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PRESENTATION

Operator

Ladies and gentlemen, thank you for standing by. Welcome to REVA Medical's Third Quarter 2018 Financial Results Call. (Operator Instructions) As a reminder, this conference call is being recorded.

And now, I would like to turn the call over to the company's Chief Executive Officer, Reggie Groves.

Regina E. Groves *REVA Medical, Inc. - CEO & Director*

Thank you, Jimmy. Before we get started, Cheryl Liberatore will read the safe harbor statement.

Cheryl Liberatore *REVA Medical, Inc. - Director of Human Resources*

This quarter's call may include forward-looking statements that involve risks, uncertainties, and assumptions. All statements that are not statements of historical fact, including those that address future operating performance and events or developments that we expect or anticipate will occur in the future, are forward-looking statements, such as statements regarding the projections and timing surrounding our plans to commence commercial operations and sell products; conduct clinical trials; develop pipeline products; incur losses from operations; list our securities for sales on a U.S. stock exchange; and assess and obtain future financing for operating and capital requirements.

We caution listeners that forward-looking statements are not guarantees of future performance, and actual results and the timing of events could differ materially from those anticipated by forward-looking statements as a result of many factors, including those discussed under risk factors in our Form 10-K for the year ended December 31, 2017, filed with the United States Securities and Exchange Commission on March 7, 2018.

Listeners are cautioned that many of the assumptions on which our forward-looking statements are based are likely to change after our statements are made. Further, we may make changes to our business plans that could affect our results. Any forward-looking statements in this conference call speak only as of today. REVA does not assume any obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

I would now like to turn the call over to Reggie.

Regina E. Groves *REVA Medical, Inc. - CEO & Director*

Thank you, Cheryl. Hello, everyone, and thank you for joining us today to discuss REVA's recently announced financial results for the third quarter of 2018 and an update on our business. With me today are Brandi Roberts, our Chief Financial Officer; and Jeff Anderson, our SVP of Clinical and Regulatory Affairs. Following the update, we will open the phone for your questions.

Our top 3 priorities remain: one, ensuring Fantom's commercial success; two, expanding our business; and three, managing our cash position. I would like to begin by discussing the priority that is on everyone's mind, managing our cash position.

I want to assure our investors that we are actively managing our cash. We are reducing our expenditures where appropriate, including reducing headcount to ensure we are sized for the expected slower growth of our coronary business but resourced appropriately to bring forward our nearer-term opportunities in our peripheral and embolics platforms. In terms of meeting our cash needs, we are pursuing

fundraising activities with strategic and financial investors that are focused on our coronary, peripheral and embolics products.

Before I address our other 2 business priorities, I will turn the financial discussion over to Brandi.

Brandi L. Roberts ***REVA Medical, Inc. - CFO & Company Secretary***

Thank you, Reggie. A quick reminder before I get started, our financial statements are prepared in accordance with U.S. generally accepted accounting principles and are presented in U.S. dollars. Our third quarter 2018 financial results press release was issued earlier today in both the United States and Australia. Our detailed results on Form 10-Q will be reported with both the SEC and ASX shortly.

We ended September 2018 with approximately $7.1 million in cash. As Reggie mentioned, cash management is a priority for us, and I will discuss this in more detail in just a bit.

In the third quarter, total billing for shipped product were $185,000. We recognized revenue of $93,000. Our net revenue represents our quarterly billings less the deferral for potential exchanges for product with short shelf life. This deferral is released when we receive a reorder from a customer. We were pleased to see an increase in the number of customers reordering in the third quarter.

Last quarter, we told you that we were working on obtaining approval for our 12-month shelf life. I'm happy to report that this was obtained for Fantom in July 2018. We also received approval for 12-month shelf life for Fantom Encore in October 2018. With our extended shelf life and the launch of Fantom Encore, we plan to begin phasing out the exchange program. At that time, we also intend to simplify our revenue recognition policy by recognizing revenue upon product shipment and maintaining a reserve against potential future product returns for breakage or spoilage.

Gross margin for the third quarter of 2018 was negative $48,000. The negative margin was impacted by several charges totaling $89,000 that all relate to the launch of Fantom Encore. These charges include potential excess and obsolete inventory and raw materials and standard cost variances. Excluding these charges, gross margin would have been 44% of net revenue.

