STXS Earnings Call Transcript

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Operator: Good afternoon. Thank you for joining us for Stereotaxis' Third Quarter 2025 Earnings Conference Call. Certain statements during the conference call and question-and-answer period to follow may relate to future events, expectations and as such, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the company in the future to be materially different from the statements that the company's executives may make today. These risks are described in detail in our public filings within the Securities and Exchange Commission including our latest periodic report on Form 10-K or 10-Q. We assume no duty to update these statements. [Operator Instructions] As a reminder, today's call is being recorded. It is now my pleasure to turn the floor over to your host, David Fischel, Chairman and CEO of Stereotaxis.

David Fischel: Thank you, operator, and good afternoon, everyone. We are in an exciting period with a lot of progress on multiple fronts. We've discussed our strategy and efforts more comprehensively on previous calls, so I'll keep today's remarks focused on a few key commercial and innovation updates. Our commercial activity can be viewed as 2 primary efforts: first, to scale robotic system sales with continued adoption of Genesis and the initial launch of GenesisX; and second, to build a robust, high-margin recurring revenue business with our portfolio of novel catheters. These 2 efforts are independent, but obviously synergistic and together support an attractive razor-razorblade business model that can deliver substantial long-term growth. On the capital side, we were pleased to receive hospital orders for 2 Genesis robots since our last call. Both orders came from European hospitals establishing entirely new robotic programs. We expect both robots to be installed and to begin clinical use in the first half of 2026. These Genesis orders are reflective of the healthy pipeline and continued interest we see across our regions particularly in Europe, where we are slightly ahead in having a more complete product ecosystem approved and commercialized. These orders add to our existing system backlog, which had over $10 million, supports a study baseline of robotic system revenue as demonstrated by our results over the last several quarters. The launch of GenesisX significantly enhances our system opportunity by removing structural barriers that limited physician interest from translating into tangible adoption. We're delighted yesterday to announce FDA approval for the GenesisX system. This is a landmark approval for Stereotaxis. There are very few companies that can successfully develop, gain regulatory approvals and deploy complex surgical robots that operate reliably in daily clinical use. This is Stereotaxis' second such robot in 5 years and a reflection on our unique expertise and our capacity and commitment to significant innovation. We are initiating a limited launch of GenesisX, while we await approval for the MAGiC catheter work to enhance compatibility of the robot with various x-rays and refine our supply chain manufacturing, installation and commercial processes for a full launch. While we are pleased with the steady demand for Genesis, we expect GenesisX orders to outpace the tempo of Genesis orders following full launch. Turning to our recurring revenue. The key driver of growth over the coming years will be our budding portfolio of proprietary catheters. Stereotaxis' recurring revenue has to date been predominantly driven by service contracts and a small single-use disposable with relatively little revenue per procedure. Catheters are the primary disposable in any procedure and Stereotaxis did not previously benefit from this revenue stream. The dearth of robotically steered catheters reduced interest in our technology and limited our revenue opportunity and razorblade business model. Over just the past year, we have started to demonstrate the tangible reality and commercial impact of our catheter portfolio, with growing sales of Map-iT

