BSEM Earnings Call Transcript

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Quarter: 2

Operator: Thank you for standing by. My name is Eric, and I will be your conference operator today. At this time, I would like to welcome everyone to the BioStem Technologies Second Quarter 2025 Earnings Call. [Operator Instructions] I'd now like to turn the call over to Adam Holdsworth, Director of Investor Relations. Please go ahead.

Adam Holdsworth: Good afternoon, everyone, and thank you for joining our conference call to discuss BioStem's Second quarter 2025 Financial Results and Corporate Highlights. Leading the call today will be Jason Matuszewski, the company's Chairman and Chief Executive Officer; Mike Fortunato, the company's Chief Accounting Officer; and Brandon Poe, BioStem's incoming 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 OTC Markets in the Form 10 we filed with the SEC in January 2025. 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. Additionally, as discussed in our Q1 2025 earnings call, we are undergoing an SEC review related to our planned uplisting to NASDAQ. Today's financial results are preliminary and unaudited and results may change pending the completion of our financial statement audit, which is predicated on the resolution of SEC comments related to the review of our Form 10. 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 would now like to turn the call over to Jason Matuszewski.

Jason V. Matuszewski: Good afternoon, and thank you for joining. I'm pleased to share our second quarter 2025 results and the progress we've made in strengthening BioStem's commercial position, advancing our clinical pipeline and preparing for long-term growth. Today, I will discuss industry environment, highlight our operational and clinical milestones and provide an update on our NASDAQ uplisting process. After my remarks, I'll turn the call over to Mike Fortunato, who will review our second quarter financial results, and I will conclude by introducing our new CFO, Brandon Poe. In Q2, BioStem delivered its sixth consecutive quarter of positive adjusted EBITDA, positive free cash flow and industry-leading gross margins. In addition to strong profitability metrics, we maintained a strong cash position, ending the quarter with $30.8 million in cash, which was an increase from $20.6 million in Q1. Revenue totaled $49.3 million for the quarter, reflecting a decline versus Q2 of 2024. Amid this noisy market environment, I want to make clear that our view on the strong clinical value of our products and the substantial market opportunity ahead of us is unchanged. However, it is important to articulate the dynamics we are seeing across the chronic wound care market, the impact they're having on our business and our action plan to return to positive revenue growth. At the highest level, in the second quarter, we experienced more pronounced pressure from reimbursement uncertainty as well as increased competitive pressure from new products that entered the market at a higher average sales price, or ASP, both of which impacted our revenues. On the reimbursement front, our products were omitted from the preliminary Medicare Part B ASP drug pricing file for the second quarter, which indicates payment rates for products reimbursed under Q codes such as ours. While the final Medicare

