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# EDITED TRANSCRIPT

Johnson & Johnson at TD Cowen Health Care Conference

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## CORPORATE PARTICIPANTS

**Hani Abouhalka** *Johnson & Johnson - Company Group Chairman of Robotics & Digital*

## CONFERENCE CALL PARTICIPANTS

**Joshua Thomas Jennings** *TD Cowen, Research Division - MD & Senior Research Analyst*

## PRESENTATION

**Joshua Thomas Jennings** *TD Cowen, Research Division - MD & Senior Research Analyst*

We are thrilled to be moving down the medical devices track with executive from Johnson & Johnson's MedTech business unit. We have Hani Abouhalka, Company Group Chairman, Robotics and Digital, Johnson & Johnson MedTech. Hani, thanks so much for joining us today at the 44th Annual TD Cowen Healthcare Conference. Thanks to the J&J team for joining as well, the IR team.

## QUESTIONS AND ANSWERS

**Joshua Thomas Jennings** *TD Cowen, Research Division - MD & Senior Research Analyst*

I'd love to just get -- start off from a high level. You've been at Johnson & Johnson for 20-plus years. You have had experience across most divisions within the J&J MedTech business. There's the 2019 acquisitions of Auris and Verily, the Verily stake of Verb Surgical. A lot of internal efforts. You guys have been delivering the OTTAVA soft tissue robot program.

But I guess the initial question is just, from a high level, where do the Johnson & Johnson's robotics and digital surgery R&D capabilities stand today versus, I guess, pre-'19, where you acquired Auris and the Verily stake?

**Hani Abouhalka** *Johnson & Johnson - Company Group Chairman of Robotics & Digital*

Well, just first, thank you for having us here. It's incredibly an honor for us to be here and I'm grateful for the opportunity.

I've been with the company for 24 years, and I worked with our different specialties across that time but also different geographies. And throughout that period, one thing never changed, is we have incredible people really trying to do what's best for patients in all our specialties. And that's very, very inspiring.

On robotics, I'll share this with you because it was a bit of a difference for me. Throughout my career in J&J, one thing was always true, is you have people incredibly passionate about health care. Our credo talks about our being patient-first, and you can see that everywhere you go.

I accepted -- and I moved to a new role. I was leading our EMEA business for MedTech and I moved to our Bay Area to lead our robotics and digital program. And I got there, and that passion for making a difference was there. But also, I saw something that was very different for me, is there are incredible talent that works in our program there in robotics and mechatronics and software.

And they grew up -- it's very similar, I'll tell you, to space. They grew up, when they're 7, 8 or 9, they have this passion around robotics. And these people can have -- can really go anywhere and work in their capabilities, but they chose that passion, to deploy it in health care. And I think we're fortunate because that incredible combination between passion for health care and passion for incredible science and technology is what excites me about our program. And you were there in November, so you saw the robot. But the people behind it, it's genuinely inspiring.

I feel very comfortable because, as you know, we've had some journey you mentioned pre-2019, but since. But where we are today, we're very excited because the program is at a place where it hasn't been before. And that's why we shared in November that we're going to be doing a submission to the FDA in the second half of this year for an investigational device, an IDE, in the second half of this year. So we're very excited, and the work continues.

**Joshua Thomas Jennings TD Cowen, Research Division - MD & Senior Research Analyst**

Excellent. And just thinking about just all those efforts over the years, it seems like we're on the cusp of those efforts bearing more fruit, clearly, with the update on OTTAVA. You have MONARCH out there, 2 different indications, in pulmonology as well as urology.

But I guess the question is, I mean, how many other development programs are behind the scenes? I think over the past number of years, Johnson & Johnson has relayed to investors that they want to take a leadership role in robotics and in building out this digital surgery ecosystem.

But after that long-winded intro, maybe just help us understand, what other indications? We may get ahead of us ourselves without talking about OTTAVA and MONARCH first. But what other indications are potentially suitable or can drive clinical value propositions with robotics.

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**Hani Abouhalka Johnson & Johnson - Company Group Chairman of Robotics & Digital**

I mean, robotics is very, very exciting, first and foremost, for what they bring in terms of difference for patients and surgical teams. And I'll start by saying, J&J MedTech, we're not new to robotics. We're the only company right now that have 3 active programs in robotics. We're into orthopedics with our VELYS program, making a difference every day for patients.