Even after the launch of Fantom Encore, we still anticipate that our gross margins will be lower than industry standards until we reach higher sales and manufacturing volume.

Research and development expenses decreased by $1.4 million to $1.7 million for the third quarter of 2018 compared to $3.1 million for the same period in 2017. The decrease is due primarily to net decreases and licensing fees of $800,000 and material costs of $300,000.

Selling, general and administrative expenses increased $1.1 million to $2.8 million for the third quarter of 2018 compared to $1.7 million for the same period in 2017. The increase is due primarily to increases in personnel costs.

Our loss from operations was $4.6 million for the third quarter of 2018, a decrease of $200,000 or 4% compared to $4.8 million for the same period in 2017.

Interest expense increased by $100,000 to $1.6 million for the third quarter of 2018 compared to $1.5 million for the same period in 2017. The increase is due to the compounding of interest for the 2014 and 2017 convertible notes. We recorded a loss of $2.9 million on the change in fair values of convertible notes and warrant liability for the third quarter of 2018 as compared to a gain of $12.6 million for the same period in 2017. The fair value of convertible notes is impacted by the number of convertible notes outstanding for each period as well as other factors that drive fair value, including management assumptions related to the timing and amount of potential financing transactions, the remaining term of the convertible notes and the market trading price of our stock.

As a result of this activity, we recorded a net loss of $9 million for the third quarter of 2018 versus net income of $6.1 million for the same period in 2017.

Now that I've highlighted the results of our operations for the third quarter of 2018, I'd like to discuss cash management in some detail. As I mentioned previously, we ended September 2018 with about $7.1 million of cash. We have been very focused on controlling our

spend. In fact, I'll note that our cash-based operating expenses for the third quarter were $200,000 less than our second quarter expenses. We have also been keeping our inventory builds low. With our new Fantom Encore builds, we were focused on building just enough to accommodate our planned demand. Smaller builds will, of course, impact our gross margins in the short term, but we feel that the conservation of cash is more important at this time.

Based on our current sales forecast and planned expenditures, our existing cash should be sufficient to fund our operations through the first quarter of 2019. We will continue to monitor cash tightly as we continue to work through the fundraising process.

We are actively working through multiple opportunities to bring funds into the company. These include the evaluation of business development and strategic opportunities across the coronary, peripheral and embolic markets. We are also considering public or private sales of our equity or debt securities. We are very excited about Tyrocore, Fantom Encore and MOTIV and how we may work with others to bring in additional capital and add value for our shareholders.

Now I will turn the call back to Reggie to address the state of our business.

Regina E. Groves *REVA Medical, Inc. - CEO & Director*

Thank you, Brandi. Before diving into the priorities of our coronary, peripheral and embolics platforms, I want to talk about the changing market conditions in our coronary business.

This past August, the European Society of Cardiology, or ESC, published an update to the clinical guidelines for myocardial revascularization, which included a new recommendation regarding bioresorbable scaffolds. The recommendation was based on peer-reviewed published clinical trial data and the only available data at the time were for Abbott's Absorb scaffold.

Using the Absorb data, the authors made a Class III recommendation for all BRS, which is defined as, and I quote "evidence or general agreement, that the given treatment or procedure is not useful or effective, and in some cases, may be harmful." The authors further stated that "BRS should not be used outside of well-controlled clinical studies."

The new guidelines have added to the concerns about BRS created by the withdrawal of Abbott's Absorb scaffold from the market in September of 2017. It has taken some time for the physician community to digest the meaning of the guidelines. The initial reaction of shock and concern has evolved into anger and disagreement.

At the Transcatheter Cardiovascular Therapeutics, or TCT, conference in September, we saw physicians state their disagreement with the guidelines from the podium. And we heard discussions about actions that these leaders may try to take to influence the guidelines moving forward.

Specifically, physicians expressed their anger that the BRS guidelines classified all BRS together, despite the substantial differences among the BRS. Our Fantom scaffold and BIOTRONIK's Magmaris scaffold stand out because they are made from Tyrocore and magnesium, respectively, which are different materials than Absorb.

Physicians believe that these different materials should be judged based on their own data and should not be lumped with Absorb or PLLA. At TCT, we also saw some very good news from Abbott when they presented positive long-term data on Absorb. 4-year results were presented from the ABSORB III trial as well as a meta-analysis from the ABSORB II, ABSORB III, Japan and China clinical trials.