Part B ASP drug pricing file did include our products, the market and providers perceived increased reimbursement risk for our products not included on the preliminary list, which impacted their product selection at the outset of the quarter. Our commercial distributor, Venture Medical, acted quickly to reassure customers that we expected inclusion on the final list. However, the uncertainty ultimately led to a slower start to Q2 than we expected as customers chose competitive products that were included on the list. We experienced heightened competitive dynamics when the final ASP list was published with the introduction of approximately a dozen new brand names with higher ASPs than BioStem's products, resulting in some customers choosing to use those alternative products. Ultimately, this became the larger of the headwinds for us in the quarter. And while it impacted results, it also provided key insights into many of the core drivers and overall industry trends for sales reps, customers and end users that we will be able to leverage as we reset strategies to rebuild growth. More importantly, while we recognize that the LCDs, adjustments to the ASP list and uncertainty around CMS proposed payment methodology may continue to impact the market for the remainder of the year, we have developed a plan focused on ensuring that BioStem will remain a leader in the advanced wound care market in any market environment for years to come. First, with regard to clinical development, in June, we completed patient enrollment in our clinical trial evaluating BR-AC for the treatment of diabetic foot ulcers, which is a key milestone that keeps us on track to report top line results and full data analysis in the fourth quarter of 2025. This trial is one of the three ongoing studies designed to demonstrate the efficacy and competitive advantage of our BioREtain process allografts. We have two additional ongoing trials, one evaluating the treatment of venous leg ulcers with BR-AC and another evaluating the treatment of diabetic foot ulcers with BR-A. Both studies continue to enroll patients and are progressing on schedule. We believe the outcomes from these trials will further validate the BioREtain platform, support broader physician adoption and drive continued commercial expansion. Furthermore, we plan to expand and diversify our product portfolio through internal R&D; efforts and through acquisitions to address the wound care continuum in a more comprehensive way and further strengthen our position as a business partner of choice for health care providers. Our manufacturing expertise, proprietary tissue processing capabilities and state-of-the-art facilities will ensure we can produce products at scale in a cost-effective way. We believe we have ample flexibility to absorb any potential pricing pressure that may be dictated by new reimbursement coverage and pricing policies. Commercially, there are several levers we can pull near term and long term to maintain our competitive advantage in the market. Venture Medical has sharpened its focus to reaccelerate growth in the year ahead by prioritizing the larger mobile wound care providers. By targeting these types of providers, we are eliminating many of the concerns exposed by the headwinds discussed above. And this strategic shift allows us to better align our offerings with key customer segments that prioritize consistency, efficiency and improve patient outcomes. Some of these organizations involve longer onboarding cycles, but they typically represent more stable contract-driven relationships with reduced product turnover. We believe Venture's OneView practice management platform, combined with our superior BioREtain technology represents a unique value prop that will align with these scaled providers' needs in the physician office and mobile sites of care. We are confident that renewing our focus on these providers is an opportunity for BioStem to generate durable revenue. Early indicators from July and August suggest positive momentum is already underway, and we are seeing stronger results in customer conversions as we move through the third quarter. In addition, we are focused on scaling our internal commercial footprint to complement Venture Medical's sales initiatives. The strategy to expand our commercial presence is centered around strengthening the sales team, broadening territory coverage and diversifying the business to other sites of service and new markets. We believe that with these core drivers, we can continue to accelerate our commercial progress and that this strategic shift will advance our long-term positioning in the chronic wound care market and improve channel stability. Now I want to briefly discuss the recent CMS calendar year 2026 proposed Medicare reimbursement rule changes for skin substitutes. The proposed rule reclassifies skin substitute products as incident to supplies and eliminates the separate ASP + 6 reimbursement methodology, which is currently standard in the physician office and mobile settings. CMS is proposing to use a single payment rate, reflecting the weighted average sales price of all skin substitute products based on historical usage in the hospital outpatient setting. The proposed price is significantly below the current ASPs of many of the products in

the market. We welcome CMS' effort to reform skin substitute payment policy and we'll continue to engage with CMS through the open commenting period to advocate for proposed changes. These changes offer an opportunity to level set the wound care market and disincentivize opportunistic players in the market. We believe those who have chosen to invest in substantial R&D; and generation of clinical evidence will emerge among a smaller group of market participants. That said, the current proposal could significantly impact the mobile wound care market. Considering the demographics of patients served by mobile wound care providers, many of these patients do not have access to or the ability to travel to medical offices or hospitals. Mobile wound care is a vital solution for treating this patient population and plays a critical role across the treatment continuum. If these patients were not able to be treated in their homes, we believe the overall cost of care could increase significantly due to an increase in infections, amputations and other life-threatening complications. We look forward to constructive engagement with CMS, providers and industry stakeholders during the 60-day comment period to help shape a fair and sustainable reimbursement framework for skin substitutes. Our objective is to support policies that recognize the value of advanced therapies, foster innovation and most importantly, improve patient outcomes, strengthening both the chronic wound care landscape and BioStem's long-term growth. Now I want to turn to an update regarding our NASDAQ uplisting. We are pursuing the uplisting as part of our long-term strategic plan. There are several benefits to trading on NASDAQ, including increased visibility for BioStem, improved share liquidity and more efficient market valuation, expanded access to capital and an enhanced ability to attract top-tier talent to drive further innovation in advanced wound care. On our Form 10 submission, we continue to work through the audit process. We now have clarity on the accounting treatment for the distribution agreement with Venture Medical and are continuing efforts to resolve all open comments. At the same time, with our new CFO on board, we are also evaluating the long-term strategic plan for the business. This includes a comprehensive review of BioStem's operations and the associated financials, which we expect to finalize over the coming months. As part of this process, we are also evaluating the optimal timing for our uplisting to NASDAQ. We are taking the necessary steps to ensure BioStem is best positioned to capture the opportunities ahead and believe it is prudent to time the uplisting accordingly. Uplisting remains a top priority for BioStem, and we plan to provide further updates when appropriate. With that, I'll now turn the call over to Mike Fortunato, who will walk you through our second quarter financial results in more detail. Mike, take it away.