catheters following our acquisition of APT last year, adoption of the MAGiC ablation catheter in Europe, following CE Mark in the first quarter and over just the past 2 months, adoption of the MAGiC Sweep high-density mapping catheter in the U.S. following the FDA approval this summer. MAGiC Sweep has been a particular recent highlight. On our last call, we described the importance of high-density mapping in the EP field and have the introduction of robotic HD mapping promised several clinical and workflow benefits. It is also important to note that MAGiC Sweep is Stereotaxis' first catheter launch in the U.S. and the first catheter innovation that allows our robot to be used in new ways, enabling clinical care that was previously not possible. We began commercial launch of sweep in late August and have had a very exciting reception to date. Physicians have shared multiple examples of MAGiC Sweep allowing them to better diagnose the source of arrhythmia safely and efficiently in areas of the heart that were otherwise inaccessible with manual mapping catheters. The clinical interest in the catheter has translated into a strong commercial start with over $300,000 in sweep revenue in the first 2 months of launch. We are still in the earliest innings of the launch with only about 1/4 of robotic accounts in the U.S. ordering the catheter to date as we work through multiple hospital approval processes. We are excited to see the catheter continue to scale this impact in the U.S. as well as gain approval and launch in Europe. The commercial impact of MAGiC Sweep, measured in direct revenue and as importantly, in the halo effect it creates for robotics in our field demonstrates the significant impact of innovation. We have a robust pipeline of innovation efforts that will continue to strengthen our commercial results. These include multiple products in the late stages of regulatory review development projects approaching submissions and earlier-stage efforts that haven't yet been disclosed. They span technologies, including robotic systems, software solutions and several EP and vascular catheters and devices. I'll add a few brief updates and comments on 3 specific projects most impactful in the short term, MAGiC in the U.S., post-field ablation and the Synchrony digital cath lab system. MAGiC is our proprietary robotically navigated ablation catheter that will replace the older J&J; catheter used with our robot. We received CE Mark and launched the catheter in Europe earlier this year, have been working through manufacturing ramp-up and country-by-country commercial processes and are working diligently with FDA to advance U.S. approval. Late in the third quarter, we responded fully to a body of questions that represented FDA's outstanding questions upon a comprehensive review of all modules in our submission. We maintain regular dialogue with FDA and appreciate their collaborative effort during the review. Post-field ablation, PFA, has been a dramatic impact -- has had a dramatic impact on the electrophysiology field over the last couple of years, driving billions of dollars in market growth and significant share shift among the large med tech players. On previous calls, we described having a few earlier-stage PFA collaborations with different partners working through the preclinical testing process. Last month, we were pleased to announce successful completion of preclinical testing and entering into a collaboration agreement with CardioFocus to their PFA system with our magic catheter. The agreement provides a framework for how we will advance this first-ever robotic PFA solution or a first-in-human clinical study, regulatory approval and commercialization. CardioFocus' PFA generator and our MAGiC catheter both already have regulatory approval in Europe. And so the effort to add compatibility to our label is expected to be relatively contained. We are preparing formal regulatory documentation to initiate first in human testing, expected to perform these procedures in the coming few months and believe it's possible to see MAGiC approved for PFA use in Europe before the end of next year. Finally, let me make a brief comment on Synchrony and SynX, our digital solution that streamlines modernizes and introduce secure remote connectivity to the cath lab. In October, we announced that we obtained CE Mark in Europe and had submitted technology for FDA approval. The technology has received less attention than most of our other innovation efforts but it holds significant promise as an entirely new business pillar. We have spent over 6 years and many millions of dollars developing Synchrony and SynX, benefiting from our previous experience with our Odyssey system but completely rearchitecting it with an improved technological foundation. Synchrony and SynX are central to our digital surgery efforts to modernize the interventional lab with enhanced workflow and remote connectivity and smart AI capabilities. The technology improves the robotic cockpit, but we believe all cath labs tend to benefit from improved workflow, connectivity, collaboration and intelligence. We have the opportunity recently to leading EPs and technology administrators to evaluate the system. The feedback was very positive, describing it as the most well-designed cath lab display technology they

have seen. We expect Synchrony to contribute at least a couple of million dollars of revenue in the first year of launch, and a growing installed base will provide the foundation for an attractive software-as-a-service revenue stream from our SynX connectivity app and future AI features. Kim will now provide additional commentary on our financial results, and then I will make a few financial comments as well before opening the call to Q&A.; Kim?

