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CORPORATE PARTICIPANTS

Andrew J. Greenfield *Abiomed, Inc. - President*

Ashley A. McEvoy *Johnson & Johnson - Executive VP & Worldwide Chairman of MedTech*

Charles A. Simonton *Abiomed, Inc. - Executive VP & Chief Medical Officer*

Michael Bodner *Abiomed, Inc. - Global Leader Heart Recovery*

CONFERENCE CALL PARTICIPANTS

Lawrence H. Biegelsen *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

PRESENTATION

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

All right. Good morning. I'm Larry Biegelsen, the medical device analyst at Wells Fargo, and it's my pleasure to host this session with the management team from J&J. With us, we have Ashley McEvoy, Executive Vice President and Worldwide Chairman of Medical Devices, as well as several members from the Abiomed team: Michael Bodner, Global Head of Heart Recovery; Andrew Greenfield, Worldwide President; and Chuck Simonton, Chief Medical Officer and Global VP of Clinical and Medical Affairs.

We're going to start with Abiomed because Ashley is running a few minutes late, but I've been told she will be here momentarily. So gentlemen, thanks so much for being here.

Michael Bodner - *Abiomed, Inc. - Global Leader Heart Recovery*

Thank you for having us.

QUESTIONS AND ANSWERS

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

So Abiomed has grown over 20% since J&J acquired it. What's driving the strong growth?

Andrew J. Greenfield - *Abiomed, Inc. - President*

Maybe, Larry, I'll start a little bit. There may be some folks in the room who aren't as familiar with us, but we have, as a company, a long history of double-digit growth. And so we have a structure of a growth company that whatever actions we take or influences from the macro environment are into a company that is built for growth in that environment that, again, has been pretty consistent for a long time.

I think the other area for the technologies that we deal with, they are actually not a single technology in a single place. It exists in the catheterization lab, with interventional cardiologists, the operating room with surgeons, which is one of our fastest growing areas as well as the ICU. So whatever the influences are that we can control, it has a broader impact across the hospital.

And I think the last piece is just the innovation and the beginning now of the influence of many benefits from Johnson & Johnson that we've started to receive, and that's kind of feeding into that growth engine. In particular, our strong brands. We hire a lot of nurses into our clinical infrastructure, and Johnson & Johnson has a really strong brand, so our recruiting is improving.

As a smaller growth company, we always had open positions somewhere. We've been able to fill a lot of those leadership roles. And I think the innovation, as I said, is now able to get impacted faster as we're growing this business. And maybe Michael, you can comment. You've been a great asset for us in kind of bringing all of those resources into this growth engine.

Michael Bodner - *Abiomed, Inc. - Global Leader Heart Recovery*

Yes. Thank you, Andrew. I'll build on those comments, maybe share some of the strategic and value-creating rationale. As you know, Abiomed is Johnson & Johnson's entry into heart failure. And as many of you know, heart failures, pump failure is the end stage for all cardiovascular disease.

When we look at the opportunities in front of us, the patients that we're treating today across high-risk PCI and cardiogenic shock are vast, but that patient population is going to open up even further as we get into other manifestations of the disease like acutely decompensating heart failure, chronic heart failure and adjacencies like respiratory failure.

As we think about this though, it's important to note that Abiomed has a 15-year head start in an extremely complex category. Pumping blood at high flow rates is extremely challenging without damaging it, and Abiomed has the inside track on understanding exactly how these pumps are being used and how that clinical workflow is best managed to get the best outcomes for those patients.

Now this step that we took with Abiomed really reengages Johnson & Johnson for the first time in a long time with the interventional cardiology call point, which is the device epicenter or innovation epicenter for all cardiovascular devices. Now as Andrew mentioned, as we look at value creation, we're looking at Abiomed docking into that vast geographical infrastructure of Johnson & Johnson.

So it's important to note that pre-acquisition, the mix of revenue for Abiomed was about 80% U.S., 20% outside the United States. But as you know, Johnson & Johnson is in over 130 countries around the world with resources in market for regulatory affairs, health economics, market development and very deep expertise and clinical acumen as well as the commercial footprint. So we're docking into that right now.