We have MONARCH, which is the first and only actually flexible robotic endoluminal system with 2 indications right now. One is the lung bronchoscopy, more than 35,000 cases in the U.S. We're the first to get approval in China, and we're excited to bring that technology to China because as you know lung cancer in China is 40% of all lung cancer cases globally. I'll talk about the difference for our patients in China.

And clearly, soft tissue robotics and OTTAVA is something we're very, very excited about. Hearing people like yourself, when they come visit us of the feedback they shared, also is an additional confidence in our program. Because things like, "We're glad J&J waited to bring something that's differentiated." That's from some of your colleagues talking about it being an elegant solution. I don't hear that being used usually in Medtech. And the reason why that's important because, when you look at soft tissue robotics, we're early innings. It's 5% global penetration. People say you guys are late to robotics. We're not late, this is just starting.

But when we heard of what's needed to really take this forward. And every surgeon I spoke to, they want us to be in this market. They want choice. They want competition. Plus, they want robotic surgery to advance and move forward. And I think some of the choices we've made from design, from architecture, we solved a lot of big engineering problems ourselves that hopefully will remove a lot of challenges and obstacles for surgical teams. And that's what excites us about going forward.

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**Joshua Thomas Jennings TD Cowen, Research Division - MD & Senior Research Analyst**

Excellent. And just in terms of building out these robotic capabilities. I mean, are you -- can you leverage them as you're -- down the line as you're building out other robotic technologies maybe outside of Ethicon? I mean, you already have VELYS in your orthopedic realm. I think that was the Orthotaxy acquisition that drove the development there. But how do you leverage robotic capabilities and R&D programs across the different business units within J&J and MedTech?

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**Hani Abouhalka Johnson & Johnson - Company Group Chairman of Robotics & Digital**

Yes. I mean, first and foremost, when it comes to talent, I think a big part of having invested so heavily in that incredible innovation starts with people. And I think, whether you're working in robotics and mechatronics and computer vision, in one program, our teams talk, they collaborate, they share, they discuss. And I think having that investment, I think that's going to be a big part of what makes us successful today, but in the future. So there is that.

Two, we know there are opportunities where we can also bring some of the robotic capabilities into the OR using some of the individual capabilities. I think there is a lot of excitement of what can happen. We know some -- our surgeons are experimenting on their own. I think we're excited to see where the technology takes us. If anybody is going to figure this out, it's going to be us, and that's exciting for patients, but for also for our company.

**Joshua Thomas Jennings TD Cowen, Research Division - MD & Senior Research Analyst**

Excellent. I think since the consumer spin, there's been increased focus by investors on J&J's MedTech business. It's always been a focus for us, but from investors as well, but just an increased, intense focus. And organic revenue growth is rewarded in the MedTech industry by investors, maybe as the top metric.

Thinking about the \$10 billion Ethicon business unit, I mean, how should ultimately investors think about the revenue growth contributions from these robotic efforts? I mean, are these needle-moving products a revenue base for Ethicon? Is it -- are they share stabilizers? Or should we think about them as a real, real big organic revenue drivers as you get approval for OTTAVA, but you also have MONARCH in urology and pulmonology today.

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**Hani Abouhalka Johnson & Johnson - Company Group Chairman of Robotics & Digital**

Maybe just a quick point before I talk about robotics. I'm new leading surgery, but I've been in the robotic, digital, leading that program for a few years. But prior to that, I had been part of the leadership team for MedTech since 2017. And what excites me is as a team, and during our EBR, Tim talked about this.

We look at our performance, we were growing at 1.5% in 2017. You fast forward to end of last year, we grew at 7.8% without Abiomed. That's an incredible performance because we're a \$30 billion company, and to be able to have that sequential improvement is incredible. But it happened not just for one thing, whether it's execution, but also around our portfolio and the innovation in our portfolio.

So if you look at our portfolio in 2018, 20% of that portfolio was what we considered is high-growth segments, segments that grew more than 5%. Last year, that number was 50%. So all that tells you that J&J's MedTech's business is in a very strong footing. It's exciting about what's coming ahead. And robotics will be definitely part of what excites us about our future.

In terms of the revenue contribution to MedTech, robotics, we're not sharing any specific data right now, but it won't be meaningful until the end of this decade. But that's going to be very, very exciting.