Kimberly Peery: Thank much, David, and good afternoon, everyone. Revenue for the third quarter of 2025 totaled $7.5 million, system revenue of $1.9 million and recurring revenue of $5.6 million compared to $4.4 million and $4.8 million in the prior year third quarter. System revenue reflects partial revenue recognition on 1 Genesis system and ancillary devices. Recurring revenue growth over the prior year reflects a full quarter's contribution of Map-iT catheters and initial sales of Stereotaxis' new robotically navigated devices: The MAGiC ablation catheter and the MAGiC Sweep high-density mapping catheter. Gross margin for the third quarter of 2025 was 55% of revenue. Recurring revenue gross margin was 67% and system gross margin was 19%. Gross margins remain impacted by fixed overhead allocated over low production levels. Operating expenses in the third quarter of $10.7 million included $4.1 million in noncash charges for stock compensation expense, mark-to-market adjustment for acquisition-related contingent earn-out consideration and amortization of acquired intangible assets. Excluding these noncash charges, adjusted operating expenses in the quarter were $6.6 million, a decrease from $7.2 million in the prior year third quarter primarily due to lower general and administrative expenses. Operating loss and net loss in the third quarter of 2025 were $6.6 million and $6.5 million compared with $6.3 million and $6.2 million in the previous year. Adjusted operating loss and adjusted net loss in the quarter, excluding noncash charges, were $2.5 million and $2.4 million compared with $3.1 million and $3 million in the previous year. Negative free cash flow for the third quarter was consistent with the previous year at $4.2 million. At September 30, Stereotaxis had cash and cash equivalents of $10.5 million and no debt. including the $4 million Stereotaxis will receive in the upcoming second closing of the registered direct financing announced in July, Stereotaxis would have had $14.5 million in cash with no debt. I will now hand the call back to David.

David Fischel: Thank you, Kim. As mentioned in our press release, we expect revenue this quarter to exceed $9 million with system revenue of approximately $3 million and recurring revenue greater than $6 million. This will provide results -- this will result in over 20% annual revenue growth for the full year 2025, in line with our previous guidance of double-digit annual revenue growth. While we are not yet providing formal guidance for next year, we want to offer directional color to help with modeling. We expect sustained growth of both systems and recurring revenue through 2026, with system revenue benefiting from our existing Genesis backlogs and the launch of GenesisX and recurring revenue continuing to ramp with increased adoption of MAGiC, MAGiC Sweep and Map-iT catheters. We expect quarterly revenue to surpass an average of $10 million per quarter in 2026. We continue to advance technologically and commercially while remaining prudent with expenses. We see significant leverage in our business with increased revenue. We expect to enter 2026 with a healthy balance sheet that allows us to advance our new technologies to market and launch them with a balanced focus on accelerating growth while also ensuring improved margins, earnings accretion and achievement of profitability. We will now take your questions. Operator, can you please open the line to Q&A.;

Operator: [Operator Instructions] And we will take our first question from Josh Jennings from TD Cowen.

Joshua Jennings: Congratulations on the GenesisX approval. I was hoping to ask about GenesisX a couple of questions. I guess, first, just maybe an update on the sales pipeline for GenesisX mostly in Europe now with approval in the U.S., but they talk about any pent-up demand in the U.S. and just how we should be thinking about the mix of orders going forward? I think you talked about GenesisX outpacing them, but should we think about more GenesisX placements next year? Or will there still be a healthy amount of Genesis placements in centers, old customer accounts that are replacing their Niobe systems?

