NMTC Earnings Call Transcript

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Quarter: 4

Operator: Good day, ladies and gentlemen. Welcome to the Fourth Quarter of Fiscal Year 2025 Financial Results Conference Call for NeuroOne Medical Technologies Corporation. Today's call will be conducted by the company's Chief Executive Officer, Dave Rosa, and Ron McClurg, the company's Chief Financial Officer. Before I turn the call over to Mr. Rosa, I'd like to remind you that this conference call will include forward-looking statements within the meaning of U.S. federal securities laws with respect to future operations, financial results, events, trends and performance, which are based on management's beliefs and assumptions as of today's call. Forward-looking statements may involve known and unknown risks, uncertainties and other factors, which may cause actual results to differ materially from those expressed or implied by such statements. See NeuroOne's financial results press release and SEC filings for information regarding specific risks and uncertainties that could cause actual results to differ. Except as required by law, NeuroOne undertakes no obligation to update such forward-looking statements. With that, I will turn the call over to Mr. Dave Rosa, CEO of NeuroOne. Please go ahead, sir.
David Rosa: Thank you, operator, and thank you to everyone for joining us today. I'd like to welcome you to our fourth quarter fiscal 2025 financial results conference call. Fiscal year 2025 was the most successful year in the history of NeuroOne Medical Technologies Corporation and an inflection point for our company. I'd like to start today with a brief overview of the most significant milestones we achieved in fiscal year 2025. Financially, we saw record product sales growth of 163% to $9.1 million, reduced operating expenses, significantly improved our product gross margins to 56.5% and strengthened the balance sheet with an $8.2 million capital raise. Operationally, we received FDA 510(k) clearance for the OneRF trigeminal nerve ablation system, advanced the development of our spinal cord stimulation electrode for lower back pain, initiated a new product development program for basivertebral nerve ablation for lower back pain, reported sales of our first preclinical drug delivery devices to a large pharmaceutical company, strengthened our infrastructure with key senior executive hires, initiated the process to gain ISO 13485 certification for international commercial expansion and lastly, bolstered our intellectual property portfolio. Additionally, we plan on providing financial guidance for fiscal year 2026 once we receive a final forecast from our distribution partner, Zimmer Biomet. Also, as previously disclosed, NASDAQ granted us a 180-day extension until May 4, 2026, to regain compliance with NASDAQ's minimum bid price rule for continued listing on the NASDAQ Capital Market. We will continue to monitor the closing bid price of our common stock and seek to regain compliance with the minimum bid price requirement within the extension period. Moving on to the fourth quarter of fiscal 2025. We continue to make strong financial progress as product revenue increased 907% to $2.7 million and product gross margins increased to 55.8% compared to 51.8% in the fourth quarter of fiscal 2024. This is a direct result of the expansion of commercialization efforts for our OneRF brain ablation system distributed by Zimmer Biomet. What made this most impressive is that we also reduced our operating expenses by 2% versus fiscal Q4 2024. With respect to expanding our product portfolio, we are now pursuing several market opportunities as potential revenue drivers. First, our drug delivery program using our sEEG platform electrode technology has received a great deal of physician interest. In addition, we have been approached by 2 organizations looking to potentially partner with us to use our technology for gene therapy, cell therapy and glioblastoma drug delivery development, and we