We're also investing heavily in the commercial footprint in the United States, particularly in Germany and in Japan on the clinical front so that we can train more physicians on how best to use the Impella pumps.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

That's helpful. You guys are running a lot of important clinical trials. Can you just remind us of the status there? I mean, PROTECT IV, RECOVER IV, STEMI DTU, I think those are the 3 big ones.

Charles A. Simonton - *Abiomed, Inc. - Executive VP & Chief Medical Officer*

Yes, maybe I'll take that one. So I oversee these trials, and they actually are a big reason why I'm at Abiomed now, is to run these trials. It's an incredible opportunity for a company -- to be in a company that's investing at the level this company is investing in Class I evidence for products that are, for the most part, already FDA-approved, CE marked and have regulatory approvals around the world.

It's exciting for clinicians to be engaged in studies like PROTECT IV. So PROTECT IV is in high-risk PCI. It's a randomized trial comparing Impella-supported high-risk coronary intervention to doing any other strategy you want to do other than Impella. Doesn't have to be a balloon pump. Could be medications, any other support strategy. 1,252 patients is the goal for enrollment.

We're about 60% of the way there and anticipate that sometime in 2024, we'll complete enrollment, depending on the adaptive design. These modern day trials use adaptive designs and sometimes the independent committee comes back and says you need to enroll a few more patients. So that might happen, but we anticipate next year completing enrollment.

It's got the interventional cardiology community, which are my buddies, my colleagues out there really pumped up because this is -- and a lot of respect to the company because this puts the big question out there in a big enough trial that's powered to answer the question of superiority. And superiority means -- you want to prove superiority because that's what moves patient care forward. So that's PROTECT IV. The other one you mentioned, STEMI DTU...

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

Sorry, when will we see the data? You said you finish enrolling in '24. The data we would see...

Charles A. Simonton - *Abiomed, Inc. - Executive VP & Chief Medical Officer*

So it's a minimum of 1-year follow-up in all patients, so you get into '25. So sometime in 2025 would be anticipated. And then for STEMI DTU, that's actually a study that's not an on-label study. It's to add to the label for Impella because Impella for patients who have heart attacks but they have to be in shock to be on label.

This is nonshock heart attack patients, anterior wall, either getting Impella for 30 minutes of supporting the heart before you open the blocked artery versus the other control arm, which is doing what everybody does today, which is immediate balloon angioplasty, okay? And what the study is intended to show is that by unloading with Impella during the procedure prior to opening the artery, you can reduce the size of the heart attack.

Ashley A. McEvoy - *Johnson & Johnson - Executive VP & Worldwide Chairman of MedTech*

Hello.

Charles A. Simonton - *Abiomed, Inc. - Executive VP & Chief Medical Officer*

Hi, Ashley. So we're about 40% to 45% enrolled in STEMI DTU at this point. We've started it before COVID. COVID really had an impact on all these trials, but now we ramped backed up, things are going well. The sites are hugely excited in it. We've actually put more field clinical specialists in the field to work on enrollment. And so we anticipate that it's on track to finish enrollment within about the next 12 to 18 months, something like that.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

And the last one, RECOVER IV?

Charles A. Simonton - *Abiomed, Inc. - Executive VP & Chief Medical Officer*

And then RECOVER IV is just getting started. This is one the FDA is really interested in having done. As you know, in acute MI cardiogenic shock, no device has been shown to be superior to just giving pressers, giving medications to keep patients going who come in with low blood pressure and shock on a big heart attack.

As recent as ESC, as you know just recently in Amsterdam 2 weeks ago, there was a big randomized trial looking at ECMO, which is another way to support perfusion of the body through cannulas. Arterial and venous cannulas showed no benefit in these patients. But we've got tremendous experience now.

I'm really excited about this one, because the way Impella impacts a patient who's in shock from a heart attack is it actually unloads the heart, which ECMO doesn't do. It's the only one that actually does that to this degree.

