Seeking Alpha

Transcripts | Healthcare

Abiomed, Inc. (ABMD) CEO Mike Minogue on Q2 2020 Results- Earnings Call Transcript

Oct. 31, 2019 1:01 PM ET8 comments | 5 Likes
by: SA Transcripts

FQ2: 10-31-19 Earnings Summary

Press Release SEC *10-Q* *Slides*

EPS of $1.0261 beats by $0.10 | Revenue of $204.97M (12.76% Y/Y) misses by $-1.48M

Earning Call Audio

Subscribers Only

00:00 -54:22

Abiomed, Inc. (NASDAQ:ABMD) Q2 2020 Earnings Conference Call October 31, 2019 8:00 AM ET

Company Participants

Ingrid Goldberg - Director of IR

Mike Minogue - Chairman, President and CEO

Todd Trapp - VP and CFO

Conference Call Participants

Raj Denhoy - Jefferies

Jayson Bedford - Raymond James

Chris Pasquale - Guggenheim

Danielle Antalffy - SVB Leerink

Margaret Kaczor - William Blair

David Lewis - Morgan Stanley

Matthew O'Brien - Piper Jaffray

Operator

Ladies and gentlemen, thank you for standing by and welcome to the Abiomed Second Quarter 2020 Earnings Conference Call. [Operator Instructions]

I would now like to hand the conference over to your speaker today, Ingrid Goldberg, Director of Investor Relations. Thank you. Please go ahead ma'am.

Ingrid Goldberg

Good morning and welcome to Abiomed's second quarter of fiscal 2020 earnings conference call. This is Ingrid Goldberg, Director of Investor Relations for Abiomed and I'm here with Mike Minogue Abiomed's, Chairman, President and Chief Executive Officer; and Todd Trapp Vice President and Chief Financial Officer.

The format for today's call will be as follows. First, Mike Minogue will discuss second quarter business and operational highlights and then Todd Trapp will review our financial results, which were outlined in today's press release. After that, we'll open the call to your questions. Before we begin, I would like to remind everyone that our presentation today includes forward-looking statements as it relates to discussion of our outlook. The company cautions investors that any forward-looking statements involve risks and uncertainties that are not guaranteed in the future.

Actual results may differ materially from those expressed or implied in forward-looking statements due to a variety of factors. These factors are described under the forward-looking statements in our earnings press release and in our most recent 10-K and 10-Q filed with the SEC. We do not undertake any obligation to update forward-looking statements.

With that let me turn our call to Abiomed's Chairman, President and Chief Executive Officer, Mike Minogue.

Mike Minogue

Thanks Ingrid. Good morning, everyone.

In the second quarter Abiomed delivered $205 million of revenue, up 13% year-over-year with an operating margin of 29.4% driven by continued strength in cardiogenic shock and overall growth in Germany and Japan. We executed on U.S. distribution initiatives. Our FDA post-approval studies and received FDA approval for Impella 5.5.

We are pleased that this quarter, we released data demonstrating our best clinical outcomes overall, for high-risk PCI, cardiogenic shock and right heart failure by utilizing our training and best practices.

In the United States while cardiogenic shock was solid with 22% growth high-risk PCI was light at 5% and we are now leveraging the PROTECT III data to drive utilization. Our innovation and our ability to improve clinical outcomes remains the driver for Impella adoption through a function of training, data, and time.

For today's call, we will provide an update on the following. First we will discuss the progress that we have made around U.S. commercial organization. Second, we will highlight positive new clinical data for high-risk PCI, cardiogenic shock and right heart failure. And third, we will discuss our recent FDA approval of the Impella 5.5 with SmartAssist and plans for the U.S. launch.

So I'll start with our U.S. commercial organization. On the last earnings call, we discussed the adjustments we are making to our U.S. distribution model and the creation of more regional leadership positions to go deeper with customer relationships and implement our strategy.

We are pleased to announce that with a healthy balance of internal promotions and external hiring, all zone General Managers and Regional Directors are now in place. We also have expanded roles for front-line sales and clinical managers and approximately 80% are now in place. These new field leaders will face the normal learning curve and be responsible for building active Impella programs, expanding users at existing sites and leveraging our hub-and-spoke network.

Turning to new clinical data for both high-risk PCI and cardiogenic shock multiple positive data sets were released at TCT, highlighting optimal treatment pathways with Impella that enable complete revascularization and improved patient outcomes.

On the first day of TCT Dr. Jeff Popma from Beth Israel discussed data from the PROTECT III study, which is our ongoing prospective single-arm FDA post-approval study for high-risk PCI.

PROTECT III followed the PROTECT II randomized controlled trial and included 898 patients enrolled at 45 U.S. sites. Comprising more complex and high-risk patients PROTECT III demonstrated improved outcomes and lower MACE at 90 days.

