018 R&D expenses were 56.5% versus 46.9% in the comparable year ago period. R&D expense of $10.8 million for the current quarter was up $2.6 million from the second quarter of fiscal 2017. As we have stated before, we anticipate R&D expense would increase in fiscal 2018 as we accelerate our whole-product solutions strategy investments, including advancing our SurVeil drug-coated balloon human clinical trials. Further, as Gary noted, we will continue to prioritize and support the ongoing development of the SurVeil DCB to meet the requirements of the Abbott transaction.

We continue to forecast R&D expenses in the range of 55% to 60% of our fiscal 2018 revenue.

SG&A expenses in the second quarter of fiscal 2018 were 33.8% of revenue versus 29% in the prior year period. On a dollar basis, SG&A expenses in the second quarter of fiscal 2018 totaled $6.4 million as compared with $5.1 million a year ago. The increase in SG&A expenses reflects the accrual of $1 million in connection with a customer claim of overpaid royalties due to their inaccurate royalty reporting.

Additionally, SG&A expenses in the second quarter include $0.5 million of costs associated with the Abbott transaction, and stock-based compensation expenses for the current quarter increased $0.2 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 $0.3 million of foreign exchange loss on our euro-denominated contingent consideration obligation related to the Creagh Medical acquisition. We also recorded a $2.2 million gain as we marked our contingent consideration obligations to fair value based on the expected achievement and milestones.

We recorded an income tax benefit of $1.2 million in the second quarter of fiscal 2018 as compared with income tax provision of $1.1 million in the prior year quarter. Both periods reflect the impact of nontax-benefited amortization, accretion, contingent consideration gains, 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 the moving pieces from tax reform and the impacts from the nontax-benefited items. Therefore, we are providing income tax expense guidance for fiscal 2018 in the dollar range of $0.5 million to $1 million.

Looking at our balance sheet, which continues to be strong, cash and investments totaled $70.3 million at quarter end. We generated cash from operating activities of $27.4 million in the first 6 months of fiscal 2018. Our cash and investment balances and operating cash flows were positively impacted by the $25 million Abbott license payment.

We invested $4 million in plants and equipment during the first 6 months of fiscal 2018. We expect to invest approximately $10 million in plants and equipment in fiscal 2018. Our current cash and investment balances and operating cash flows provide adequate capacity to support our corporate strategic growth initiatives.

As a result of revenue performance in the first 6 months of fiscal 2018 and to reflect the impact of the Abbott transaction, we have increased our fiscal 2018 revenue and earnings performance guidance. We expect fiscal 2018 revenue to range from $75 million to $79 million, up from the previous expectations in the range of $72 million to $75 million. We expect diluted loss to range between $0.20 to $0.35 per share as compared with the prior guidance of $0.45 to $0.70 per share. Non-GAAP diluted loss earnings per share guidance is now in the range of a loss of $0.06 per share to earnings of $0.09 per share, as compared with the prior guidance of a loss of $0.20 per share to earnings of $0.05 per share.

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

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

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Mike Matson with Needham & Company.

Michael Stephen Matson - *Needham & Company, LLC, Research Division - Senior Analyst*

I guess, I just wanted to start with the Abbott deal. I was wondering if you could give us any additional insight into the financial aspects of the deal. You mentioned you're going to get paid for initial supply of the balloon and then there's some profit sharing. But can you just walk us through this, because this is pretty critical to the growth outlook for the company.

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

Mike, thank you for the question. There's a number of different revenue streams that are being generated from the Abbott transaction. Obviously, the first one that we started recognizing revenue this quarter is the $25 million upfront payment, which will be recognized as we incur costs to complete our first deliverable in the contract. And you'll note from the balance sheet, we have about $12 million in current deferred income that has been classed as current and about $12 million net is long-term. So if you look at that over the next 12 months, we anticipate our current estimates would suggest $12 million of income between now and the second quarter fiscal 2019. Related to other milestones, now we're working through the accounting for those. As you might recall, that the accounting changes as of October 1, 2018, so beginning of fiscal 2019 for us, and we're working through with our auditors how the additional $67 million of revenue will be recorded. But we do not anticipate recording any revenue for that in the 2018 period. What we can tell you is that we have staffed up our team to make sure that we are focused on meeting those milestones over the next several years and that is a period of time which we expect to achieve the $67 million of milestone -- earning those milestones.

