

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (date of earliest event reported): June 1, 2018



Merit Medical Systems, Inc.

(Exact name of registrant as specified in its charter)

Utah
(State or other jurisdiction of
incorporation or organization)

0-18592
(Commission
File Number)

87-0447695
(I.R.S. Employer
Identification No.)

1600 West Merit Parkway
South Jordan, Utah
(Address of principal executive offices)

84095
(Zip Code)

(801) 253-1600
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Forward-Looking Statements

This Current Report on Form 8-K (including Exhibit 99.1 attached hereto) contains certain estimates and other “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements generally are accompanied by words such as “will,” “expect,” “outlook,” “anticipate,” “intend,” “plan,” “believe,” “seek,” “see,” “would,” “target” or other similar words, phrases or expressions and variations or negatives of these words. Such forward-looking statements may address the forecasts, plans, revenues, net income, financial results or anticipated or completed acquisitions of Merit Medical Systems, Inc. (“Merit”), and are subject to risks and uncertainties such as those described in Merit’s Annual Report on Form 10-K for the year ended December 31, 2017 and subsequent filings with the Securities and Exchange Commission (the “Commission”). Such risks and uncertainties include risks relating to Merit’s potential inability to successfully manage growth through acquisitions, including the inability to commercialize technology acquired through completed, proposed or future transactions; expenditures relating to research, development, testing and regulatory approval or clearance of Merit’s products and risks that such products may not be developed successfully, may not perform as expected in tests or trials, may be delayed or may not be approved for commercial use; governmental scrutiny and regulation of the medical device industry, including governmental inquiries, investigations and proceedings involving Merit; restrictions on Merit’s liquidity or business operations resulting from its debt agreements; infringement of Merit’s technology or the assertion that Merit’s technology infringes the rights of other parties; product recalls and product liability claims; changes in customer purchasing patterns or the mix of products Merit sells and the potential adverse effect on gross margins of increases in sales of low-margin products relative to high-margin products; the potential of fines, penalties or other adverse consequences if Merit’s employees or agents violate the U.S. Foreign Corrupt Practices Act or other laws or regulations; laws and regulations targeting fraud and abuse in the healthcare industry; potential for significant adverse changes in governing regulations, including reforms to the procedures for approval or clearance of Merit’s products by the U.S. Food & Drug Administration or comparable regulatory authorities in other jurisdictions; changes in tax laws and regulations in the United States or other countries; increases in the prices of commodity components; negative changes in economic and industry conditions in the United States or other countries; termination or interruption of relationships with Merit’s suppliers, or failure of such suppliers to perform; fluctuations in exchange rates; concentration of a substantial portion of Merit’s revenues among a few products and procedures; development by our competitors of new products and technology that could render Merit’s existing products obsolete; market acceptance of new products; volatility in the market price of Merit’s common stock; modification or limitation of governmental or private insurance reimbursement policies; changes in healthcare policies or markets related to healthcare reform initiatives; failure to comply with applicable environmental laws; changes in key personnel; work stoppage or transportation risks; introduction of products in a timely fashion; price and product competition, particularly if we begin to displace a dominant product in a market; availability of labor and materials; fluctuations in and obsolescence of inventory; and other factors referred to in Merit’s Annual Report on Form 10-K for the year ended December 31, 2017 and other materials filed with the Commission. All subsequent forward-looking statements attributable to Merit or persons acting on its behalf are expressly qualified in their entirety by these cautionary statements. Actual results will likely differ, and may differ materially, from anticipated results. Financial estimates are subject to change, including as a result of any of the factors identified above, and are not intended to be relied upon as predictions of future operating results. Any forward-looking statements in this report and the exhibit attached hereto speak only as of date of this report and Merit undertakes no obligation to update any forward-looking statement to reflect events or circumstances after the date hereof, except as required by applicable laws or regulations.

Item 7.01. Regulation FD Disclosure.

On June 1, 2018, Fred P. Lampropoulos, Merit’s Chairman of the Board and Chief Executive Officer, and Raul Parra, Jr., Merit’s interim Chief Financial Officer, participated in a business update conference call hosted by Wells Fargo Bank, N.A., in which they discussed Merit’s operations and products. A copy of the transcript of such conference call is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Merit is furnishing the information in this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) pursuant to Regulation FD promulgated under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Such information shall not be deemed “filed” for purposes of the Exchange Act or otherwise subject to the liabilities of that section, and is not deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

EXHIBIT NUMBER	DESCRIPTION
99.1	Transcript of conference call hosted by Wells Fargo Bank, N.A., held on June 1, 2018.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MERIT MEDICAL SYSTEMS, INC.

Date: June 6, 2018

By: /s/ Brian G. Lloyd
Brian G. Lloyd
Chief Legal Officer and Corporate Secretary

EXHIBIT INDEX

EXHIBIT NUMBER	DESCRIPTION
99.1	Transcript of conference call hosted by Wells Fargo Bank, N.A., held on June 1, 2018.

Wells Fargo Bank, N.A.

Moderator: Larry Biegelsen

June 01, 2018

2:00 p.m. ET

OPERATOR: This is Conference #2779677

Operator: Hello, ladies and gentlemen. My name is (Carrie) and I will be your conference operator today. At this time, I would like to welcome everyone to the Merit Medical Business Update call hosted by Wells Fargo.

All lines have been placed on mute to prevent any background noise. After the speaker's remarks, there will be a question and answer session. If you would like to ask a question during this time, simply press start then the number one on your telephone keypad.

If you would like to withdraw a question, press the pound key. Please note that today's call is being recorded. Thank you. I would now like to turn the call over to your host, Mr. Larry Biegelsen. You may begin your conference.