Patients in PROTECT III were statistically older at 71, more often women, received longer support and had more complex procedures with more vessels treated relative to PROTECT II. Yet the 90-day MACE rate in PROTECT III was lower with 17% MACE versus PROTECT II's control arm at 31% and the Impella 2.5 arm at 22%.

The PROTECT series is now the largest data set in the world for hemodynamic assisted high-risk PCI and spans 13 years of clinical practice. Replays of both the physician breakfast and annual TCT investor event are available on our website and at protectedpci.com. Our studies and real world experience continue to demonstrate that Impella assisted PCI can enable better outcomes for patients like Jim Houge.

Jim, a 67-year-old grandfather struggled with such extreme weakness and fatigue that he could barely walk from the parking lot to the field for his grandsons' little league games. He went to Spectrum Health and Grand Rapids, Michigan, where a diagnostic catheterization revealed severe blockages and poor heart function with an ejection fraction of 25%.

Jim was referred to the advanced heart failure clinic where he was identified by the heart team as an appropriate candidate for Protected PCI. Covered by CMS, Dr. David Wohns and Dr. Kevin Wolshlager implanted the Impella 2.5 Heart pump to support Jim's weak heart while they placed multiple stents.

Jim was discharged home one day later and within two months his heart function had returned to near normal with an EF of 55%. Today, Jim feels better than he has in years, attended our summer headquarters event at Abiomed, and now climbs to the top of the stands to cheer on his grandchildren. This is the true benefit of Protected PCI and complete revascularization.

Turning to cardiogenic shock updated data from the National cardiogenic shock Initiative was also presented at TCT, showing 250 consecutive patients from 49 sites demonstrating survival of 72% percent at discharge with 98% receiving or having native heart recovery. This compares to the historic rates of 50% survival without heart recovery as noted in the earnings slides posted today.

Based on learnings from the IQ database, NCSI, cardiogenic shock working group and the cVAD study, investigators are now instituting additional escalation protocols for left and right heart support that will be applied in the cath lab immediately after an Impella supported PCI.

This new escalation protocol allows physicians to identify and reduce future risk factors responsible for patient mortality within 72 hours of cardiogenic shock. We also recently announced with a press release that Impella RP post approval outcomes now match the pre-approval study for patients meeting the FDA study protocol.

Additionally this quarter Abiomed announced the procedural outcomes data on the first one thousand patients treated in Japan. Protocols in Japan were developed based on best practices learned from patients treated in the U.S. and Europe.

Today initial outcomes in Japan mimic that of top U.S. hospitals with 87% survival to Impella explant with 90% heart recovery in the AMI cardiogenic shock population. It is rewarding to see the profound impact of Impella on patient survival and heart recovery across the globe.

Moving to our product portfolio, we'd like to briefly touch on the significant milestones that we've achieved during the quarter. We continue the commercial launch of our SmartAssist platform, which improves ease of use for patient management and has weaning

algorithms to optimize survival and native heart recovery. Impella CP with SmartAssist is now being used in 328 of our 1401 CP sites. Additionally, we received FDA approval, PMA approval for Impella 5.5 with SmartAssist .

Impella 5.5 provides a minimally invasive forward flow fully unloading heart pump to treat shock patients with acute or chronic heart failure and fills a significant clinical gap for a growing heart failure population. Designed for heart surgeons the 5.5 is indicated for the treatment of all forms of cardiogenic shock and delivers peak flows greater than 6 liters per minute 45% shorter and thinner than the Impella 5.0, the 5.5 is approved for up to 14 days and 30 days in the U.S. and Europe, respectively.

We are excited to announce today that we've introduced the Impella 5.5 in the U.S. through a limited market release with over 10 patients treated in October at some of the best heart hospitals in the world, Cedar Sinai in LA, Cleveland Clinic and Hackensack Hospitals. I believe this product is a breakthrough for heart failure. In conclusion, we've made progress on our key initiatives, but we still have more work to do.

We are a stronger and more advanced company today than ever before. We have just announced our best clinical outcomes across all indications and our innovation continues to improve and expand to optimize native heart recovery with SmartAssist. The last six months have driven us to adapt to the external noise and focus on internal execution.

We will regain our momentum based on our flywheel of innovation and improving clinical outcomes. I personally have never been more confident that Impella will become the global standard of care for high-risk PCI, cardiogenic shock, STEMI and heart failure

I would like to thank our employees and customers who put patients first every day and our shareholders for their continued support.

I will now turn the call over to Todd.

Todd Trapp

Thanks, Mike, and good morning everyone.

In the quarter, we delivered revenue of $205 million, an increase of 13% on a reported basis versus a tough comparison of 37% growth in Q2 of last year. By region, U.S. revenue grew 9% to $172 million, driven by a 14% increase in patient utilization. In the quarter, we opened 62 sites compared to 135 last year, which impacted U.S. sales by $3 million or approximately 2 points of growth.

