NRXS Earnings Call Transcript

Date: 2025-11-11

Quarter: 3

Operator: Good day, and thank you for standing by. Welcome to the NeurAxis, Inc. Third Quarter 2025 Financial Results Conference Call. At this time, all participants are in a listen-only mode. After the speaker's presentation, there will be a question and answer session. To ask a question during the session, you will need to press 11 on your telephone. You will then hear an automated message advising your hand is raised. To withdraw your question, please press 11 again. Please be advised today's conference is being recorded. I would now like to hand the conference over to your speaker today, Ben Shamsian, Investor Relations. Please go ahead.

Ben Shamsian: Thank you. Good morning, everyone. And thank you for joining us for NeurAxis, Inc.'s Third Quarter 2025 Financial Results and corporate update conference call. Joining us on today's call is Brian Carrico, CEO of NeurAxis, Inc., and Timothy Robert Henrichs, CFO. At the conclusion of today's prepared remarks, we'll open the call to questions. If you are listening through the webcast, you can follow the operator's instructions to ask questions. If you are dialed into the call live, you can press star 11 button. Finally, I'd like to call your attention to customary safe harbor disclosures regarding forward-looking information. The conference call today will contain certain forward-looking statements, including statements regarding the goals, strategies, beliefs, expectations, and future potential operating results of NeurAxis, Inc. Although management believes these statements are reasonable based on estimates, assumptions, and projections as of today, these statements are not guarantees of future performance. Time-sensitive information may no longer be accurate at the time of any telephonic or webcast replay. Actual results may differ materially as a result of risks, uncertainties, and other factors including, but not limited to, the factors set forth in the company's filings with the SEC. NeurAxis, Inc. undertakes no obligation to update or revise any of these forward-looking statements. With that said, I would like to now turn the event over to Brian Carrico, Chief Executive Officer of NeurAxis, Inc. Brian, please proceed.

Brian Carrico: Thank you, Ben. Good morning, and thank you for attending the third quarter 2025 Earnings Call. During today's call, I will highlight the continued execution of our commercialization strategy for IV Stem, our neuromodulation technology for both the pediatric and adult patient populations, and RED, our product for patients with evacuation disorders. The continued execution has set the stage for continued growth in the recent quarters and stronger growth expected in 2026 and beyond. We will recap Q3 and discuss the milestones and growth plans for 2026. Following my remarks, Timothy Robert Henrichs, our CFO, will review our financial results for 2025. We'll start with commercial execution and reimbursement progress. Our strategy remains laser-focused on expanding access through medical policy coverage and accelerating utilization of IV Stem as we approach the effective date of category one CPT code on 01/01/2026. While revenue growth has strengthened in recent quarters, providers are still treating only a fraction of the addressable market because national policy coverage and a permanent CPT code are not yet in place. Our top priority remains securing coverage under medical policy. Our internal prior authorization team continues to expand, helping hospitals reduce administrative burden and improve patient access. A critical step toward broader adoption. We believe we are making progress with payers. Many of the nation's largest insurers are now in active dialogue as they approach policy review dates at many points between now and through 2026. Our advocacy emphasized the urgent need for pediatric coverage in the clinical risks of the