David Fischel: Josh, thanks for the good questions. And so GenesisX, I'd look at it as additive to Genesis. As you see just in the last quarter, even with GenesisX being approved in Europe, we continue to see demand for Genesis and from sites that have been engaged with us for longer periods of time in the process that are either replacing existing labs or like the 2 hospitals that are establishing new robotic programs. They're building new wins to the hospital, new areas and the construction process then isn't that much of a factor for them. And so we continue to see demand for Genesis that has generally been at a pace of approximately 1 to 2 systems a quarter. And so I think that's going to continue for the foreseeable period, both in the U.S. and Europe. GenesisX is really additive to that by offering access to robotics to many physicians that otherwise would have wanted it, but just couldn't advance through the process because of the challenges logistically at the hospital level. And so we have been engaging with multiple hospitals in Europe over this past year. We've done a little bit of work in the U.S. with a few hospitals, and so we have to start to have a pipeline of physicians and hospitals that are interested in engaging with us. And we predominantly focused in the earlier periods on the sales process. And we have historically always only sold our robot. And we start to -- as we ramp manufacturing, and we feel comfortable with the ability to supply the system at a higher scale, we will also be opening up the model to leases and placements with significant disposable commitments. And so that's really kind of over the next few months. Our goal is to make sure that manufacturing is in place to demonstrate that the system is working reliably in the real world, in regular clinical use and then to be able to start a full launch. And we expect, once we start a full launch that the rate of orders for GenesisX and sales of GenesisX is going to be meaningfully higher than what it's been to date with Genesis.

Joshua Jennings: I appreciate that, David. And then just a reminder, is GenesisX going to be sold at a price point that's similar to Genesis or at a premium? And then just as you think about or as we think about the high-level color you provided for 2026 and quarterly revenues averaging at $10 million-plus range, within that, are you assuming that GenesisX systems are sold to non-EP accounts or neurovascular, endovascular centers in 2026? Or maybe just help us think about when that could kick in?

David Fischel: Sure. So GenesisX is a new technology. It's a premium system. We expect the system to save a hospital materially on their own expenses, and we are pricing the system at a premium to Genesis. It's in the same ballpark, but at a premium price to Genesis. And so we're comfortable with that decision. And we believe the market is accepting of that as a reasonable appropriate price. And when it goes to your second question on non-EP applications, we do expect to have our first at least 1, 2 non-EP centers next year that will start using the robot in non-EP procedures. We still do not have approval for guide catheter or guidewire. And so that is still -- the guide catheter is in -- it was submitted earlier this year. And we're still working through the regulatory process there, the guidewire we expect to submit for regulatory approval early next year. And so as those come to market, I would expect the majority of their use to be in existing robotic accounts where every EP department is part of an interventional cardiology department, there's easy access to the system for interventional cardiologists who want to start using the robot and experimenting with it in a range of other procedures. But we do also believe that there will be a few sites that do not currently have the robot where non-EP applications are the driver of adoption.

Operator: Your next question comes from the line of Adam Maeder from Piper Sandler. .

Adam Maeder: I actually wanted to piggyback off of Josh's line of questioning. And maybe starting on the approval in the U.S., it sounds like that will be a limited launch phase for at least a couple of months, if I'm hearing correctly. But David, are you able to put a finer point on when we should expect that to kind of move to full launch? It certainly sounds like you're working through supply chain a little bit. Understand you're waiting on the MAGiC RF approval in the U.S. I don't know if you can give a time line update there as well. But just trying to think about when we move from the limited launch phase to kind of full steam ahead? And then I had a follow-up.

David Fischel: Sure. So the 2 things you mentioned, obviously, getting the MAGiC approval in the U.S. and then kind of ramping our manufacturing are the kind of 2 major factors in transitioning from a limited launch to a full launch. And in terms of MAGiC in the U.S., I gave some color on the prepared remarks about our interactions with FDA. I believe those interactions are going well. Things like the recent permit shutdown, while they have some impacts on FDA activity, they don't seem to have any impact on the review of MAGiC, which is funded as a PMA submission previously. And so even in very, very recent discussions, there seems to be no impact whatsoever from the shutdown on the FDA's review. And so I think that's kind of advancing well, and we expect overall likely approval in line with what we've described previously. I would think that kind of as we have that approval, also on the manufacturing side, we continue to grind through the process and to improve it. And so I think on our last call, we described having produced the first GenesisX commercial system in the early summer period. We've kind of built now another system. We are kind of ramping the manufacturing and the supply chain overall well, and that's just kind of a steady progress there. I'd say that kind of you should expect probably a transition to a full launch of GenesisX sometime in the earlier parts of next year at the latest, the natural time to do so would be at the era and HRS conferences, which are in the spring that will be kind of the latest natural time to do so.