Outside the U.S. revenue totaled $33 million, up 43% on constant currency driven by continued strength in both Europe and Japan. In the U.S. at the end of our fiscal Q2, the Impella 2.5 and CP are in 1401 sites. The Impella 5.0 has been placed in 624 sites, while the RP is currently in 498 sites.

The number of site openings in Q2 was the same as Q1 as we continue to prioritize patient utilization and physician training at our existing sites. Q2 reorder performance was solid with a rate slightly above 100%. Average combined inventory at the hospitals for the Impella 2.5 and CP was approximately 4.5 units per site. Again consistent with the inventory levels we saw last quarter.

Outside the U.S., we continue to see strong growth in Impella adoption. In Q2 our European revenue increased 27% in local currency, due to higher patient utilization in Germany in both high-risk PCI and cardiogenic shock and further adoption in other countries like Switzerland, Austria and Italy. Additionally, the controlled rollout in Japan continues to gain traction as we generated $9.6 million of sales in the quarter due to new sites and patient utilization.

We opened 17 sites in Q2 and now are in approximately 100 hospitals with 135 hospitals currently approved by the government. It is worth noting that we do expect to open fewer sites in the second half of the year as the team closes out the post-approval study and prioritizes a broader CP launch, which will require additional training at existing sites.

Moving to key financial metrics. Gross margin was 83% in the quarter compared to 83.6% in the prior year. The year-over-year variance was driven by the SmartAssist launch and sales mix, which more than offset plant productivity. We introduced SmartAssist at approximately 180 sites in the quarter and we continue to receive very positive feedback from our customers on this new technology.

In the quarter, R&D expense totaled $24 million, an increase of 6% from the prior year, driven by our ongoing investments in clinical research, including STEMI and our post-approval studies in the U.S. and in Japan.

We also continue to fund our pipeline of products such as the expandable sheath and Impella ECP a true 9 French expandable pump ideal for high-risk PCI procedures. SG&A expense for the second quarter totaled $86 million, 9% higher versus prior year.

The lift was driven by the investment in our global commercial team, incremental physician training and marketing programs. We expect more investment in SG&A in the second half of the year as the commercial team continues to grow and we provide additional U.S. field training for all zones in early November.

In the quarter, operating income grew 20% to $60 million translating to an operating margin of 29.4%. Margins expanded 170 basis points due to higher volume, productivity, and timing related to some R&D spend, which shifted into the second half of the year. We delivered strong margins, while making what we believe are the necessary growth investments. This highlights the benefits and leverage of our business model.

GAAP net income for the quarter was $13 million or $0.28 per diluted share versus a $1.09 in Q2 of '19. The year-over-year variance was primarily driven by a mark-to-market adjustment on our Shockwave investment, which equated to an after-tax non-cash charge of $35 million or $0.75 per diluted share in the quarter.

Our tax rate for Q2 was 24.7% versus 3.3% in the prior year due to $13 million of excess tax benefits in last year's reported rate compared to only $500,000 in the current quarter. Excluding the impact from Shockwave in excess tax benefits, earnings per share grew 27% year-over-year.

We also had another strong quarter on cash as we generated $74 million of operating cash flow, an increase of 23% from the prior year. The balance sheet remains debt free and we ended the quarter with $551 million of cash and marketable securities.

In Q2, we bought back roughly $35 million of stock in the open market under our share repurchase program. However, our Number 1 capital deployment priority continues to be investment in our internal growth programs, which we believe will generate higher returns for the shareholders over time.

Based on our performance in the first half of the year and our projections for the next 6 months, we are maintaining our revenue guidance of 15% to 20%. That said, we acknowledge that the strategic actions we are implementing will take time and therefore are anticipating being towards the lower end of that range. Additionally, we are maintaining operating margin guidance of 28% to 30% for the fiscal year.

So in summary, we are confident in our overall strategy in both the technical and clinical advantages of Impella. There is no other product like Impella and no other FDA approvals for this patient population. We continue to see improved patient outcomes and build powerful clinical data like PROTECT III and NCSI.

With new products, new indications and new countries on the horizon along with our strong IP portfolio of over 715 patents and 620 pending, we have a path to sustainable growth. Coupled with our profitability and strong balance sheet, Abiomed is well positioned for today and the future.

Operator, please now open the line for questions.

Question-and-Answer Session

Operator

[Operator Instructions] Our first question comes from Raj Denhoy with Jefferies. Your line is now open.

Raj Denhoy

I wonder if, maybe I could just start with a point of clarification, you guys used to break out I think U.S. Impella sales separately out of a total U.S. number. I'm not sure if you gave that in the scripted remarks, I don't think it was in the press release. So can you give us the total U.S. Impella sales?

Mike Minogue

Sure, Raj. In the quarter Impella revenue was for the U.S. $164 million and service was about $7.8 million.