reported the first sales of other preclinical devices to a large pharmaceutical company for testing purposes. This interest gives us confidence that our technology can offer advantages over competitive devices that both caregivers and pharmaceutical organizations value. You will be hearing more about our progress in fiscal 2026 as well as our comprehensive strategy to offer various sizes of both preclinical and clinical use devices that are appropriate for the drug development cycle through commercialization for human use, which is dependent on FDA approval to market. Based on physician feedback, we also believe we have an opportunity to offer a new platform to treat glioblastomas that provides a better solution for both patients and caregivers. Unfortunately, I am sure most of us know someone who has been affected by a brain tumor. At NeuroOne, our Chief Technology Officer, Steve Mertens, was diagnosed with one 2 years ago. Thankfully, he is doing well, but is also committed to trying to help others by advancing NeuroOne's technology. Drug delivery represents a potentially massive opportunity when you consider the number of patients suffering with brain-related neurological disorders such as glioblastomas, epilepsy and Parkinson's disease, to name a few. In 2026, our goal is to be commercially ready with our preclinical drug delivery offerings as well as to develop a pathway to gain FDA clearance. Regarding our pain management platform, we have 2 active programs in development for treating lower back pain. The first is our percutaneously placed paddle electrode, which can be delivered through a 14-gauge needle in the spine, which then expands to offer broader customizable stimulation, requiring less energy consumption than traditional standard percutaneous electrodes. We are in the process of finishing chronic animal studies to evaluate histology and other product metrics and expect to initiate additional long-term studies in fiscal Q2 2026. We also continue to explore partnership opportunities with strategic organizations. The second technology in our pain management platform is our basivertebral nerve ablation system, which was kicked off in fiscal Q4 2025. This past quarter, we held our first advisory board meeting with leading pain experts that have great experience with performing this procedure. Our strategy is to leverage our existing OneRF generator and sEEG probe to perform this procedure. To that end, we are in early discussions with strategics regarding this product technology and will seek a partnership with an established organization with a presence in the pain management space. Up next are animal studies with continued R&D; testing to confirm that the system will perform as required. In August, we received FDA 510(k) clearance for our OneRF trigeminal nerve ablation system to treat facial pain by ablating the trigeminal nerve, further validating our technology platform and providing an alternative to pharmaceutical and other surgical treatments. As discussed previously, we indicated that we would have a limited commercial launch in the fourth quarter of calendar 2025. To that end, I am pleased to report that the first 2 patients were successfully treated at the University Hospitals Cleveland with both patients reporting pain relief from the procedure without any complications. The cases confirm that unlike traditional ablation systems, our probe required only one placement due to the multiple contacts present on the device. This allowed the neurosurgeon to easily locate the area of the nerve, triggering the patient's facial pain. The traditional systems may require multiple probe placements, which can cause additional patient discomfort. As a reminder, this system utilizes the same OneRF brain ablation system, yet also includes additional accessories specific to the procedure. We pursued this indication based on neurosurgeon interest and the fact that this is the same customer performing brain ablations with our system. This additional capability also potentially helps justify a financial case given its multi-use capabilities. We will continue to perform additional cases to obtain post-market clinical performance information. Regarding distribution, we currently have interest from a strategic to potentially license this technology, and we'll provide an update on those discussions when appropriate. Regarding the OneRF brain ablation system currently marketed by Zimmer Biomet, we continue to gain traction with accounts as the product is released to additional sites. Clinical outcomes have also continued to be reportedly positive without any adverse events to date. Our temperature control probe is performing exactly as intended in offering an additional safety mechanism during procedures that ensures excessive temperatures do not occur during the ablation. We also recently met with key personnel from sites participating in the OneRF registry, which is intended to gather a variety of performance data for patients that have had ablations with our system. Hospital institutional review board approvals and site contracts are expected to occur during the course of this year and can vary by center. We attended the following trade shows in fiscal Q4 2025 through today: the Society for

Neuroscience, Congress of Neurological Surgeons and the American Epilepsy Society meeting. All meetings included posters and/or presentations on our technology as well as Mayo Clinic physician testimonials on their experience with our technology at the AES at the Zimmer Biomet booth. As we progress our technology platform and enter new markets, we concurrently continue to strengthen our patent portfolio. Recently, we were granted a notice of allowance by the U.S. Patent and Trade Office for both the manufacturing methods used to deposit our contact material onto our electrode and a second notice of allowance that covers our proprietary temperature control probe when used with our sEEG electrode. On the international front, we have also received our first granted European patent for the temperature probe. In total, the company has 17 issued and pending patents, which were all developed and owned in-house with the exception of the initial 3 patents we licensed pertaining to our cortical electrode family. Before I turn the call over to Ron, I wanted to reiterate our confidence in driving increased revenue from our OneRF ablation system, along with initiating preparation for future international sales. I'd also like to note that our anticipated growth will not include trigeminal neuralgia ablation revenue, strategic agreements for pain management technology or drug delivery partnerships or sales. The prospects for current and future growth are bright, and our goal is to continue to execute on this plan. I would now like to turn the call over to Ron McClurg, Chief Financial Officer, to provide a review of our fiscal fourth quarter and full year financial results. Ron?