And so we'll be testing that strategy versus not using Impella in these patients in the U.S., including exemption from informed consent, which is something new for the United States. And it will be in over 500 patients. We're just starting. The goal this year is to get sites up and get enrollment just initiated with a few patients this year.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

That's helpful. And so at ESC, we also heard that the DanGer study, another cardiogenic shock trial in Europe, just completed, and we should expect the results shortly. How is that similar or different from RECOVER IV?

Charles A. Simonton - *Abiomed, Inc. - Executive VP & Chief Medical Officer*

Really good question. So that study, the first patient was enrolled in February 2013. So it's been going for 10 years. And it's the only randomized trial right now with Impella versus a non-Impella strategy. And so it's going to be very valuable. It's going to inform us on RECOVER IV and may help us with the design of RECOVER IV going forward to amend the protocol how we may see fit.

But the challenge with DanGer shock, which is fully enrolled, as you know, it's a 6-month follow-up period. So all the patients will be followed up by December, and then there will be a public presentation at a major meeting next year. What we're going to be interested to see in that study is best practices for how to use Impella in these patients have really changed over the last 10 years.

And the registries that have developed best practices really didn't refine that until the last 4, 5 years. So we're going to be very interested to see how the patients did later in the phase of the study as opposed to earlier, and we'll be interested to see how that study results come out next year.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

That's helpful. When do you expect competition? And what are you guys doing to stay ahead of it?

Andrew J. Greenfield - *Abiomed, Inc. - President*

Yes, maybe I'll take that one. I think from a competitive standpoint, our biggest competition remains the decision-making in the transition to a standard of care within the cath lab ICU and operating room that I mentioned. And that's really where our focus is going to be for the next several years.

And that's an adoption question. It's about comfort with the technology, and yes, a lot of innovation. Most recently, our surgical product called the Impella 5.5. It's a full flow catheter-based technology that ends up going in an insertion up here, which what that means for a patient is you can get up and walk around with an Impella for longer-term care.

And so that type of innovation is going to continue to increase adoption and that's where almost all of our focus is. You may ask about things that look similar to an Impella from around the globe, and that's been -- I've been in the company 18 years, and we've always had some element of that development.

And there is a lot of innovation that's required. You have to continue to invest in the studies. Obviously, intellectual property. We're very strong in our IP. And it's a big investment to build the clinical resources that are required to treat. These are the sickest patients in the cardiovascular space.

So we believe in the end, I personally think additional innovation is great. If there's new value for patients, this is generally a very untapped patient population, and the more technology that can help gain access to it can help all of us.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

That's great. So Ashley, welcome.

Ashley A. McEvoy - *Johnson & Johnson - Executive VP & Worldwide Chairman of MedTech*

Thank you, Larry. Good to be here, everyone.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

Let's transition to some big picture topics, and if we have time at the end, we'll come back to Abiomed. I still have more Abiomed questions, but I want to make sure...

Ashley A. McEvoy - *Johnson & Johnson - Executive VP & Worldwide Chairman of MedTech*

Thank you, Larry. I think you just have to turn on. Maybe -- good. On.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

I think we can hear you. Good. So Ashley, when Joaquin took over as CEO, he talked about building a best-in-class med tech business. Where are you in that process and what still needs to be done?

Ashley A. McEvoy - *Johnson & Johnson - Executive VP & Worldwide Chairman of MedTech*

Thank you, Larry. First of all, I just want to acknowledge my Abiomed team over here. It's great. This is home court for them in Boston and as well as Aachen. Well, I would say first and foremost, it's about patient care. MedTech, we're all about driving impact to the world. And we serve over 350 million patients around the world. You're going to hear from our Abiomed colleagues serving over 250,000 patients, and that's really what drives us every day.

We get after the 5 leading causes of mortality as the new J&J, both in our pharmaceutical industry and med tech. So we -- that is cardiovascular health, oncology, respiratory health, stroke and trauma. We have 12 $1 billion platforms, and 11 out of those 12, we're #1 or #2. What we've been really getting after is performance, Larry, and I'm really pleased to see the J&J MedTech team take it from low single-digit growth.