Larry Biegelsen: Thank you, Operator and good afternoon, everyone. I'm Larry Biegelsen, the Medical Device Analyst at Wells Fargo. Thanks for joining us today on short notice.

I'm pleased to introduce Fred Lampropoulos, the Founder, Chairman, and CEO of Merit Medical, and Raul Parra, the interim CFO. We were originally planning on doing this call next Friday, June 8th, but given yesterday's news we figured it made more sense to move the call up to today.

So it -- as a backdrop over the past couple of years, the team at Merit has done an excellent job executing against the company's strategic and financial initiatives to create shareholder value.

Merit has been able to deliver above average top line growth driven by a mix of acquisitions and internally developed products. The margin profile has also been improving, and that's translating into strong, non-GAAP EPS growth.

So on today's call, we'll start with the CFO change, which was announced yesterday, some bigger-picture financial and strategic-focused questions for management, and then transition to the product pipeline.

In terms of format, I'll ask Fred and Raul a series of questions, and then we'll open the call up to questions from participants on the line.

If anyone has a question that they want me to ask on their behalf, please email it to me. So before we jump into questions, the Merit folks want to read a forward-looking statement. So Fred, thanks for doing the call on short notice. Please go ahead.

Fred Lampropoulos: Larry, thank you very much for hosting us, and I'm going to ask Raul Parra, our interim Chief Financial Officer, to read a brief safe harbor provision. Raul?

Raul Parra: During our discussion today, reference may be made to projections, anticipated events, or other information which is not purely historical. Statements made in this call which are not purely historical may be considered forward-looking statements.

We caution you that all forward-looking statements involve risks, unanticipated events, and uncertainties that could cause our actual results to differ materially from those anticipated in such statements.

Many of these risks are discussed in our Annual Report on Form 10-K and other reports and filings with the Securities and Exchange Commission available on our website. Any forward-looking statements made in this call

Male: (Hey, sorry)

Raul Parra: ...are made only as of today's date, and except as required by law or regulation, we do not assume any obligation to update any such statements, whether at -- whether as a result of new information, future events, or otherwise.

Please refer to the section of our Quarterly Report on Form 10-Q filed on May 10th, 2018, entitled "Disclosures regarding forward-looking statements" for important information regarding such statements.

Fred Lampropoulos: Raul, thank you very much. I think you're a little nervous over there. So we're going to have to kind of get you in the saddle there. Larry, let's turn the time back over to you, and we're ready to go.

Larry Biegelsen: Thanks, Fred. So let's begin with yesterday's news of Bernard resigning to pursue another role or opportunity. I think the press release said that Bernard left to pursue other opportunities. Are you willing to say or do you know where he ended up going? Is it fair to say that his decision came as a surprise?

Fred Lampropoulos: Yes Larry, as I discussed yesterday and -- and I'm happy to again today, we had a shareholders meeting on Thursday and on Friday morning I received his letter of resignation just simply stating that he was going to seek other business opportunities. It came as an absolute surprise to me, and wherever he is and wherever he's going, I just simply do not know. So I simply wish him the best.

And that's where we are. Raul has worked here for 8 1/2 years as the corporate controller, as our chief accounting officer, and while we're going through this process, we thought it was appropriate for him to take control. He was the guy preparing all the numbers, and so that's where we are today, and I've told you everything I know.

Larry Biegelsen: That's very helpful. So I think the street looked at Bernard as the steward of financial discipline, if you will, while Fred, you as the CEO were running the strategy, you were the visionary at Merit.

So what -- what gives you the confidence that you'll be able to deliver against the financial initiatives -- you've put in place, both for the 2018 guidance and the long-range plan that you provided last year?

Fred Lampropoulos: You know, Larry, I think in your opening comments, you used the word "team." And you know, this is in fact a team.

We -- I set forth a vision prior to Bernard arriving, and we thought it was good for us to have a statement that everybody could grasp onto and that we could achieve, and we put out that 3-year plan, as you will recall, and then subsequently added two additional years to it.

Remember it starts up in the operations. We have to have products that are built efficiently, we have to have the pricing and all that sort of thing - including cost of goods, that is Ron Frost, our COO.

Then we get down to the discipline required in sales and general administrative expenses, and I think that we have put systems in place, reviews in place, and -- and Raul has been part of that. And -- so Raul, maybe -- why don't you just share your thoughts about how you're going to assist the team in making sure that we stay on focus to achieve our financial goals.

Raul Parra:

Yes, thank you Fred. You kind of nailed it, right? I think it's integrated into our philosophy now. We've been doing this for a while now, and it's just ingrained in people. I think it's natural for us to think that way. I don't see any changes to that plan, and we'll continue to march forward.

Fred Lampropoulos:

Thank you. And so Larry, I think it's -- we want people to have comfort that we're committed, and you know, I -- we want to reiterate what we said in our guidance back in February when we talked about our goals, and then we reiterated actually on a call and a question that you asked on April 25th, when we had our quarterly call about reiterating our guidance for 2018, and I want everybody to feel that comfort that we in fact reiterate what we had previously said in terms of our guidance for our business for 2018.

Larry Biegelsen:

OK, that is good to hear. And so the fact that you didn't formally reaffirm the 2018 guidance in the press release yesterday announcing the CFO change, people shouldn't read too much into that. Is that fair?

Fred Lampropoulos:

Well, they should read nothing into it. I -- hopefully what I've just said covers that, and -- and again, we reaffirm what we have previously said.

Larry Biegelsen:

That's helpful. And Fred, can you talk about the process as it relates to filling the CFO role on a permanent basis?

