

# **HYPR Earnings Call Transcript**

**Date: 2025-11-13**

**Quarter: 3**

Operator: Good afternoon, and welcome to Hyperfine, Inc.'s Third Quarter 2025 Earnings Conference Call. Currently, all participants are in a listen-only mode. We will be facilitating a question and answer session towards the end of today's call. As a reminder, this call is being recorded for replay purposes. I would now like to turn the call over to Webb Campbell from Jill Martin Group for introductory disclosure.

Webb Campbell: Thank you for joining today's call. Earlier today, Hyperfine, Inc. released financial results for the quarter ended September 30, 2025. A copy of the press release is available on the company's website as well as sec.gov. Before we begin, I would like to remind you that management will make statements during this call that include forward-looking statements within the meaning of federal securities laws, which are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Any statements contained on this call that relate to expectations or predictions of future events, results, or performance are forward-looking statements. All forward-looking statements, including, without limitation, those related to our operating trends and future financial performance, expense management, expectations for hiring, training and adoption, growth in our organization, market opportunity, commercial and international expansion, regulatory approvals, and product development, are based upon our current estimates and various assumptions. These statements involve material risks and uncertainties that could cause actual results or events to materially differ from those anticipated or implied by the forward-looking statements. Accordingly, you should not place undue reliance on these statements. For a list and description of the risks and uncertainties associated with our business, please refer to the risk factors section of our latest periodic filings with the Securities and Exchange Commission. This conference call contains time-sensitive information and is accurate only as of the live broadcast today, November 13, 2025. Hyperfine, Inc. disclaims any intention or obligation, except as required by law, to update or revise any financial projections or forward-looking statements, whether because of new information, future events, or otherwise. With that, I will turn the call over to Maria Sainz, President and Chief Executive Officer.

Maria Sainz: Good afternoon, and thank you for joining us. On the call with me today is our Chief Administrative Officer and Chief Financial Officer, Brett Hale. The third quarter marked an important new beginning for our business, driven by the launches of our next-generation subsystem and the Optive AI software. We delivered revenue of \$3.4 million, up 27% sequentially, and materially expanded gross margins to a record of nearly 54%, supported by a record average selling price of \$361,000. We also drove a meaningful reduction in cash burn, down 27% sequentially, excluding financing. And in October, we strengthened our balance sheet by raising over \$20 million to extend our cash runway into 2027. We have discussed 2025 as a year of transformation and a tale of two halves, with the second half of the year's performance driven by the growth catalyst that came to fruition over the last few months, namely the new technology launches as well as the full launch into the new office market. I am pleased to report that after the first hundred days with our next-generation subsystem and the Optive AI software in the market, we have user feedback and proof points to feel confident our technology is now ready for mainstream adoption across the hospital, office, and international markets. In addition, we also have capital to support our commercial rollout for the foreseeable future. The third quarter is just the beginning of the next exciting chapter for Hyperfine as we meaningfully accelerate growth, drive commercial adoption, gain operational leverage, and improve our financial performance.