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

Yes. And I just want to emphasize something Andy said that, given -- for our shareholders, the milestone-based revenues of the further $67 million, within Surmodics, we've gone through and really scrubbed our capital allocation to ensure that we are actually allocating the right resources and the right investment towards that, because that -- clearly, from a shareholder point of view, we want to go get those milestones. While we haven't disclosed the actual detailed nature, you can imagine they deal with clinical progress, the clinical performance and European and U.S. regulatory approval. So as you look at those, those are the buckets on which those things will be paid upon and over a period of time, leading up to the PMA approval in the U.S. So that -- I hope that helps sort of bracket it a little more.

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

And then -- and to -- and then, to answer the other 2 components of the earning stream that we'll have is that we have not disclosed either the transfer price that we will receive based upon manufacturing the balloons, and those balloons will be manufactured, the coated balloons will be manufactured both in the U.S. and in Ireland as well as the profit sharing split. But what I can tell you is that we truly believe that this is a partnership and that we're not a cost-plus manufacturer to our partner Abbott. And they recognize the value that we are providing to them. And that we expect it to start earning some revenues later -- in the latter part of fiscal 2019 from Europe. Again, that's depending upon what Gary noted in his prepared remarks on the feedback we receive from the authorities there regarding the regulatory path. And then, we still are looking at a 2021 launch in the U.S.

Michael Stephen Matson - *Needham & Company, LLC, Research Division - Senior Analyst*

Okay. That is very helpful. And I guess, just to be clear, once the balloon is launched, you will get -- you will be reselling that to Abbott at some sort of transfer price, so you get revenue from that and then you also get some profit sharing. Will the profit sharing, from an accounting standpoint, be recorded as revenue as well or?

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

That is correct. So we will be recording product sales and then we'll -- and then the profit sharing will also be recorded -- most likely will be recorded, I think, in the royalty and license fee line part of our revenue line.

Michael Stephen Matson - *Needham & Company, LLC, Research Division - Senior Analyst*

Okay. All right. And then, you made some comments on Telemark, it sounds like it's being well-received. But you also mentioned that you're going to continue to do some more clinical -- I won't say clinical trials, but I guess, using it in procedures to get feedback for the next -- for another few

months. So I mean, is that kind of consistent with your plan, or does that mean that you've delayed it a little bit in terms of when you'd sign some kind of agreement?

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

No, it's consistent. When I look at -- I think, one of the devices, the ASAHI Caravel, and I'm trying to check my memory here, I believe they got clearance in January of '16 maybe, but they didn't actually -- and it's their product with their sales force, but they didn't actually launch it until midsummer or June. And so that is not atypical, and in fact, our -- meaning, getting clinical feedback, getting manufacturing readiness. When you get clearances of these products, it's also not that you can typically turn the switch and make 5,000 of them as well. So we're making sure that our automated breathing machines and all those things can actually deal with it. But in the interim, we believe the clinical feedback helps our shareholders get a better deal with the strategic because then we have data. The spec sheet that I read out part of in the call here, while interesting and then we were excited about it, is actually in the hands of clinicians and very tough lesions and in the hands of certain key opinion leaders. If they believe this tool is actually helping them, that helps the strategic who may be over-shouldering with us in the cath lab to then make the case. And then, we believe it will lead to a better deal. So we're being very patient in -- to exaggerate to make the point, instead of signing a deal early, let's sign the right deal later with the data that we need to demonstrate the value to product.

Michael Stephen Matson - *Needham & Company, LLC, Research Division - Senior Analyst*

Okay. All right. That makes sense. And then, just with regard to the potential distribution agreements for Telemark and some of the 510(k) products, I mean, is -- are those going to follow kind of a similar template to this SurVeil deal with Abbott or -- I mean, SurVeil is that just kind of a unique situation given the potential market opportunity and so forth. In other words, do we -- should we expect any kind of cash payments with any of these products, or is it mainly just going to be you supply the product and then you can get -- they purchase it at some kind of transfer price from you guys?

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

Well, I wouldn't comment on the forms of the deal just because we made -- in terms of negotiating with our strategic partners. But keep in mind, SurVeil is a PMA product, so it's a very high investment, in the tens of millions. And so the nature of these deals will be different in magnitude and probably in form as well. But clearly, these are not trivial products we're developing, but in the 510(k) spectrum of regulatory clearances, the investment required is an order of magnitude less than SurVeil.

Michael Stephen Matson - *Needham & Company, LLC, Research Division - Senior Analyst*

Okay. Great...