Raj Denhoy

I guess the other question is just on the outlook here because I guess you guys have kept guidance the same, the low end of the range of 15 to 20, but it still does imply a little bit of a pickup in the back half of the year. And when we think about sort of last couple of quarters and I guess we've sort of now come to maybe believe this narrative that is just sort of difficult to get additional doctors to use the technology, additional cardiologists particularly in PCI it seems with the 5% you reported this quarter. So I guess the question is around the confidence you have that what you're doing is going to accelerate that growth profile and whether it might be something a little more deep in terms of needing additional clinical data or other things to get more cardiologists onboard to using Impella?

Mike Minogue

So Raj, thanks the question. We had a stronger quarter for cardiogenic shock and in the past we have seen a seesaw affect, but not to this extreme. But what we've learned over the last two quarters and starting in March is that we need to have high-risk PCI programs at hospitals that are identifying and recruiting patients in the community that are - either have advanced coronary disease or turned down for surgery.

And as a result we've had individual users and champions that do multiple types of patients, but we haven't been able to get deep enough for the high-risk programs. So that when that person is either doing another procedure or is not in attendance, other physicians will either choose to treat the patient with Protected PCI or not turn the patient down or try to get in and out.

One of the benefits of watching the development of the heart team with TAVR is really looked at the lessons learned on how they've developed a program. So the physicians are deep in the hospital, there is a funnel and a system in place to identify back then all the

80-year olds roles that have aortic stenosis, and then get them referred into the different hospitals. In our case, we want to leverage the same approach. The majority of our patients are much younger.

So on average they are 69 years old, but we've really got to have a program versus individual physicians and there's two types of physicians. There are those physicians that are comfortable with TAVR. So the access closure is not an issue.

And then we do also acknowledge that there is a next wave of physicians that require a little more training and education around access and closure and there are those that are just dedicated to Protected PCI.

So those three buckets or where we're working there a little bit of different messaging, but the best thing we have right now that gives us this confidence as you mentioned, is the PROTECT III data. And I think the opportunity to PROTECT III is first to tell the story that in PROTECT II Impella lowered major adverse events.

Second is that Impella lowered MACE, it also these showed from discharge to 90 days, a statistical difference in those irreversible endpoints of death, stroke, MI and repeat procedures. And in PROTECT III, we continue to show that we can treat a sicker patient population many that have no other options and what we see is positive outcomes and most important these patients have an improvement in their EF which gives them that quality of life that they're entitled to and that should be the ultimate goal of Protected PCI.

Raj Denhoy

Maybe just as a follow-up. And I don't even know if there is an appropriate answer to this, but when you think about that group of cardiologists who maybe aren't as comfortable using the Impella, you know, this next wave of doctors, if that's right way to put it. Is there a way to characterize what is the major push back. Is it the difficulty in using the Impella access and closure as you've described it or is it something deeper maybe it's data or belief in the technology. Is there any way that you can maybe parse out what the biggest push backs are in additional adoption.

Mike Minogue

There is and I think there is no one-off or any one item, but, so for the doctors that are comfortable with TAVR and access of large bore, their focus is time management, prioritization and making sure they have PCI time as well as TAVR time. For the next wave of user that's doing PCI, they're not comfortable with access closure, the biggest push back for them is the fear of vascular complications and bleeding.

And the way we approach them is starting with education in the PROTECT II data set, so the FDA study Impella had numerically the same vascular complications as the intra-aortic balloon pump and both had zero percent damage to the aortic valve.

And so that's in an FDA audited dataset. So we start with the training, what we've also demonstrated and continue to publish it from the original PROTECT II to now, we've been further able to reduce bleeding. And if you look at PROTECT II, the initial bleeding rates in balloon pumps studies has been 4% to 14% whether it's elective or high-risk PCI.

And what's happened with the Impella is it in 2008 we started at 11% for PROTECT II, but by the end of the PROTECT II study, we were in the 7% range. With the STEMI DTU recent study, so this is a population of patients that are having a heart attack and they're being rushed, we had a 6%. But we really believe that on the elective cases with training and education, we can be at or below what the intra-aortic balloon pump was in the PROTECT II study in 2008.

So as we start to train and go through access closure, different techniques, and we have an online tutorial manual that's on the Interventional Cardiology Society website called SCAI, we're now getting into looking at the risk of bleeding and or the concern or fear of it versus the benefits of being able to do a complete revascularization.

And we feel very confident that the results and education and training is really going to end up with outcomes, similar to the way TAVR has brought down their bleeding outcomes. Our difference is, we have a 9 French catheter in it and a 14 French motor head for the CP, whereas the TAVR is started at 21 and is 14 French all the way through.

So we think we're going to get as good or better. It gets a little more complicated when patients go to the ICU and so that's the other part of our training, but in the end, we think we can train that fear away. We can educate that fear away.