You saw us in the middle of the year posting performance of up 8.5% for the first half of 2023 on a soon-to-be $30 billion base for 2023. You're going to hear us talk about in our December Analyst Day, we welcome everybody to come. It's been a long time, 5 years, since we've been able to tell our MedTech story live. And what we really compare ourselves is how are we doing versus our peer set.

And you're going to see in 2023 that it's going to be the third consecutive year that J&J MedTech is performing in line with the competitive composite from a revenue point of view, despite the majority of our composite being half our size. And we've outperformed the composite for the past 2 years in operating profit, and our net income margin is above the competitive composite.

So what's enabled that, Larry, is really what -- portfolio shifting. Five years ago, we had about 14% of our portfolio was in end state markets that grew north of 5%. We're going to exit this year with 50% of our portfolio in end state markets growing. Abiomed happens to be one of them.

And then importantly, innovation. Five years ago, we had a value of our pipeline of around $5 billion. Right now, the value of our pipeline is around $12 billion. So we're not done but we really are pleased to see us with the foothold in heart recovery. You're going to hear from the team today.

On the tip of the pyramid, I would say, in health care, is really quite frankly saving people's lives and really, they are the world leader in heart recovery. I'm very pleased to talk about our small but mighty soon-to-be $4.5 billion business in Biosense Webster, where we lead the world in AFib and managing AFib and really all things robotics, which we'll talk about.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

Great. That's super helpful. So on the second quarter earnings call, obviously, Joe's comments about having a voracious appetite for M&A got people's attention, and I think it was intended. I've told people when you have a voracious appetite, I don't think you have a snack. When we've listened to Joaquin's last 2 public comments, I've heard him lead with ophthalmology and cardiovascular. So what can you add to Joaquin and Joe's comments about deal size and strategic goals?

Ashley A. McEvoy - *Johnson & Johnson - Executive VP & Worldwide Chairman of MedTech*

I mean, if you look at history, 90% of our deals are less than $1 billion. So that's -- if you're looking at the data, that's what I would tell you. A lot of that portfolio reshaping got us stronger footholds in robotics. It got us -- we deployed over $22 billion of capital over the past 5 years. We sold about -- we received about $5 billion through divestitures.

Obviously, we're betting big on the world of heart recovery, and we have the world experts here, where I would say, even though Andrew mentioned is 18 years, so have huge respect for what the team has been doing over 2 decades, but we want to take this $1 billion asset to a $4 billion asset. We want to take 250,000 patients in heart recovery and treat more than 1 million patients.

So that is the ambition for heart recovery. And then all things robotics. We are in orthopedic robotics. You'll hear much more in November and then December about our soft tissue robotics, all of our multi-indicational platform in Monarch. But we're very interested in fast-growing areas like robotics, like all things interventional and to make sure that we all have really robust tuck-ins like in orthopedics. We added a fast-growing foot and ankle, some really nice tuck-in adjacencies.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

Okay, got it. Nothing on deal size, areas of interest?

Ashley A. McEvoy - *Johnson & Johnson - Executive VP & Worldwide Chairman of MedTech*

We love all of our businesses, franchises. We're a world leader in ortho, world leader in surgery. Interventional, we're adding to. Neurovascular, we don't have scale. We have a small but mighty neurovascular business, over $300 million, growing double digit right now. We like stroke a lot, so we're looking at how we could be more meaningful in the area of stroke, as an example.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

Okay. And Ashley, procedure volume has been strong across the medical device industry. How sustainable is that momentum? And how are you thinking about seasonality with kind of pent-up demand for vacations and things like that, that we hear about?

Ashley A. McEvoy - *Johnson & Johnson - Executive VP & Worldwide Chairman of MedTech*

Yes. It's funny. It's bringing back like memories of our COVID days because I was -- every breath was like what's the month look like? What's the quarter look like? I'd love for us to get back to what does year 3 look like? What does year 5 look like? But because I'm very bullish of MedTech as

an industry, and I'm really bullish on what the science and what the evidence, as Dr. Simonton was talking about, really investing in the science and evidence-based medicine to change standards of care.