Michael A. Fortunato: Thank you, Jason, and good afternoon, everyone. In the second quarter of 2025, net revenue was $49.3 million compared to $74.5 million in Q2 of 2024, representing a 34% decrease. This decrease was primarily driven by lower sales volume in our wound care portfolio, resulting from perceived reimbursement uncertainty in the marketplace for our products and increased competition from higher ASP products. Gross profit was $48.6 million or 98.6% of net revenue compared to $70.7 million or 95% of net revenue in Q2 of '24. The increase in gross margin reflects product mix benefits, particularly as VENDAJE AC continues to gain traction in the market. Importantly, VENDAJE AC does not carry licensing fees, which supports margin expansion. Operating expenses for Q2 were $48.5 million, down from $61.9 million in the prior year period. This decline primarily reflects a decrease in bona fide service fees due to lower sales volume of our products through our distribution channel. GAAP net loss for the quarter was $564,000 or $0.03 per share compared to net income of $6.3 million or $0.39 per share in Q2 of 2024. Adjusted EBITDA was $2.5 million compared to $10.1 million in the same period last year. I'll now pass the call back to Jason.

Jason V. Matuszewski: Thanks, Mike. Before we end the call, I want to take a moment to thank Mike for his time as our CFO, and welcome Brandon Poe to the BioStem team as our new CFO. Brandon has stepped into the CFO role this week as Mike continues as our Chief Accounting Officer. Brandon is a veteran executive with more than 25 years of financial experience across various industries, including life science, medical device and health care services. Not only does Brandon bring with him a wealth of industry knowledge, but as he is transitioning from the BioStem Board of Directors, he's already familiar with the company's strategy and objectives. As we are entering this new chapter at BioStem, we believe that Brandon's significant experience leading finance teams in the health care industry will be critical to defining, prioritizing and achieving our strategic objectives and will help position us for the opportunities ahead. We look forward to working with him, and we have him here with us today. So I'll

let him say a few words before we open up for Q&A.;
Brandon Poe: Thanks, Jason. I'm excited to take on a more active role with this exceptional team. Having served on the Board, I've had a front row seat to the dedication and momentum behind BioStem's business. This is a pivotal time to capitalize on the growing opportunities in the chronic wound care market, and I believe our BioREtain platform, in-house manufacturing capabilities and expansion potential position us well for continued success. Stepping into the CFO role, I look forward to leveraging my experience to help drive growth. I am excited to share more on our progress in future updates. And with that, I'll turn it back over to Jason for closing.
Jason V. Matuszewski: Thanks, Brandon, and welcome to the Stem. While reimbursement-related uncertainty has weighed on the broader market and our recent performance, BioStem's business model remains fundamentally strong. With a solid financial foundation, a growing partnership with Venture Medical, ongoing capital markets initiatives and a solid plan to diversify and grow our business, we believe we are well positioned to drive strong performance in the quarters ahead. With that, operator, please open the line for questions.
Operator: [Operator Instructions] Your first question comes from the line of Bruce Jackson with The Benchmark Company.
Bruce David Jackson: Really, I just have one question. It's about the proposed local coverage decision that's being contemplated right now by CMS and set to go into effect on January 1. So there could be some major changes to the reimbursement climate. Your partner, Venture Medical has been very vocal in their view about how things should play out. What does this mean for BioStem? What are your possible approaches? And what scenarios are you preparing for?
Jason V. Matuszewski: Bruce, thanks for the question. Jason Matuszewski here. I think when we're looking at a multitude of scenarios here, we have the OPPS, PFS preliminary ruling that came out just over a month ago. That is -- theoretically, we should have an effectiveness of that sometime in November for published pricing rates. And we'll see where that dictates how the LCD unfolds going forward. As many of you know, the LCD was really driven around what we believe is more cost containment than really about coverage. And there was a lot of vocal response through the open commenting period by companies, providers, and frankly, advocacy groups saying how restrictive the LCD would be to the industry around providing skin substitutes to patients more specifically in the mobile wound care segment or in the physician office segment. So I think for us, we're watching to see how the OPPS and PFS rule comes out. We are actively going to comment within the 60-day comment window on both the OPPS and PFS. And then we'll see once that becomes final, how the LCD is -- kind of unfolds.
Operator: [Operator Instructions] There are no further questions at this time. Ladies and gentlemen, that concludes the BioStem Technologies Second Quarter 2025 Earnings Call. Thank you all for joining, and you may now disconnect.