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JNJ.N - Johnson & Johnson at RBC Capital Markets Global
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OVERVIEW:

Company Summary

CORPORATE PARTICIPANTS

Michael Bodner *Johnson & Johnson - Company Group Chair, Electrophysiology & Neurovascular*

CONFERENCE CALL PARTICIPANTS

Shagun Singh *RBC Capital Markets Inc - Analyst*

PRESENTATION

Shagun Singh - *RBC Capital Markets Inc - Analyst*

To have here Michael Bodner, company, Group Chair, EP and Neurovascular from J&J MedTech as well as Ryan and [Sandra](corrected by company after the call) from Investor Relations. So thank you so much for being here -- just a quick background. Michael has been with J&J for almost 10 years, previously served as Worldwide President of Biosense Webster.

He also led the integrations of Abiomed and Shockwave and he now oversees two high-growth, high innovation franchises within J&J's Cardiovascular portfolio. So Michael, thank you so much for being here today.

Michael Bodner - *Johnson & Johnson - Company Group Chair, Electrophysiology & Neurovascular*

Thank you for inviting me.

QUESTIONS AND ANSWERS

Shagun Singh - *RBC Capital Markets Inc - Analyst*

Okay. Great. So maybe we'll dive into the EP market because that's definitely the hot topic here. I think you've described the global market as a \$16 billion opportunity, growing about 12%, 13%. And it is still highly underpenetrated.

Maybe you can talk to us about where you see the opportunity for growth -- is it geographic expansion, procedure expansion beyond [AFib] or a function of improvement in diagnosis that's going to drive growth here.

Michael Bodner - *Johnson & Johnson - Company Group Chair, Electrophysiology & Neurovascular*

So as you were doing the intro, I was reflecting on my time at Biosense back in 2022. And back then, it was an \$8 billion market. So 4 years later, it's doubled to \$16 billion and as you stated, it's growing 12% to 13% procedurally. The biggest segment of that growth is AFib. AFib is at least 60% percent of the mix.

And that AFib market is most likely growing north of 15%. And -- the driver of that is all of us. 1 in 4 people over the age of 40 will develop atrial fibrillation. And it's still significantly underdiagnosed, it's undertreated -- we estimate that of the patients that could benefit from a catheter ablation, it's still in the single digits that are getting access to care.

So still extremely underpenetrated. Growth in this segment will continue to be driven by two major factors: market development, and I'll get into that detail as well as innovation. From a market development perspective, that's patient awareness. 10 years ago, nobody knew what AFib was. Now that's more of a household name.

So truly understanding whether a patient has AFib or not is becoming easier to understand, particularly with smartwatches and everybody measuring everything they possibly can. That is also spreading globally outside the United States into Europe and in Asia. But there are more arrhythmias beyond AFib. That's just one of them, right? There's SVTs, there's flutters, there's VTs.

And those are also significantly underpenetrated. So the opportunity for growth is on geographic expansion in Europe and in Asia, patient awareness, but also the referring physicians truly understanding that there are treatment options beyond a pill in the pocket and that those treatment options are getting better and better, and those outcomes are improving.

We also have opportunities to introduce innovation to these physicians and to do clinical evidence generation that proves out the safety and efficacy of these new modalities. But the innovation curve right now is steep. There is extremely -- there's an extreme acceleration of innovation and helping guide physicians on what to use when to best serve patient outcomes.

So AFib is the driver, innovation that brings technologies that help physicians to know where to ablate and how to do that in a safer and more effective way, we'll continue with driving that growth.

Shagun Singh - RBC Capital Markets Inc - Analyst

Got it. Just as a follow-up there. You were talking about the growth rates. So 12% to 13% is global, and you said it's a procedure number. And then AFib is north of 15%. Is that a procedure number as well?

Michael Bodner - Johnson & Johnson - Company Group Chair, Electrophysiology & Neurovascular

Correct.

Shagun Singh - RBC Capital Markets Inc - Analyst

Okay. Got it. And then I believe about 75% plus of the US market has already converted to PFA.

And so in terms of the pricing premium going forward, adding to that revenue growth is going to be a smaller percentage. So how -- can you parse out US growth?

Michael Bodner - Johnson & Johnson - Company Group Chair, Electrophysiology & Neurovascular

That's why I quote procedural versus revenue growth because the revenue growth is harder to size because, yes, there is price premium of the conversion from RF to PF. Some of that's going to be unpredictable. As you stated in the US, PFA penetration is probably north of 75%, lower in Europe and just starting in Asia. So there is going to be a price premium that will be layered on top beyond the 12% to 13%.

