

BSEM Earnings Call Transcript

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Quarter: 3

Operator: Hello, and welcome to the BioStem Technologies Third Quarter 2025 Earnings Call. [Operator Instructions] I would now like to turn the conference over to Trip Taylor, Investor Relations. You may begin.

Philip Taylor: Good afternoon, everyone, and thank you for joining our conference call to discuss BioStem's Third Quarter 2025 financial results and corporate highlights. Leading the call today will be Jason Matuszewski, the company's Chairman and Chief Executive Officer; and Brandon Poe, the company's Chief Financial Officer. Before we begin, I'd like to remind everyone that our remarks may contain forward-looking statements based on management's current expectations. These involve inherent risks and uncertainties that could cause actual results to differ materially from those indicated. These risks are described in our filings with the OTC markets. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date made. The company undertakes no obligation to update them unless required by law. Today's financial results are unaudited, and results may change pending the completion of our financial statement independent audit, including an audit of our restated financial statements, which were released earlier today. Finally, this call also includes references to non-GAAP financial measures. A reconciliation to comparable GAAP measures and related information can be found in our earnings press release posted on the Investor Relations section of BioStem's website. With that, I'd now like to turn the call over to Jason Matuszewski.

Jason Matuszewski: Good afternoon, everyone, and thank you for joining us to discuss BioStem Technologies' third quarter results. This has been a busy and productive quarter for the company, and we're eager to share an update on the meaningful progress we've made across the business. I'd also like to welcome our CFO, Brandon Poe, who we introduced last quarter and will walk through our restated historical financials and Q3 financial results in a few minutes. This quarter once again demonstrated the resilience of our business model, our disciplined operations and the strength of our team as we continue to execute through the headwinds of an evolving reimbursement landscape. While reported revenue was down modestly from Q2 under the current ASP Plus 6 reimbursement dynamics, we sold 40% more product on a volume basis. This highlights the strength of the underlying demand for our clinically validated advanced wound care products and BioStem's ability to grow market share even in a difficult pricing environment. BioStem remains well positioned to lead through this transition and to emerge even stronger. We've now delivered 7 consecutive quarters of positive adjusted EBITDA, maintained industry-leading gross margins and continue to reinforce the financial, operational and clinical foundation that will support our long-term growth strategy. The recent restatement of our historical financials will now be subject to audit in accordance with U.S. GAAP as we prepare for our planned NASDAQ uplisting. Post restatement and pre-uplisting, BioStem is emerging as one of the few profitable small-cap medical technology companies with differentiated IP and a proven clinical foundation. The setup into 2026 is asymmetrically positive. At the same time, we've taken important steps to position the company for continued market share gains, including advancing our BioREtain clinical program, preparing to drive adoption as CMS payment reform takes effect in 2026, expanding patient access through new payers and sites of care such as Medicaid and the VA and continuing to evaluate strategic acquisitions that diversify our product portfolio and commercial reach. Before we do

a deeper dive into our business updates, I want to address our restated financial statements, and then Brandon will provide more color. At first glance, our restated financials look substantially different than what we have provided in prior quarters. However, the only change that has been made is regarding the geography of our bona fide service fees paid to distribution partner, Venture Medical. The net result on the income statement is a reduction in top line revenue and an equivalent reduction in sales and marketing expense, which results in no change to EBITDA or net income. The resilience of our business model is clear as our gross margins and efficient cost structure enable continued profitability and demonstrate the potential to generate substantial cash flow as we scale the business. Restating the financials is an important milestone, representing progress on the path to our uplisting. Now I'll turn the call over to our CFO, Brandon Poe, to walk through the restated financials and our third quarter results in detail.