off-label drugs with FDA black box warnings. To strengthen our message, we've mobilized a coalition that includes formal letters of support from the academic society, direct correspondence from leading children's hospitals, and national key opinion leaders, detailed updates from NeurAxis, Inc. to the payers, including the guidelines, the favorable ECRI clinical evidence assessment, the favorable up-to-date recommendations, and several additional strategies, which we will not be disclosing. Based on expert opinion, we have the most comprehensive payer engagement effort in our industry. The tone has been constructive, and we're confident this multichannel approach will drive favorable policy considerations. That said, we expect policy changes and prior authorization improvements to unfold gradually, not overnight. I want to now focus on and highlight the catalyst for what we expect to be continued revenue growth in the coming quarters. Two elements remain key to IV Stem's success. Number one, insurance coverage for access. And number two, physician RVU compensation for adoption. We now have roughly 55 million covered lives and continue to see positive payer momentum supported by the clinical practice guidelines published earlier this year. Regarding commercial readiness for 2026, in addition to the two key elements just mentioned, the commercial execution team utilizing these two elements is equally important and the primary focus of our commercial strategy. As the new CPT code takes effect and coverage becomes more available, it is paramount for children's hospitals to have enough dedicated time slots each week to treat the patients in need. Our commercial organization is fully aligned for the 2026 transition. We've prioritized target children's hospitals based on their utilization potential and launched comprehensive education and outreach, including direct engagement with the 75 children's hospitals who previously ordered IV Stem, division chief meetings with detailed RVU and financial modeling, comprehensive partnership with NASA beginning with a CME accredited presentation on November 12, integrated marketing, highlights the positive reimbursement shift, field programs focused on the clinical and economic value of the new CPT code, and we are working closely with all stakeholders to ensure there are dedicated weekly time slots available for patient treatment with IV Stem. These coordinated efforts are cultivating awareness and positioning IV Stem for broad adoption once the new CPT code takes effect. Our forecast remains conservative, recognizing that initial revenue conversion may lag as hospitals refine workflows and navigate early payer hurdles. As I just mentioned, coming off another quarter of growth year over year with Q3 coming in at a 22% increase marking the fifth consecutive quarter of double-digit growth. As this is our fifth quarter of double-digit growth, we are pleased that this amount of growth is coming considering the organic growth from the small number of hospitals comfortable with the current category three CPT code. More importantly, we hit another milestone as the big picture comes into more focus. This milestone is the indication expansion to functional abdominal pain associated with IBS and functional dyspepsia with associated nausea symptoms in the adult population, significantly increasing our market opportunity. Regarding the category one CPT code, the new category one CPT code represents a true inflection point. Effective 01/01/2026, this will streamline coding and reimbursement, introduce work RVUs for providers, and should substantially lessen the no authorization required response barrier that currently limits access with the category three CPT code. The reason this new CPT code is so critical is that it brings a permanent code with RVUs, making it much easier for providers to bill a procedure. It will allow reimbursement amounts for transparency and consistency, and it will provide work RVUs which is how physician productivity is measured. One could easily argue, as I've mentioned before, that physicians in a children's hospital setting are treating patients for free because there is no current work RVU associated with the category three CPT code. This will no longer be the case come January 1. As mentioned earlier, the new category one CPT code was assigned by the American Medical Association CPT panel and will be effective for utilization on January 1. Furthermore, the RVUs and payment values are now finalized for 2026, and we are very pleased with these numbers. This brings me to our commercial plan for IV Stem in adults. The FDA indication that was just awarded. As we all know, the category one CPT code for IV Stem will translate to adults because it's the same physician work for the same device technology. What everyone may not know is that although we have FDA clearance for adults with IV Stem, it was based on extrapolation of adolescent data to adults. Thus, there is not a large study conducted in adult patients alone. So medical policy coverage is not immediately likely. This means there could be 2026 coverage and reimbursement issues for IV Stem in adults. None of this is a big surprise to us, and is why we have

been and will be spending our focus on the pediatric side of the business. Having said all that, we are approaching the adult IV Stem market from three angles. First, we are in the final stages of signing a contract with a prestigious institution to do a randomized controlled trial in adults. Second, we have submitted for a federal supply schedule contract, also known as an SSS contract, for access into the Veterans Administration. We are cautiously optimistic we will have an SSS contract by early 2026 with IV Stem on that contract. This will enable a commercial path into the VA, which is responsible for nearly seven million active patients per year with a functional dyspepsia prevalence rate of 3%. We are dedicating sales resources to this endeavor and will expand as we get feedback and see results. Third, we are doing a limited market release on the private and commercial side for IV Stem to gauge the insurance acceptance of IV Stem in adults using the cat one code and ultimately gauge whether there is a cash pay market if insurance is not favorable. Turning to RED, our rectal expulsion device. RED allows for earlier, more targeted treatment decisions for patients with chronic constipation, a meaningful improvement for patients and providers. We are selling the device and continue to see good physician interest. But being a new technology means practice flow changes and physician habit changes. Furthermore, there is an existing category one CPT code and strong reimbursement, but we have learned that there will be a new CPT code effective January 1, which may or may not be positive for RED. So we expect to learn in detail what this means before January 1. To this point, RED in the private market is to be determined but we will be exploring RED in the VA due to the synergy of a sales force calling on adult gastroenterologists in that location. In summary, we're executing against the milestones that matter most. Payer coverage expansion, CPT code implementation, commercial readiness, and execution. As we move into 2026, the focus is clear: drive national medical policy coverage, maintain disciplined commercial execution, and achieve cash flow breakeven as adoption accelerates. Although we are far from satisfied, we're proud of the progress made this year to date and energized by the opportunities ahead. For our shareholders, our team, and the 1,000,000 patients who stand to benefit from our therapies. I will now turn the call over to our CFO, Timothy Robert Henrichs, to discuss the financials.

