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**BioStem Technologies,
Inc.** OTCPK:BSEM

Earnings Call

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Call Participants

EXECUTIVES

Adam Holdsworth

Jason V. Matuszewski
CEO, President, Director & Secretary

Michael A. Fortunato
Chief Financial Officer

ANALYSTS

Unknown Analyst

Presentation

Operator

Thank you for standing by. My name is Rebecca, and I will be your conference operator today. At this time, I would like to welcome everyone to the BioStem Technologies Third Quarter Results Webcast Call. [Operator Instructions]

Thank you. I would now like to turn the call over to Adam Holdsworth, Managing Director of Investor Relations. Please go ahead.

Adam Holdsworth

Good afternoon, everyone, and thank you for joining our conference call to discuss BioStem's third quarter 2024 financial results and corporate highlights. Leading the call today will be Jason Matuszewski, the company's Founder and Chief Executive Officer; and Mike Fortunato, the company's Chief Financial Officer.

Before we begin, I'd like to remind everyone that our remarks today may contain forward-looking statements based on the current expectations of management, which involve inherent risks and uncertainties that could cause actual results to differ materially from those indicated. These risks are described in the company's filings with the over-the-counter market. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date made and may change at any time. While we may update or revise the statements from time to time, the company undertakes no commitment to do so unless required by typical securities laws.

This call also includes references to certain financial measures that are not calculated in accordance with generally accepted accounting principles or GAAP. We generally refer to these as non-GAAP financial measures. Reconciliations of these non-GAAP financial measures to the most comparable GAAP measures are available in the company's press release on the Investor Relations section of BioStem's website.

With that, I'm now pleased to turn the call over to Jason Matuszewski.

Jason V. Matuszewski

CEO, President, Director & Secretary

Thank you, Adam, and thank you all for joining us today. I'm pleased to report that BioStem Technologies has achieved another milestone, marking our third consecutive quarter of record-setting growth.

In Q3 of 2024, we posted revenue of \$82.6 million, adjusted EBITDA of \$9.9 million and our cash position improved to \$14.6 million, establishing a new revenue high for the company and demonstrating our robust financial performance. For the first 9 months of this year, we've generated \$199 million in net revenue, highlighting our continued momentum and resilience in the market. Our success this quarter is a testament to the strength of our portfolio of skin substitutes, especially our AmnioWrap2 allograft, powered by our patented BioRetain technology. This innovative technology is driving strong commercial performance across a wide range of non-acute segments.

Our gross margin remained solid at 95%, reflecting our commitment to operational excellence and the efficiency of our manufacturing processes. I want to take this moment to recognize the dedication of the entire BioStem team. Your commitment to our vision and the honor you bring to the gift to donation are what drives these outstanding results.

As part of our efforts to ensure patient access to high-quality, life-changing products, we've been actively engaging with CMS, congressional leaders and industry partners to advocate for fair and effective Medicare reimbursement policies. We recognize that certain players have caused overutilization within the Medicare reimbursement system impacting policy and patient access. Our goal is to help shape our reimbursement landscape that not only supports ethical practices, but also ensures that millions of Medicare beneficiaries have access to vital treatments.

BioStem remains at the forefront of this conversation, collaborating with government and industry leaders to support responsible patient-centered policy solutions.

Turning to partnerships. I'd like to extend my gratitude to our commercialization partner, Venture Medical. Their role has been instrumental in our growth journey. As they led the nationwide launch of AmnioWrap2 in Q4 of 2023, and are now preparing for VENDAJE AC's launch in Q4 of 2024. Venture Medical is a key commercialization and marketing partner, and we're thrilled to work side by side with them once again with VENDAJE AC, which recently had national ASP published for Q4 2024, allowing reimbursement across all MAC regions.

Early in the quarter, we received IRB approval for 2 major clinical studies on nonhealing diabetic foot ulcers. These approvals are essential milestones in our clinical journey and support our commitment to rigorous impactful research. We recently enrolled our first patients in 2 randomized controlled clinical trials this quarter, evaluating our BioRetain allografts. We anticipate an early readout of these results from these studies by mid-2025 and final results in early 2026, providing us with clinical data that will strengthen our clinical approach, broaden our payer coverage base and support expanded access to our innovative products.

Additionally, we're in the final stages of designing a study protocol for venous leg ulcers with time lines to be communicated once finalized.

We recently reported positive results from a retrospective data study comparing our BioRetain allografts to the standard of care for diabetic foot ulcers, underscoring our commitment to advancing clinical data on our products. In October, these findings were published in an International Loon Journal, providing valuable peer-review validation of our technology's effectiveness. This achievement further reinforces BioStem's standing as a leader in research-backed innovation.