Fred Lampropoulos:

Sure. Well, what we will do is that over the next 90 days, I'll be working with the Audit Committee Chairman, Nolan Karras, who's also our Lead Director, and we will be making assessments of the needs in the business. We will look to see what's available in the marketplace.

Now that being said -- listen, Raul -- I have a lot of confidence in Raul. He would -- you know, I would have to say today, he is that lead candidate. He knows the business. He's been preparing the statements and that sort of thing

But I think in fairness to the business and to our shareholders, it's important that we take a look to see who might be able to fill that role and we will go through that process over the next 90 days.

We -- if we make a decision any time between now and then, then we will of course make sure that the shareholders are aware of that.

Larry Biegelsen: That's helpful. And you talked about being comfortable with the 2018 guidance. I guess another way to ask the question is I assume you've looked at kind of where consensus is for sales and EPS; are they consistent with your guidance? In other words, are you comfortable where -- with where consensus is?

Fred Lampropoulos: Yes, and again, Larry, it is consensus out there -- I will say that we are comfortable with the guidance and where consensus falls into our guidance, we're comfortable with the numbers that we had previously stated for the year.

Larry Biegelsen: That's helpful. And -- and you delivered about 7 percent organic growth in the first quarter, which was the toughest quarter of the year. The guidance for the top line I think is 7.5 to 8.5 percent organic growth in 2018. And -- and I assume you're feeling comfortable with that now based on what you said, but any -- any color on the cadence of organic growth across the quarters?

Fred Lampropoulos: Well, maybe rather than cadence, maybe this fits in that terminology, but we expect that to accelerate and move up from where we were at the beginning of the year.
So we'll see improvements in that as we go through the year. You know, as I -- I've said and I'm happy to say it here again, is that business is robust, we're very, very, very busy, we've just finished our second month of the quarter, and we're on plan to do the things we said we would do.

Larry Biegelsen: That's very helpful. And -- and you know, over the past few years or throughout its history, Merit's been very acquisitive. So my question is, do you believe you have the capacity to be acquisitive in the near term, after you've just finished -- you know, completed the Becton deal? And are there particular areas of interest where M&A might make sense?

Fred Lampropoulos: Yes, Larry, I think that what we've always tried to do is to find businesses that meet -- first of all, our business plan. there are a lot of opportunities out there. I think that the bolt-on kind of ideas, the smaller opportunities, are the things that we're most focused on.
But to the question of the Becton Dickinson issue that has gone -- I think ahead of expectations, and that transitions has -- has moved from what we'll call order to cash, so receiving the orders, shipping the orders, billing for the orders, all of that commercial work is all now totally controlled by Merit.
Mexico finished our clean room there, and now over the next six to nine months, there'll be the transferring of -- of manufacturing into that.
So I think it's gone -- I think fabulously well, and I -- in fact, what it has done is freed up a lot of the Salt Lake people, because now it's in the Mexico hands of the management there to do the transfer part. All of the commercial part, training, launching, and all the commercial points that I just finished have all been completed.

Larry Biegelsen: That's very helpful. So just a few more big picture questions before we transition to the pipeline. So non-GAAP EPS has been growing double digits. I think the gross margin was about 48 percent in 2017 which is below the mid-tech peer group average.

As part of your long-range plan, you have goals of 100 to 150 basis points of improvement in the gross margin each year. Can you talk about some of the initiatives or levers you have to help drive that margin expansion?

Fred Lampropoulos:

Yes, well it starts out first with the efficiency and manufacturing in utilization of the facilities, and all of the -- the facilities are essentially running hot. There are a few little places, but I mean generally, we're operating I think positively in those facilities.

You know, we look at negotiations. We have a full-time negotiating staff looking at contracts and volumes, national accounts negotiating with -- with carriers. So this is an active part of our business all the way through the line.

And maybe something that's equally important is the mix, and I think in terms of sales force that the initiatives and the things we want to get sold, so we've put together incentives to make sure that we get the results of the products, where we think there's the most opportunity, where we get the margins, and that comes to our sales force.

And then when you get down into the operating side of things over the last several years, we've not made a lot of commitments -- in fact, we've made no commitments as to getting any leverage out of that SG&A line. And it's all been on that top line.

The reason for that, Larry, is as the business kind of goes from the accessory side into more complex, we thought we may need those additional dollars that you might have for more clinical support and other things that would help to grow products that are much more complex. So it's really top to bottom.

It's mix, it's operational efficiencies, negotiating our costs, making sure that labor, which as we all know is becoming more and more scarce and more and more costly, is properly proportioned into facilities that give us benefit. And then moving down into the discipline and the sales department and general administrative.

Those all have our focus. We review it monthly with our staff, with those that are responsible, and that's a role that Raul and his staff will pick up to make sure that those things that we've been doing continue. So we're committed to that.

Larry Biegelsen:

That's helpful. Sticking with gross margin, focusing on 2018 for a minute. In the first quarter, the gross margin was down a bit slightly year over year at about 47.5.

The guidance is 49.7 to 50.8. How should we think about the ramp in the gross margin through 2018? And again, is there anything else that drives the improvement other than the factors that you just mentioned (within the discount)?

Fred Lampropoulos:

Yes, Raul, do you want to comment on that? Go ahead.

Raul Parra:

I think we're going to stick to our talking points in Q1, right. It's going to kind of ramp over the year. We had some TSA and integration expenses if you remember, Larry that we had in Q1. Those are going to continue into Q2 and they'll start kind of to go away in Q3 and Q4. So we see it improving over the year.