Shagun Singh - RBC Capital Markets Inc - Analyst

Okay. That's really helpful. The market has definitely gotten very competitive. And I think recently noted for the US trends that you are gaining some unit market leadership in the US Can you maybe elaborate on that? What is driving it and how sustainable that is?

Michael Bodner - Johnson & Johnson - Company Group Chair, Electrophysiology & Neurovascular

Yes. So when we talk about therapeutic unit leadership, that is across all arrhythmia types, all ablation types. So that's RF and PF. So we're the clear leader in electrophysiology, and we're the leader in mapping and diagnostic and imaging and RF catheters, and we are now

building momentum with PFA. So when we look at total unit leadership, we are now there, and that happened late last year in the United States.

And then week over week over week, we're seeing significant momentum building, particularly with our Varipulse Plus platform in the United States. So that's where we've had catheter enhancements to Varipulse, where we have automated the irrigation rate. Physician feedback has been very positive and the momentum is significantly building. And that anchors to our full ecosystem of CARTO where everything is fully integrated.

Shagun Singh - RBC Capital Markets Inc - Analyst

Can you maybe elaborate on that just as a follow-up. So you have indicated that you would be launching a new catheter every year through 2030 and at least two CARTO updates each year. Where is J&J driving the differentiation given that it's so competitive. And you mentioned that the innovation curve is pretty steep right now? And what gives you the confidence that you can execute on that pipeline?

Michael Bodner - Johnson & Johnson - Company Group Chair, Electrophysiology & Neurovascular

So we expect to have the most comprehensive and complete PFA portfolio in the market. And that portfolio will be multimodal. And what I mean by that is there will be a small focal, a large focal, there will be a catheter for regional ablation and for single shots. So when we think about the workflow of the EP community, it really depends on physician preference but also where that patient is in disease progression and the continuum of care? Is this their first procedure?

Or have they had multiple procedures? And so when we look at the strength that we have with, again, the full ecosystem, given that our catheters are integrated into CARTO, we're able to provide physicians with real-time procedural feedback. Are they touching tissue? Have they provided the right amount of dosing to the vein to the posterior wall.

And do they have contact and how many grams of contact and then the dosing, again, with a PF index, we used to have an RF index, but now we have a PF index that guides them to how much pulse field they've actually delivered into that tissue itself. And that will drive outcomes. So when I look at the cadence of innovation that we're bringing, and I look at the depth of our team globally, we actually have a surge of innovation coming, and we're accelerating. We're not slowing down. We're actually speeding up.

And when we look at how we've structured our organization with R&D, advanced R&D, our incubator group and how everything works seamlessly with CARTO, we're well positioned to continue this momentum.

Shagun Singh - RBC Capital Markets Inc - Analyst

That's really helpful. Maybe we can talk a little bit more about CARTO. I think you have indicated some of the differences there with tissue proximity indicators, contact force management that you just mentioned, ablation indexes. Is there anything else we're missing or what feedback you're getting from physicians which they really appreciate.

Because as we know, the market is getting competitive, Abbott has their own mapping system, Boston and Medtronic are launching theirs as well. Where do you think that differentiation lies?

Michael Bodner - Johnson & Johnson - Company Group Chair, Electrophysiology & Neurovascular

So those intraprocedural cues really make a difference in patient outcomes. Earlier this year, we had a data readout that showed that CARTO, particularly because of the TPI, the tissue proximity indicators, which tells the physician that they're truly delivering the energy into the tissue and not into the blood showed a 61% reduction in rehospitalization rates of 30 days, 61% reduction.

Said differently, patients that were treated with CARTO were 2.5 times less likely to go back to the hospital within 30 days because of an arrhythmia driven rehospitalization. So it matters. And with the introduction of PFA, the traditional cues that they used to see with RF are now missing.

With RF, they would see signal attenuation in real time. They would see the amplitude of that signal getting smaller and smaller until it disappeared. They would be able to see changes to the tissue itself with impedance drops.

With PFA, they don't have that. And so given them those intraprocedural cues that help guide them on therapy delivery significantly improves outcomes. And we're starting to see that in our real-world evidence with our Varipulse data in Europe and in the United States. And pleasingly, that data is matching.