So we kind of play for the long term, Larry. As you know, we've been in this business for over 130 years. But listen, the market and the world is recovering at slightly different paces. China is back. I would tell you right now. Europe is coming back to pre COVID, but they'll have -- there's more waiting lines in certain countries in Europe.

The United States has had a very healthy rebound. We're not as much in the pinch from a staffing point of view, from a materials point of view, availability. So I think the numbers in quarter 2 reflected that. I think you're going to see more natural seasonality start to happen in areas like quarter 3. And as we start to get into 2024, I think you're going to see a little bit of a modest rebalancing.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

So normal seasonality, nothing out of the -- nothing out of the ordinary?

Ashley A. McEvoy - *Johnson & Johnson - Executive VP & Worldwide Chairman of MedTech*

Yes, I think we're seeing -- we always say that historically, the MedTech category is between 4% and 6%. We're probably going to see that be about 1 point higher this year to kind of manage through the backlog. And then we'll see a bit of return to normalcy in 2024.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

So this year, you're saying 5% to 7%, I think, and you're saying next year, closer to that 4% to 6%?

Ashley A. McEvoy - *Johnson & Johnson - Executive VP & Worldwide Chairman of MedTech*

That's correct.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

Okay. Because people have been concerned about the backlog coming through this year creating a headwind for next year, but you still think we can have normal growth next year.

Ashley A. McEvoy - *Johnson & Johnson - Executive VP & Worldwide Chairman of MedTech*

I do.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

That's helpful. You touched upon China. Good to hear that procedures are recovering there. Investors are concerned about, A, macro headwinds there, and B, anticorruption initiatives. What can you share with us about specifically the anticorruption initiatives?

Ashley A. McEvoy - *Johnson & Johnson - Executive VP & Worldwide Chairman of MedTech*

Well, listen, we've been in China for 37 years. We like to be in business for the long term. We make quality and compliance with uber -- as an uber priority in Johnson & Johnson. And we all knew coming out of COVID, when we hadn't been there for 3 years, we're going to find things, not just in China but in India and Brazil and everywhere, in certain high-risk markets. And so we have a very strong program. If we see things that we're not comfortable with, we'll take action.

And I think that from a patient care point of view, there's 1.4 billion people in China. A lot of folks, the Tier 2 and Tier 3 cities are really opening up. I think we're seeing a shift in human behavior, where a lot of patients used to go to the Tier 1 cities, and now they're starting to get higher quality care in Tier 2 and Tier 3 and don't want to have to make that extra mileage. So we are -- at J&J, we are the leader in MedTech in China. We're investing in that quality care in Tier 2 and Tier 3.

There's still a lot of volume in Tier 1. And importantly, we're seeing a nice diversity of a portfolio that we have, Larry, and I'll come back to this theme. Our Biosense Webster business, China is our second largest market right now in Biosense Webster, out growing double digit. And we have a strong, very strong surgical business in Ethicon. A very strong vision business. We took over the #1 position in intraocular lens and cataract surgery, and a strong ortho. So we're able to weather the puts and takes on certain categories with that breadth.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

The anticorruption initiatives there, how -- we've heard some concerns that maybe doctors will take less overtime, maybe it could have an impact on procedures. It's been mixed, to be honest, in terms of what we've heard from companies here. Some have said no impact. What's your expectation?

Ashley A. McEvoy - *Johnson & Johnson - Executive VP & Worldwide Chairman of MedTech*

I just -- I think that like any country that goes through -- again, the world got shocks coming out of COVID in China and a lot of lockdowns, a lot of COVID intervention. An underscoring of the importance of doing business the right way is only going to be good for the industry and is only going to be good for customers, is only going to be good for hospitals.

So we're all in favor of that. We have not seen an impact to procedures due to the perhaps enhanced scrutiny that's going through. Now, is it weighing on customers' mindset? Yes, to make sure that their businesses are doing business the right way, and that's a healthy thing.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

Okay. And do you expect it to impact procedures?