Brandon Poe: Thanks, Jason, and good afternoon, everyone. It's great to be able to announce our financial results for my first time and share our progress over the last quarter. I will start with some more details with regard to our restatement, which I will remind you is subject to audit. In September, we had filed a non-reliance disclosure with regard to our quarterly financial statements from Q1 2024 through Q2 2025 as well as the annual financial statements for 2023 and 2024. This disclosure was the result of internal and external discussions regarding the appropriate accounting treatment for our agreement with Venture Medical. Earlier today, we issued restated unaudited financial statements covering all of the time periods I just described. The full details are in the press release, but I want to briefly explain what changed. Reiterating Jason's comments, the primary changes made in the restated financial statements relate to how we account for and report the bona fide service fees associated with our arrangement with Venture Medical, which impacts both the income statement and the balance sheet. Previously, these fees were recorded as a sales and marketing expense on the income statement. In the restated financials and going forward beginning in Q3 2025, those fees are now classified as a contra revenue, meaning they're reported as an offset to gross revenue to arrive at net revenue. This change reduces reported revenue and reduces sales and marketing expense by the same amount. It's important to note that there is no impact on EBITDA, net income or cash flow. However, because revenue is now reported net, percentage-based metrics such as gross margin and EBITDA margin will look slightly different. On the balance sheet, the amounts owed by BioStem to Venture related to bona fide service fees payable were previously shown as a separate current liability. In the restated financials, those amounts are now netted against accounts receivable due from venture, effectively offsetting the amounts owed between the 2 companies. Again, this is purely a presentation change for revenue, current assets and current liabilities. It does not affect EBITDA, net income or cash flow for any period. One further note, while we had previously considered potential restatement changes related to the timing of revenue recognition that is moving from a sell-in accounting model to a sell-through model, we have determined that the sell-in model is the appropriate accounting treatment. The restatement adjustments made were primarily related to the treatment of bona fide service fees, as I just described, plus some minor cleanup of balance sheet classifications. For clarity, you may hear us use the terms sell-in and sell to interchangeably. They both indicate revenue recognition upon sale to venture. The restatement was the culmination of a comprehensive review of the applicable U.S. GAAP revenue recognition guidance in consultation with our external technical accounting advisers. We determined that the restated accounting treatment of the company's arrangement with Venture Medical is appropriate and consistent with authoritative accounting standards. Again, this conclusion remains subject to completion of the audit to be conducted by our newly appointed independent auditors, KPMG. We anticipate that KPMG will complete the independent audits for fiscal years 2024 and 2025 by the end of Q1 2026, which will be an important step as we move toward our planned NASDAQ uplisting. I will now turn to our Q3 results. All the numbers referenced on this call prior to Q3 have been restated. Revenue in the quarter totaled \$10.5 million compared to \$11 million in Q2 of this year and \$18.4 million in Q3 of 2024. The sequential decrease is primarily due to continued competition from higher-priced products under the current ASP Plus 6 reimbursement model and a lower selling price to Venture, partially offset by higher product volumes. Gross profit for the quarter was \$9.3 million, representing gross margin of 88.5% compared to \$10.3 million and 93.8% in the prior period and \$14.2 million and 77% in Q3 of 2024. The sequential decline in gross margin was a result of a mix shift

towards our products that carry a licensing fee and a lower selling price to venture. Operating expenses for Q3 totaled \$7.8 million compared to \$10.2 million in the prior period and \$4.9 million in Q3 of 2024. The sequential decrease in operating expenses was mainly driven by lower stock-based compensation and disciplined G&A; spending aligned to our revenue performance, including lower outside services spend. Moving to the balance sheet. Our cash balance was \$27.2 million at the end of Q3 compared to \$30.8 million at the end of Q2. The decline is largely due to the purchase of land to support our future headquarters in the Research Park at Florida Atlantic University as well as the timing of collections from Venture Medical. Despite the Q3 headwinds, this is our seventh consecutive quarter of positive adjusted EBITDA, highlighting the strength of our business model. Our gross margins remain among the best in the industry, and our healthy balance sheet gives us flexibility to continue to execute on our growth initiatives. With that, I'll turn it back to Jason.