Market interest and demand for our next-generation system is very strong. In the third quarter, we focused on deal activation and executed a seamless commercial launch, selling multiple units and building our sales funnel. Taking a step back, our journey to date has been driven by continuous innovation and iteration to deliver portable AI-powered MRI technology ready for mainstream adoption and scale. We launched the first-generation portable brain MRI system in 2020 with a very compelling clinical promise. The 64 millitesla mass net strength allowed for safe scanning anywhere, and the system was portable. The original image quality was in its infancy. Over the last five years, we have greatly improved image quality, incorporated AI, and have listened to our users closely to deliver a next-generation system that is ready for broad adoption. The next-generation system operates on the Optive AI software, which is our tenth-generation AI-powered software. In addition to a step-function improvement in image quality, additional upgrades include a user and patient-centric design to accommodate a broad patient population, especially beneficial for pediatric, elderly, or anxious patients, making MRI more accessible for all. Early users appreciate this system's high level of image quality, functionality, and usability. Many users have commented on how closely our Optive AI image quality resembles that of high-field scanners. Moreover, our office clinical study enrolled in the last few months will give us a robust dataset of comparative cases between the subsystem and high field, which I will discuss later in this call. The proprietary hardware in the new scanner enables us to drive image quality innovation through software updates going forward at a cadence of one to two releases per year. We are planning our first upgrade to the Optive AI software to be released in 2026. I am very proud of the AI expertise and leadership we have built at Hyperfine. We continue to be featured prominently on the AI-enabled medical devices list published by the FDA amongst the largest players in healthcare. Observing clinicians note that the images produced by our next-generation system with Optive AI approach those of conventional 1.5 Tesla MRI scanners, which is a testament to the impressive technical lead Hyperfine has developed in ultra-low field MRI. The radiology community is key to the adoption of our subsystem. This community has provided overwhelmingly positive feedback on our current image quality and is now broadly supportive. This new subsystem paired with Optive AI has triggered an activation of commercial deals markedly different than what we have seen in the past, with interest from multiple sites of care inside hospitals down to the most remote community health setting. I will now provide an update on our three diversified commercial verticals: the hospital, the office, and our international markets. Starting with our progress in the US hospital setting, we have placed our new system in all the hospital sites of care we call upon today, including adult critical care, pediatric critical care, and the emergency department. The device MSRP of our new subsystem is \$550,000, roughly a 15% premium to the prior version. And these next-generation subsystem hospital placements resulted in a significant average selling price uplift in the third quarter. We have also converted our entire hospital deal pipeline to the next-generation subsystem. Compelling clinical utility, strong economic value proposition, multiple sites of care placement, and broad health system and IDN engagement are key long-term drivers to our hospital strategy. The clinical interest for the subsystem in ICUs, ERs, ORs, and clinics continues to increase to address the very real issues related to timely access to MRI and patient progress. The economic value proposition associated with the adoption of the subsystem, reducing cost, accelerating patient progress, and freeing up conventional MRI scanners for additional elective procedures, is compelling to administrators. Hospitals' return on investment assessments are showing one to one and a half year breakeven timeline versus three to four years typical for capital equipment. Although the subsystem is a capital acquisition process in the hospital setting, with strong radiology support, clinical interest, and administrative buy-in, we are now seeing higher priority placed on subsystem projects and acceleration of the deals in our pipeline. Our ability to go deep in the hospital and broad through health systems and integrated delivery networks is beginning to materialize. I am happy to share that in the third quarter, we sold two subsystems into the same hospital network, and our pipeline of multiple deals by hospitals is robust. Today, we are actively engaged with several health systems and IDNs to evaluate system-wide deals to standardize care. Generating evidence to further clinical relevance continues to be an important investment for us. Our work in stroke triage supports expansion into the emergency room, with the value proposition of the subsystem being strong given the importance of time to scan and the focus on patient progress in the ER setting. Our most recent effort, the PRIME study, being led by the Yale School of Medicine,