Fred Lampropoulos:

And Larry, let me just add into that, that you also have products like the Prelude IDeal™ we'll talk about in a minute. And as those products ramp up, they're now absorbing overhead. So if you look at all of those issues, we should see a progression throughout the year.

Larry Biegelsen: Raul or Fred, have you guys quantified the TSA expenses, how much of a benefit those are when they go away after Q2?

Fred Lampropoulos: I'm just going from memory now, but I think there was about between \$750,000 to \$1 million of expenses in that first quarter that had to do with the TSA work that was part of the contraction arrangements with Becton Dickinson. So that's the best of my recollection, Raul. Where are you on that one? Is that pretty close?

Raul Parra: Well, in total, yes. Some of those were in SG&A. I would say it was probably around \$250,000 to \$300,000 in cost of sales.

Fred Lampropoulos: And the gross margin side of things? It was about \$700,000 in total SG&A expenses.

Larry Biegelsen: That's helpful. And then you're in the midst of transitioning the Japan business through a direct sales force to capture the potential sales and margin upside there. Personally based on the math, we've done -- it feels like an under-appreciated opportunity. So Fred, can you give us an update of where you are in that process? Are there any numbers you can point us towards to help us quantify the potential impact? And then just lastly, when will we start seeing noticeable impact from those sales on margins?

Fred Lampropoulos: Larry, I think we're starting to see that already because as we mentioned, it was going from essentially wholesale to retail. But if you recall, there were a number of factors.

We purchased Argon critical care, which was actually below our standard gross margins for the company. But the reason that we thought that was important is half of the business there is sold in Japan and although we get higher costs, or sales revenues there, margins, there are higher SG&A expenses.

So when we combine those two, it made the model work; in other words, it didn't distract a lot. There's a little bit as you first move it, but we combined two companies, two locations, and we now are selling those products.

Now here's maybe what's the most important point, where Japan has generally been flat while most of southeast Asia, China, and that region has been growing at almost 20 percent, Japan has been flat for several years.

And we believe that those sales this year will be part -- probably about 15 percent and we can see that going forward. So we're starting to see that now. Remember we had -- some of that is going to come on the last half of this year as we transition. We first started with the OEM side of it, and then certain products and it'll ramp throughout the year.

So those numbers are in our numbers, in our gross margin number and they're already in -- a little bit in the first quarter. You'll see more of an impact second, and even that business then, will ramp throughout the year.

By the time we get to the end of the year, the big deal is, here's a location that just simply hasn't performed because as I mentioned, we had a distributor, a great distributor. But as over 30 years, they had other products that Merit was selling that they had made commitments to and our products weren't getting sold.

And that's why we believe that this transaction -- which again, has gone smoothly, we had to have new facilities, new warehouses, combining two sales organizations. I think it's gone fabulously well and it'll be part of Merit's ongoing story as we discuss in future quarters in years.

Larry Biegelsen:

That's very helpful. So let's close out this portion of the questions. The Becton acquisition, Becton-Bard, if you will. I heard what you said earlier that it's gone well; if anything it's ahead of your expectations. So can you talk about your optimism around having a completed portfolio biopsy products with the CorVocet™, Laurane Medical, and the acquired BD assets. Why is it so important to have that complete portfolio?

Fred Lampropoulos:

Listen, these were great products and there was a great transition and opportunity for Merit to be able to pick these up. We hiccupped a year ago on the CorVocet, we've re-engineered it, we fixed its issues.

We relaunched the CorVocet with our sales force. As you'll recall, the Laurane opportunity was one that we had to move from France into Ireland. That has been accomplished and the first launch of stock are being built and will be done in the next couple of weeks.

And you now walk in with full core biopsy, you walk in with the BD products, you walk in with bone biopsy, and another little product that we've just added to that on a distribution bases called the BiopSafe™, which is a collection system for the specimen. So think about this, whether its bone, whether its full core or semi-automatic, we now have everything.

Our competitors generally don't have both things, they have bits and pieces. And then we have, not only that, but a system that you collect it in that works right along with our safety theme in terms of making sure that healthcare workers are not exposed to those things which are detrimental to their health.

So we have that package of products and it's going to be a growth driver for a long time. In addition to that, Merit has already started on two or three new products, and in fact, improvements to the other products that we bought from Becton Dickenson.

They've been around for a good period of time and I think that we immediately started working on some other things internally as part of our R&D pipeline.

So it's a big deal, and again, remember, it's at the same call point, Larry, of many of our other products. So from a margin point of view, point of sale, global opportunities, it hits on all of those numbers. Raul, do you want to add anything to that?

Raul Parra:

No, I think the only thing I would add is Laurane starts to get into our core growth, sometime in the August time frame.

Fred Lampropoulos:

Yes, it's another really good point, because we bought it a year ago. It would be considered an acquisition. The only thing we did was to maintain the existing business, which was a couple of million dollars. So it was very little and really, with two sales people globally. And now you have this full sales force, and then that's going to contribute very nicely to our ongoing core growth.

Larry Biegelsen:

Fred, who is the target physician audience here? You said that it fits into our call point right now. Who

Fred Lampropoulos: It is interventional radiologists. These are the guys -- also the guys that are buying our embolics, our dialysis products, our catheters -- it's that same group. It's getting to be a very, very big part of our business.

I would say approaching 50 percent, maybe slightly more if you back out OEM; it's a very, very, very big part of our business and a very big call point. It is very fragmented and very helpful as opposed to, let's say, cardiology where you have the big three. So it's always been part of Merit's growth strategy to be in that interventional radiology business.

Larry Biegelsen: So the 50 percent refers to the interventional radiologists account for about 50 percent of your total business. Is that what you're saying?