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**Joshua Thomas Jennings TD Cowen, Research Division - MD & Senior Research Analyst**

I wanted to focus a couple -- these next questions on the OTTAVA platform. It was a fantastic unveiling late last year out in Santa Clara at the J&J MedTech headquarters. And you guys called out some regulatory milestones that you would look to achieve this year, primarily just submitting the IDE to the FDA.

Investors are keen to kind of focus on these time lines. I'm sorry if we're getting specific here. But just any work that's needed to be done before that submission? Or is that pretty much a clear shot? And then maybe just talk about what the clinical trial could -- design could look like? And what's the requirement from the agency?

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**Hani Abouhalka Johnson & Johnson - Company Group Chairman of Robotics & Digital**

I mean, first and foremost, I wish Jess would let me bring the robot here. But actually, it's not Jess, just it's for IP reasons. We've been very careful in what we share, this is very competitive, to protect our own IP. So what we even what we shared in November, we didn't share everything. So we tried to share a few things, but hopefully, we'll be able to share more as the program advances.

We have a world-class team leading our regulatory, our clinical, preclinical, and they've been in constant discussions in alignment with FDA, and that's why we publicly shared that we'll be ready to submit an IDE to the FDA in the second half of this year.

A lot of questions we got, why the U.S. first? And a couple of reasons. One, it's the most experienced market in terms of robotics. But also, we feel very confident about our program, and we wanted to come to the U.S. first. But beyond that, we're not saying anything more. But I will say stay tuned on that.

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**Joshua Thomas Jennings TD Cowen, Research Division - MD & Senior Research Analyst**

Great. And maybe -- we talked -- you referenced some of the feedback you received after that event just on the robotic design, and it seems like an elegant solution. Definitely a unique design. We were -- our team was impressed. Maybe just to give some quick snippets

on some of the design features. Some of this is already out in public, clearly, but that drives that elegance and how J&J got to where it is today with the OTTAVA system.

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**Hani Abouhalka *Johnson & Johnson - Company Group Chairman of Robotics & Digital***

I mean as a company, we were founded in surgery, patient-first always. Our history goes back to our founding with, say, sterile sutures, with surgical gauze. And throughout our history, any time there was an intersection, we as a company wanted to be part of that journey.

What we heard about the last 20 years of robotic surgery clearly made a big difference for a lot of patients, clearly made a difference for our surgical teams. But we heard a few things that were also clear, that more needed to be done. And we felt that a lot of this feedback needed to be solved, first and foremost, with putting a lot of effort around the architecture and the engineering of it.

We believe we're going to be the company that creates what's next in surgery. And you cannot do that if you don't have a starting point that's foundationally different. So I start with our architecture, and our engineers were able to solve for big problems where you have what we call unified architecture. And the best way I'll try to explain that is the actual robotic arms, there are 4 of them, they're incorporated into the table.

That sounds simple, but if you try to see what you're trying to solve for in terms of having access and reach for a broad spectrum of procedures, this is not a small engineering feat. As you know, there are multiple robotic programs globally available and none of them have that architectural choice.

Now we didn't do it just because it was more elegant or more beautiful. We believe that part of creating what's next in surgery is around the surgical experience. We know, fundamentally, there's friction between surgical teams and the robot. If you've been to ORs, it's very crowded. If we can give space back, and that's very powerful. That's why this design choice's architecture is incredibly powerful.

But also, there is clinical benefit. So if you talk to urologists or a bariatric surgeon, when they do laparoscopic surgery, they talk about using gravity to move organs to minimize some of the impact on the actual organs.

For example, in gastric bypass, to access, to get a view of the stomach; in nephrectomy, is to get a view of the posterior tumor. The beauty of our design, we have a feature called twin motion. And again, I wish I can show it to you live. You saw it where the table and the arms move natively together or naturally together. That's incredibly powerful because when the surgeon is in the console, he or she is looking through their viewer and the table is moving in their field of view, nothing is changing, so they can continue their work.

If you think about it, this is something they're used to doing in laparoscopy, so this is natural for them to continue doing it. They had to stop doing some of that in some cases or they have to disrupt workflow, the -- disconnect either the boom or the cards or use some software bridges to do this. No other system allows this native movement, so we believe that's very, very important.