In support of our equity capital market strategy, we filed our Form 10 on September 27 with the SEC and submitted an application for uplisting to NASDAQ at the same time. We are currently working through our initial SEC review comments and expect to submit a formal response in Q4, along with amended Form 10. Uplifting to a national exchange and becoming fully reporting with the SEC is the strategic commitment to enhance BioStem's visibility and provide wider accessibility to a broader investor base.

As we look to the remainder of 2024 and beyond, BioStem is well positioned for continued growth and innovation. Despite industry challenges, our strong foundation, evidenced by our robust portfolio and effective partnerships positions us to adapt and grow. We are confident that our strategic initiatives, groundbreaking products and dedicated team provide a solid foundation for future success.

Looking ahead, we are optimistic about our upcoming clinical trial results and the potential for broadening our market access, which could provide further clinical validation of our products' superiority and drive broader payer coverage and adoption of BioStem's allografts. These initiatives have the potential to diversify and expand our product offerings, positioning us on a strong trajectory to deliver value for our shareholders, expand our market presence and improve patient outcomes with our innovative solutions. Thank you to our shareholders, Venture Medical and our team members for their ongoing trust, dedication and support as we work to bring transformative solutions across the continuum of care to patients and providers.

With that, I'll now hand the call over to Mike Fortunato, who will provide a detailed review of our financial results for Q3 2024.

Michael A. Fortunato
Chief Financial Officer

Thank you, Jason, and good afternoon to everyone. We appreciate you being here with us today. I am pleased to share BioStem's Q3 2024 financial results, which highlight continued strong growth and significant milestones for the company.

2024 has been a transformative year for BioStem. When we compare this quarter to the same period last year, the progress we've made is significant, and we're excited to share the results. For the third quarter

of 2024, net revenue reached a record \$82.6 million, reflecting an increase of \$79 million compared to the same period in 2023. This growth is primarily driven by continued strong demand for AmnioWrap2, which has been performing exceptionally well across a range of patient applications.

Our gross profit for Q3 was \$78.3 million or 95% of net revenue compared to \$3.2 million or 91% of net revenue in the prior year same period. This represents an increase of \$75.1 million, driven by robust sales growth of AmnioWrap2 and highlights our manufacturing and operational efficiencies. Operating expenses for Q3 2024 were \$69 million, up from \$4.5 million in the same period last year, an increase of \$64.5 million. This increase was largely due to workforce expansion, higher bona fide service fees associated with our distributor agreements for AmnioWrap2 and increased share-based compensation as we continue to go on operations.

For the 9-month period ended September 30, 2024, we reported net revenue of \$199 million, an increase of approximately \$194 million compared to the same period in 2023. The majority of this growth was driven by AmnioWrap2, which continues to experience strong market demand. Our gross profit for the first 9 months was \$188.7 million or 95% of net revenue compared to \$4.5 million or 88% of net revenue for the same period last year. This increase of \$184.2 million reflects higher sales volumes of AmnioWrap2 and improved manufacturing and operational efficiencies.

Operating expenses for the first 9 months of 2024 were \$166 million, an increase of \$154 million follows from the same period last year. This increase was driven by continued investments in scaling our operations, including workforce growth, higher bona fide service fees related to AmnioWrap2 distribution and increases in share-based compensation.

We are pleased to report that we have achieved positive GAAP net income for the third consecutive quarter. Net income and adjusted EBITDA for the quarter was \$6.8 million and \$9.9 million, respectively. These results demonstrate our ability to continue to scale the business to meet strong revenue growth while remaining profitable. In addition, our cash balance has increased from \$6.8 million from the previous quarter to \$14.6 million in the current quarter, an increase of \$7.8 million.

Regarding income taxes payable on the balance sheet, management has estimated income tax expense of \$2.3 million for the third quarter and \$5.8 million year-to-date September 30, 2024, heading the completion of the Internal Revenue Code Section 382 study currently underway. This study will determine if there are any limitations on the timing of using previously generated net operating losses to offset current year taxable income. Although these amounts are recorded as income tax payable, management expects that most, if not all, of this estimate will be offset by the NOLs by December 31, 2024.

As we look to the remainder of 2024, we are confident that these strong financial results, paired with the successful execution of our strategic initiatives, position BioStem for continued success. We will continue to drive growth, enhance profitability and maximize value for our shareholders.

I'll now turn over the call to Jason for closing remarks.