And long term, we plan to innovate that away with the expandable sheath and the Impella ECP. But one final point on the challenges of going through this is the benefit of Impella is it's a unique one of a kind technology that's supported by our 600-plus patents and 600-plus patents pending.

We do have an exclusive and first of its kind indication for high-risk PCI. So that's the benefit, the negative is we're the only ones truly creating the Protected PCI market, truly talking about the benefits of complete revascularization for a population that probably half do not get to the cath lab today.

Whereas in shock, it's more intuitive and there's many pharma and med-tech companies around both STEMI and cardiogenic shock, whereas Protected PCI, we have to create a TAVR like market individually as a single company.

Operator

And our next question comes from Jayson Bedford with Raymond James. Your line is now open.

Jayson Bedford

Just a few quick questions here. I wanted to ask about pricing and I bring it out just from the standpoint of, it looked like usage growth of 14%, which was quite strong and I realize there's a comp issue here with fewer new hospitals added, but I'm just trying to put that 14% with what looks like about 8% U.S. Impella growth.

Todd Trapp

Jason, this is Todd. I'll take that one. So as I mentioned in my prepared remarks, we are opening less sites and we opened up 73 fewer sites, which again impacted sales by about $3 million or 2% versus prior year. The other headwind that we had in the quarter was slightly a lower reorder rate versus prior year.

So in Q2 of '19, we had a reorder rate of about 103%. In this quarter, it was still a healthy 101% and where we have seen slightly lower reorder rate was really in the Impella 2.5 and that makes sense, kind of given where we are transitioning to CP with SmartAssist at

some of these sites. So again, as an organization, I mean, we're focused on that patient utilization number, that 14% in the quarter. Again, which was about 1 point ahead of where we were last quarter.

Jayson Bedford

And maybe a broader question, has there been any change in the breadth of growth in the U.S. More specifically, large versus small centers, new versus more established centers and have you seen an impact from the broader sales distribution?

Mike Minogue

Jason, one of the things we've seen is that we do have some centers that have big programs and they do - they have high demand focus and they do, they do a lot of everything. So whether it's high-risk PCI or structural heart they move back and forth.

And so for an example, after we had an Expanded FDA label on high-risk PCI we did see a bit of a bolus of high-risk PCI and TAVR's seen a little bit of a bolus the last two quarters on the anticipated approval and then approval of the low-risk patients.

And what we hear is the physicians want to capture kind of the bolus of patients in their community ahead of other hospitals, that would also apply to mitral valve enlargement. So what we need to do is identify whether they're big or small. We need to train a deeper bench of physicians that essentially prioritize and specialize in high-risk PCI programs alone and they're out there.

So for example, some other - some of these other physicians that are in that bench, they want to get trained, they want to get comfortable with the access and the closure and they are not necessarily going to be TAVR operators and their core skill set is really around PCI.

And as we're identifying those we're linking that to a current study we have called Restore EF, and that's a single-arm study that's underway and it's with expert PCI physicians and what we want to do is continue to validate these best practices in the real world and again show benefits of improvement in EF which has been demonstrated in all of our FDA studies.

To our knowledge, if you look at stenting or angioplasty studies with the FDA, you don't see a permanent improvement in ejection fraction or the quality of life for these patients. Historically, you do see symptomatic relief, relief of pain in the chest, but with an Impella supported PCI to be able to achieve an improvement in EF gives that quality of life that these patients are looking for and it's why open heart surgery with CABG has been the gold standard, because you do establish complete revasc and these patients also see an improvement in EF.

So as we continue to work with these Restore EF centers, these physicians that are utilizing the best practices, they are almost an analogy or they are much like the NCSI investigators that are utilizing the best practices for cardiogenic shock and we can continue to leverage the Restore EF physicians to put out case studies and share their best practices for other physicians that want to get more hands on and more online training.

Operator

Our next question comes from Chris Pasquale with Guggenheim. Your line is now open.

Chris Pasquale

Mike. I'm curious whether at this point, you have any sense of the impact SmartAssist is having on the business and if you look at the sites where it's being introduced is it impacting utilization at those sites. It's a tool that I would think would lead to more ubiquitous use of Impella at sites that are adopting it. I'm just curious if you're seeing any of that?

Mike Minogue

So, Chris there is an impact. So number one, it is positive, the ease of use is there, the physicians are - they now get information on weaning and the ICU nurses, as well as the heart failure community in the ICU gets to really understand what's happening to a patient. And that's a positive. We do see a somewhat of an increase in utilization with it. It's too soon to tell if it's sustainable, but part of it is when they get a new technology they were going to our top sites first, or they were already some of our bigger growers.

Now there is a downside to it which is maybe that it does require a lot of time and energy and coordination, because we've got to take the consoles back, then we've got to train the techs, we've got to train the ICU. It is a bit of a distraction and it's worth it because we believe we're going to get better outcomes and more adoption, but it has been a bit of prioritization that we have to manage as a company.