Jason Matuszewski: Thanks, Brandon. Let's talk about recent business progress and where we're headed. Our strategy continues to focus on 3 core priorities: advancing high-quality clinical evidence, scaling operational excellence and driving disciplined commercial growth. In late October, we presented top line results from our randomized controlled trial of BioREtain-processed amnion chorion or BR-AC published in the International Journal of Tissue Repair. This prospective multicenter RCT compared BioREtain plus standard of care versus standard of care alone in patients with hard-to-heal diabetic foot ulcers at 11 U.S. clinical sites. The study enrolled 71 patients after a 2-week run-in to confirm chronic non-healing wounds. By week 12, 36.7% of BioREtain-treated patients achieved complete wound closure compared to 17.1% in the control group, more than doubling the healing rate with a 97% probability of superiority and no product-related safety events. Of particular note in this study, the protocol established the highest standards of rigor in the wound care sector. Specifically, patients whose wounds reduced in size by more than 30% during the run-in period did not proceed to treatment, ensuring that only patients with hard-to-heal wounds were evaluated. Furthermore, patients' wounds had to remain closed for 4 weeks after initial closure to achieve what is known as lasting closure. We presented the top line results in early Q4 and expect to publish the full data set, including secondary endpoints and detailed statistical analysis as we move into Q1 next year. More importantly, we completed the top line analysis in time to submit to CMS for consideration and inclusion as a covered product when the new LCD is implemented. In fact, we were the only placental tissue manufacturer to submit a Level 1 randomized controlled trial by the November 1 deadline. Following that submission, we are actively reaching out to all 7 MACs to submit our data directly to each regional contractor. These results corroborate what we've seen in real-world practice. BioREtain process placental allografts preserve the tissue's native structure and bioactivity, translating to faster, more durable wound closure. Additionally, we are making great progress with our BR-AC venous leg ulcer study enrolling subjects ahead of schedule. We remain on track to share results in early '26, and we believe these findings will further validate BioREtain's platform and drive broader physician adoption and commercial growth. Operationally, our vertically integrated facility continues to deliver industry-leading margins and high-quality performance. In late Q3, the FDA performed a follow-up and routine inspection of our facility, confirming remedial actions arising from the prior 2023 inspection as well as a comprehensive review of our current 361 products and quality management system. The FDA found no nonconformance observations or comments in a clean inspection. We expect to receive an establishment inspection report showing no action indicated, which would officially close out the 2023 inspection. That result reflects the strength of our quality system, our operational discipline and our readiness to scale production to meet future demand. On the commercial front, we continue to navigate a competitive market shaped by the ASP plus 6% reimbursement system, where providers are reimbursed for the average selling price of the products plus 6%. This structure incentivizes the use of higher ASP products, and we've seen a continued increase in pricing, which has created a more competitive environment over the year. Our VENDAJE AC product with an ASP of \$2,385 was well positioned on the pricing list in the first quarter of this year. However, during 2025, the gap between VENDAJE AC and the highest priced product has grown from \$1,000 to over \$3,400 per square centimeter, with the top-priced product climbing to \$5,893 per square centimeter for the fourth quarter, a substantial increase in just a few quarters. Many manufacturers and marketers of placental products have taken advantage of the payment system, which continues to drive up the cost of care. This price