Fred Lampropoulos: That's correct. When you back out the OEM part of it, which is about 100 million.

Larry Biegelsen: I got it. And biopsy -- two follow up questions on biopsy. Number one, is Bard -- Becton, is that your largest -- who are your largest competitors? Is it Bard? Becton and anybody else you'd call out?

Fred Lampropoulos: Yes, there are two players there. The big players are of course BD/Bard, and then Argon, and then Merit now is essentially now about equal to where Argon is. I think with these other products coming online; we should clearly be able to move into that number two position over the next year or so.

Larry Biegelsen: And how big a business are you willing to disclose kind of when you aggregate those products? Approximately how big is the biopsy business now in aggregate?

Fred Lampropoulos: Probably about \$40 million now, but remember you're just launching the CorVocet; we're just really launching the bone biopsy; and the BiopSafe, which is the biopsy collection system, is brand new.

So if you ask me that question a year from now, it'll be one of the growth drivers in the company. It'll be much higher than of course than where it is today.

Larry Biegelsen: So that's helpful. So let's transition the discussion to a handful of your key pipeline products, and let's start with my favorite, PAE, which is prostate artery embolization, and something that you've been talking about now for about six to 12 months.

So Fred, you talked a little bit about some of the enthusiasm you saw at the SIR, the Society of Interventional Radiology meeting earlier this year. How are you thinking about PAE as a growth opportunity for Merit?

Fred Lampropoulos: Yes, you know that -- that enthusiasm is maintained. All of the classes that we have that are taught by physicians here and in Europe and other locations are filled.

One of the things that I think that is important, that I would like to reiterate is that the -- the PAE is so significant because it's really a process and a procedure in which you really have to have those who are really skilled in imaging. And the interventional radiologist is really the person that's the best in that group of physicians.

And so because they can generate revenues and capture patients, it's really important to them. You know, I think I shared with you a podium discussion that we had when we were at the SIR meeting. You know, we had 200, 250 physicians standing in front of our booth. In fact, our neighbors were getting mad at us because we were -- they were standing in their booths watching us.

But I think the big part comes not just from the embolics, because that's a small part. The big part comes from the vascular access products, which include the SwiftNINJA®, our new IDEal sheath, radial procedures. That part of it all feeds into it.

So when you look at the numbers in the groups, you'll see that they're all these pieces sitting in the various selling parts that we report in our business. So the -- the excitement is still there. We -- if you talk to an IR doctor, you -- they're excited because of the business opportunity, the reimbursement.

Maybe more importantly is when you talk to a patient who's had the procedure done, and you know, it's essentially a nick and an outpatient procedure that has had great benefit. So my enthusiasm is maintained.

Larry Biegelsen:

That's good to hear. So you touched upon a couple other growth drivers. One was the SwiftNINJA. That's a unique product for medical, right now, and your catheter business has performed pretty well over the past several quarters. So, how much of the growth in the catheter business has been driven by the SwiftNINJA and how should we think about that going forward?

Fred Lampropoulos:

Well, again, the SwiftNINJA continues to be a very big deal. There's nothing quite like it. One of the areas, of course, Larry, is the price point. We list it for \$2,400. It's a lot of money for a catheter, but what we have seen, that is, and what we're after is, if we get hospitals to commit and IR groups to commit to fives and tens and twenties, then we're able to discount the price.

So, I think that we're able to do that. If it's ones, we're going to stay where we are, but when we can consolidate them, we have less cost and we also use that as an incentive for our sales force and for our buyers.

So, I think that's a big part of it. But, while you're on catheters, I think there's another part that we had discussed and you asked quite a bit in some of previous calls and historically -- and that was -- remember the Cook deal.

It's not talked about much anymore, but interestingly enough, after going up and maybe plateauing, last year, a little bit, kind of leveling off, as you will recall in our first quarter call, we saw that rise by 16, almost 17 percent over the year ago period and we're continuing to see that trend, where our Impress® catheters, some of which are used for PAE and most of which, are directed to that same interventional radiology doctors.

And again, I'm talking about pull-throughs and a broad suite of products. That product and the hydrophilic version of that product are growing rather dramatically, and I'm going to have to tell you. I was a little surprised when we saw this thing start to go up again. So, I don't know how to explain it but it's a pretty big number now and we're seeing it on that catheter side, the Impress catheters.

Some of that is PAE. Some of it is our presence. Some of it will be even more so, as we start to bring through more of the biopsy product lines too, so, a nice pleasant surprise for us, that continues to grow, and we expect to continue to see that throughout the year now.

Larry Biegelsen: For people on the line, who may not be familiar the SwiftNINJA and what's special about it, maybe just a couple words on why it's unique or using your words, nothing quite like it?

Fred Lampropoulos: Yes. Well, it's a steerable microcatheter that has a 180 degree turning, so you can -- if you go straight in, you can go left or right. And when you get these tortuous anatomies, and it's not just with PAE but for UFE and some liver work, these are really tortuous areas to work in. PAE is the most difficult but it's used in a lot of places, and then, the ability to lock it, so, once you get there and you have that curve, you can, then, lock it in place so that you can maintain that in the -- in that selected vessel.

It's hydrophilic, and it's one of those things where, over the years, I've been doing this a long time, and it's kind of fun when you show it to somebody and the words are very simple. Wow, I've never seen anything quite like that.

So, it's a fun product to show, sales guys are excited about it, and again, it differentiates us because, even though others may have gotten approval based on our leadership in PAE, they don't have that product and they don't have products like the IDEal sheath.

So, we have things that they just simply don't have, and remember, we're still the market leader for our embolic materials, our Embosphere. So, you add all those up, it's a pretty nice combination.