Shagun Singh - RBC Capital Markets Inc - Analyst

That's really helpful. And my guess is that you are in the field with that data showing to physicians.

Michael Bodner - Johnson & Johnson - Company Group Chair, Electrophysiology & Neurovascular

Yes.

Shagun Singh - RBC Capital Markets Inc - Analyst

Okay. Perfect. I guess on CARTO EDGE, how would you differentiate that versus CARTO 3. And then also at HRS, you launched the CARTOSOUND, the Sonata model. And so can you walk us through those modalities, what's different here?

Michael Bodner - Johnson & Johnson - Company Group Chair, Electrophysiology & Neurovascular

So I'll take Sonata first because it's what we're launching now. Sonata is our next-gen imaging modality. It is AI-enabled, and it can take ultrasound images from our ICE catheter. So ICE is intracardiac echo, and automatically build high-quality, accurate maps of the heart. Now it used to be that we could do this with the left atrium only -- we can now do this also with a left ventricle, which is important for BT ventricular tachycardias.

But we can build an even more detailed map of the left atrium with the new Sonata model that is CT-like and as a result, we don't need to use fluoroscopy. We have a zero fluoro indication. And physicians like the speed, the accuracy, and they rely on that and enables them to see things they couldn't see before.

It also auto labels different structures. It tells them what they're looking at on the image, but it also tells them tissue thickness. So by knowing the thickness of the tissue, they can tailor their ablation strategy to those patients. Some areas that are thin may not need as many ablations, whereas others that are thick may need more and they want to ensure that they're creating effective lesion sets that those patients don't have recurrences.

Shagun Singh - RBC Capital Markets Inc - Analyst

Got it. That's helpful.

Michael Bodner - *Johnson & Johnson - Company Group Chair, Electrophysiology & Neurovascular*

You want to know about CARTO EDGE though. So CARTO EDGE. CARTO is now best in class in terms of mapping in the total tech stack is leading edge. But we don't want to rest on our laurels. We want to take it to the next level.

In order to do so, we want to bring in more artificial intelligence and machine learning into our software modules. And we have a cadence of about two major mapping releases per year, but we're getting to the limits of what we can do with our current platform. And so CARTO EDGE is a play on the word edge, meaning it's cutting edge, but it's also bringing in edge computing.

And by bringing in edge computing, we bring in much more powerful computing power so that we can have better insights. And so what it will be enabling is tissue characterization. where we're able to understand the underlying tissue. Is it calcified, -- is it scarred? Is there fat? And based on that, how would you address your ablation strategy.

We're also able to see deeper into the tissue. And sometimes the arrhythmia is not on the surface, it can dive deep into the tissue and knowing that helps physicians with their guidance in more complex patient sets. And then with CARTO EDGE and the tech stack that we've got coming, we're also able to have insights into the quality of the lesions.

With PFA, there is this period of time where it can be reversible or irreversible, and we're able to implement multifrequency impedance mapping where we can guide the physician is that lesion actually effective or not? And is there more ablation to do?

Shagun Singh - *RBC Capital Markets Inc - Analyst*

Got it. Just moving to -- actually, what about the timing on CARTO?

Michael Bodner - *Johnson & Johnson - Company Group Chair, Electrophysiology & Neurovascular*

On Carto Edge, we haven't guided to that timing yet, but more to come.

Shagun Singh - *RBC Capital Markets Inc - Analyst*

Okay. Understood. Just shifting gears to Varipulse Pro that you launched in Europe in March of this year. I think you've indicated that it delivers 5x faster ablation times. Can you maybe elaborate on that product?

When do we see it come to the US? And then you're also doing a head-to-head study with Farawave on persistent Afib. Maybe you can talk about that study?

Michael Bodner - *Johnson & Johnson - Company Group Chair, Electrophysiology & Neurovascular*

Okay. So Varipulse is our commitment to delivering not just multiple form factors, but multigenerational catheters with pulse sequence innovation. So we're on Plus in the United States, which is the bump in the irrigation rate at 30 mL and then Pro is a further build with second-generation pulse sequence. That second-generation pulse sequence is 3.8 seconds versus 21 seconds. And we only do 4 per vein.

So it's an extremely fast, efficient and easy workflow. The physician feedback has been extremely positive. It's the workflow they already know. It just works better and it's smoother. The data that's building is significant.

So we have data sets in the real world from Varipulse and from REAL-AF that is showing extremely safe profiles with very good efficacy.