The third thing is, which we also very excited about, we mentioned it also, is around instruments. Today, there are many, many surgeons using robotic systems. They would still choose to use our Ethicon instruments for manual filing. So they're telling us, "You're the leader in stapling, you're the trusted performance brand we relied on for years." And that's why we shared that when we launched OTTAVA, our Ethicon instruments will only be available on OTTAVA.

So when you look at the architectural design, you look at the instruments. And the last thing I'll say is we also heard there's a need to connect data better. And everyone talks about digital. It's -- again, I think it's a space that all MedTech companies are trying to go and make a difference there.

We believe our approach to that, being open, working with other companies have the same interest, whether small companies, midsize or large, to try to come in and use the best of digital to really change outcomes for patients and to help with the burden for surgeons. So we're hoping all of that would be quite unique. We believe it is, and we're just excited to bring it to the market.

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**Joshua Thomas Jennings** *TD Cowen, Research Division - MD & Senior Research Analyst*

I would love to follow up on that answer just on this digital ecosystem build-out in Johnson & Johnson and some of your competitors are working on creating this advanced digital ecosystem to improve outcomes.

I guess what is -- how do you see the end game? And are we talking 5 to 10 years? I mean, our understanding of the end game is to take a preoperative plan with some advanced imaging, help -- using AI, machine learning and data to help the surgical team craft that pre-operative plan, take that into the OR. And then with big data, these systems are -- this digital ecosystem will actually help advise surgeons on each step of the way. And in a particular procedure, maybe even showing data in it procedurally. And then being able to confirm that the operative plan was completed.

And then postoperatively doing the same thing, getting that follow-up data and then feeding that all back into the system and having that ecosystem created. I don't know if that's the right vision or the same vision you have, but any tweaks to that or just full on changes to that? And then any time line where you think industry can get there...

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**Hani Abouhalka** *Johnson & Johnson - Company Group Chairman of Robotics & Digital*

I mean, I'll say a few things, and I feel very strongly about this. First, disease is connected, data should be connected, too. The second thing is 30% of all data globally is health care data, so to be able to do something meaningful about this is important.

Now where our approach is different is a few things. First, there are some people who believe digital is the aim, some people believe that it's technology for the sake of technology. We're a company, as I mentioned, we're funded with a very basic premise that we're patient-first. It doesn't matter what happens, that will never change.

So we're approaching this with a lens -- and by the way, when surgeons talk to us, they never talk about I need AI. They talk about improving outcomes, reducing variability, making their workflow more efficient, reducing waste. So for them, this is the problems to be solved, and we believe we have that approach because we believe it has to be meaningful for patients.

The other thing I'll say when it comes to that, it has to be done in a way where there are a few things that are super important. And there's a lot of tech being thrown at hospitals. And they're being -- for them, it's becoming now more of an issue of how to go through all of that to make sure that what needs to happen actually makes sense.

So some of the bets we're making that is different than others. First and foremost, we believe that this is a huge opportunity, but also a big problem to solve. It cannot be one company that goes in and does this. I think we're humble enough that -- to believe that this is not just a J&J thing to solve. But we believe someone needs to play a role of a convener and work with small, mid and large companies that have the same interest, the same values to go out and solve for this problem.

So first, we're coming and saying, "We're not going to be the one company to solve it. We're going to be a company that have -- that will be willing to work with anybody and to solve some of these problems." That's one.

Two, it's also important to talk about some of the foundations that hospital surgeons always known, which is a trust. I think when we talk to a lot of people across the world, people trust J&J to come in and really help in convening those willing parties, but also to provide a foundational element around things like privacy, cybersecurity. We believe we can be a company that can lead on that.

The third thing is access. We're the largest surgical company in the world. We are present in a lot of ORs across the world because we're going to make a difference. You need people to go and be able to connect that.

And the last thing I'll say, it has a surgery lens, but also it has the rest-of-MedTech lens. On the surgery lens, we also believe that this has to be connected to some of our robots like MONARCH, like OTTAVA, but also some of our other businesses across MedTech. Some of the work we do in with Biosense with CARTONET electrophysiology, some of the work that's happening in orthopedics with VELYS. That ability to bring also the rest of MedTech will also be meaningful.