Jason V. Matuszewski

CEO, President, Director & Secretary

Thank you, Mike. As we just outlined this quarter marked several significant milestones that have driven BioStem's growth and demonstrated exceptional financial performance, with Q3 revenue reaching a new high of \$82.6 million and an adjusted EBITDA of \$9.9 million and a strengthened cash position of \$14.6 million, our results underscore the effectiveness of our strategy and the resilience of our team.

I'd like to address some updates on coverage and payment policies for skin substitutes, specifically, for our products. Last Friday, the centers for Medicare and Medicaid Services, CMS, finalize their pricing methodology for skin substitutes in a physician office space or nonacute segment for 2025. CMS confirmed they will continue with [ASPs plus 6] as the pricing model. This decision bolsters our confidence in pricing stability for the coming year, and ensures that BioStem can maintain its current pricing and commercial strategy as we continue to scale our business.

Now regarding the coverage policy, we're actively engaging with CMS, Congress, the MAC and industry leaders to address the proposed LCD. This proposal could impact undescended products, including ours, potentially limiting access for Medicare beneficiaries who rely on these treatments. Our goal is to advocate for a well-founded and equitable coverage policy that balances ethical practice with patient safety. While we acknowledge overutilization by some parties in the market, we believe a more rigorous approach is needed, one that doesn't place patient access at risk.

BioStem remains at the forefront of this effort, collaborating closely with government and industry stakeholders to support policies that responsibly expand patient access to life-changing products. Our efforts, which include engaging closely with Capital Health leaders, anger better, more equitable coverage for skin subsidies, benefiting both the Medicare beneficiaries and BioStem.

October marked the kickoff of pivotal clinical trial on diabetic foot ulcers, comparing our treatment to the standard of care. This study involving 60 patients across 10 sites is essential to building evidence on the clinical superiority of BioStem's products. Alongside an upcoming study focused on venous leg ulcers, these trials are key to demonstrating BioStem's value and expanding payer coverage across commercial plans, Medicare Advantage and Medicaid.

In addition, we announced groundbreaking results in October from a retrospective study on diabetic foot ulcer wound closure, underscoring the clinical superiority of our BioRetain process placental membrane over the standard of care published in the International [Loom] Journal.

These results highlight the potential for BioRetain to address significant gaps in the DSP market, often involving challenging treatment-resistant wounds. This publication strengthens BioStem's clinical credibility and supports our strategy to expand payer coverage and commercial traction across Medicare, Medicare Advantage and Medicaid and other payer channels. We are excited about the strategic value this study brings as it reinforces BioStem's position as a leader in providing effective evidence-based solutions for chronic wound care. We remain optimistic that the concurrent proposed LCD will not get implemented in 2025 without amendments being implemented, which could favor BioStem.

Looking forward, we're confident that these trials will provide additional clinical validation for our commercial products, efficacy, driving expanded payer coverage and broader adoption of BioStem's allografts. Committing to the equity capital markets front, we made a significant advancement in September by filing our Form 10 with the SEC on the 27th and simultaneously submitting our tech uplifting application. We are now working through our initial SEC review comments and plan to submit a formal response along with an amended Form 10 in Q4. This uplifting to a national exchange and transition to fully reporting status are key milestones in BioStem's strategy, aimed at enhancing our credibility, broadening our investor reach and increasing access to capital, essential drivers of a long-term shareholder value as we continue to execute on our growth initiatives.

In closing, as we enter the fourth quarter, we remain optimistic about BioStem's continued growth and the significant milestones on the horizon. With the recent nationwide launch of VENDAJE AC and established reimbursement across all MAC regions, we're well positioned to see strong revenue contributions from this product. This quarter marks our third consecutive record of growth, and we're excited about the initiatives underway that have the potential to diversify and expand our product offerings.

As we continue to advance our strategic priorities, we're confident that BioStem is on a strong trajectory to deliver value to our shareholders, expand our market presence and improve patient outcomes with innovative solutions. We look forward to keeping you up to date on our progress and appreciate your continued support as we work towards greater success. Thank you, and we'll now open the call for questions.

Question and Answer

Operator

[Operator Instructions] Your first question comes from the line of Kevin Bennett, an individual investor.

Unknown Analyst

A Good job on the quarter there. Just had a few questions. I guess, the distribution cost, maybe like my biggest thing that I have, I don't know if we could restructure that, maybe give them like an exclusive deal with us or something. Maybe more profit for us and then give them a security of having all of their business?

Second question is the -- I'm assuming this is like a cream that you put on diabetic wounds. Is it actually possible to have this? Like an air brush, like spray thing, like they burn victims, would that actually work on a product like that? And then my third question is on the uplisting, the share structure, what will happen with the share structure? I know we're liking about 16 million and 11 million, out and 5 million, restricted. Just curious what will happen with that? If I can say, that's all the questions I have.