escalation underscores why CMS is implementing a flat rate reimbursement model. Beginning January 1, 2026, all skin substitutes will be reimbursed at roughly \$127 per square centimeter across the physician office, hospital outpatient and ambulatory surgery center sites of care. We have long been an advocate for reform of the Medicare reimbursement system for skin substitutes. And while the flat rate of \$127 was lower than we initially advocated, we have been preparing for a wide range of outcomes to set the company up for success. In CMS' transition to the flat rate next year, the pricing gap limiting our growth under ASP Plus 6 will be eliminated. We are pleased that focus will shift away from products with inflated prices and instead clinical performance, operational efficiency and commercial reach will drive continued market adoption. BioStem is exceptionally positioned to capture share in what we expect to be a very dynamic market going into next year. To prepare for this new landscape, we've expanded our commercial strategy with Venture Medical and plan to address additional markets through new distribution channels as we continue to evolve our commercial structure. To start, Venture has prioritized large mobile wound care providers with broad geographic reach, groups that prefer long-term contracts and stable supply partnerships, which drove an increase in volume from the previous quarter. Even in today's ASP-driven market, our products continue to reach more patients. In Q3, we saw a 40% increase in volume over Q2. As Brandon noted earlier, even though volumes increased, revenue remained flat from Q2 to Q3 due to a pricing initiative introduced in late Q2, where we lowered prices to our distribution partner, Venture Medical. This allowed Venture to be competitive with higher ASP products and drive demand. We estimate that the total physician office market for skin substitutes is 6 million to 7 million square centimeters annually. Venture Medical's network represents less than 1% of market volume, a small share today, but a massive opportunity ahead. Beyond our core mobile wound care segment and as we look to the future, we're expanding into new markets. We will leverage our existing commercial partnership to deliver our products to more customers. One example is our partnership with a Service-Disabled Veteran-Owned Small Business to serve the Department of Veteran Affairs beginning in Q4. The VA is one of the largest and fastest-growing wound care markets in the country with over 170 medical centers, 1,100 outpatient sites and nearly 9 million veterans enrolled. Chronic wounds affect roughly 10% to 15% of veterans, largely due to diabetes and vascular disease. Placental tissue utilization in the VA has grown over 50% in 5 years and the Advanced Wound Care segment in the VA exceeds \$200 million annually. Placental-derived allografts represent \$63 million of that total and continues to grow at 9.5% annually. Importantly, this growth has occurred in a setting that is reimbursement agnostic. The federal supply schedule ensures that the VA procures products with most favored nation pricing, so this is a site of care where manufacturers are competing on the basis of clinical efficacy where BioStem excels. Through our Service-Disabled Veteran-Owned Small Business partnership, BioStem gains preferred procurement access to the VA network. Our new product for this channel, American Amnion, will launch at the Desert Foot Conference in early December. In Q3, we entered and have begun to see early traction in the Medicaid market, another meaningful growth opportunity. We've achieved initial success with Medi-Cal coverage and early wins in Texas Medicaid. These large programs validate our clinical value proposition and reimbursement strategy. More than 70 million Americans are enrolled in Medicaid and approximately 10% of those are over the age of 65. Expanding into this underserved segment will be an important long-term driver as state programs adopt evidence-based coverage. We're now working to broaden access across additional state programs in 2026, reaching more patients and driving sustainable growth beyond Medicare. In addition to organic expansion, we are evaluating strategic and accretive acquisition opportunities to broaden our product offering and more importantly, in this new reimbursement environment to focus on expanding to additional sites of service, including the ambulatory surgery centers and hospital settings. Our goal is to expand access to BioStem's technology while maintaining the same financial discipline and operational efficiency that define our company. These initiatives, preparing for reimbursement reform, expanding into VA and Medicaid channels and exploring strategic M&A; are part of our large effort to scale BioStem for sustainable growth. To support our next phase, we took an important step this quarter by purchasing land at the Research Park at Florida Atlantic University in Boca Raton for our future headquarters and manufacturing expansion. This land purchase will provide future capacity to continue to scale, access to strong life sciences talent pipeline and proximity to a leading research institution to enable collaboration and accelerate innovation. This

investment underscores our commitment to building BioStem for the long term with the operational scale, infrastructure and talent to meet growing demand and deliver on our mission. Finally, on the uplisting, as we shared in October, our Audit Committee appointed KPMG as BioStem's new independent registered public accounting firm, replacing Marcum. We're grateful for Marcum's support over the past 2 years and excited to engage with KPMG, a firm with a dedicated life sciences team and deep experience supporting companies as they prepare for national exchange listings. As part of that transition, we withdrew our previously filed Form 10, and we'll move forward with audits of our 2024 and 2025 financial statements. Once those audits are completed, we will reengage in the process with the SEC for our planned NASDAQ uplisting. We know this process has taken longer than we hoped, but it remains a top priority for this management team. A national exchange listing will enhance our visibility, improve shareholder liquidity and strengthen our ability to attract and retain top-tier talent. Before we open the line for questions, I want to take a moment to recognize the incredible work of our team. First, to our quality and manufacturing team, thank you for your exceptional focus and execution in our successful FDA inspection this quarter with no nonconformances, observations or comments. That result is a direct reflection of the discipline, expertise and commitment to excellence across our organization. Second, to our clinical operations and research teams, thank you for the outstanding effort in the publication of the BioREtain randomized controlled trial results ahead of the November 1 CMS submission deadline. Your work continues to strengthen the evidence base that validates our technology and drives improved patient access to this important technology. And finally, to our providers, partners and most importantly, our shareholders. Thank you for your continued trust, collaboration and belief in our mission. Your support enables us to keep investing in innovation, expanding access to care and building long-term value for all stakeholders. I'm incredibly proud of what this team continues to accomplish and deeply grateful for everyone's contribution to BioStem's success. Operator, you can now open the line for questions.