evaluates the potential of AI-powered portable MRI technology to triage a broad, diversified set of patients who present to the emergency department. Enrollment in PRIME is going well, with over 75 patients enrolled. We have also begun evaluating the use of the subsystem in the Operating Room for neurosurgery, which represents a potential additional use case and expansion of our total addressable market. We recently commenced PRISM PMR, a study designed to collect data and optimize the subsystem's real-world clinical utility in this setting. We have enrolled over 20 cases at this point. Now turning to the office. In the third quarter, we commenced our full commercial launch of the subsystem into the neurology office setting. A completed pilot program in which multiple sites secured IAC accreditation, scanned patients, and received payment through the reimbursement process with CNS and private payers validated this opportunity. As I have previously mentioned, neurology offices represent a very compelling opportunity for the subsystem. Neurologists directly impact 100 million patient lives in the United States and order an average of 500 to 600 MRIs annually. But only approximately 10% of private neurology practices have MRI equipment on-site. The neurology office call point is large and diversified, with practices of many sizes based on the number of practitioners and volume of patients. We are proceeding with selling both the first model subsystem with Optive AI and the next-generation subsystem with Optive AI to provide more pricing flexibility in this setting. To drive the adoption in the office, similar to our strategy in the hospital, we have several clinical studies underway. Our most recent study, Neuro PMR, is run in the neurology offices to compare portable ultra-low field MRI and conventional 1.5 and 3 Tesla high-field MRI with respect to pathology findings, clinical utility, and patient experience. I am happy to share that the study has completed enrollment, and data is expected in early 2026. Additionally, our Alzheimer's study, Care PMR, continues enrollment with ongoing presentations of the increasing dataset at major medical conferences, most recently at AAIC 2025. Our team has been actively selling into both single and multiple clinician practices, building relationships and pipelines of both first and next-generation subsystems as we deploy a strategic segmentation pricing strategy to engage offices of all sizes. Additionally, we have been leveraging our partnership with NeuroNet to promote the subsystem to their network of neurology practices. Our full commercial launch in the office is still in its early days, and I have high optimism for this business vertical and its growth potential. Finally, turning toward international markets, where we are focused on selling primarily into the hospital setting. During the third quarter, we received CE Mark and UK CA Mark approvals for Optive AI software, and we now expect to launch Optive AI in 10 different European languages by the end of the year. We also expect our next-generation subsystem to be available in Europe and Canada markets by 2026. In the past few weeks, the subsystem was referenced in France's largest public hospital procurement body to facilitate nationwide purchases of portable MRI technology. Our international strategy includes our goal to launch in India, where we continue to anticipate regulatory approval before the end of this year. Looking ahead, we are driving three pipelines, one for each of our business verticals. The aggregate Hyperfine pipeline is stronger and more diversified than it has ever been. In conclusion, I am more optimistic than ever about the path ahead for Hyperfine. We now have a system that is ready for mainstream adoption and a diversified set of revenue-generating opportunities as we sell into hospitals, offices, and international markets. With this offering, we will be driving significant growth and financial performance improvement going forward. With that, I will now turn over the call to Brett to review our financial performance and 2025 guidance.

Brett Hale: Thank you, Maria. I will recap our financial results for 2025 before providing an update on our financial guidance. Revenue for 2025 was \$3.4 million, up 27% sequentially. In 2025, we sold eight units, had a strong mix of next-generation subsystem sales, and delivered a record average selling price. Gross profit for 2025 was \$1.8 million, and gross margin for 2025 was 53.8%, a record and representing a 450 basis point increase sequentially driven by the increased average selling price. We continue to drive healthy margins for our stage and believe we are well-positioned for meaningful margin expansion at scale. R&D; expenses for 2025 were \$4 million, a sequential quarterly decrease from \$4.5 million in the previous quarter. We continue to realize the benefits of the reorganization completed in the first quarter as we transition to a commercial growth stage organization. Sales, general, and administrative expenses for 2025 were \$6.7 million, as compared to \$6.4 million in the previous quarter. Net loss for 2025 was \$11 million, equating to a net loss of \$0.14 per share, as compared to a net loss of \$9.2 million or a net loss of \$0.12 per share in the prior sequential quarter.

The third quarter 2025 net loss and the second quarter 2025 net loss included a non-cash change in fair value of warrant liabilities of \$2.3 million and \$0, respectively. For 2025, our net cash burn excluding financing was \$5.9 million, down 27% sequentially from the prior quarter. Reducing our cash burn remains a significant focus of ours, and we will continue to prioritize spending discipline and optimize our operating leverage while also balancing the needs of our ongoing commercial launch and associated growth trajectory in 2025 and beyond. Our net cash burn including financing in 2025 was \$3.9 million, and as of September 30, 2025, we have \$21.6 million in cash and cash equivalents on our balance sheets. This cash balance does not include the \$18.4 million in net proceeds raised from our October 16 equity financing and subsequent greenshoe that totaled \$20.1 million in gross proceeds. We are in a strong capital position to continue fueling our commercial efforts. Now turning to our financial guidance. We expect revenue in 2025 to be approximately \$5 to \$6 million. This guidance range equates to a very significant revenue step-up and at the midpoint represents sequential and year-over-year quarterly growth of 60% and 137%, respectively. Accordingly, for the full year 2025, we now expect revenue to be \$30 million to \$40 million. For the full year 2025, we are now increasing our gross margin range to 49% to 51%, representing a 430 basis point increase in gross margin on a year-over-year basis at the midpoint. We expect the progression of gross margin percentage increase to closely follow our sales growth. We expect gross margins to exceed 50% going forward as we realize higher volumes and average selling prices driven by the execution upon our growth catalyst. Lastly, we now expect total cash burn to be in the range of \$29 million to \$31 million for the full year 2025, representing a 22% decline in cash burn on a year-over-year basis at the midpoint. We continue to operate lean, with strong spending discipline while making investments in areas such as inventory and commercialization to support our recent launches and capitalize on our strong commercial growth prospects. With our strengthened capital position, we now see our cash runway for the business lasting into 2027. I would now like to turn the call back to Maria for closing comments.