So you can hear from my voice, we're very, very excited because it's definitely meaningful. But again, it won't happen on its own without our incredible products across robotics and our other devices. I think that's also very important.

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**Joshua Thomas Jennings** *TD Cowen, Research Division - MD & Senior Research Analyst*

As we think about the evolution of OTTAVA, you mentioned, just the closed system with Ethicon instruments only being able to be used with the OTTAVA platform. Is there a cadence that you can share? Just do you expect to have that instrument integration by the time of the IDE trial? Or is that -- I can't remember if you guys broke that out at the Investor Day, where instrument integration will be down the line or a next step after you get approval for the platform.

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**Hani Abouhalka** *Johnson & Johnson - Company Group Chairman of Robotics & Digital*

We're not, right now, specifically doing specific launch dates for the instruments. But we're working, our teams in Ethicon, both in Santa Clara, but also in Cincinnati, on a cadence of launches of a list of instruments, and then the rest of the other instruments. We're hoping to bring the best of our saving technologies to OTTAVA, and that's what excites us. To have the experience that surgeons are used to in laparoscopy will be something that we'll also experience at the right time in OTTAVA.

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**Joshua Thomas Jennings** *TD Cowen, Research Division - MD & Senior Research Analyst*

So most robotic systems today are they're robotic assistants. They're not fully automated robotic systems. How do you envision automation getting incorporated into OTTAVA or your platform? I think the FDA currently is against fully automated systems, and that's not fully in play. But maybe just help us understand what automation is already built into OTTAVA at this stage? And how do you expect just in general for the field to move forward and incorporate? I guess, will we ever get to a state where these systems are fully automated?

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**Hani Abouhalka** *Johnson & Johnson - Company Group Chairman of Robotics & Digital*

Yes. I mean, there's a lot of talk and discussion around the role of autonomy in surgery. As you know from other industries, this goes through a lot of steps. We're in health care. There's a patient on the table, and there's incredible people working in that OR, from nurses to surgeons.

And the way I see it is we need to make sure that their work is augmented in a way that can help them deliver the magic that they do. And if there's technology that can assist with things like workflow, decision support, inefficiencies, we should all be going for that. But when it comes to building capabilities that go beyond that, we need to understand, first and foremost, the clinical value and the risk versus the reward piece of it.

What I can tell you is I do think the future is going to be exciting in terms of using some of the technologies to make our surgeons, our surgical teams, much more equipped to do some of the things they do. And that will be a big part of that future and that vision.

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**Joshua Thomas Jennings** *TD Cowen, Research Division - MD & Senior Research Analyst*

Great. I'd like to touch on the MONARCH system. It's the first and only multispecialty flexible robotic endoscopy platform. I think there's more than 35,000, maybe approaching 40,000 bronchoscopy procedures in the United States today. And that's a significant increase, I think, from less than 5,000 in 2020.

But any updates on -- I think one of the rationales for keeping Johnson & Johnson Pharma and MedTech units together, is there are synergies across those 2 business units, and this has been one where synergy is clear in our view, and what your team has shared in terms of the development program for this lung cancer initiative that Johnson Johnson's embarked on.

But to start, maybe just talk -- anything you can share just on where MONARCH sits today? Any metric that you can share on installed base or procedure volumes? And how that multi-year launch has fared relative to internal expectations.

**Hani Abouhalka Johnson & Johnson - Company Group Chairman of Robotics & Digital**

I mean, MONARCH is a platform that's incredible. First, right now, it's as I said, first and only multispecialty. We're in 2 spaces, in lung and in kidney stone, and I'll talk briefly about that. Commercially in the U.S., it's in lung, 35,000 procedures. We were the first and only so far getting approval for China, which is very important for patients there. In terms of lung and kidney stones, we're looking at a potential of 7 million procedures globally. So it's significant.

But the power of what's there, and we start with lung, if you talk to any pulmonologist or a surgeon who is using MONARCH today, the ability to get to earlier diagnosis and reach places of the lung that's not reachable with manual bronchoscopy, it's very powerful because the current standard of care, if we don't have a robotic access to some of these lesions in parts of the lung which are hard to reach, most of the time, you tell patients to wait. If you ever met a patient with their family, this is very, very painful for them. This issue of wait and see.