Larry Biegelsen: Yes, I had a question e-mailed to me on the BD deal, beyond 2018. How much does the gross margin profile change? So, the question is, how to think about BD beyond 2018? How does the gross margin profile change when it's fully Merit manufactured in the growth ...

Fred Lampropoulos: Yes, it's a good question. So, Larry, when we model this out, I think we were using margins, like, about 60 to 65 percent, when we modeled it. We're going to be moving it across the Dominican Republic to our facilities in Mexico. There's a little bit, I'm going to say, maybe a 5 percent -- 10 percent difference in cost. It costs us a little bit more in Mexico from labor than it does in the Dominican Republic.

However, reports from my staff, my engineering staff and operational staff, tell me that, if they look at how the product is manufactured and again, I don't want to be, you know, being respectful for BD but it's been there for a long time, on equipment that's seen a lot of days.

And if we take that and we take a look at the things we're doing with new automated CNC type equipment and grinding equipment, my staff is telling me that our efficiencies are going to be substantially better.

So, although my initial assessment was that we would be slightly below what they were, and that's why we came at 60 to 65 percent, my feelings now, at least based on preliminary information without having the benefit of actually being in production, have actually been elevated because my guys are telling me, they think we can produce it more efficiently and at lower cost than they were.

That being said, if all of that, in fact, works out, then we will, in fact, see improvements in gross margins, not that 65 percent. There'll be a pathway to, probably closer to 75, maybe even as high as 80. So, that's where those opportunities are.

Larry Biegelsen: That's helpful. So, sticking with the pipeline, you touched on a couple of other products that I had wanted to ask about. You've talked about the Prelude IDEal vascular sheath. Why has that been such a successful product for you?

Fred Lampropoulos: What I think of as a sheath, it's just like talking about the SwiftNINJA. It is the best, most flexible, non-kinking, thin-walled sheath in the marketplace. There's no doubt that it is the best product in its category.

It's also -- the exciting part of it is, is where'd you normally get about \$10 for a sheath, of course, it doesn't have the coils and hydrophilic and this and that, we're getting pretty close to 5 to 6, 7 times, so let's just settle on 6 in the middle, over what you would get for a standard sheath.

And very candidly, we're selling this as fast as we can make them. We've had to slow down our introduction in Europe because they're all being utilized in the United States. So we haven't been able to launch it globally but it's -- we're still beating our forecast, internally, and we're starting a second production line, we hope to have up and running in the next 60 days.

So you add all of that up, there's just nothing quite like this product, and we just came back from PCR. We just went to another meeting, and I think it was a SCAI meeting, and it's a product that's just the best in class, Larry, so. And when you see the production, you see the orders. You see the opportunities for the upside.

My competitor, by the way, which is another great company, one of the best in the world, has a product but it doesn't have the capability that this has. In that one area alone, in the United States, according to IMS data, they're doing almost \$100 million dollars a year. Well, maybe I shouldn't say this but I'm going to. They won't be doing a \$100 million dollars a year, in the future. Maybe that's an overstatement.

Larry Biegelsen: Well, that's good to know.

Fred Lampropoulos: Yes.

Larry Biegelsen: That's interesting. So, Fred, the other products. So you have the Wrapsody™ venous stent. Can you remind us of the expected commercial timing of that product? I think you previously said that

Fred Lampropoulos: Yes.

Larry Biegelsen: would be a hundred million dollar product?

Fred Lampropoulos: Yes, it could be, and we're excited because we're just a few months away for our first-in-man in Europe, then we'll go and seek the CE Mark later this year, and as we go through that process, as we go into 2019, could be mid, maybe late first, early second in that kind of range, that product will be launched in Europe.

Now, once that's launched, then that is kind of the segue into Canada and Australia. We're still a couple years, two or three years away from it being launched in the U.S. because of the regulatory requirements, but it is a very big deal.

It has the opportunity, I believe, for Merit, alone, to produce over \$100 million dollars a year in revenues. A reminder, Larry, this is for the central veins. So if we're looking up -- when you put in a PICC line, you put it in a dialysis catheter. You do these things.

It does damage. These areas, then, get blocked off, and this product is one that we've been working on for five years. I think we're going on our sixth year and we will have invested \$30 million dollars when we're all said and done in it, but as we show it to physicians, we show the delivery system.

It is really something that I think is going to be a lot to talk about, and we will, of course, report that first-in-man and the results of that and then that process on the CE Mark, which then leads, of course, to the U.S.

We'll have to do a study in the U.S., but that's part of this program and will, of course, all be budgeted into our future numbers that we'll talk about, as we move down the road.

Larry Biegelsen:

Fred, I'm not that familiar with the venous stent market. How big is the international market? I'm just trying to understand if this is a situation where there's significant revenue opportunity outside the U.S., where you'll be launching much earlier than the U.S. or is this primarily a U.S. opportunity?

Fred Lampropoulos:

No, no, no. I think -- listen, we generally use a number that is, whatever the U.S. is, the numbers, the rest of world is generally about double. So this is several hundred thousand -- several hundred million -- dollars worth of opportunity.

You've got players and they're like W.L. Gore. You've got some stuff that's coming on Bard, now BD. There's products out there but nothing quite like this.

So, without tipping the hand, I think one of the things we'll do, as we set our next Investor Day, and we hope that will come sometime, maybe in the fall, we'll be, now, I think, once we have that, we're trying to time something like that around getting that first-in-man and being able to discuss that in the pipeline, more thoroughly, in the fall.