Last year, we saw that Absorb fared worse than Xience, the metal arm in the 3-year event rates, but this year, we saw that Absorb performed identically to Xience between 3 and 4 years in terms of Target Lesion Failure, or TLF.

Furthermore, between 3 and 4 years, both Xience and Absorb each had 1 stent thrombosis. Since the ABSORB III trial had twice as many patients in the Absorb arm as the Xience arm, the result was that Xience had twice the rate of stent thrombosis as Absorb in the 3- to 4-year time frame.

In order to understand the importance of these results, you should understand 2 important points: First, while Absorb bioresorbs around 3 years, the vessel is not completely healed from the Absorb resorption. We should, therefore, expect the Absorb results to continue to get better with time as the healing completes; second, Xience had a 2.6% TLF rate in the third year and a 0.2% rate of stent thrombosis. This performance is in line with other studies of long-term performance of metal stents and such performance should be expected to continue every year.

Looking out past 4 or 5 years, it is reasonable to expect Absorb's performance to continue to improve, whereas Xience should remain consistent at a 2% to 3% annual TLF rate. Therefore, with more time, we believe Absorb will demonstrate the long-term value of BRS.

The challenge, therefore, is to find a BRS that performs as well as DES before resorption. We believe that Fantom and Fantom Encore are the answer. Fantom's features like thinner strut profiles and x-ray visibility, coupled with our uniquely biocompatible polymer, should help reduce event rates and achieve the goal of equivalence to DES in the short term and better than DES after resorption.

The guidelines and Absorb's performance have changed the landscape. Our competitors pursuing PLLA scaffolds have all disappeared from the European market and many have gone out of business. REVA is positioned well with CE Mark and excellent 2-year clinical results. We anticipated the new guidelines would present a challenge, and prepared by launching our 1,500-patient post-market trial earlier this year. We are now planning to add a randomized controlled trial to begin in early 2019, which, we believe, will be the key to influencing a change to the ESC guidelines.

While it is clear that REVA sits very well positioned to be the winner in the coronary market, it is also clear that the time frame to achieve a significant market position has been extended. As a consequence, we have taken 2 important actions: first, this morning, we implemented a reduction in force to ensure we are properly staffed for our revised forecast; and second, we have shifted resources to increase focus on our peripheral and embolization therapy programs. These 2 programs are as promising as the coronary but present nearer-term value creation opportunity for REVA.

I will talk in a bit about our peripheral and embolic efforts. But first, I will discuss our priority of ensuring Fantom's commercial success.

We continued to see positive commercial momentum in the third quarter with total unit sales growth of 25%. The growth was driven by a near doubling of the number of customers reordering Fantom as well as an 18% increase in our customer base. While the actual results are still smaller than we would like, this increase in reorders demonstrates that once a customer uses Fantom, they believe.

In order to sustain this growth and generate the clinical evidence needed for commercial success, we are focused on 4 key activities: one, generating and publishing positive clinical data from existing premarket trials; two, leveraging our newer post-market studies; three, transitioning from Fantom to Fantom Encore; and four, geographic expansion in countries that accept CE Mark.

Our first key activity for Fantom's commercial success is generating and publishing positive clinical data from our existing premarket trials. As I mentioned before, we believe that peer-reviewed published data is needed to build physician confidence in Fantom and change the ESC guidelines.

We presented 2-year results from the FANTOM II trial at EuroPCR earlier this year and expect to release 3-year results during EuroPCR in May of next year. Our 6-month clinical results appeared in the peer-reviewed journal, JACC: Cardiovascular Interventions last fall. We anticipate peer-reviewed publication of our 12-month results before the end of this year, followed by publication of our 24-month results early next year.

Our second key activity for Fantom's commercial success is to continue leveraging our post-market trials. In May, we began enrollment in our 1,500 patient post-market trial. Today, we have 6 centers actively recruiting patients, 6 centers at the final stage of activation and nearly 30 additional centers in the pipeline. We are also now planning to launch a randomized clinical trial in Europe. This trial, like the post-market trial, will include selling our devices and as such will support commercial momentum. This randomization trial, when combined with our other clinical and commercial data, should provide the evidence needed to get the guidelines updated for Fantom. We will seek to achieve a Class II designation on our early evidence, and ultimately, to achieve a Class Ia designation, the highest level of

evidence supporting the use of our product.