Maria Sainz: Thank you, Brett. I am very proud of the Hyperfine team and the excellent work done to bring to market the Optive AI software and the next-generation subsystem. Medical technology businesses that build new markets often go through this transition from a first-generation pioneering technology to a next-gen ready for broad adoption. That is the transition we are undergoing at Hyperfine. The fundamentals remain strong, with broad labeling and existing reimbursement. Our strategy to diversify into multiple sites of care inside and outside the hospital and expand internationally is beginning to yield results. In addition, we now have capital to support our commercial growth for the foreseeable future. Q3 is just the beginning of the next exciting chapter for Hyperfine. With that, we now open the line for questions.

Operator: Thank you. You will need to press star then the number one on your telephone keypad. And if you would like to withdraw your question, press star 1 again. We do request for today's session that you please limit to one question and one follow-up. Your first question comes from the line of Frank Takkinen with Lake Street Capital Markets. Your line is open.

Frank Takkinen: Great. Thank you for taking the questions, and congrats on the progress. I was hoping to talk a little bit more about the composition of the backlog, maybe by setting would help as you are entering some new settings, maybe where have you seen backlog growth? And then as a second part to that question, just maybe talk about what is really supporting the \$5 million to \$6 million fourth quarter guidance. Is that record backlog? Is that faster conversion from order to actual shipment and revenue recognition? Any kind of context around that to support the guide would be helpful. Thanks.

Maria Sainz: Sure. Hi, Frank. So, our pipeline, I think, it has evolved now with the full launch in the office business to be really three pipelines that we are really managing independently, and I would argue that we have the eyes of our sales leaders, but also our strategy leaders by business vertical, very, very intently involved in it. So we are managing a pipeline only associated with US hospital deals, another on US office deals, and the third one, which is our international business. So when you really add those three layers, the total continues to be an incredibly robust pipeline that is growing significantly from anything we have seen in previous quarters before we had again the new technology on the one hand but definitely the office business. The \$5 to \$6 million is predicated on what we are seeing in the pipeline, exactly the deals that are there. We do not comment on intra quarters. Sort of numbers. But I would say we are not only seeing more rows in the pipeline, but we are seeing more

rows that have more than one unit. For some of the accounts that are looking to purchase this quarter and more going deeper into some of the IDNs with going from the first hospital in an IDN to a second hospital in the IDN. We are also managing the pipeline by individual, fed territory or sales area. So we are also very triangulating to make sure that we have confidence that we are not putting sort of all of the eggs in the one basket or one area, and we have a very nicely diversified across geographies and across the three verticals.

Brett Hale: Yeah. I would add. This is Brett. I would add that the fourth quarter is the second quarter of the launch for both the next-generation technology in the hospital as well as in the office setting. So we, I think, commented previously that the first quarter was that first hundred days, and now we are into that, really, that second quarter where we converted the entire pipeline of hospital deals to next-generation technology in Q3. And we are seeing those that well, they are working through the process, and we anticipate, you know, them landing, you know, a subset of them landing here in Q4. So just kind of the natural order of the launch trajectory. Both with the next-generation technology as well as the office setting.

Frank Takkinen: Got it. Really helpful. Thank you. And then maybe if I could try for 2026, I realize you are only talking about 2025 today, but any directional comments you can speak to on 2026 as we have a confluence of different growth drivers coming together at one.

Maria Sainz: Appreciate the question, but I am going to tell you we are not really going to provide a lot of direction around 2026, a little bit because as Brett just mentioned, we are on quarter two of the launch. And a lot of what we are going to use, really, I like to think of Q3 as an incredibly important quarter where the first quarter showed sort of the excitement and the feedback on the actual technology and the beginning of that activation. This is the second quarter. A lot of it is going to be the launch pad into 2026. So we really would prefer to reserve the commentary around 2026 until we get into the beginning of 2026 with a closed Q4 as well. Again, it will continue to be composed of the things that I just outlined, so it is the three pipelines and it is clearly, time is always a friend because more things get added into the pipeline, and the hospital deals, as we know, sometimes take time. So, but for now, I think we are going to focus more on just what is near term Q4, 2025.