Ashley A. McEvoy - *Johnson & Johnson - Executive VP & Worldwide Chairman of MedTech*

I do not.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

Okay. Good to hear. The other topic that's been weighing on investors is GLP-1. You have some potential exposure with bariatric procedures and hip and knee procedures. How are you thinking about the potential impact of GLP-1's near term so on bariatric procedures? And I think long term, people are worried about the impact on the TAM, particularly in hip and knee procedures.

Ashley A. McEvoy - *Johnson & Johnson - Executive VP & Worldwide Chairman of MedTech*

Yes. I mean, Larry, we're a little bit goofy, right, because we're -- we have a pharma company, a MedTech company. So I would say J&J, we're still the largest health care company. We're excited about the advancements that are going to happen to patient care. This is a good thing for patients. And as Dr. Simonton was talking about the evidence of building evidence-based medicine, that's what we're about. And I think it's like 1% of folks who experience obesity, which is a disease, are actually getting treatment.

So we are encouraged by the advancements of the GLP-1s in the space of obesity. And listen, we think that they're going to be very complementary. There's a lot of noise right now in the impact to surgery and will surgeries go down. And in certain countries where it's completely out of pocket, they might have a modest effect.

But I think in the medium and the long term, this is going to build a much broader patient funnel which is really good for patients. And we actually see them very complementary because there's going to be patients that are going to need to be on medicines, and there's going to be patients that need to be in surgery. And there are going to be patients that can't respond to medicine and there are going to be patients who surgery is not the right action for them.

So it's a good thing for the TAM in general. It's a good thing for patients. We -- all of the KOLs that we've talked to, in fact, there was a congress in Italy recently, view these as very complementary. And while there might be a small immediate-term impact on procedures in the next 12 months, just as folks are sorting out the science and the data, we believe that this is actually a good thing for the category and a good thing for patients.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

And that's bariatric?

Ashley A. McEvoy - *Johnson & Johnson - Executive VP & Worldwide Chairman of MedTech*

And that's bariatric. We do not anticipate a meaningful impact to orthopedic.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

And 1 way to think about orthopedics, I'm curious, one follow-up there. There are a lot of patients that are too obese to undergo a hip and knee procedure. Could you see a benefit from those patients reducing their BMI?

Ashley A. McEvoy - *Johnson & Johnson - Executive VP & Worldwide Chairman of MedTech*

Yes, we do. I mean, particularly folks over 35 BMI. Again, I would say that we view this as a good thing for patients who are not getting treatment of, one, the destigmatization that obesity is, in fact, a disease. It needs to go through the process to get reimbursement.

A lot of patients, will seek care, and having access and having the right payment methodologies and the right stratification on segmentation of folks with obesity can get the right kind of care, whether it be through pharmacologics like the GLP-1s or whether that be through surgery.

Surgery -- bariatric surgery has very good evidence. It's been well established, its efficacy and safety rates. And we also believe if we can get people healthier, they can make them more eligible for more surgeries, more in a medium to longer term, Larry.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

That's helpful. And big picture, you talked about 2024 MedTech market maybe coming back to the normalized 4% to 6% growth. How are you thinking about J&J's MedTech business next year? What are some of the things you're excited about?

Ashley A. McEvoy - *Johnson & Johnson - Executive VP & Worldwide Chairman of MedTech*

Well, I'm going to pause here because I'm going to turn to these guys. I want you to take advantage of their mind and their skill set and their talent and what they're going to do for patients. But I would say -- I talked a lot about innovation. I mean, one is we're very, very committed to keep the performance as the second largest MedTech company, getting revenue and profitability consistent with the composite at a net income margin that's above the composite and using that to get after really meaningful unmet needs in health care.

And cardiovascular health is very important for us. We have a very strong foothold in managing AFib. We are the world leader in Biosense Webster. We have a 20-year track record of Biosense Webster. We have 5,000 installed base of CARTO. You're going to hear talk a lot about our point of view on PFA. We're actively pursuing -- we're in, right now, 4 clinical trials of PFA. We anticipate to be in Europe next year. We anticipate to exit this year with the 12-month follow-up in the -- with patients in the United States.