So we're seeing acute performance, acute success, and we're seeing greater than 90% freedom from Afib at one year and our event rates are extremely low. So with PFA, we can see hemolysis. Ours is extremely low. We can see with other modalities, coronary spasm, we haven't seen that with this platform in over 70,000 cases.

and or other adverse events like growing complications and others. Now given our experience base with Varipulse, we have confidence to do a head-to-head. Now PERSIGMA is an indication expansion study for persistent indication in the United States.

We could have made this a single-arm study just for an indication expansion. But given the confidence that we have in this platform, the data that we're seeing from a safety and efficacy perspective gave us confidence to go head-to-head to guide physicians on platform choice to enable them to have better treatment options as they look through the data.

Shagun Singh - RBC Capital Markets Inc - Analyst

That's great. When can we expect Pro in the US

Michael Bodner - Johnson & Johnson - Company Group Chair, Electrophysiology & Neurovascular

We are actively working with the FDA on that as we speak. But PERSIGMA is not linked to Pro coming to the US

Shagun Singh - RBC Capital Markets Inc - Analyst

Okay. Got it. That's helpful. I wanted to touch on dual energy catheters. I think what we've heard from our checks is that it's used in about 20%, 30% of the cases.

I think you've indicated in 20%, 30% of simple cases and slightly higher in the more complex cases. And our KOL checks were indicating that could help you regain more share in the complicated end of the procedure spectrum. So can you just maybe talk about the opportunity with the dual energy catheter?

Michael Bodner - Johnson & Johnson - Company Group Chair, Electrophysiology & Neurovascular

So dual energy STSF is our small focal ablation catheter. It's based on the STSF platform, which is the most widely used RF catheter globally it's what physicians train on. It's what they're most used to. So it has like muscle memory for them, and there's a lot of comfort to that catheter for them. And now has dual energy.

So we can seamlessly toggle between RF and PF. It has contact force. It has a PF index. So it is a workflow that they're most comfortable with. And the ability to toggle gives them a lot of versatility, depending on the complexity of the patient.

There are clinical situations where RF may be more suitable than PF. For instance, if there's an ablation needed near the conduction zone like the AV node, PF may not be suitable or if there's an ablation near the coronary arteries or coronary spasm may be something to be avoided an RF approach may be more suitable.

Shagun Singh - RBC Capital Markets Inc - Analyst

Understood. With respect to OMNYPULSE, I think you've indicated that it could potentially redefine PFA. What did you mean?

Michael Bodner - Johnson & Johnson - Company Group Chair, Electrophysiology & Neurovascular

So with OMNYPULSE, it is a map and a blade catheter with contact force and a PF index. So the contact force tells them how much they're touching tissue and how many grams of force that they're pushing, the PF index indicates have they delivered the therapeutic dosing or not. This is novel to us. And the fact that it's a 12-millimeter basket creates a lot of efficiency.

So with STSF this is a 3.5-millimeter tip to upgrade that to 12 millimeters enables the physician to have a very efficient workflow if it is a patient that's having an index procedure but they're complex, the physician can rapidly map with a high-density mapper, they can quickly isolate the veins and then based on what's happening in the substrate because it's a single catheter, they're then able to decide where else to ablate with that catheter.

So it creates a significant efficiency in that more complex patient population.

Shagun Singh - RBC Capital Markets Inc - Analyst

Actually, just a follow-up to what you said earlier, I think there are different form factors. You've talked about Varipulse small focal, large focal single shot, how do you think the market is going to be split between those modalities?

Michael Bodner - Johnson & Johnson - Company Group Chair, Electrophysiology & Neurovascular

It's going to be reliant on two things: physician preference, just what they like to use as well as where the patient is in their continuum of disease progression and the continuum of care. So if the patient is a young patient and this is their first procedure. And all that's needed is to isolate the veins. Our large basket, which is referred to as ISOPULSE, Actually, I think we've just named it today. for you.

ISOPULSE. we didn't disclose the name. ISOPULSE would be a great option. I suppose can map and ablate. It could very safely and effectively take out the veins.

-- if the patient needs beyond the veins, then it would be Varipulse Pro, where we can segmentally isolate the veins with 4 ablations and then potentially go beyond the veins to the posterior wall. If that patient is even more complex and work needs to be down ablations beyond the posterior wall than an OMNYPULSE could be suitable. And then finally, if the patient is extremely complex, and you need the ability to toggle between RF and PF and you need that smaller tip to get into hard-to-reach areas of the atrium than dual energy STSF might be most suitable.