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

Go ahead. Sorry, go ahead.

Michael Stephen Matson - *Needham & Company, LLC, Research Division - Senior Analyst*

No, I was just going to say that, that's my last question. But if you want to continue to answer, it's fine.

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

Well, clearly, we do want a partnership with strategics. The products are ours, they're our regulatory filings and applications. And so that part of the deal will not change. These are Surmodics' products that we are helping our strategic partners by putting it in their bags. And so that part will be consistent.

Operator

Our next question comes from Jim Sidoti with Sidoti & Company.

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

Andy, can you just clear up what you said about recognizing the revenue from Abbott? I believe you said you recognized $0.5 million in the quarter that ended in March. Is that correct?

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

That is correct, Jim, and we'll be recognizing that revenue over the clinical trial period and all the costs associated with the clinical trial, including those post clearance. We still have a couple year tail behind that. But the majority of that revenue will be over the period, which is between now and 2021.

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

Okay. So for the 1 month you had the deal in place, you recognized $0.5 million. So should we assume $1.5 million per quarter? Because then you also said that you have $12 million in deferred revenue, in near-term deferred revenue, which would work out to more like $3 million a quarter.

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

Yes, I think with the guidance we have for fiscal 2018, Jim, we're looking at $3 million to $4 million of revenue associated with Abbott, and then the remainder would be fiscal 2019. Again...

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

So that's $3 million to $4 million per quarter?

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

No, $3 million to $4 million in total for fiscal 2018.

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

Okay. $3 million to $4 million for fiscal 2018. And that's for the remaining portion of fiscal '18?

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

That is correct. And I will tell you that, that is dependent upon the clinical costs associated with the European trial because that will not be fully known until we hear back from our regulators there. So that estimate may change but our current estimate is in that $3 million to $4 million range.

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

Okay. And then we should assume for fiscal '19 it would be double that because you'd have the full year worth of it -- worth of the revenue?

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

Well we anticipate that given our balance sheet classification is current through March 31 is that we couldn't have -- we could have up to $8 million of revenue in the first half of fiscal '19 given the fact that we'd have $3 million to $4 million this year, and then we have the remaining component of that $12 million in the first half of '19. And obviously, there'll be more revenue recognized in the latter half of '19 associated with the arrangement, but we're not providing further guidance on that at this point.

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

Okay. All right. And then in the quarter, even without that $0.5 million of revenue that you recognize from Abbott, your royalty number was up from a year ago. Should we assume that the bulk of the royalty rate declines have now been anniversaried and that's no longer a headwind?

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

Yes, as we've talked about actually back in December is that we expected about $2.5 million to $3.5 million royalty headwind and about 2/3 of that would be in the first half of the year. And what we're looking at now is more of a $2.5 million to $3 million royalty headwind. So I think we're in a position where it's getting less and less material to the financial statements and to the royalty line. I would also tell you that we've seen strong performance in -- we've seen from many of our customers, in terms of their performance where there's been, I think, some uptick related to the FX rate out there for us. So there's been a number of factors that have driven hydrophilic coatings to better performance. So we, again, expect what -- expect the headwind to be $2.5 million to $3 million, but as you start to look at the revenue for this year, we would expect there to be diminished headwinds in the second half of the year.

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

Okay. And then in the quarter, the contingent consideration income you recognized, is that because one of your acquisitions failed to hit a milestone?

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

Well we evaluate the contingent consideration milestones every quarter. So you've seen in the past we've had mostly gains associated with that. So it's our -- there's a number of different milestones that are operationally focused and those that are also revenue focused. So as we calibrate the future revenues associated with the transactions as well the milestones that need to be achieved, those probabilities can change. As we looked at those milestones, we believe that they're changed, and that's one of the reasons why we had contingent consideration embedded in the transaction. So what I would tell you is that both these acquisitions are really focused on our whole-product solutions strategy and executing that strategy and that the milestones were a combination of revenues being generated from new products as well as historical legacy businesses that we had and that we feel very good about those 2 acquisitions and what they're doing to contribute in the integration of those businesses together.

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

Okay. So we shouldn't assume anything negative about those acquisitions just because you recognized this revenue?

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

That is correct. And if you think about for the full year, we would anticipate that we would have approximately $900 million worth of gain. We will have accretion expense in the second half of the year. But in terms of modeling for the total fiscal year, it should be somewhere right around a gain of $1 million.

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

Okay. And then the last, the tax benefit in the quarter, is that related to the contingent consideration income? Or was that related to tax reform? Or just can you tell us where that came from?