Jason V. Matuszewski

CEO, President, Director & Secretary

Thanks, Kevin, for being a long-term shareholder, and I really appreciate the questions. First and foremost, on the distribution side with Venture Medical. Right now, we're continuing to kind of work through that team, and they've done an amazing job of expanding access to our product across all the MAC regions. I think right now, we're looking at continuing that type of relationship in the near term. And to kind of compare it to, I guess, maybe competitors, if we were to internalize this type of sales force from a W-2 perspective, I think we would see similar costs associated with this marketplace in getting product out into the marketplace.

On the second question in regards to a cream, actually, our products are considered what they call tissue allografts. So we actually harvest a piece of tissue off of the placenta. And -- so it's like a sheet like format that's laid into the wound bed across the wound, and it acts as a barrier or cover for these chronic type wounds, diabetic foot ulcers, pressure ulcers and venous leg ulcers.

And then third, in regards to the capital structure -- excuse me, the equity capital structure. Right now, I believe there's about 16 and so million shares outstanding common stock. That would be kind of ultimately move from OTC up to NASDAQ. And then any of the warrants and options that are outstanding would also move up to Nasdaq. So currently, that's kind of the plan with the direct listing.

Operator

[Operator Instructions] Your next question comes from the line of [Paige Taggart] with APT Capital.

Unknown Analyst

Congrats on another record quarter. Just a quick question. If you could provide some more color around distribution channel with Venture Medical. I guess specifically, the sales cycle would be helpful for me.

Jason V. Matuszewski

CEO, President, Director & Secretary

Yes. Thanks, [Paige]. So just kind of get a little bit more color to kind of how we fulfill and manage the pipeline with Venture Medical. So Venture Medical on a daily basis is ordering product from us, and we are shipping it out on a daily basis. It's a very lean and FFO type arrangement with that organization. And then secondly, they're continuing to have weekly conversations with us about what is the demand pipeline looking like. And we're continuing to kind of monitor from a manufacturing perspective, how quickly you need to increase production in specific sizes and that's associated with their robust platform called Venture

OneView that they utilize with their downstream customers to ultimately kind of see where these types of wounds are going.

In this process, typically, these wounds -- or these providers ultimately run what's called an IVR, insurance verification requests, and they can see kind of where and what size of the wound is. And can get an idea of, okay, where is the wound going from an initial size and then kind of, as the wound gets closer to closure. So that allows us to have a little bit more insight on product needs and kind of product production.

Operator

Your next question comes from the line of [Ernest Watts] with Watts Associates.

Unknown Analyst

You mentioned in the release that buildup costs were significant and fairly much more significant than the second quarter. Could you give a comment on roughly what they were in each of the 2 quarters, please?

Jason V. Matuszewski

CEO, President, Director & Secretary

Ernest, could you clarify your question a little bit. When you say build-up costs, what do you mean?

Unknown Analyst

It costs money to get your product out into the field and you have to have people to do that. Those people are hired before the actual revenues come in. So I'm referring to cost that precede revenues.

Jason V. Matuszewski

CEO, President, Director & Secretary

Got it. So yes, as mentioned on the income statement, I noticed there's obviously elements of the SG&A. Obviously, the biggest one is bona fide services. Those services are specific to Venture Medical being out into the field and commercializing our product. And those are a direct correlation to the revenue. Top line revenue, specifically. So as top line revenue increases, those specific bona fide services, which make up a large portion of the SG&A kind of incrementally shift in that direction.

Unknown Analyst

Could you give a figure for the 2 quarters?

Michael A. Fortunato

Chief Financial Officer

I could help with that, Jason, if you want. Yes. So sales and marketing -- so bona fide service fees are included in sales and marketing expenses for a few -- for Q3, they were \$65.1 million for 3 months. And from the previous quarter, I would say we were around 50 -- around mid-50s, 50-something million. Again, listen directly, those costs go up or dialed with in relation to revenue. So as revenue increases, you can expect those bona fide service fees and so the marketing expense to go up.

Operator

I will now turn the call back over to Jason Matuszewski for closing remarks.

Jason V. Matuszewski

CEO, President, Director & Secretary

Well, thanks, everyone, for joining the call today. We had an amazing Q3 results, and I want to thank everybody, specifically, all of the BioStem team members as well as the folks at Venture Medical for all the amazing success that we had in Q3 of this year. And looking forward to sharing our results for the end of the year and Q4 results with you all in the near term. Thank you, everyone, have a great night.

Operator

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

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