Our view of the world is we would love for patients to be able to benefit from the durability of radio frequency and the benefit of the hope evidence-based ability to have improved safety. And we think it's a combination of both. That's why we're doing a clinical trial right now in Dual Energy, which has radio frequency with pulsed-field ablation with the most used catheter in the world.

So we are in this business. We still think we're in early innings in the world of electrophysiology. It's a business that's $4.5 billion. It grew north of 20% in quarter 2. We want to double that size of the business and double patients. That's one on electrophysiology. And on that, I'd love for the team to talk about heart recovery.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

That was perfect. On heart recovery, what I want to ask is Ashley talked about going from $1 billion to $4 billion, which is interesting because there's a CVR, $35 a share. And I think it's $3.7 billion in 2029, something like that. So it's a 20% CAGR. What has to happen for you to go from $1 billion to -- was it $4 billion? $4 billion that Ashley said to hit the CVR.

Michael Bodner - *Abiomed, Inc. - Global Leader Heart Recovery*

I'll take that. So Abiomed's a growth story, as you know. And there are really 4 major catalysts that are coming through. As Chuck mentioned, there are major indication expansions with the PROTECT IV study, STEMI DTU and RECOVER IV. And there are many patients that are not getting access to care today, particularly in high-risk PCI. There are many high-risk prohibitive risk patients that could be opened up with the data that's coming through with PROTECT IV.

On STEMI DTU, this is about reducing the infarct size. This is going to be great for patients. That data set will come out in the coming years, but it's right on the horizon. So again, that will become the standard of care for how we treat STEMI patients. And then RECOVER IV, in cardiogenic shock, many of those patients are not getting put on pump particularly in those first few hours and first day or 2 of presenting with cardiogenic shock, either left heart or right heart failure.

And so that data set is going to make it easier for physicians to know how to treat those patients. So the indication expansions are on the horizon. From a new product development perspective, the team is actively working on lower profile, easier to use, longer dwell time devices, such as the ECP. So the ECP is the expandable cardiac pump. So the CP is the current interventional device that's 14 French. The ECP is 9 French.

The lower profile will be easier to use. We'll make it accessible for more patients around the world because doctors will be more comfortable with the device. The other product is BTR, which is bridge to recovery. This is a longer dwell time device that has potential for chronic heart failure and allowing those patients that need mechanical circulatory support have full flow for longer periods of time to fully rest and recover their native heart, so they don't have to get invasive VADs or heart transplants.

Three, getting into new market segments. Category segments like respiratory failure with the Breethe device, getting into chronic heart failure, like we talked about with BTR as well as getting into other manifestations of heart failure, like acutely decompensating heart failure.

And then finally, tapping into all of what's available to Abiomed as part of being part of Johnson & Johnson with the global infrastructure. So as stated before, 80% of the mix today from a revenue perspective is the United States. So there's so much opportunity to tap into our commercial footprint and go deeper in Europe and go deeper in Asia.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

Remind us of the status of BTR, please?

Michael Bodner - *Abiomed, Inc. - Global Leader Heart Recovery*

You want to take that one?

Andrew J. Greenfield - *Abiomed, Inc. - President*

Yes, sure. So BTR in its early feasibility study, so that's an FDA category that allows for its early first-in-human experience. So that's continuing its plan and doing well. And Abiomed is one of the companies that's been one of the early adopters of that program to the FDA. So I think that's a key component of our innovation and our long-term future.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

And ECP?

Andrew J. Greenfield - *Abiomed, Inc. - President*

ECP, it's in a similar environment in this early feasibility study for the FDA going very well. I don't know, Chuck, if you want to comment on the study itself.

Charles A. Simonton - *Abiomed, Inc. - Executive VP & Chief Medical Officer*

Sure. Yes, we're now actually in the pivotal study, IDE for approval, and anticipate finishing that up this year. So then that will go into a PMA review. So we're really excited about getting -- bringing ECP to patients. Sometime in 2024 would be the goal. I think we're right on track for that.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

That's helpful. Ashley, just a follow-up on pulsed-field ablation. Any reaction to the Varipulse data at ESC?