Our third key activity for Fantom's commercial success is transitioning to Fantom Encore, and we were extremely excited to announce the commercialization last week. Fantom Encore is our third-generation bioresorbable scaffold with the thinnest strut profile of any commercially available CE Mark BRS. It is made from our Tyrocore polymer making it strong and x-ray visible. These advanced features are associated with improved outcomes and ease-of-use, which, we believe, are critical for broader adoption of bioresorbable scaffolds technology.

Fantom Encore is immediately available in all countries where we sell Fantom. During the next few months, we will transition all of our customers to Fantom Encore and then phase out Fantom entirely. With its thinner struts and excellent ease of use, we believe that the transition to Fantom Encore will help drive use of our scaffold.

The fourth key activity for Fantom's commercial success is geographic expansion in countries that accept CE Mark. We are pursuing geographic expansion with direct sales in select countries and commercializing through distributors in countries with challenging local market conditions like long tender processes and extended payment terms. We have a direct sales force in Germany, Switzerland and Austria. In the third quarter of 2018, we onboarded an independent sales agent in the Benelux region, which includes Belgium, the Netherlands and Luxembourg. This region is small and utilizing an agent as our market entry strategy provides a very efficient go-to-market approach.

During the third quarter, we added our second distributor partnership with Bio Vascular in Italy. Italy is one of Europe's 5 largest stent markets with 150,000 PCI procedures performed every year. We have successfully completed training of the Bio Vascular sales team and are working with the Bio Vascular team to initiate an Italian post-market trial.

We are now also working to evaluate distributors in 10 additional regions in Europe and the Middle East and expect to add 3 or 4 new partnerships in the next 6 months.

Australia also accepts CE Mark but does require additional registration activities. We have engaged with a partner to begin the process for commercialization in Australia and New Zealand. We believe that successful execution of these 4 activities, including generating and publishing positive clinical data, leveraging our newer post-market trials, transitioning to Fantom Encore and geographic expansion will grow sales for Fantom, influence the ESC guidelines and lead to long-term success.

Transitioning to our final priority, we are shifting resources to expand our business through our peripheral and embolization therapy programs. Peripheral and embolics are exciting opportunities for us. In July, we announced CE Mark for MOTIV, the first bioresorbable scaffold approved for the treatment of below-the-knee peripheral artery disease. Below-the-knee peripheral artery disease, or BTK, is a large underserved patient population and represents a huge opportunity. The most common indication for BTK revascularization is critical limb ischemia. We estimate that nearly 2.5 million people globally suffer from critical limb ischemia and could benefit from treatment.

Current treatment options for these patients are limited, and they frequently require surgery or limb amputation. Restoring blood flow to the limbs with percutaneous interventional procedures has been shown to improve outcomes, but there is reluctance to use drug-eluting metal stents and drug-coated balloons in these patients. In the below-the-knee setting, drug-eluting metal stents have been associated with complications like stent fracture and interfering with retreatment. Drug-coated balloons avoid the risk of a permanent implant but do not provide mechanical support or a sustained drug dose.

Bioresorbable scaffolds like MOTIV address these concerns by providing scaffolding and a sustained drug dose, while the vessel heals and then disappearing by resorbing from the vessel over time.

There is some prior history using BRS below the knee, both the Absorb scaffold from Abbott and the credence scaffold from Meril Life Sciences have been evaluated in small series of patients treated for critical limb ischemia.

In both cases, the clinical results were impressive with a limb salvage rate of 100% at 1 year for Absorb and 97% at 6 months for Credence, meaning that there was a significant reduction in major amputation compared to the 20% to 30% for conventional treatment over a year. These results are very encouraging and many of the physicians we speak to want access to MOTIV for below-the-knee patients.

We are extremely excited to kick off our commercial efforts with MOTIV. We are beginning with an evaluation of MOTIV with a small number of physicians in Germany. We have already selected the centers and are in the process of designing our clinical goals and getting these sites up and running. We anticipate initiating implants in the first quarter of 2019. We have also been approached by a number of distributors who are anxious to have access to MOTIV. We will be evaluating these requests and expanding commercial activities as appropriate. As we gain experience, we may seek regulatory approval in the U.S. and select Asian countries.