Timothy Robert Henrichs: Thank you, Brian, and let me add my welcome to everyone joining us on this call. These financial results were included within our press release, which was issued earlier this morning and were also provided in more detail within our 10-Q that was filed yesterday. I will provide some additional detail in key areas such as our financial results and liquidity position as well as an outlook on certain areas. The 2025 marked the fifth straight quarter of double-digit revenue growth year over year, as Brian mentioned previously. We are proud of our achievements and market penetration in 2025. Especially since that double-digit revenue growth is not even reflective of the milestones we achieved this year. Namely the FDA indication expansion to functional abdominal pain and functional dyspepsia with associated nausea symptoms in both children and adults, IV Stem label expansion from 11 to 18 years of age to 18 to 21 years old, including an increase of devices per patient to four. The published Naspigan Academic Society guidelines, the new category one CPT code, work RVUs, and reimbursement values as well as the RED device. Our operational, regulatory, and clinical accomplishments coupled with our revenue growth, strong gross margins, and operating expense leverage are setting us up well for strong growth in 2026 when a category one CPT code becomes effective. With that, I'll go through the financial highlights in detail. Revenues in 2025 were $811,000, up 22% compared to $677,000 in 2024. Unit deliveries increased approximately 38% compared to the prior year due to volume growth from patients in the company's financial assistance program that provides discounts to those without insurance coverage. In fact, 2025 marked the sixth straight quarter of double-digit unit growth. And although our average selling price to these patients was lower, we are encouraged by the increase in the volume for the quarter because these transactions are expected to convert to full reimbursement at a higher gross margin once insurance coverage is obtained in the future. In fact, this growth does not come as a surprise to us, as we assembled a dedicated internal team to deliver for these specific patients as our mission is to treat everyone regardless of their income level or insurance coverage. Additionally, a smaller portion of the revenue growth in the quarter is due to the soft launch of the RED product line in 2025. Given the achievement of the recent milestones, we expect revenue growth to continue in the fourth quarter prior to the effective date of the new category one CPT code given the strong demand and acceptance on the part of healthcare providers and

patients for our products. Gross margin in 2025 was 83.3% compared to 85.4% in 2024. Despite the double-digit growth in sales, the decline in our gross margin year over year was due to one, higher discounting on devices sold through the financial assistance program to patients with lower income levels, two, stronger unit growth in the lower margin financial assistance program compared to the full reimbursement program, and three, expired RED inventory charges as the soft launch ramped slower than expected. Despite the decline in our gross margin in the third quarter, we expect our gross margin to recover into 2026 when a new category one CPT code becomes effective on 01/01/2026, which we expect will transition currently discounted device sales to full reimbursement revenue with insurance coverage. Total operating expenses in the third quarter of 2025 were $2,800,000, an increase of 25% compared to $2,200,000 in 2024. We measure and manage our operating expenses in three distinct buckets: sales and marketing, research and development, and general and administrative. As we continue to grow at a double-digit pace, we realized that investors would benefit from a more transparent presentation of our sales and marketing and research and development costs as those are indicators of our future success. As a result, we reclassified $243,000 and $54,000 from general and administrative expenses into sales and marketing and research and development costs respectively, in 2024 to conform to current period presentation. Selling expenses in 2025 were $762,000, a 125% increase compared to $339,000 in 2024. The increase is due to sales commissions that are directly proportional to our higher sales volume, a temporary commission structure to facilitate growth and adoption in new states, and higher targeted advertising and marketing costs as we prepare for IV Stem's CPT category one code effective date on 01/01/2026. Research and development expenses in 2025 were $131,000, an increase of 4% compared to $126,000 in 2024. The increase is reflective of higher year-over-year spending on a medical research project. It is worth noting that our research and development expenditures are up 18% year to date in 2025 compared to 2024 due to our successful efforts in achieving FDA approvals for multiple indications including the first-ever clearances for functional abdominal pain and functional dyspepsia with associated nausea symptoms in both children and adults. The expansion of the IV Stem label to allow for a larger patient population beyond eleven to eighteen years of age to eighteen to twenty-one years of age, including an increase of devices per patient to four, and the RED device. We expect our research and development activities will continue to grow into 2026 and beyond as we identify incremental patients and markets that will benefit from our technologies. General and administrative expenses of $1,900,000 in 2025 were 7% higher than the $1,800,000 in 2024. This increase was due to the introduction of a long-term incentive plan in 2025 that did not exist in 2024, and third-party costs incurred to enhance the company's systems and its internal control environment, partially offset by the absence of certain one-time nonrecurring consulting and advisory costs incurred in 2024. Our operating loss in 2025 was $2,100,000, 27% higher compared to a $1,700,000 loss in 2024. And our net loss in 2025 was $2,100,000, 21% higher compared to $1,800,000 in 2024. Our higher gross profit from increased quarterly sales year over year was offset by the higher operating expenses that I just walked through. As it relates to liquidity, cash on hand as of 09/30/2025 was $4,400,000. And we improved our liquidity position in October 2025 by raising an incremental $2,800,000 through an at-the-market equity offering and the exercise of warrants. Lastly, our free cash flow in 2025 remained at our expected burn rate of $1,500,000. Increased cash collections from our growth were offset by our higher inventory purchases to prepare for the IV Stem CPT category one code effective date on 01/01/2026 and higher advertising spend that I previously mentioned. And with that, let me turn the call back over to Brian.