Ronald McClurg: Thanks, Dave. Product revenue increased 907% to $2.7 million in the fourth quarter of fiscal 2025 compared to product revenue of $0.3 million in the fourth quarter of fiscal 2024. For the full fiscal year 2025, product revenue increased 163% to $9.1 million compared to $3.5 million for the full fiscal year 2024. The company also had license revenue of $3 million in fiscal 2025, which is not included in our product revenue compared to no license revenue in fiscal 2024. License revenue in fiscal 2025 was derived from the expanded exclusive distribution agreement with Zimmer Biomet. Product gross profit increased significantly to $1.5 million or 55.8% of revenue in the fourth quarter of fiscal 2025 compared to product gross profit of $0.1 million or 51.8% of revenue in the same quarter of the prior fiscal year. For the full fiscal year 2025, product gross profit increased significantly to $5.1 million or 56.5% of revenue compared to product gross profit of $1.1 million or 31.3% of revenue in the full fiscal year 2024. Total operating expenses decreased 2% to $2.9 million in the fourth quarter of fiscal 2025 compared to $3.0 million in the same quarter of the prior year. R&D; expenses in the fourth quarter of fiscal 2025 was $1.1 million, the same as the fourth quarter of fiscal 2024. SG&A; expense in the fourth quarter of fiscal 2025 was $1.8 million compared to $1.8 million in the same quarter of the prior year. For the full fiscal year 2025, total operating expenses decreased 5% to $12.4 million compared to $13.0 million for the full fiscal year 2024. R&D; expense in the full fiscal year 2025 decreased 2% to $5.0 million compared to $5.1 million in fiscal year 2024. SG&A; expense in the full fiscal year 2025 decreased 7% to $7.4 million compared to $7.9 million in the fiscal year 2024. Net loss in the fourth quarter of fiscal 2025 improved by 52% to $1.6 million or $0.03 per share compared to a net loss of $3.4 million or $0.11 per share in the same quarter of the prior year. Net loss for the full fiscal year 2025 improved by 71% to $3.6 million or $0.09 per share compared with a net loss of $12.3 million or $0.46 per share for full fiscal year 2024. As of September 30, 2025, the company had cash and cash equivalents of $6.6 million compared to $1.5 million as of September 30, 2024. Of note, NeuroOne is funded through at least fiscal 2026, potentially longer if key milestones are hit. The company had working capital of $7.9 million as of September 30, 2025, compared to working capital of $2.4 million as of September 30, 2024. We had no debt outstanding as of September 30, 2025. I will now turn the call back over to Dave for his closing remarks.

David Rosa: Thank you, Ron. As I stated at the top of the call, fiscal 2025 was the most successful year in the history of the company. From our FDA 510(k) clearance for the OneRF trigeminal nerve ablation system to our expanded partnership with Zimmer Biomet, our first preclinical sales for our drug delivery platform, initiation of a new product development program for basivertebral nerve ablation and strong financial performance and balance sheet, NeuroOne Medical Technologies successfully executed our technical, commercial and financial plan. We also have great momentum leading into fiscal year 2026 with the recent announcement that our first 2 OneRF trigeminal neurology cases were successfully performed. Expect to hear more about advancements with our brain, pain management and drug delivery platforms in the near future. Finally, in January, we will be attending the JPMorgan Healthcare

Conference and invite investors and analysts to meet with NeuroOne January 12, 13 or 14 to learn more about our amazing company and its story. Operator, at this time, I think we can open up for questions.

Operator: [Operator Instructions] Your first question for today is from Jeff Cohen with Ladenburg.

Unknown Analyst: This is Destiny on for Jeff. I'd like to start with face pain, if we could. I know that you had those 2 patients treated earlier this month, so congratulations on that. I'm wondering if we should expect any more procedures prior to year-end. I know we're getting into the thick of the holidays. So I'm just curious.

David Rosa: Yes. Thanks for joining the call, Destiny. We do have 3 other centers that have indicated that they have cases that they have planned. The question is more around getting some of the ancillary equipment that they need to do the procedure, not our equipment. And at one of the centers, local centers here, they're also waiting to get the generator installed in the facility. So the cases are there. There's just a few more steps that we have to go through. And we do think that there's a good chance we'll have more cases done this month.

Unknown Analyst: Okay. Great. And I know historically, you had said that with this type of procedure, they could be stacked. So the treating physicians could do more. I'm wondering, first of all, were these procedures back-to-back, maybe even not -- maybe if not on the hour, but in terms of the days. And then based on what you heard just from those 2, do you still feel like that's something that is feasible or attainable?