Operator: [Operator Instructions] Your first question comes from the line of Bruce Jackson with Benchmark.

Bruce Jackson: So if you're going to be pursuing the hospital market more aggressively, what are the steps you have to take to do that? And where are you right now, for example, in the hiring process and trying to build a sales force?

Jason Matuszewski: Bruce, thanks for the question. We are actively working towards looking to achieve GPO coverage for our products. Now that we have this initial top line results and the data for the DFU study, and we're also actively working to get top line results for the VLU study near term, leveraging that clinical data to then communicate and work with several of the major GPO contractors to get on to those GPO agreements and then actively commercialize the product into the hospitals and ambulatory center -- ASC setting. So as you mentioned, that also requires us to scale our commercial efforts inorganically or organically, and those are some of the efforts that we'll be looking to focus on as we close out this year and into next year.

Bruce Jackson: Okay. And then for my follow-up, I guess I'd be curious to know, do you have an anticipated time line for the uplist?

Jason Matuszewski: I'll give that one to Brandon.

Brandon Poe: Yes, we do. So as we mentioned on the call, the building block toward the uplist is completing the financial audits with KPMG. We anticipate those to be done by the end of Q1 of 2026. And shortly thereafter, we'll reengage with the SEC. So I don't have an exact time line of when we'll get that completed, but I would call it, we're targeting sometime in the middle of 2026.

Operator: Your next question comes from the line of Eric Schlanger with D2C.

Eric Schlanger: Jason, congratulations on the milestones you've achieved and the platform that you're building going forward. My question is in regard to BioREtain and assuming a good result there, which looks like you're on track for. Can you talk a little bit about the total addressable market that will open up to you and the possibilities around the share that you can garner from that market?

Jason Matuszewski: No, it's a great question. As we -- as I kind of alluded to Bruce's question around access to GPO agreements in some of these other areas where we can start commercializing the product. Once we get the final results out for the DFU study and we get some top line results out for the VLU study, I think that gives us a lot of opportunity to look at focusing into the hospital outpatient setting

as well as ambulatory surgery center setting. As I alluded to on the call earlier, with this change in reimbursement as far as payment methodology going to this flat rate of about \$127, if you all remember, currently, the reimbursement methodology and payment methodology is roughly about \$1,700 as a capitated payment rate in the hospital outpatient as well as a capitated rate of roughly around \$800 in the ambulatory surgery center. So those rates are going to now be uncapped, meaning reimbursement for products in those 2 sites of service, which happen to be in the hospital, can be reimbursed at \$127, roughly about \$127 a square centimeter. So if you use a 10 or 15 or 20 square centimeter graft, something like large venous leg ulcers or large burns, there's an opportunity to not have to really compress pricing in those areas. And so I think this really opens up a large TAM for those areas. And leading with clinical evidence and some of the superiority of the current top line results, I think that allows us to look at some of the market share that's currently out there north of \$300 million to \$350 million from some of our competitors and look at capitalizing on that.

Operator: [Operator Instructions] Your next question comes from the line of Kevin Bennett, private investor.

Kevin Bennett: Yes. Congratulations on the quarter again there. It keeps getting better. I was curious about the investors here taking care of the investors that have stayed with you for a while. As far as like share buyback, I mean, with the stock price dropping from \$28 to \$3, \$4, \$5, you would think that the company, if it has any money, they could spend would be issue a share buyback to kind of protect investors plus future investment for the company. Is the share buyback an issue? Or can we do that?

Brandon Poe: Yes. Jason, I can step in there. So Kevin, thanks for the question. Appreciate it. Thanks for being a shareholder. I would say we're exploring all options as we sort of think about that space, like how we should spend our cash. Obviously, we're at \$27 million of cash at the end of the quarter. We're looking at all options. And I would say we've discussed a buyback as an option. It's something we're thinking about, at least overall in general and relative to maybe other options. So it is something that we could do and we're considering, but we don't have any plans at the moment to take that on.

Operator: This concludes the question-and-answer session, and we will conclude today's conference call. We thank you for joining. You may now disconnect.