So after having a tool at their disposal that can give them to earlier detection, which we know is linked to survival rates, I think that's meaningful. And it's hard when you know something is as impactful. That's why we need to do our best to make sure that it continues to scale and it continues to launch.

On the kidney stall side, we're in clinical studies right now. Kidney stone, again, 3 million potential cases globally. A lot of patients, I'm sure there are people in this room who have suffered from kidney stone. The problem is there's not a very effective solution. It's either very invasive and then you have low recurrence rate or it's high recurrence and it's less invasive. So with this solution, what we're seeing so far, reading kind of early results, and that's what's exciting about that piece.

But put it all together, I go back to the concept of the platform. You said it, we talk about J&J and the new J&J of having an incredible innovative medicine and J&J MedTech. And our CEO, Chairman talks about them having to stand on their own and being very strong individually. But the pure difference we can make is around areas where we can come together to solve big problems.

Interventional oncology is one of them, and we have an incredible team with incredible scientists. And the way I look at it, we know from other cancers, like in dermatology, delivering a drug to treat topically dermatologic cancers does make a difference. Our theory is that if you can do that intratumorally using some of our drug components with our team in our Innovative Medicine business, we believe that has the potential to be very impactful for patients.

Bringing that delivered through the platform to reach places in the lung which you cannot do on your own, we have a clinical study with some agents right now with some drugs, that's exciting. It could be ablation, and we can open to look at how we can do that. And that's what we have in our company, having that as a platform, giving the best science from our Innovative Medicine and our best science and technology from MedTech, I don't know any company that can do this. And that's powerful for us, but way more powerful for patients.

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**Joshua Thomas Jennings TD Cowen, Research Division - MD & Senior Research Analyst**

You mentioned the ablation approach. And I believe that the NeuWave of transbronchial microwave ablation during a robotic-assisted bronchoscopy received FDA breakthrough designation in mid-2020. Any just updates on the development path there and where that stands? Is there a clinical trial being enrolled today? Or is that...

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**Hani Abouhalka Johnson & Johnson - Company Group Chairman of Robotics & Digital**

It's currently in clinical studies. And we're assessing the data from the clinical studies.

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**Joshua Thomas Jennings TD Cowen, Research Division - MD & Senior Research Analyst**

And then just that NeuWave, microwave ablation platform without robotic assistance, has that been a -- where does that stand just in terms of utilization and penetration into the opportunity?

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**Hani Abouhalka Johnson & Johnson - Company Group Chairman of Robotics & Digital**

Well, I don't believe we have specific numbers we shared about NeuWave. But it is available in the U.S., and we're looking at that also.

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**Joshua Thomas Jennings *TD Cowen, Research Division - MD & Senior Research Analyst***

Wanted to ask about -- I mean, my understanding is that there is a convergence R&D team. I think you may have mentioned it in your last answer or one of your last answers. But just you focus on integrating Johnson & Johnson's Innovative Medicine and MedTech expertise to develop, I think you were mentioning the intratumoral therapies. Are there other research initiatives across the 2 business units involving robotic assistance or the robotic platforms outside of this lung cancer initiative?

**Hani Abouhalka *Johnson & Johnson - Company Group Chairman of Robotics & Digital***

Well first, I just mentioned on the -- it's not like 2 teams collaborating. It's some of the best minds coming together to solve a problem. And what's exciting in my time in MedTech. There's a drug that, sometimes when we look at a problem, the answer is always one thing. And in this case, you go to these meetings and you have incredible scientists working together, forgetting what they're presenting to solve for a problem. For me, that's very powerful than any other company claimed for.

In terms of other areas within MedTech and Innovative Medicine, I heard earlier -- just mentioned a few areas that we're always open to looking into, and we have some incredible science in our Vision business on both sides. So there are opportunities, they're looking at it. But within robotics, right now the biggest one is interventional oncology.

**Joshua Thomas Jennings *TD Cowen, Research Division - MD & Senior Research Analyst***

Excellent. Any last questions from the audience before we wrap up?

Well, Hani, Thank you so much for the discussion. Thanks for participating in the conference this year. Great to see you again in person, and we're looking forward to future updates on the robotics initiatives down the line here as move to '24 and into next year.

**Hani Abouhalka *Johnson & Johnson - Company Group Chairman of Robotics & Digital***

Thank you so much for the time. Thank you, Josh.

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