Ashley A. McEvoy - *Johnson & Johnson - Executive VP & Worldwide Chairman of MedTech*

Yes. We don't -- we kind of are focused around, I would say, the whole category is still less than 10% of penetration. So we're always looking to -- we know that there's more healthier competition entering, and that's going to -- everybody is going to have to scale up to kind of what their highest point of differentiation and clinical relevance is what I would say. And we think that we can still continue to be a big part of the armamentarium with electrophysiologists around the world.

Michael was talking about kind of using our global infrastructure, and there's been a significant rebalancing, if you will, of our $4.5 billion Biosense Webster business going from markets outside of the United States, as an example. And I always go back to we have a 5,000 installed base in the CARTO system.

We believe in the integrated mapping. We believe that having visualization and live navigation is important for outcomes. Our THERMOCOOL STS is the most used catheter in the world, so there's a huge preference and loyalties to that.

And we believe in choice, giving the clinician the choice of understanding that what parts of the case or what patient segmentation should they be using radio frequency or PFA, and we're going to allow the combination of folks on 1 system. So we welcome a healthy competition. I think it will be a good thing for patients. It's a good thing for people getting access to treatment.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

And Ashley, you talked about the focus on robotics. I don't want to -- I know you don't want to front-run the analyst meeting in December, but what can you share with us that gives you confidence that Ottava is -- I don't want to say on track, or -- that you're still optimistic about its future?

Ashley A. McEvoy - *Johnson & Johnson - Executive VP & Worldwide Chairman of MedTech*

I would say please join us coming -- we have a whole demo and ready to go for the community and back up this year, and then we have a whole MedTech day after we ring the bell in December. I think it's December 5. But I would tell you a couple of things.

One, let me quickly -- so VELYS, orthopedic, we were not #1. We were third in -- it's done over 20,000 cases. We're launching VELYS in orthopedics to Europe right now and has very small footprint. That coupled with, I would say, the most studied, most advanced modern knee in the world is a winning combination for the future of knees and then what we're going to be doing in hips.

MONARCH, we are doing -- we've just completed 8 patients in for kidney stones. So we are the first multi-indication endoluminal robot in the world. We are active in clinical trials right now with lung to do treatment both with ablation of energy as well as with pharmacologics. We are in first-in-human. We've just completed 10 cases for the treatment of kidney stones. Unfortunately, 50% of folks have to have a repeat surgery with kidney stones. So very encouraged with the urology indication that will go with MONARCH.

And I was just with our team in Ottava, you're going to hear a lot more about it, but I will tell you there's still very low penetration of robots around the world. I know we keep looking to the United States, but we're going to take advantage of our global footprint in Asia and Europe to make sure that the market has choice.

We believe in choice. We believe clinicians -- we know clinicians like choice. It will be a very competent, very capable robotic system with, I would like to say, the world's best instruments, which are Ethicon instruments, advanced instrumentation.

And it will also take advantage of our world-leading position in laparoscopic surgery. Similar to what I talked about in managing AFib and treating with the use of RF and PFA, we believe that surgeons and hospitals shouldn't have to have so much -- should have more flexibility of whether they're doing a lab case or actually converting it into a multi-quadrant robotic case.

And J&J will be kind of a unique offering to enable that choice during the moment or (inaudible) stuff. So stay tuned. We know we weren't first in, and a huge acknowledgment to the market leader who's built this category, but we still feel we have a view to 10 years from now, 20 years from now around how this is really going to change health care.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst*

Perfect. Great place to end. Thank you, everybody, for joining us. I appreciate the Abiomed folks coming. Ashley, nice to see you.

Ashley A. McEvoy - *Johnson & Johnson - Executive VP & Worldwide Chairman of MedTech*

Thanks, Larry.

Michael Bodner - *Abiomed, Inc. - Global Leader Heart Recovery*

Thank you for having us.

Andrew J. Greenfield - *Abiomed, Inc. - President*

Thank you, Larry.