David Rosa: Yes. So both of those cases were back to back. I'm not sure they were done within an hour, but they were done back-to-back. And yes, that's one of the nice things, I think, about these trigeminal neurology cases is that the neurosurgeons will schedule them in advance. It makes it a lot more convenient for us to support those cases, too, because we know that the ablation is going to be done in that particular case as opposed to brain ablations where there's usually a waiting period until the [indiscernible] has been identified. So yes, we expect that moving forward.

Unknown Analyst: Okay. Great. And I know you mentioned a strategic partner here. At what point do you feel like you would just go forward and do it yourself?

David Rosa: Well, if discussions didn't appear to be going in a fruitful direction, we could do that. But I feel confident that we'll be able to reach an agreement with a strategic partner for this.

Unknown Analyst: Okay. Okay. And then just a couple on drug delivery, if I may. I'm wondering if there will be more orders from this large pharma player. And I'm not sure how much visibility you have there, but are they going to do additional testing? Is there the opportunity to expand a bit? What are you seeing there?

David Rosa: Yes, I do think that somewhere around midyear will be in a situation where we'll be able to ship additional units. These units are all going to be for preclinical testing. But really, the work that we're doing now is to get the devices manufactured to get our processes validated, so that we can be in a position mid-year to ship preclinical devices.

Unknown Analyst: Okay. Got it. And then for epilepsy, I missed what you said about the registry. What is the timing on getting that established and opened?

David Rosa: Yes. So in terms of like the protocol, we feel very confident that the protocol that we have makes sense. We just met at AES, which was the first week in December with sites that had agreed to participate. They have some comments, offered some suggestions and also each site has its own internal process that it has to go through to be able to participate in these registries and get sign off from administration. Some are a matter of months; some could take longer. So I really think that in terms of when that paperwork is done and the actual sites get signed off, I don't think we'll see that happen until Q2. But it really helped at this meeting in December, getting a better idea of when some of these sites are going to be able to actually start enrolling.

Unknown Analyst: Okay. Great. And then last one for me. I know you've mentioned raising patient awareness. And I'm wondering if you've kind of implemented any strategies or initiatives there that we could -- that could maybe help with awareness in 2026, like another Clara story, if you will.

David Rosa: Yes. So we have done some work with the Care organization, which is -- sorry, Cure, which is an epilepsy organization. And we're also talking to the Epilepsy Foundation to be able to partner with them to make this therapy more visible to patients. We just recently posted about a recent

patient that was a professional pianist in Chicago and was unable to continue his career because of seizures. And we found out this case was done this summer. And there were a couple of articles published in the Chicago newspapers that were sent to us by the neurosurgeon who performed the procedure. We were completely unaware of it. But it's stories like that and getting that information out to other patients, that's really critical. I mean, in this particular gentleman's case, he was able to resume his professional career when he was told there really weren't any other options. And lucky for him, he heard about that the patient Clara that we've reported on in the past went to the same doctor and had a very positive outcome. So we are still continuing to figure out in terms of partnering with these organizations on the best way of getting the message out through their help.

Unknown Analyst: Got it. Okay. I appreciate you taking the questions and looking forward to seeing you at JPMorgan.

David Rosa: Thanks, Destiny.

Operator: Your next question for today is from Anthony Vendetti with Maxim Group.

Anthony Vendetti: Dave, I was wondering if you could expand on the distribution agreement that you have with Zimmer Biomet. I mean, I know you said it has expanded, but can you provide a little more color on what that includes? And then just on the lower back pain, you said you advanced the development of that product. Can you talk about what that -- the development program looks like for lower back pain? And then I'll hop back in with one other question.