Shagun Singh - RBC Capital Markets Inc - Analyst

That's really helpful. So you really will have the entire toolkit with refreshed ...

Michael Bodner - Johnson & Johnson - Company Group Chair, Electrophysiology & Neurovascular

Not just the toolkit. We will have the most comprehensive therapeutic and mapping tech stack.

Shagun Singh - RBC Capital Markets Inc - Analyst

That's really helpful. I wanted to touch on the Neurovascular franchise. Maybe can you talk to us about the strategic importance of this franchise? And what are the greatest growth opportunities here?

Michael Bodner - Johnson & Johnson - Company Group Chair, Electrophysiology & Neurovascular

A high-impact area, particularly stroke. And you've heard the saying time is brain. So the devices and how they perform really matters. -- how can if we can get that patient to the right interventionalists quickly, but then how do we get deeper into the brain to remove that clot safely and effectively. So the performance of those devices matter how they track how they aspirate and that they're predictable and reliable.

So our focus is on ischemic stroke with aspiration and aspiration catheters, but also going after new use cases for our TRUFILL liquid embolic for chronic subdermal hematoma.

And so those are patients that are elderly, that can slip and bump and have a bleed. Those bleeds can be difficult to resolve and they're hard to dry out. The traditional approach is surgical. So you can imagine a patient over 80 having a surgical approach to help deal with hematoma doesn't have a great recovery and the recurrence rates can be quite high. By taking a percutaneous approach with TRUFILL, we can improve the patient experience and the physician experience by embolizing the middlemeningeal artery to help dry out that chronic subdermal hematoma and reduce the recurrence rate.

Shagun Singh - RBC Capital Markets Inc - Analyst

I got it. I guess as we think about this franchise, where do you see portfolio gaps? Is it even on the peripheral side? And I don't know, any thoughts on the Boston Penumbra acquisition.

Michael Bodner - Johnson & Johnson - Company Group Chair, Electrophysiology & Neurovascular

I won't comment to competitive activity, but we do have a lot of interest in continuing to expand into high-growth high unmet need areas. -- like we've done previously with our acquisitions in the past with Shockwave and Abiomed into heart failure into complex PCI.

Shagun Singh - RBC Capital Markets Inc - Analyst

Got it. That's helpful. I guess just a big focus on innovation on the EP side, it sounds like you continue to looking at -- you'll be looking at expansion opportunities on the neurovascular or vascular side. Where else should investors be focused, what is underappreciated about the two franchises that you're running right now?

Michael Bodner - Johnson & Johnson - Company Group Chair, Electrophysiology & Neurovascular

Yes. So on the EP side. I think what's underappreciated, this isn't about a single catheter. It's about a full ecosystem from imaging to mapping to diagnostic to therapeutic and how it all works together in the ecosystem with the clinical mappers, the R&D strength, the know-how and that commitment to an accelerated launch of innovation, multigenerational catheters, pulse sequence innovation, and its an exciting time in EP.

On the neurovascular front, this is about having consistent performance of our products that enable the interventionalists to quickly and effectively get to the clot and remove it in a predictable way that is -- that cracks well.

These are little small catheters and how they push along that wire. And then as they connect it to an aspiration system that the constraint stays there, that doesn't collapse and that they're truly able to remove that clot safely and effectively, and it doesn't break off and go distally.

And so having technology that is safe and effective, but also predictable in their hands and gets them to that clot quickly because, again, time is brain and we want to remove those clots as quickly as we can.

Shagun Singh - RBC Capital Markets Inc - Analyst

Got it. I know we're out of time. Just one last question, maybe a rapid fire here. Just any impact on the macro front, anything you're worried about?

Michael Bodner - Johnson & Johnson - Company Group Chair, Electrophysiology & Neurovascular

In terms of EP, the market situation is very favorable, lots of unmet need, very underpenetrated. Innovation is coming rapidly, and there's economic value because the innovation that's coming is driving safety, it's driving efficacy and it's driving efficiency.

Shagun Singh - RBC Capital Markets Inc - Analyst

Okay. Very helpful. Thank you very much. Thanks for being here.

Michael Bodner - Johnson & Johnson - Company Group Chair, Electrophysiology & Neurovascular

Thank you.

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