We are also working on development of a novel polymer formulation for a scaffold to treat above-the-knee peripheral artery disease. The most common indication for above-the-knee revascularization is intermittent claudication, and we estimate that as many as 5 million patients could benefit from treatment annually.

Arteries above the knee are large and undergo stress and strain with motions like walking. Our new polymer formulation will be designed to accommodate mechanical requirements such as crush recoverability. We have successfully produced a polymer material with our target characteristics and are in the planning stages of moving this polymer forward into a scaffold.

The third application of our Tyrocore polymer technology is in vascular embolization therapy. Embolization is an established procedure used to reduce the size of cancers tumors such as liver cancer, and of noncancerous tumors such as uterine fibroid and benign prostatic hyperplasia, or BPH.

Embolization procedures are performed in a cath lab by an interventional radiologist. The physician gains access to the arterial system through a small incision and then navigates catheters through the arteries using x-ray guidance. Once the catheter is in place, the physician injects the embolic beads through the catheter, so that the beads will travel through the arteries to the tumor and block blood flow. With less access to blood, the tumor will shrink.

Our technology offers a unique value proposition for embolization therapy, because it is x-ray visible and bioresorbable. While there were recent FDA approvals for an x-ray visible embolic bead and an absorbable embolic bead, no other company offers a product that combines these 2 features. The x-ray visibility is advantageous, because it allows the physician to see which arteries are occluded during the procedure. The bioresorption is important because it creates opportunities for retreatment, and it avoids the risk of an immune response to a foreign body in the blood vessel.

Embolic therapies are an exciting path for our Tyrocore technology because of the established procedures and reimbursement. Attractive margins and relatively straightforward regulatory path. We are currently evaluating the 510(k) process as a pathway for U.S. clearance. We are also working on prototypes for loading small molecule and large molecule drugs onto our embolic beads with a focus on oncology. Our embolic beads would offer local, sustained release of drugs with 2 potential therapeutic goals: One, a sustained release of powerful chemotherapy drugs to shrink tumors; and the second, a sustained release of therapeutic agents designed to stimulate the immune system to attack tumors.

Now I'd like to open the line to take your questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Derek Jellinek with Morgans.

Derek Jellinek ***Morgans Financial Limited, Research Division - Senior Analyst***

Just first for me, I mean, looking at the challenging market conditions, obviously, whether you are seeing the ESC guidelines, updated guidelines were kind of disappointing, to say the least. Obviously, it's clinical data that's going to drive changing the guidelines. You are definitely working on the post-marketing studies, that 1,500-patient study. You did say that there are 6 sites actively recruiting and you have 30 in the pipeline, maybe you can kind of talk us through when you're going to get any kind of relevant data from that trial? And as well, the current -- sorry, the randomized trial that you were planning to study -- sorry, start in the EU maybe -- and you said something interesting, you look to see selling the device during that trial. Maybe you can walk us through the trail design there and the cost and the data time line, if you wouldn't -- if you do it would be great?

Regina E. Groves ***REVA Medical, Inc. - CEO & Director***

Okay. And I'll start but I may ask Jeff Anderson to jump in here a little bit on some of the details. But let me start first by backing up to talk about the ESC guidelines and what it takes to change guidelines. Because it's not a single simple answer to the question. So generally speaking across all guidelines, the society will write updates about every 4 years. They are, however, known to write as frequently as every year as new data emerges that warrants changes to the guidelines. So things like the physicians talking from the podium, writing editorials, physicians publishing single center results, REVA successfully differentiating Tyrocore from PLA and results from our FANTOM II trial are all things that can influence the guidelines in the short run. You may remember I mentioned trying to move from Class III designation to Class II, what that's -- so the Class III basically is the evidence as against you. Class II is -- the evidence isn't against you, but isn't yet quite strong enough for us to say absolutely it should be used. So we'll be using some of this earlier information to try to get moved from Class III to Class II, which is a much better place to be and then the longer-term data to get to that Class I designation.

But, Jeff, maybe I can ask you to talk a little bit about the randomized clinical trial timing and the post-market trial data sets, how we'll see staged data coming out of these.