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

Yes, Jim, there are so many moving pieces on that, and what it really has to do with is the projection of income and where we're at. We're -- as we've called at the beginning of the year, we were really close to an EBITDA-neutral position and you start thinking about whether we're going to have profits and carrybacks. And so it's, again, very complex, and that's why we just gave a number of the -- for the entire year of $0.5 million and $1 million because you're going to see things kind of go back and forth in the quarter. So I would just focus on the total numbers because there's, again, a lot of moving pieces there.

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

Okay. And then last thing, I believe the cash balance now is around $70 million. Is that correct?

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

That is correct.

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

Any plans to buy back shares?

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

If we think about capital allocation, our first and primary focus is to invest in our whole-product solutions strategy and to make sure that we're giving it the proper attention. And as Gary mentioned a few minutes ago, first and foremost is making sure that we've got adequate attention to meet the obligations under the Abbott transaction. We've also talked about completing our plant and equipment. That's why we had $10 million of CapEx this year, and that includes our facility. We're moving our former Plymouth facility. The lease runs out. We're moving that to a new facility where we'll encompass all of our whole-product solutions, cath and development technology and eventually all the drug delivery will be. And so that will be a separate facility from the hydrophilic coatings and IVD facility. So that is really, I would say, our second component of capital allocation. Our third component then, Jim, would be focused on any incremental products or R&D -- excuse me, business development opportunities out there. We continue to focus on looking for new products that we -- that either can be put into the facility in Ireland or new products that we can continue to develop. So business development will be our third. And I would say our fourth and last would be share repurchases, which I do not

have on the radar at this point in time. So if you think about our average shares for the year, we're looking at something like 13.4 million to 13.6 million, which does not contemplate repurchases of shares.

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

All right. That's a lot of cash. You better keep your eye on Gary.

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

We keep an eye on each other.

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

Yes.

Operator

Our next question comes from Brooks O'Neil with Lake Street Capital Markets.

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

I was hoping you might just elaborate a little bit on the level of involvement you're seeing from Abbott in product development and testing. Is it in your view a significant involvement from them? Or are they just kind of monitoring what you guys are doing?

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

I'll tell you, it is -- it hits the mark for me in terms of the appropriate level of involvement. I am on the -- one of the operating committees dealing with things like clinical and regulatory issues, and I've been impressed -- the Abbott very high-level team has been here post the deal, and I've been impressed with, first of all, their knowledge. They run many, many more clinicals than we hope to. And so it's really been very collaborative in their sharing of the knowledge and giving us suggestions and helping guide us through some fairly complex pathways. So my short answer, and I'm actually not gushing about it, it's been what I hoped for: a very collaborative environment.

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

Sounds good. Could you, Gary, also talk just a little bit about any reaction you've seen from many of your other existing customers related to the deal with Abbott, their involvement, what's going on out there with the big products, the small products, et cetera?

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

Yes, it's -- I think our business development team will probably have seen more of that. I have not heard much of it. All our customers, we serve them so well in our legacy businesses that my hope is that, that dilutes any reaction towards what we're doing. This was -- we didn't -- anyone had the opportunity to come to -- for SurVeil and negotiate the deal. So it wasn't like we kept people out of it. And so I haven't felt any blowback, and I don't think -- Andy, I'll turn it over to you.

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

Yes, Brooks, what I would tell you is that the cadence of, for example, new licensing in hydrophilic coatings business continues to be on a normal cadence. And so there's no external signals that would cause us any concern. And I think clearly, one of things we're doing is -- we talked about the physical separation of that business away from the hydrophilic coatings. We strongly believe that we have appropriate controls in place to make sure there's not any cross-contamination between the 2. So I think we've reassured our customers that there's no significant issues out there.

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

Yes, and if anything, Abbott has a reputation for having really high standards on products that they look at and acquire. So if anything, it's credentialized Surmodics' technology content to our further strategic partners. So even as we look at things like our Telemark and .014" and .018" balloon, I think if anything, other strategic partners, it's sort of, ah, like where did Surmodics come out of the weeds to have these premium offerings all of a sudden. And I think it's actually alerted more of our customers to take a deeper, longer look at the technologies that we're offering. So I think it's been positive, if anything.

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

That's great. Would you comment at all about their real interest in the BTK and the AV fistula products? They seem pretty genuinely interested in those as well.