So, great opportunity to get out there, and again, remember, that all these products require access, require all the other products that Merit sells as well. Basically, by the way, to that same interventional radiologist who's doing these procedures, so, right at that sales point again, Larry.

Larry Biegelsen:

That's helpful. And I had a question e-mailed to me. And, Fred, I don't know if you're willing to answer this but it seems like, well, a good -- a good question. Have you talked about a competitor that has a hundred million dollars of business at risk, when you were talking about the Prelude IDEal sheath? Who is your largest competitor there?

Fred Lampropoulos:

Terumo.

Larry Biegelsen:

OK.

Fred Lampropoulos:

A great company.

Larry Biegelsen:

OK, that's very helpful.

Fred Lampropoulos:

They have good products, but ...

Larry Biegelsen:

Yes.

Fred Lampropoulos:

We have a better one.

Larry Biegelsen: OK, all right. So, the others, there's a couple other pipeline products, a few of them, I think, you may have touched upon. So, you have, I think, the inflation business. So, you posted very strong growth in Q1, in that business, so how should we be thinking of the trajectory of this business looking ahead?

You have a new product there called the TAU, T, A, U, I believe, inflation device, which I think you're pretty (inaudible), so can you help us get a better understanding of that business, the inflation business and the contribution from the TAU?

Fred Lampropoulos: Sure. So, first of all, the inflation device is Merit's, essentially flagship product line. We're the market leader.

It's a product that, I think, over the years, we've continued to invest, whereas many of our competitors have one product, Merit has a product in our endoscopy division. We have a product that's for cardiology and one for peripheral.

Now, these are different areas of the body. They use different pressures, different delivery systems, and so on and so forth. So, Merit has always really stayed ahead, and we have digital, we have analog, and we will soon have a Bluetooth® version.

So, the TAU, I think, solves a major problem with fatigue. It has a patent pending. It's ready to launch in, I think, 30 days or so.

And then another one that have, in fact, launched is the BasixTouch™. So we've taken the chassis of the touch inflation device, and Larry, I don't want to go on too long on this, but I have to. I remember when people said you're developing the Touch that it was a bad idea.

It is not a bad idea. It's approaching, I think - I'm just looking at the numbers here - I think a product that was launched not too long ago - let me just quickly look at - how much do you have there?

Raul Parra: \$12 million.

Fred Lampropoulos: \$12 million. I need more lousy products that sell \$12 million worth in the first 12 to 18 months, and it's a great product. Now what we've done is combined that chassis along with the digital. We call it the Diamond Touch. That's in the marketplace and that commands a premium. And was it \$6 million?

Raul Parra: \$6 million.

Fred Lampropoulos: I'm sorry. \$6 million, but it's a brand new product. So when you take a look at the breadth, the location, what Merit has done in terms of looking at cardiology, radiology, and endoscopy, and take this whole mix - plus because of that we have just - not recently, about a year ago, we were able to sign a major, national account in which two large competitors were removed and we have a co-exclusive with one other company in that area, one of the big three.

And we've just done very, very well, and my expectation is it will continue to grow and Merit will not only maintain its market share lead, but I think I've said this publicly many times, we're about a 50 percent player. If we're talking 18 months from now, we're a 65 percent market player. Two-thirds of the market will be using Merit products globally.

Larry Biegelsen: That's impressive.

Fred Lampropoulos:

Thank you.

Larry Biegelsen:

One area we didn't talk about was NinePoint, and you recently announced that in a partnership with NinePoint, which is an OCD - OCT-excuse me - platform for GI applications, so that's a pretty recent deal. I think maybe that it was even announced in May or early May, so how's that going?

Fred Lampropoulos:

Well, I'm glad you asked. All right, listen. We've sold a couple of the consoles. They sell for almost \$200,000 apiece. We've actually had to increase our forecast on those because of the demand. And one of the really fun parts of this is NinePoint has great technology, but they did not have the market breadth.

We've got customers, one in the upper Midwest, a rather large metropolitan area where we have four or five areas - hospitals that we're doing demonstrations that we think will convert some percentage. They don't waste their time on these things, and they [NinePoint] just didn't have the resources to get there and they didn't have - we have people on the ground; clinical and selling and support.

So we've sold a couple. We've increased our forecast. As you know, you also have the probes that go along with it, so it's the razor blade, but maybe equally important is what that means to our endoscopy because now our Elation® balloons, our stents, our probes, all of the other things that kind of go along with this, I think it's - I think people are paying a lot of attention to Merit now in the endoscopy business.

We've been paying attention to it, but it's on its way to \$100 million in revenues over the next several years and it's been, I think, a big boost for the sales force because now we can compete. We're bringing great new ideas.

In addition to that, we also now have a five-stage balloon that our competitors and Merit currently have a three-stage balloon. Merit is the only company that has a five-stage balloon.

We've been out doing trials on it, customers love it. Almost anybody you talk to about, Larry, in the endoscopy uses about - 20 percent of them are using more than one balloon procedure.

With this five-stage balloon, you just use one. So it's beneficial, it saves time, and we're the only guys that have it. It's being launched as we speak. So there's a lot of excitement on the NinePoint on having that full sales force out there. Everybody's trained, everybody's engaged, and then on top of that you throw the new five-stage balloon.

And if you looked at that first quarter, things were a little slow for that because we're working on a bunch of things, but I think you'll start to see that also start to accelerate, which, again, will add to that core sales number that we've been talking about most of today.

Larry Biegelsen:

Fred, have you disclosed the economics of NinePoint? I mean, it's \$200,000 times two. That's nice incremental revenue, but it's a distribution agreement I believe. So how are the economics for Merit on the NinePoint agreement?