Jeffrey A. Anderson ***REVA Medical, Inc. - SVP of Clinical & Regulatory Affairs***

Okay. First, Derek, on the post-market trial, as Reggie mentioned, that trial is currently enrolling 1,500 patients and will be across up to 150 clinical centers. We currently have 6 centers enrolling, 6 centers that will probably be enrolling with additional centers within the next month and 30 that are in the Ethics Committee approval pipeline. So we expect that at all of the major conferences such as EuroPCR and TCT, being the 2 primary targets, to have data sets for those particular meetings. You'll first see at EuroPCR likely the acute results on the first group of patients that have been enrolled, and we'll add to that as the meetings progress and we get through the year. The next trial will be the randomized controlled trial. We're currently in the process of designing the trial and the statistics around that trial, I don't have any specific numbers for you today. However, that will be a randomized controlled trial that will likely be implanting in a one-to-one fashion against one of the more popular metal drug-eluting stents. We anticipate that trial to start in the first quarter of 2019 and should fairly rapidly enroll depending upon the total number of patients. And again, as we get to the major meetings, we'll be presenting the data available on that trial. That trial, because it is a randomized controlled trial, will actually be the basis for moving the ESC guidelines to the Class I. They have stated that to get to Class I, they really need to see you testing against a control group and have an active comparator. To get to a Class IIb, we can probably move the bar with our post-market trial and supported by the 240-patient FANTOM II trial, which has already passed 2 years and about half of the patients passed 3 with excellent clinical results to date.

Regina E. Groves ***REVA Medical, Inc. - CEO & Director***

Yes. So one other part of your question, Derek, was about the randomized trial, how do you charge. Our randomized trial is a post-market randomized trial. We already have approval for the product in the market, and therefore, are able to charge both for our product as well as the physicians will be reimbursed for the control arm drug-eluting metal stent they use, so we wouldn't be paying for either the scaffold or the metal stent for the trial. So the trial cost will be not significantly more than the cost of our existing post-market trial.

Derek Jellinek ***Morgans Financial Limited, Research Division - Senior Analyst***

Great. Got it. And, Jeff, on the randomized study, if I may. So why -- I'm assuming you're using Fantom, why not Fantom Encore? Because you're changing your focus from Fantom to Fantom Encore. So is that going to be used in the randomized trial?

Regina E. Groves ***REVA Medical, Inc. - CEO & Director***

Yes, so -- it will all be Fantom Encore. We tend to use Fantom as the umbrella name for Fantom and Fantom Encore. You're correct. We are turning Fantom itself off and going to only Fantom Encore. Whether a few Fantoms get into the trial, will simply depend on how fast we get the trial off the ground in which centers versus how fast the Fantom inventory gets used up and converted to Encore.

Jeffrey A. Anderson ***REVA Medical, Inc. - SVP of Clinical & Regulatory Affairs***

Another thing to mention on that, Derek, is we're not seeing physicians push back on actually buying the products for the trial. They are more concerned with the ESC guidelines, which state that they recommend the device as being used within a trial. It's not as much focused on being able to pay but that they can demonstrate that they are following good clinical practice by following their patients and collecting data on those patients they implant.

Derek Jellinek ***Morgans Financial Limited, Research Division - Senior Analyst***

Right. Got you. And just on the uptake of the product. So obviously, you're looking at the randomized controlled study, as you said, to really drive from a Class III to Class I and really drive uptick of the product inevitably. You're hoping to get Class II on the basis of the data that you currently have now. But for us, it's not really the inflection point, it's really the Class I obviously. So getting back to the time line, so obviously, what we've seen with Absorb, the 4 to 5 years kind of data looks to be approving, as -- Reggie, as you said, it looks to be improving as you go out in time. So I'm trying to get to a point, where do you see an inflection of how much time do you think has elapsed for the agency -- sorry, the ESC guidelines to potentially change into a Class I rating? You're talking 4 years, 5 years, 3 years, can you give me as a ballpark what you're thinking?