Brian Carrico: Thank you, Tim. To summarize, while we have recently achieved several critical milestones, we are still in the very early stages of what we expect to be substantial top and bottom line growth over the coming quarters. Our continued execution of the commercial strategy highlighted by the assignment of a category one CPT code for PE and FS and the broadened 510(k) clearances is expected to drive the scale and growth. With that, operator, we'd be happy to take any questions.

Operator: Thank you. As a reminder, to ask a question, please press 11 on your telephone and wait for your name to be announced. To withdraw your question, please press 11 again. You can also ask a question on the webcast by typing into the ask a question box. Please stand by while we compile the Q and A roster. And our first question comes from Chase Richard Knickerbocker at Craig Hallum. Your line is open.

Chase Richard Knickerbocker: Good morning. Thanks for taking the questions. Congrats on the progress. Brian, I just wanted to start maybe on how you're tracking success and, you know, incentivizing your team ahead of kind of that expected volume inflection next year? Obviously, there's a lot of kind of prep work to prep the ground for that potential volume inflection with the CAT one code and hopefully national coverage at some point in the future here. Can you speak to kind of how you're incentivizing your commercial team to make sure those, you know, IV Stem days are getting set up and kind of prepping those accounts to handle more patients?

Brian Carrico: Well, two answers for you. One, we have a strong commercial sales force. We have a sales force that has been here for five, six, eight, ten years. They know the technology extremely well. I will tell you that from an internal forecast, this team forecasted what appears to be our 2025 revenue that they're going to come in within $50,000 on the year, which speaks to how well they know the account and the stage of the account. I would tell you they're highly incentivized from a commission structure standpoint. And I would tell you that they are being extremely diligent from a prioritization standpoint. When I say that, I mean areas and states that have good insurance policy coverage. That will now have a category one CPT code. That takes highest priority. And then even accounts that have ordered previously in those states become the top priority because it's always easier to grow legs on an account with champions than it is to open a new account, which takes time regardless. So I don't know if that answers your question, Chase, but I would tell you that there's not a lot of noise. No one's off in the weeds. They're highly motivated from a financial standpoint and from the fact that they've been here as long as they have, and they know the accounts as well as they do. The demand has always been there. So these relationships, this is all coming to fruition. And look, everyone's going to learn to some degree in the first quarter together on how this category one code responds in areas with insurance coverage and in areas that don't have written insurance policy coverage. And the good news is as we implement the category one CPT code, which, of course, affects every physician and patient nationally, it will give Tim and I an opportunity to be more predictive with how we see revenue rolling out, and we'll do that. We do that from a macro standpoint and from a micro standpoint. We go through the commercial sales team has gone through for the last several years account by account, state by state, and put together a forecast for the upcoming quarters and year. And that hasn't changed, and I believe with this category one code rolling out, we'll be able to look at again, how the revenues respond in areas with or without insurance policy coverage. That will give us an opportunity to predict, I believe, better than we have. What revenue looks like going forward. But I do think that will take thirty, sixty, ninety, at least a quarter, if not two quarters. I think by mid-2026, we've got a really good handle on what's working, what's not, and how we can materialize and drive revenues in all areas based on the success where we are.