Fred Lampropoulos:

Yes, Larry, we're making on the monitor - if we sell them at full retail, we're making about 40, 45 percent gross margin on that. When - now remember, we have an option to purchase that company. And we do that, then that margin would jump up to about 65 percent, so and that's in 18 months.

We wanted to go out and make sure that we could do what we thought we could do. It's still early, but that's playing out very nicely. And those economics will improve on the probes. We make more money than that, more margin than that, so we're up on the probes at somewhere in about the 65 percent range right now.

So as you add it all up, it's going to do just fine and it has even more opportunity down the road as we take a look at how the companies would then blend together.

Larry Biegelsen:

That's very helpful. So another question that was emailed to me that's not pipeline related is just on China. You have a pretty big presence in China. Just maybe if you could remind us as to how big that is and how your business there has been performing?

Fred Lampropoulos:

Yes. Listen, all of Southeast Asia has been the number one performing area in the company. If we take a look at Malaysia, Indonesia, Singapore, Thailand, Vietnam, all of that areas has performed very well for Merit. I'm going to say in the 20 percent plus range. Grew 31?

Raul Parra:

Yes, 31 percent is what it grew in Q1.

Fred Lampropoulos:

So 31 percent in the first quarter. China I think was at about 20 percent for the first quarter?

Raul Parra:

That one I don't have.

Fred Lampropoulos:

Yes, but anyway, I think it's meeting our expectations. It continues to grow very nicely, and we think there's - remember, there's - it's a two or three-year cycle to be able to take products in there and get them approved, so there's things that have been sitting out there that ever since we took control of that business, I think, six years ago on a direct basis, the pipeline is full of products that haven't been approved but are in the process.

If those roll out, we continue to believe that you'll continue to see even on higher numbers those kinds of growth rates in China. We have about 150 Chinese nationals on the ground, give or take. And finance, regulatory, we do our own logistics.

And if you're not going to ask this question, I'll ask it and answer it, and that is do we see anything in terms of trade or anything like that that would affect the business? And the answer is we don't see anything that would affect that. Now, I can't predict trade policy, but we just don't see anything there that seems to be slowing us down.

Larry Biegelsen:

That's very helpful. So before we wrap up here, I wanted to see if there were questions from people on the call. Operator, (Terry), could you please read the instructions for people to ask a question?

Operator:

At this time, if you would like to ask a question, simply press star then the number one on your telephone keypad. And we'll pause for just a moment to compile the Q&A roster.

Larry Biegelsen:

Operator?

Operator:

There seems to be no question at this time.

Larry Biegelsen: OK. Fred, so before your closing remarks, I know there - you're always excited about different products, and we went through a bunch here today. Are there any that we left out that you wanted to highlight on this call? New products?

Fred Lampropoulos: Yes, there's another one that was really hot over in at the PCR and one that is also very hot here. This is the distal radial device called the Distal RadialSync™ and Distal AccessSync™, and this is a product that nobody else has.

It's patent pending, it's approved in Europe and the United States, it's one in which you essentially - if you'll excuse the expression - access the snuff box. So if you hold your hand out and you'll recall in maybe some movies when we were kids or whatever watching somebody snuff up.

Well, that's an access area, and physicians argue that you get less spasm and that you have much quicker healing and mobility there. And it's being driven by Dr. Kiemeneij, who is the father of interventional radial procedures out of the Netherlands.

So we just came back from PCR. Our booth was swamped. It's a product that we sell for a fixed price of \$30. I can just tell you on the margin side of it, it's about 75 percent, maybe 80 percent margin, and it's just getting launched, and it goes along with both our sheaths like the IDEal Sheath, but this is essentially the closure device.

So I'm very, very excited about that, and then the Prelude Choice. You'll see a lot of these things, Larry, vascular access oriented. The Prelude Choice allows you to be able to go into a patient and do multiple balloons, kissing balloons, kissing wires, these sorts of things.

But when you do that traditionally, you get a lot of blood loss through the hemostatic valve. Merit's also the world leader on hemostatic valves, and now we have this device that allows you to put multiple devices into a single sheath without blood loss, and we're going to be introducing that in the next 30 days or so in the United States as well as in Europe.

In fact, in Canada, we've already received approval there. We also have the Fast Break™, which is a break away system for drainage catheters which get pulled out all the time. We also have the Lindsay catheter, which is a product called the CirQ™. It's a nephrostomy catheter. I could go on and on, Larry.

I mean, we're loaded. We always have been, and right behind these, there's 15 to 20 more out of 55 in process products in our R&D pipeline. So we're loaded up. The sales force is out there. We have the logistics. We have the points of sale. Business is exciting at Merit.

So I'll just close by saying it's business as usual and that usual is to deliver on our numbers, to be able to introduce new ideas, and to continue to build this company into a premiere healthcare company globally. So that's where we are. Raul, just before we sign off, anything you want to say?

Raul Parra: No, just I think you hit it. I agree with you. It's - yes, I'm just excited. There's a lot going on right now. We're on track, nothing's changed.

Fred Lampropoulos: Well good. All right. Thanks, Raul. OK, we'll turn it back to you, Larry.

Larry Biegelsen: Thanks, Fred. So that's a great place to wrap, and Fred, really appreciate you and Raul taking the time to do this call on short notice. I know how busy you've been the last 36 hours.

And everybody on the line, thank you for listening in and just want to wish everybody a good weekend and we'll talk again soon. Thank you, Fred. Thank you, Raul.

Fred Lampropoulos:

You're welcome.

Raul Parra:

Thank you.

Operator:

Ladies and gentlemen, this concludes today's conference. You all may now disconnect. Speakers, please standby.

END