And then the second important on the complexity is this hub-and-spoke network that we continue to try to maintain and leverage. So for example if patients are out in the spoke hospitals and the patient is then sent to the hub, we have to make sure that both sides have the new SmartAssist, the new consoles, and are trained appropriately.

So that's been a bit of a challenge for us. But that's also why the new heads, the - more management in the field and what I'd call right-sizing our distribution allows us to kind of anticipate that and manage it a little better.

Chris Pasquale

And then just two updates on the clinical pipeline front, if you could give us any update on where the STEMI trial stands, how that's going. If you think the original timeline there is still reasonable. And just curious, ECP has been sort of just over the horizon for a while now. When you think you'll get into first in man there? Thank you.

Mike Minogue

Sure. So two things, we anticipate our first in man STEMI patient, what I would say is this month, in the next probably three weeks, we've had a lot of great progress. We've got a good executive committee of physicians, there is tremendous excitement and we'll give further updates on that in the future. That would be one of the subjects of our upcoming Investor Day that we'll have likely in April, May, which - we'll announce that in the future.

And on ECP, we feel confident, we're making good progress there and we expect to have our first in man by the end of our fiscal year in the March timeframe. I'd reiterate that is a game-changing product, because it's a 9 French all the way through and it's ideal for high-

risk PCI and as all of you have surveyed many times many customers, you know, that people are a little intimidated with the larger motor head, even though the Impella has a 9 French catheter.

But when you talk to physicians about a 9 French all the way through pump, you'll hear immediate positive responses, talk about adoption, and really that's the second half of the market that we'll get to as well.

Operator

Our next question comes from Danielle Antalffy with SVB Leerink. Your line is now open.

Danielle Antalffy

Mike just wanted to follow up on the SmartAssist contribution and just curious how we should be thinking about that as we look at our models going forward? I mean it sounds like that will be a growing contributor. I assume that would have been in the service other revenue now included in Impella. So just trying to think about how to think of those two separate lines as we go forward.

Mike Minogue

Sure, Danielle, SmartAssist is not being charged for, our inherent belief is it will allow us to get better outcomes, it will make the management of the patient easier, and that will help us drive more adoption. Clinically why it's so important is because when a patient is on SmartAssist, we're able to look at the pressure in their left ventricle, we're able to understand and in the future potentially predict some right heart failure.

So we're going to integrate some of those algorithms. And essentially it gives the physicians for the first time real-time information about managing a patient. So although we're not in the majority of all our sites yet, we think that as that rolls out it has an overall positive impact. But there is some hiccups and there is some challenges with rolling this out while we're focusing on growth, but we're going to continue to try to take big chunks out of it each quarter.

Danielle Antalffy

Understood, okay. So it's not actually, you're not generating revenue from that. That's helpful. And then one really quick question, well actually might not be so quick, but just curious how the conversations you're having with the sort of next wave of the doctors that are skeptical about the data, how is that conversation going. How much do you need to show them to bring them over the fence and get them to be a believer? Is it a matter of just like, hey we'll hold your hand while you try this and getting them comfortable with the device itself and that gets them more comfortable with data.

Can you talk a little bit about how those dynamics are working as you approach these sort of this next wave of physicians that have been using it, but not as much as they could or should? Thanks so much.

Mike Minogue

Sure. So I think the first part of the conversation, talks about the patient population that's in the cath lab today and how they could potentially do a better procedure. And the second part of the conversation is the patients that are out there that they don't get that they could potentially treat in the cath lab, the surgical turndown patients.

So for the first part about the quality metrics and how they can improve is we put some information out in collaboration with some of the different groups and research firms that show some of these areas improvements. So for example, for all of PCI for patients that get triple vessel disease, only 55% get complete revasc, that means 45% of the patients get incomplete revascularization.

And if you get incomplete revascularization you actually don't get the benefit of the PCI, you likely won't see an improvement in their EF and with complete revascularization, and this is published and well accepted in med analysis, you see a 30% to 50% reduction in MACE.

In the PROTECT II with Dr. Popma, we recently published and released the data is showing the exactly that, that if you've got complete revasc, you had a much better outcome rather than the control arm.

So that's the number one goal of doing high-risk PCI. The second is about 14% of patients in the U.S. are staged. And some of them are staged for the right reasons, some of them though they are staging them because they are worried about either too much contrast or the patient's stability on the cath lab table and unfortunately many of this staged patients don't come back for a second procedure. So the goal of Restore EF, of our top physicians utilizing the best practices, is they are really focused now on doing complete revascularization in a single setting.

Now you have the real concern about acute kidney injury, which is a significant problem for PCI, TAVR and CABG, and it's about 7% to 10% of all these patients or for PCI get AKI but for the high-risk PCI population is around 50%. So we've got very compelling information and data and there is a sub-study in the PROTECT III data further demonstrating the ability of Impella to reduce AKI for these patients.