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

Yes, and I think as -- and I can't speak for how they build out their portfolio. But you can imagine, if you're a big strategic and you have a peripheral portfolio, the landscape of the superficial femoral artery is a good place to start. Below-the-knee is still a remarkably unsolved problem from a interventional vascular medicine program, and we all know the issues with AV fistulas and the cost and the inconvenience for these patients. So that's not surprising. From their viewpoint, they would love to see clinical data. And I think their interest is if they see the early clinical data and at the time they see that data, their portfolio interest is still in these products, they would like the opportunity to negotiate first. So clearly, those 2 products are very interesting to many strategics. But we gave Abbott first in line on that, and we thought that was appropriate given the partnership we had with SurVeil.

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

Sure. That makes total sense. Last thing I'm curious about, obviously, I don't expect you to identify the strategics interested in the smaller products, the 510(k) products. But could you just comment about whether you're seeing, in your mind, the level of interest you expected? And I'm guessing we're talking people beyond Abbott as you think about finding distribution partners for those products. Is that true?

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

Yes, so these companies would be, not excluding Abbott, but certainly beyond Abbott as well. And this -- who are interested, these products, the .014" and .018", I consider them, and I may be biased, the world's best .014" and .018" balloons. And I think the Telemark microcatheter clearly is a cut above. It's almost a new category in what we can do with the Pristyne coating on it and the Xtreme technology. But these products also fill gaps. The balloons especially, fill gaps in different strategics' portfolio. So it's not only a question of the product performance, but what's the gap in that. So if you're a strategic and you have a reasonably good .018" balloon, even though ours might be incrementally better in the hands of a clinician, the need may not be as much. But if you're a strategic that either doesn't have an .018" balloon or your .018" balloon sucks, you might want to -- you might want to look at ours longer and harder. So it's more than just a product, and that's -- if .018" balloon doesn't perform as well, let's put it that way. You may want to look at -- take a longer -- long, hard look at that. So product performance is important, but the strategic fit given the gaps strategic has is actually quite important in who's coming to the table.

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

That all makes sense to me. I will just say I think you guys are doing a great job of spending the money. I hope you will continue to spend the money, and I'm looking forward to the future.

Operator

Our next question comes from Mike Petusky with Barrington Research.

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

So I guess on -- just going back to the below-the-knee and AV fistula. You guys have indicated in the past, hey, the data is going to determine how we kind of move those ahead in terms of the time line and how we invest in those initiatives. I guess, does Abbott's view on the potential success upside of each of those efforts, does that matter? Are you taking any -- are they giving you any feedback? Are you taking any of that into account in terms of how you might move forward?

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

I'll say right now, speaking for the partnership -- I can't speak in any great detail on their view, but from the partnership viewpoint, all eyes are on SurVeil and things like the CE Mark and the TRANSCEND enrollment. That's really the prime focus now for the partnership. I think as we move through those early stages, clearly, we'll be working with them in terms of what type of clinical data will be important for them to maximize their interest. So what I wouldn't want Surmodics to do is independently go run a first-in-human trial and the safety and secondary endpoints don't match up with what they wanted to see. So I think in the preclinical data set, that's ours to really run through. We'll clearly share that with them. But in terms of the regulatory and first-in-human strategy, that -- the partnership will really work together on that because at the end of the day, we want to be able to demonstrate data that's compelling to them and potentially other strategic partners if Abbott has a portfolio decision that they're not interested later.

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

Yes, that's really helpful. And then just jumping over to the 510(k) products, and this question of partnership. I think you sort of put some level of time line around generally when partnerships may be struck. And I think -- don't -- if I'm wrong on this then feel free to correct me, but I think that you previously said maybe 6 to 12 months after regulatory clearance would be a reasonable time frame for partnerships to be struck. I mean, is that still your view?

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

Yes, so that's our view, and our R&D and marketing team wouldn't probably appreciate me saying that. But you want to get, to me, a minimum of 100 clinical uses of the product for feedback. I would say more is better. But after about 100 uses, you've got what I call a stable database of you're hearing the good, the bad and if there's any ugly, right? And so for us, it's important if there's any ugly, we address those issues and we either improve the product design. But so far, no ugly, by the way, just to be clear. But clearly, we want to be able to demonstrate to the strategics. And keep in mind, some of the strategics are doing -- will be doing their own independent analysis where we're not in the cath lab with the doctors that they know who will be using it. So I want to be painfully patient with it. And I don't want to say one's covering for the other, but what I hope is, given the nature of the Abbott deal, and the patients or investors kind of went with us all these years to be able to get to that point, in a similar vein, sort of the patients to say, look, we want to develop good deals for our customers and it might be excruciatingly patient to wait 3 to 4 quarters for a deal on a 510(k) product, but we believe it will be worth it in the long run. And so that's -- it's the same genre of thinking.