Adam Maeder: That's really helpful color, David. Appreciate all that. And the second question is around the early commentary for 2026. And I was hoping you could give us just a little bit more color in terms of how you're thinking about the revenue mix? You talked about the average of $10 million per quarter. but how that kind of bifurcates between system revenue and consumable revenue? Just any additional thoughts there would be much appreciated.

David Fischel: Sure. So that's always the split between systems and disposables is always difficult because systems are somewhat lumpy. And like you see in this quarter, we're at the low end of the $2 million to $3 million range that we kind of said we expect every quarter. In the fourth quarter, we'll be at the high end of that range. And so it's kind of -- there's a lumpiness to that, that shift percentage distribution between system and recurring revenue in any given quarter. Generally, if you're modeling this year's system revenue of about $10 million and recurring revenue in the low mid-$20 million range. We expect the recurring revenue to scale relatively linearly as we get kind of the catheters further approved and then further launched in each geography. And I'd expect that to kind of continue to just scale as we go account by account and gain adoption. And then systems will fluctuate, but generally, you should expect numbers clearly in the teens or high teens in terms of the system revenue amount. And so that probably takes you where system revenue is going to end up being somewhere between 30% to 50% of overall revenue.

Operator: Our next question comes from the line of Frank Takkinen from Lake Street Capital Markets.

Frank Takkinen: Congrats on the GenesisX approval. Wanted to start with maybe some additional questions around the MAGiC FDA interactions. Can you talk to some of the questions that the FDA had for the Q3 response that you spoke to on the call? Any significant areas outstanding that they're still looking for? And then I realized it just went in at the end of Q3, but any response from them from that?

David Fischel: Sure. So the FDA's questions, which we were able to respond to at the end of the third quarter, we're a comprehensive review. There's many modules included in the PMA submission. So you have obviously preclinical testing and clinical data you have biocompatibility and sterility information, you have packaging information. You have your label, you have all the technical testing of the device. So it's really kind of -- there's many, many modules to the PMA, many kind of sets of data. Their questions were explained to us as the result of their comprehensive review of all the available data that they had reviewed, which they viewed as kind of comprehensive for the submission. And then so there was a range kind of across the different modules, definitely some on the clinical data on the various kind of stability, biocompatibility portions, but really kind of it was a comprehensive set of questions. We responded to those. We felt good about our response. There was nothing kind of strange or particularly troublesome in the questions. So it's still an effort to respond to everything, but we felt kind of good with the tone and the content and the questions we good with our responses. And

as described in the prepared remarks, we do maintain regular dialogue with FDA on all our submissions. But obviously, MAGiC is a particularly significant one and communication since then, nothing in writing. We feel overall good with them having received the response and able to review the response fully and access all the documentation that we provided. And so we see things kind of continuing to progress as would be wanted.

Frank Takkinen: Okay. That's helpful. That's great. And then maybe just one on the Q4 guide. I think originally, we were expecting something like $7 million in revenue in the disposables and service line for Q4. I think now that's at $6 million, maybe talk through some of the change in assumptions for Q4. Now I realize you said at least $6 million, so at least the door open for higher than that, but just curious if there's any change in assumptions.

David Fischel: Sure. So we provided the original guidance at the beginning of this year. At the beginning of this year, we didn't know exactly when we would receive FDA approvals for the various devices or CE marks for the various devices we've had from the catheter perspective, main drivers of recurring revenue growth. We're going to be MAGiC Sweep and MAGiC in both geographies for both catheters. So far, we've gotten 2 out of the 4 approvals done. We got MAGiC approved in Europe. We got MAGiC Sweep approved in the U.S. and we're still working on the 2 other approvals. And so I think just given the timing of those approvals and given what we've seen to date in the ramp, we're happy with the ramp of the devices, particularly MAGiC Sweep. I think it's a reflection of the U.S. market environment where there's far fewer structural barriers to gaining adoption. But so we've been overall very pleased with the tempo of adoption, but we're still in the earliest innings. And so we think that guidance kind of feels appropriate at this time.