And then last, we talk about and this is clearly demonstrated in the PROTECT II study is the quality metric of readmissions and in all PCI cases, you'll see anywhere from 12% readmission rate for PCI at 30 days and up to 25% at six months. So there is tremendous room for improvement for high-risk PCI. And so what we're trying to do with physicians is look at their benchmark data at their centers and look at ways that we can improve that.

And then on the second population that's out there is a tremendous number of patients that have advanced coronary disease. There was an article or a publication in JAMA yesterday and there was an article in the Wall Street Journal demonstrating that for the first time they're acknowledging that from 2011 to 2017, there is an increase in heart failure, there is an increase in mortality in heart failure and there was an increase in mortality in heart for people that are aged 45 to 65.

So this is, that means the curve is now sloping back up and heart failure remains the number one killer and if we're going to treat these patients, we believe you treat them by doing complete revascularization with Protected PCI or you try to keep them alive and recover their heart muscle if they're in cardiogenic shock and in the case of heart failure, with tools like the Impella 5.5 or the study like the STEMI, we think we can prevent people from going into heart failure in the future. So that's just to the conversation.

Q

Operator

And our next question comes from Margaret Kaczor with William Blair. Your line is now open.

Margaret Kaczor

And the first one from me and it's kind of got two pieces to it. First, it sounds like you're really identifying the use in the market for Protected PCI and you're trying to address them but granted they might take a little bit of time for those investments come to fruition. So maybe the first question is does guidance assume that high-risk PCI growth improves this year and can it return to that double-digit growth.

And then second, from an operational level, how are you incentivizing the organization to double down on trading for that second category of docs that you mentioned, when it seems like shock is actually reaccelerating pretty nicely right now. Does that group maybe require more time or is it just education and training dollars on your part?

Mike Minogue

Margaret, the inherent belief about the growth returning in high-risk PCI is purely based on the clinical need and the massive population, there is at least 121,000 high-risk PCI patients today that have an opportunity to get better care, get treated with the cath lab with Impella.

And the indication itself for high-risk PCI is a first of its kind and it also is based on our FDA approval and our technology is the only FDA-approved devise for high-risk PCI. And then there is an additional 300,000 plus patients that are either turned down for surgery or don't want to have surgery and can get a benefit of Protected PCI.

So those numbers are very large, and if you look at any data sets or you talk to any physicians there is general acceptance that coronary disease is still the number one killer. Even in TAVR, there's papers demonstrating that if you do it - if you do TAVR on a patient that - but if you leave ischemic disease or blocked coronary arteries, you also have a higher mortality at one year versus if you treat that patient and you treat them to get complete revasc.

And then the second component is just going through and looking at the quality metrics of readmissions. What's unique about the PROTECT II study was that's the first time we looked at outcomes at 90 days and not at discharge and these physicians want better outcomes for their patients. The referring physicians want better outcomes. And so looking at the success rate of getting off the table is really not the end goal. The end goal is at 90 days later that patient's home and feeling better after having a minimally invasive procedure to address their heart failure symptoms.

So I think organizationally that - those are the things we're going to lead with, the training data in time, and then from an incentive or a program or access that next wave, we are stepping up our training and education will be doing more online, and we'll be doing more tutorials and proctoring in the future at sites that have dedicated programs.

Margaret Kaczor

And then in terms of the expandable sheath. Can you guys give us an update on timing and the regulatory process on that. And then when that does launch, is it going to take a little bit of time to train folks are pretty straightforward? Thank you.

Mike Minogue

We've done 16 patients outside the U.S., we're working on that timeline right now, but to remind everyone, it's a 510 (k). So the regulatory process is a lot shorter and it's going to be utilized with the already FDA, PMA approved device and we're planning to bring into the market in the optimal time frame to ensure that we get great outcomes.

Operator

And our next question comes from David Lewis with Morgan Stanley. Your line is now open.

David Lewis

Just two for me like. Mike appreciate the - U.S. revenue growth was slower than patient growth and I know, I appreciate your commentary around the drivers there, but do want to follow up on the commentary about lower reorder rate. Can you kind of walk through in the

U.S., what are some of those factors that are impacting lower reorder rate and then I had a quick product follow up.

Todd Trapp

Yes, David, this is Todd here, thanks for the question. I think when it's all said and done if I look at the products, the reorder rate by products, I mean the one that jumps out is really the 2.5 and that's slightly above - below 100% as we stand here today, and again the big driver of that is just when we're rolling out SmartAssist at some of these sites, I mean they're just - they're waiting the CP, it's just a much better pump. So we're seeing a little bit of a lower reorder rate on the 2.5. Again, it's still a healthy overall over 100%. So some of it is just a little bit of timing at this point in time.

David Lewis

But your comfort with the level of inventory that's in the U.S. channel right now?

Todd Trapp

Yes.