Regina E. Groves ***REVA Medical, Inc. - CEO & Director***

Yes. So to get all the way to the Class I is going to require likely a 12-month endpoint on a randomized clinical trial, okay? And the better Absorb does at 4 years and 5 years, the easier that 12- month endpoint becomes because everybody gets that once you're gone, your good. And so we will get the Class Ia designation with a 12-month result. Now, you're next question is going to be, when are you going to have a 12-month result from your randomized trial and that one I can't answer yet, because we need to size the trial, and we need to see the market's reaction. My expectation right now from the physicians we've talked to is, REVA launching a randomized trial will be met with tremendous enthusiasm. The physicians really want a bioresorbable product. They feel terrible that these guidelines have come out and everybody else is gone. I mean literally, our competitors have shut their doors and gone because they all had PLLA. So the physicians really want something. Their only choice is going to be our randomized trial. They don't even have BIOTRONIK as a choice right now, because BIOTRONIK's gone back to redesign their product. So they've got to redesign it, they've got to do first in man, we don't know what their process fort CE Mark will be for their product, depends on how different it is from their current product. So it could -- they could launch a trial sometime next year or it could be further than that. So demand for our trial could be very high in which case it might enroll much more quickly than other trials enroll. So we're not going to speculate exactly on timing right now of when that trial will reach a 12-month endpoint that gets to the results. That would substantially ensure we get to a Class Ia designation.

Derek Jellinek ***Morgans Financial Limited, Research Division - Senior Analyst***

Right. Understood. And I guess just lastly from me, obviously, you stated Reggie that you're shifting resources to look at the kind of the advanced peripheral embolization programs. Maybe if you can talk if you may, sorry, about the MOTIV -- sorry, going back to the BTK and PAD, so obviously, of CE Mark, you're looking to start your first patients in Germany you said and implants in Q1 '19, if I heard correctly. Maybe can you walk us through what the commercialization strategy is for that product? When will you start selling it? And you also talked about U.S. approval, is that in the cards near term like next year? And maybe shifting to the embolic side, obviously, you're evaluating a 510(k) pathway in the states, why not go for a CE Mark in Europe and launch there first?

Regina E. Groves ***REVA Medical, Inc. - CEO & Director***

So let me take you in reverse order. The embolics market is larger in the U.S. than it is in Europe and the regulatory pathway is very straightforward. So generally, companies go to Europe first because the regulatory pathway is lower, and you can get some commercial experience and get some revenue going and then you come to the U.S. because the regulatory pathway is so hairy over here and so expensive. But in the case of the bland beads for embolization, a 510(k) path in the U.S. is very straightforward, and as I said, the market is very well developed here, the reimbursement is there. So we would anticipate actually doing better financially launching first in the U.S. than in Europe, and we don't think the time frame would be any different. Going back to MOTIV. We are doing 2 things. One is we

are launching selectively in Germany, and we have a couple of centers that have a whole lot of experience with peripheral artery disease who want to work with us and who want to evaluate the product. There are multiple sub-applications, if you will, of MOTIV in below the knee from short stenting to dissections to long stenting and areas where you are from how far below the knee to how far above-the-ankle. And so we want to get more human work done with these centers. We want to make sure we're evaluating well our drug delivery profile to make sure we believe we have the right product to launch broadly. Meanwhile, we have been quite astounded by the strong pressure we're getting to release the product more broadly. And so as we get our early experience in Germany, we will be making decisions about going ahead and moving forward more quickly than we might otherwise have thought to because of the very high demand for the product. But we don't at this point, Derek, have a full launch plan, and obviously, we're not in a position to give you any kind of revenue guidance.

Operator

(Operator Instructions) And as I am showing no further questions, I'd like to turn the call back over to Reggie for any closing remarks.

Regina E. Groves *REVA Medical, Inc. - CEO & Director*

Thank you. REVA has achieved 2 milestones in bioresorbable scaffolds. The launch of Fantom Encore with the thinnest strut profiles of any commercially available BRS in Europe and CE Mark of MOTIV, the first bioresorbable scaffold approved for the treatment of arteries below the knee. These products illustrate the advantages of our Tyrocore polymer, which we are leveraging to create significant advancements in the areas of coronary artery disease, peripheral artery disease and embolization therapies.

While the coronary bioresorbable scaffold market presents significant challenges and will take more time to develop, we believe that we are well positioned to capitalize on the absence of competitors as we produce additional clinical evidence and commercial momentum for Fantom and Fantom Encore. We are extremely excited to be shifting our focus on near-term value creation opportunities in peripheral stenting and embolization therapies. Both markets have large unmet needs and our technology offers a unique value proposition for patients. We look forward to the opportunity to provide value to our stakeholders by progressing multiple products into the markets where patients greatly need them. Thank you again for joining us today.

Operator

Ladies and gentlemen, thank you for your participation in today's conference. This does conclude your program, and you may all disconnect. Everyone, have a great day.