Operator: [Operator Instructions] Our next question comes from the line of Kyle Bauser from ROTH Capital Partners. .

Unknown Analyst: This is [Kevin] on for Kyle. And congrats on the GenesisX. Just kind of starting with the GenesisX and all the new catheters, how should we be thinking about the head count of the commercial organization expanding over the next 12 to 24 months?

David Fischel: Kevin, thanks for the question. And so we've discussed in the past that as we -- on the clinical side of the business, we have about a total commercial team of approximately 40 people globally, about 20 of them in the U.S., 15 or so in Europe, and then a smaller team in Asia. We've talked about how the clinical team, particularly will see meaningful growth over the coming year or 2. We expect, as we are scaling catheter revenue that we will shift more and more to a model where you can have a one-to-one relationship between clinical reps and hospitals. That is something that in our field -- typically, there's more than 1 clinical rep per hospital. We've always had 1 for every 3 or 4 hospitals. And so having catheter revenue as part of our product mix allows you to sustainably and attractively grow your clinical team to have that style of coverage that can be done kind of in a profitable fashion that can also kind of then help drive greater utilization. And so that's kind of probably the largest source of growth will be in that clinical team. On the capital side, we've done everything to date with a very, very lean dedicated capital team and some additional contribution from sales management. As we've shipped to a full launch of GenesisX are comfortable that we can scale China FX system sales to the dozen, a couple of dozen in short order, then we will kind of start to invest incrementally in probably a handful or so dedicated capital reps that can really kind of push that model much further.

Unknown Analyst: Great. That's very helpful. And then maybe just kind of focusing in on the disposables business and catheters. I know with the launches of MAGiC and you're working with CardioFocus on the PFA and that collaboration there. But longer term, are there any other opportunities with the disposables business and maybe building out this portfolio that you're kind of looking at?

David Fischel: Definitely. There's a lot of thought and a lot of energy being spent on the disposables side of the business. I think that's where, obviously, most businesses make most of their money, most of the revenue from catheters and most medtech companies, and that's to see the higher-margin

aspect of the business. And strategically, there is also something that our robot has in reliable and kind of special in allowing physicians to do things that were otherwise impossible. A robot is only as good as the catheters that can also deliver. And so a robot by itself without a portfolio of catheters has limited value. And so I think there's a lot of opportunity now that we have a catheter R&D; and manufacturing expertise and infrastructure in-house, there's this kind of beautiful breadth of fresh air in terms of being able to play with ideas and to think about things much more aggressively than we have in the past. I think that kind of the overall portfolio mix of having 3 main portfolios of interventional devices and makes a lot of sense for the coming few years. And that is really the MAGiC family of catheters, which are robotically steered ablation cardiac completion catheters, so both therapeutic and diagnostic robotically steered catheters into cardio ablation field, then imagine, which are and for stents for endovascular magnetic interventions, our various interventional guidewires, guide catheters, microcast or similar devices of that sort for vascular navigation and then Map-iT, which are manual diagnostic EP catheters. So I think you're going to see continuous innovation in those 3 categories. There's a pipeline beyond that, which has been disclosed to date. There is a pipeline that we have been working on. And so I think you're going to see a steady tempo of innovation beyond what we've discussed today.

Operator: There are no further questions. I will now turn the call back to Mr. Fischel for closing remarks.

David Fischel: Okay. Thank you for all the questions. We'll work hard on your behalf to finish the year strong and to set things up for a very successful 2026. Thank thank you very much.

Operator: The meeting has now concluded. Thank you all for joining. You may now disconnect.