David Lewis

And then Mike post TCT and frankly for the last six months, you've been very focused on reducing barriers to access and reducing bleeding and thanks for the ECP update, you've also talked continuously about the expandable sheath and I kind of thought that was a product that comes out before the ECP. What is the timeline for getting the expandable sheath into the U.S. market? Thanks so much.

Mike Minogue

Today with the expandable sheath is a 510 (k). We've done, we've done 16 patients. I'm not - I haven't given the exact time, it's going to be as soon as possible, and it will be out before the ECP in the U.S., and it will be first in Europe and then we'll come to the States.

It's likely not as challenging for the Impella 2.5, we just want to make sure we get it right for the Impella CP because we want people to have the option, also to close the CP at a 9 French - with a 9 French device. So that's our goal, that's what we're working on and we feel relatively confident that that will be on the market as soon as possible.

David Lewis

And this next year, is fiscal '20, a possibility for the U.S. for that product?

Mike Minogue

Yes, the goal is to have something in Europe next year for sure. And the goal is to have a portion of a limited rollout, limited release in the end of next fiscal year in the U.S.

Operator

And our next question comes from Matthew O'Brien with Piper Jaffray. Your line is now open.

Matthew O'Brien

You know the quarter I think it was pretty good versus what - I think some people were thinking about versus, you know, what - I think some people were thinking about. You reiterating guidance, we kind of push and everybody to the low end of the range I think is also going to be welcomed by investors but it does - it is kind of a steep back half ramp sequentially. So I would love it if you could just deconstruct a little bit and you might be met with a little bit of skepticism just because it is so big sequentially.

The last time you did this kind of sequential growth in the back half of the year was coming off of the National CSI registry out at TCT and the call to action. So you seen about $20 million sequential increase Q3-Q4 just for easy math and that's what we saw back in fiscal '18. So how do people get comfort that you're going to be able to deliver that type of performance, is it PROTECT III, is it 5.5, RP getting better at the same time as you're still building out the sales force in that group.

Todd Trapp

So thanks, Matt. Good question. This is Todd. I'll jump in. So again our range does imply some improvement in the second half of the year. And first, we have, I would say that normal seasonality where we've done typically 54%, 55% of the year in the second half and then as we mentioned on the call, we had some new product launches and investments that should drive some lift in the second half. So SmartAssist, which is the largest product launch yet for Abiomed.

We did receive the FDA PMA approval in September for the 5.5. So we have that limited market release in the second half. So we expect to see some lift from some of these new product introductions and then quite frankly some of the investments that we're making in the U.S. distribution structure around field leadership team should start yielding benefits in Q4 and beyond.

So one of the things to just mention is we do have some easier comps. I mean last year in the first half, we grew 37% and in the second half it was 24% and really the comps get easier in the fourth quarter. So I think it's a combination of all those things where we firmly believe that why we guided towards maintaining the 15% to 20% but guided towards the low end of the range.

Matthew O'Brien

And then the follow-up question would be just in Japan. You've got the first thousand patients treated with Impella. I'd love to hear just a little bit about - the results there were really good. You know the performance in Japan has been really good. But what can that data do for you to just continue to see really strong performance out of Japan for the next maybe couple of years?

Mike Minogue

Thanks for the question, Matt. We've been very focused in Japan to think about this for the next 10 plus years. Japan does not necessarily utilize heart transplants. Culturally they're opposed to sternotomies and heart transplant concept, they do them but an extremely small number. And the country of Japan matches our focus around recovering hearts and saving lives.

So as we've rolled out and really focused on the training and the execution and utilizing the best practices from NCSI and in Europe, we're very pleased to see that for AMI cardiogenic shock the survival to explant matches our top sites in the U.S. and most important, the majority of all these patients, more than 90% are able to go home with their native heart.

So as we establish heart recovery as the standard of care in Japan with the CP now being launched, we really have the ability to transform the focus. In Japan the intra-aortic balloon pump is also a Class III indication, which means it's harmful and not recommended to be used.

So they've already implemented and analyzed the data that's out there for the last 40 years. And so they are moving forward with Impella and we're very pleased. And what it means is that the second largest market in medtech in the world will become our second largest medtech market and it will likely also help us drive more success throughout Asia.

So I do, I'm really proud of what that team has done, we've got some great champions with the physicians there and we expect to see a plethora of clinical publications and further validation of heart recovery.

Operator

I'm not showing any further questions at this time, I would now like to turn the call back over to Michael Minogue for any closing remarks.

Mike Minogue

Great, thanks everyone for your time today, we will be available to talk. But just to close out, we feel good about the positive new clinical data. Our new innovation, our progress on the U.S. distribution, our global growth in shock, as well as our growth in Europe and Japan, we'll continue to focus on adapting and executing and we appreciate your support. Have a great day.

Operator

Ladies and gentlemen, this concludes today's conference call. Thank you for participating. You may now disconnect.