Frank Takkinen: Okay. Fair enough. Thank you.

Operator: Sure.

Maria Sainz: Thank you.

Operator: Your next question comes from the line of Yuan Zhi with B. Riley Securities. Your line is open. Hi. This is Paula on for Yuan. Thank you for taking our questions and congratulations on the quarter. I have a couple of questions. First, can you provide an update on the timeline and initial trajectory of market penetration in the neurology office? And when can we see a ramp-up of orders? And the second is for international expansion. Does it take similar time or longer time to sign the contract versus those in the US? Based on your current experience, what do you think are the major bottlenecks for international expansion? Thank you.

Brett Hale: Great. So I think the I'll just maybe repeat the question, make sure we've got that right is that you're speaking about the penetration and foremost, into the neurology office. And then the timeline on international deals. Did I get that correct?

Maria Sainz: Yes.

Operator: Okay.

Maria Sainz: So great question. So in I think in neurology offices, we really have a very active pipeline. We have said I think the call point is very, very large. So thinking in terms of percentage penetration, it's a little bit more challenging because I think what is really, really important to understand is how the offices are really grouped between what I would call the more solo practitioners, a single practitioner versus multiple practitioners. That immediately dictates the size of the practice. And with the size of the practice, there's a very strong correlation to the volume of scans that they are going to do and how they think about the economics of being in technology like the subsystem to add on imaging to their offering. Right now, we have a bit of a segmentation approach where we are using our first model with the latest software with Optive AI at a price point that offers more flexibility to go into the smaller offices. And we are using, of course, our next generation with the same software, Optive AI, for the larger. We also have a partnership with NeuroNet, which de facto operates a little bit like an IDN, if you want, of the

office space. To be able to penetrate that group. We're also going to be going for the first time to one of the meetings that groups those kinds of offices together, which is a headache meeting, which is happening early December in the US. So we're really trying to drive the strategy to go and approach both call points, but we haven't really and we're looking at growing on both. On the solo practices as well as on the multipractitioner, larger volume practice but I don't have a good metric of penetration. It will be more about the growth and the adoption. You remember maybe that we conducted a study called Neuro PMR. We conducted it in two very, very large practices. The Dent Institute in Buffalo and Texas Neurology in Dallas. We started in April, but we were able to put the new devices into those two practices for the study so that the data that comes out, which is now only literally a few a couple of months away because it will be early 2026, is with the latest technology, both hardware and software. So that's going to be really exciting. To your question about international, I said, international is not about the office. International is about hospitals. So there are some procurement processes. There are some tendering processes. There are some multidimensional processes like in the US. One of the big wins this quarter was the French referencing. So this body called UniHA, which is really a very large catalog procurement process that allows all French hospitals to more swiftly buy through that without a lot of the procurement process kind of timelines. So we think, for instance, in a market like France, we will start seeing a more expedited way of being able to transact with hospitals, but it is still hospitals. So it's not a swift decision-making as the, as the. And for international, it's really important that it really is going to be this quarter when we bring to them the new image quality. Although we did get the clearances both on the CE Mark front and the UK CA front last quarter. There's another work stream that we need to do beyond the regulatory approval, which is produce the software and all the labeling and the documentation in local languages. We now have 10 different local languages. So the Optive AI with the new level of image quality will get launched in local languages in 10 of those local languages. Only here in Q4.

Paula: Okay. Okay. Thank you.

Operator: Of course. Thank you.

Maria Sainz: Thank you for your question.

Operator: No further questions at this time. I would like to turn the call back over to Maria Sainz, CEO, for closing remarks.

Maria Sainz: Thanks, everyone, for joining us in today's call. I'm truly, truly excited about the inflection point in which we are at our company, and I look forward to providing you further updates here in just a few short months. Thanks, everyone.

Operator: Ladies and gentlemen, that concludes today's call. Thank you all for joining. You may now disconnect.