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

Okay. All right. Great. So I -- and I may have missed this because I got momentarily distracted from the call, I heard you guys say that you'd have the U. S. clinical sites up and running by the end of fiscal '18, but I did not hear if you mentioned how many are up running now or a patient number in terms of enrollment. Did you guys give any of that, or could you?

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

No, we -- we typically, and it's not typical even in the industry, to give enrollment data. I will tell you, we probably have -- hoping the clinical team will be mad at me on saying this, but half the sites are up and running. So we're on track to get the rest up and running. I think that what's -- by the time we said at the end of the fiscal year, we've also selected the majority of the European sites. I was in Charing Cross in London last week with our clinical team, and the -- I would tell you, the investigators there are quite excited to get going. And so those sites -- in Europe, to get sites up and running, you also have to deal with in-country-specific regulatory approvals. And so those may take a little bit longer. I hope by the end of the fiscal year. In Germany it takes a lot longer to get sites up and running. But the German sites usually have very nice enrollment, so they're worth the wait. So -- but the U.S. sites, clearly, we're on track. I think what struck me is every site, there's a contracting, the budgeting and we've actually staffed up internally, as an example, hiring contract attorneys because it's not trivial. The business side of getting the site up and running is what struck me of how untrivial that is. So we're pleased with our progress by the end of the fiscal year. If we hit that, I will be happy.

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

Okay. Great. And just last one. I think probably a number of investors and analysts are interested in some of the details. And I understand you've given, hey, this is more -- in terms of the Abbott deal, hey, this is a partnership, not cost-plus, and you've given some helpful detail around this. But is there a point at which you say, okay, we're going to open up the kimono. We're going to give you everything in terms of so you can really model this as opposed to sort of guess at it. I mean, is there a time frame or kind of regulatory clearances or milestones where you say, okay, we're going to give these guys sort of what they want in terms of detail around this agreement?

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

Right. Two things. I would say Andy is still explaining to me also some of the new revenue recognition standards that we'll be under starting October 1. And so that's one issue of how we recognize the revenue. What I can say is if you think of the pathway to the U.S. approval up to 2021, okay, and then think of that $67 million as being captured by that bucket, we can't speak about whether you straight-line that because these can be lumpy or different according to the revenue recognition standards at that point. But if you think about enrollment of SurVeil, it's critical, right, if you think about achieving a CE Mark, if you think about getting the U.S. approval. So on a broad basis, you can contemplate what those milestones might be, not the amounts, but that $67 million will incorporate all of those type of activities. The recognition of that is a little more complicated than I should be speaking of in terms of how we look at that.

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

And let me put a little color around that, Mike, is that right now as we go through the analysis and we also talked to our external advisers, the big 4 accounting firms all have different perspectives on the concept of when do you get to a point with milestones that revenue cannot be reversed and that -- and you have to meet that threshold in order to start recognizing revenue. And while generally these milestones, as Gary has talked about in the past, are related to development milestones that could be things like enrollment and achievement of approvals and the like, is that, that nebulous concept of reversal of revenue is one that I actually think the big 4 is talking here in the next month or 2 to get some concurrence in terms of the judgments around that. So -- and I'm not trying to be opaque here, but we just don't know. But what I can tell you is that the majority of that $92 million, including the $25 million upfront we've received, will be recognized during the period through FDA approval and that we do anticipate that we will get to those milestones based upon the actions we've taken this quarter to allocate capital to make sure that we've got all the swim lanes that we need filled for those physicians. So it is, in our viewpoint, an opportunity to earn revenue and just not milestones, but it's

an important part of our shareholder value in the near term as we then get to the back end, which we're very excited about, which is going to be both the product sales and the profit splits.

Operator

At this time, we have no further questions. So I'd like to turn it back to management for closing comments.

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

Well thank you for all of your questions. We enjoyed answering them. We're pleased with our second quarter results and progress on our whole-product solutions strategy, and we look forward to speaking with you on our third quarter earnings call. Thanks, everyone.

Operator

Ladies and gentlemen, that concludes this morning's presentation. You may disconnect your phone lines, and thank you for joining us this morning.