Chase Richard Knickerbocker: Is there any way you can help us think about kind of that volume inflection that would be seen, you know, just from the CAT one CPT code alone even kind of before national payer coverage? Have you kind of started that, any of that forecasting exercise with your commercial team as far as kind of how you're thinking about Q1 and Q2 year if we just kind of get the CAT one code, you know, in isolation?

Brian Carrico: Yeah. We have in areas where we have insurance policy coverage, if you saw our internal forecast, you would see a better adoption rate and more confidence in the projection in areas where there is insurance policy coverage or some insurance policy coverage because we know those children's hospitals will have insurance policy coverage and a category one code, whereas areas without policy coverage, the trial by fire will be, you know, there is some confidence from children's hospitals without policy coverage that they will still do decent and get some approvals, more approvals than they are now with a category one CPT code for multiple reasons. But that's, you know, we're not going to step out on that limb yet. We want to wait and see what the response is right now. Our focus from a forecast standpoint is absolutely being in those areas where there is insurance policy coverage and there will be a cat one code, which in our world is a perfect world.

Chase Richard Knickerbocker: Got it. And then just last couple for me. Any update, Brian, you'd be willing to give us on kind of engagement with payers? Any sort of new thoughts there as far as we kind of track towards, you know, hopefully, payer coverage at some point in the future here. And then just

second for Tim on the SG&A;, just as far as if you could help us quantify any additional commercial investment that we'll be making ahead of that CAT one code and how that flows through to incremental SG&A; growth as we look into Q1 and Q2?
Brian Carrico: Yeah. On the payer coverage, I would just say that payers traditionally don't engage heavily with industry, and that's the same with us. They're responsive. We believe that they're fully aware of this, you know, the category one code, which we believe brings strong credibility. They're fully aware of equity and up-to-date. And the society's feelings on the technology and the society's feelings on the concern for the antidepressants and the drugs that are being given to the children before IV Stem and the need for IV Stem policy coverage. But, you know, there are some things I'm just not going to get into publicly right now. But, you know, I would just say I like our position. And we feel good about the comprehensive approach we're taking with these payers. And they are responsive, and, you know, in most, if not all policies that we currently have, we didn't know until they were announced publicly that we had policy coverage. So I don't expect that to change and don't expect to get some big heads up that we were receiving another policy coverage.
Timothy Robert Henrichs: And, Chase, to follow-up on your question regarding the SG&A; expenses, so two areas as we head into 2026 and beyond where I think we're gonna focus special attention. And we saw it here in the third quarter, is that our sales and marketing efforts first. Historically, our marketing efforts have been, you know, kind of general across the patient population. In the third quarter, we moved the ball a little bit and decided to change our strategy and specifically target payers because of what's at stake here. And we think it's a matter of when, not if, which you can see in the third quarter, obviously, our marketing expenses, you know, more than doubled quarter over quarter. And I'm not necessarily committing to doubling that every single quarter, but I think that once we start to see that increased insurance coverage from the change in our marketing effort, I do think we're gonna continue to see higher marketing costs as we go into 2026. Because that is a direct, in my opinion, direct link to our sales. So as long as the sales are there, which we believe they will be, we will continue our new and improved marketing efforts targeting payers. Secondly, on the other area is R&D.; Brian mentioned particular with, you know, the adult population and IV Stem because we got that indication from the FDA. When we head into 2026, we're gonna have, you know, an additional randomized controlled study or trial as well as other costs because our market is expanding with the device. The beauty of the IV Stem device is it has many purposes, but, obviously, we continue to work with the FDA to get those approvals and when we do get that approved, it expands our market share. So as long as that continues to happen, which it has and we expect it will, we will continue to invest in R&D; in the device in order to expand our market share. So I expect our R&D; cost to increase when we head into 2026. From a G&A; perspective, you know, generally speaking, as our sales grow, we will hire more sales reps. And then there'll be commission associated with that. But I, you know, really look at that as variable. If you will. It'll be direct relation to sales. And the rest of the G&A;, albeit not necessarily all fixed, I think we've been holding that pretty steady and taking some cost out just behind the scenes. Obviously, not doing anything to harm the business, but just to do, you know, good financial discipline and negotiate and continue good contracts for the company at cheaper rates and better services. So that's how I would sum up how we're thinking about 2026 G&A; expenses.
Brian Carrico: And, Chase, I would add to that that based on the results of the category one CPT code in areas with insurance policy coverage and in areas without insurance policy coverage, we have some plans teed up and that's in our internal budget for 2026. My point is we'll be ready to pull the trigger regardless of what works and where. We're ready to do some things whether, albeit, add additional salespeople on the pediatric side, whether, albeit, add additional salespeople on the adult side, whether it's private or VA, whether it's additional targeted marketing to healthcare providers to make sure this is top of mind and used early and often. There are multiple levers we have teed up to pull, enter in the budget, and we'll pull those accordingly. Doing that before January 1 or even in January, I think, would be equivalent to shooting before you aim. We want to make sure that we understand exactly what's happening before we utilize resources.
Chase Richard Knickerbocker: Helpful. Thank you, guys.
Operator: Okay. Brian, we have some questions that have come in. Question on RED. It's not a priority right now, but how do you see the revenue ramp here in the early innings in terms of what do you need