David Rosa: Sure. And thanks for joining the call. So let's talk about back pain first. That's probably the longer of the 2 questions. We actually have 2 programs for lower back pain. One that is the paddle electrode that I spoke about that can be placed percutaneously through a 14-gauge needle. So that program is ongoing. We did some testing last year in a chronic animal model. And we received some biocompatibility, some histology information. We also have some stimulation testing that we still need to do, which is what we'll be initiating in early next year. But that program is strictly the electrode, and the goal here is to really partner with an established company in the space. We've mentioned that we're having discussions with some of the larger companies that are well established in spinal cord stimulation. And the reason for that is twofold. One, we don't have internal resources for developing pulse generators. And I really don't feel like that's a core competency that the company has. The larger companies have this. We have the razor blade, and they have the razor, and we can provide something that they can't, or they haven't been able to at this point, which has advantages over the therapy today. But the real great advantage in my mind is the ability to kind of piggyback onto their PMA. Clearly, they've already gotten FDA clearances for their systems. And if we're able to do that, it's going to shave years off of our time line to get to market. So that's that program. The second one is the BVNA or the Basivertebral Nerve Ablation system and completely different concept, completely different condition that patients experience for this type of lower back pain. And what we're doing is, again, leveraging the generator that we're using for brain ablation, now facial ablation to really utilize that same system with our electrode to be able to go in and ablate the basivertebral nerve. So we've put together an advisory board of leading pain specialists who are very familiar with this procedure. We've had multiple meetings with them. We feel pretty confident that what we have will be able to offer advantages over the existing systems. Our multi-contact device has advantages over existing probes today. And of course, our temperature probe also has -- provides additional safety features when you're doing any of these ablations. But like our other pain management ablation systems, we will have to source other accessories to allow the pain specialists to be able to access the basivertebral nerve. So with respect to that program, we also are having separate discussions with strategics that have established businesses in treating lower back pain. One of the strategics that we're talking to is actually interested in both the basivertebral system as well as the spinal cord stimulation platform. So we still do need to do additional testing on the generator to ensure that we're able to develop the same size lesions for the basivertebral nerve that pain specialists are looking for. And then obviously, the development of the accessories through a third party. So that's the work that's needed on that program, but the goal is to really leverage what we already have, which is really the same strategy that we've employed over the last couple of years with the generator. And then with respect to the agreement, so the expansion really pertains to a year ago when we expanded the agreement beyond just the diagnostic sEEG electrodes with Zimmer to include the brain ablation system. So that was from, I believe, October a year ago. So

there's also the potential to expand beyond that. We obviously have the facial pain technology. So there's a potential that the relationship could grow beyond that as well.
Anthony Vendetti: Okay. So just to be clear, right now, the OneRF for trigeminal nerve ablation is not part of the Zimmer agreement and as well as the lower back pain, it sounds like you're speaking to strategic about that. It doesn't mean Zimmer Biomet wouldn't be one of the strategics, but you're having discussions with other strategics for those 2 programs, correct?
David Rosa: Yes. That's absolutely correct. Today, Zimmer does not have any distribution rights for facial pain. And the strategics that we're talking to for back pain do not include Zimmer Biomet. Zimmer, actually a few years ago, it may have been longer than that, divested their spine business. So this is not an active area that they participate in today.
Anthony Vendetti: Okay. Great. And then my last question is on reimbursement, the reimbursement landscape and the challenges that are always present when an emerging growth company comes to market with new technologies. Maybe just talk about a little bit of how you're navigating that?
David Rosa: Yes. So -- and that's a big question because the devices that we have in development have all different reimbursement codes. Some are well established. Some are -- some codes are more or less catchall codes in the event that there isn't one in particular for a certain procedure. I think the reimbursement codes for the devices in development are very well established. When you're talking about brain ablation, there is some generic codes that neurosurgeons or hospitals have been using to gain reimbursement, but not a specific code per se. It really hasn't seemed to, I'll say, be a hindrance with any of these neurosurgeons in terms of adoption. There's clearly cost advantages in using our brain ablation system. And the one that is pretty obvious is ablations today done with other competing systems are done in the operating room. And to our knowledge, there hasn't been one brain ablation done in the operating room. They've been done at the patient's bedside. And the cost of tying up an operating room for most of a given day are extreme. So the ability to do this at the patient's bedside without occupying the operating room is a huge cost advantage in the hospital today. But so far, we've been very fortunate. Neurosurgeons see the value of the technology, and it hasn't gotten in our way to date.
Anthony Vendetti: Okay. Great. Appreciate it.
David Rosa: Thank you.
Operator: [Operator Instructions] That appears to be the last question at this time. I would now like to turn the call back to Dave Rosa.
David Rosa: Thank you, operator. I would like to first thank everyone again for attending the call, and we look forward to connecting with the investor community throughout the quarter. If we were unable to answer any of your questions today, please reach out to our Investor Relations firm, MZ Group, who would be more than happy to assist.
Operator: Thank you. This concludes today's conference. We thank you for your participation. You may disconnect your lines at this time, and have a great day.