to do to further educate the doctors on this?
Brian Carrico: Well, first off, this to some degree, competes with ARM, and ARM is well entrenched in the market. ARM reimburses very well. RED has a nice reimbursement right now. But as I mentioned in the call, RED changes not only physician practice habits, but it changes physician practice flow. And when you combine those two, it takes longer to get this up to the scale that we expected as fast or, I should say, as we wanted. And going into 2026, this is pretty straightforward. We've got to understand the CPT code reimbursement and the work involved in that CPT code, and we're waiting on some answers from the AMA and from societies, and we won't have that information, I believe, until mid-December. I do expect we'll have it by January 1. Look, it's a nice-to-have product. It's in the bag with the reps who are at that call point. That should also be the case in the VA going into 2026. But our focus without question is on IV Stem in the children's hospitals.
Operator: Okay. Thank you. A question for you, Tim. Can you speak about the current cash balance and sort of where do you see that taking you here?
Timothy Robert Henrichs: As I previously mentioned, we ended the quarter with $4,400,000. Then in October, we utilized the aftermarket offering and some warrants were exercised for an incremental $2,800,000. When we head into and in the third quarter, we were still in our run rate at $1,500,000 a quarter. Now in the fourth quarter, then as we head into next year, we have two, what I would call, nonstandard payments going into 2026. If you recall back in July, we reacquired the license from Massimo for our NSS Bridge device. There's a payment due at the end of this calendar year and then another payment next year. And then we settled a lawsuit in the first quarter and that will be paid out in 2026 as well. And so those are incremental payments when we move into 2026. But having said all of that, excluding that, our $1,500,000 burn rate is still intact in 2026, and I expect the current cash balance to last us well into 2026. And then what that does is that gives us a chance. Everything that Brian talked about with the category one CPT code, depending on how that ramps with IV Stem, if it ramps faster than what we expect, our cash and liquidity will last us longer. If it's slower, I would tell you as we look into 2026, we generally try to be conservative with our internal forecast. We feel pretty confident about that $1,500,000 run rate. So it could go even longer into 2026. I mean, it ramps even faster if we get one big insurance payer that could obviously change the game for us and really limit any additional equity raises that we may need. But as it stands right now, my current expectation is that the current cash position and our liquidity lasts us into 2026.
Operator: Thank you. And as a reminder, if you have an audio question, please press 11. And at this point, there are no more questions in the queue. Therefore, I'd like to turn the call back over to Brian Carrico for closing remarks.
Brian Carrico: Thank you, everyone, for joining the call today. If anyone wants to follow-up in the coming weeks and months, I'm generally available. And we look forward to communicating any additional successes in the coming months. And everyone have a nice rest of the fall and winter. Thank you.
Operator: This concludes today's conference call. Thank you for participating and you may now disconnect.