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Earnings Call

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CALL PARTICIPANTS	2
PRESENTATION	3
QUESTION AND ANSWER	8

Call Participants

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Michael A. Fortunato
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Swayampakula Ramakanth
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Unknown Analyst

Presentation

Operator

Good day, everyone, and welcome to the BioStem Technologies Fourth Quarter and Full Year 2024 Conference Call. Just a reminder that today's call is being recorded. At this time, I would like to hand things over to Mr. Adam Holdsworth. Please go ahead.

Adam Holdsworth

Good afternoon, everyone, and thank you for joining our conference call to discuss BioStem 's Fourth Quarter and Full Year 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 these statements from time to time, the company undertakes no commitment to do so unless required by applicable 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 earnings 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?

Jason V. Matuszewski
CEO, President, Director & Secretary

Thank you, Adam, and thank you all for joining us today. Before we begin today's call, I want to turn the call over to Mike to address the delay in our Form 10 and the challenges we've encountered related to revenue recognition under ASC 606. I -- we believe that these are the remaining issues associated with allowing our Form 10 to become effective.

Michael A. Fortunato
Chief Financial Officer

Thanks, Jason. The accounting complexity surrounding our distribution agreement with Venture has required a significant amount of dialogue with our auditors and the SEC, particularly around the treatment of bona fide service fees paid to Venture. We believe there are 3 potential outcomes for our financial reporting going forward, depending on the final resolution.

One, a gross revenue model with adjustments to the timing of revenue recognition based on sell-through to end user physicians; two, a hybrid net model where a portion of the bona fide service fees are treated as pass-throughs and remain in sales and marketing expense; and three, a fully net model where all of the bona fide service fees are netted against revenue, which could materially impact reported revenue.

We would not expect any material change in net income, adjusted EBITDA or EPS as a result of these discussions or the SEC review process. We are working diligently with our legal and accounting advisers to resolve this matter, and we remain confident in our underlying business fundamentals. We appreciate your patience as we complete this important step to ensure our Form 10 is both accurate and aligned with all applicable guidance.

I'll turn the call back over to Jason.

Jason V. Matuszewski
CEO, President, Director & Secretary

Thanks, Mike. I'm proud to report a milestone quarter and year for BioStem Technologies. For Q4 2024, consistent with our current accounting policies, we achieved revenue of $102.9 million, a significant increase from $11.5 million in the same quarter of 2023. For the full year, revenue reached $301.8 million, reflecting robust market demand, successful nationwide launches and strategic execution across our portfolio.

Our strong gross margin of 95% underscores our focus on operational efficiency and scalability, and -- particularly during the significant product launch such as that VENDAJE AC. We delivered positive GAAP net income of $15.5 million this quarter and $37.9 million for the year. with adjusted EBITDA of $11.1 million for Q4 and $39.4 million for the year. These outstanding results were driven by strong adoption of our proprietary bio retain technology powering AmnioWrap2 and VENDAJE AC.

I want to specifically recognize our partner, Venture Medical, for their instrumental role in accelerating our growth and commercial success. Looking ahead, our nationwide CMS approved pricing for VENDAJE AC positions us competitively for 2025. And -- we continue to invest strategically in clinical validation efforts to substantiate the clinical superiority of our products, which we believe will continue to drive market penetration and payer coverage.

Our first randomized clinical trials are underway in diabetic foot ulcers and venous leg ulcers with initial data expected by mid-2025.

We -- in the policy landscape, we've actively engaged with CMS, congressional leaders and industry stakeholders to advocate for fair reimbursement frameworks that balance patient access to the most innovative technologies and responsible utilization. We were pleased that this past Friday, CMS announced a second delay in the implementation of the local coverage and termination policy and has now been delayed until January 1, 2026.

The -- we remain confident that through continued dialogue with all stakeholders, the final resolution will be a positive outcome for patients, providers, payers and the overall industry. On our uplisting strategy, we are working toward addressing the remaining SEC comments and finalizing necessary documentation. Our NASDAQ listing approval is contingent only on the effect of Form 10, which we anticipate soon.

Uplisting to NASDAQ remains a pivotal milestone broadening our access to institutional investors and enhancing our long-term shareholder value.

I'll now turn the call over to Mike Fortunato for a more detailed financial review.

Michael A. Fortunato
Chief Financial Officer

Thank you, Jason, and good afternoon, everyone. We appreciate you joining us today, and I will now present BioStem's fourth quarter 2024 and year-end financial results, which were a record achievement for the company. As I discussed earlier, these results are unaudited and reported consistent with our current accounting policies and are subject to change, which could be material based on our resolution of SEC comments and final closing of our year-end audit.

For the fourth quarter of 2024, net revenue was $102.9 million compared to $11.5 million for the same period in 2023, reflecting an increase of $91.3 million year-over-year. This increase was driven primarily by the nationwide launch of VENDAJE AC and continued market demand for AmnioWrap2. Gross profit for the fourth quarter was $99.3 million or 97% of net revenue compared to $10.9 million or 95% of net revenue for the same period in 2023, reflecting an increase of $88.4 million. This improvement was largely due to nationwide launch of VENDAJE AC and continued demand for AmnioWrap2.

Operating expenses for the fourth quarter of 2024 were $90.9 million compared to $11.2 million for the fourth quarter of 2023, an increase of $79.7 million. The increase in operating expenses is primarily due

to increased headcount, higher bona fide service fees driven by an increase in sales through our partner, Venture Medical, expenses associated with the launch of VENDAJE AC and increases in share-based compensation.

We are also pleased to report that we achieved our fourth consecutive quarter of positive GAAP net income. Net income for the fourth quarter was $15.5 million or $0.94 per share with adjusted EBITDA of $11.1 million.

Turning now to full year results. Net revenue for 2024 was $301.8 million compared to $16.7 million for the same period in 2023, an increase of $285.1 million. This increase was driven primarily by the nationwide launch of VENDAJE AC and a continued market demand for AmnioWrap2.

Gross profit for the 12-month period was $288.1 million or 95% of net revenue compared to $15.4 million or 92% of net revenue for the same period last year, an increase of $272.7 million. This growth is primarily attributable to new sales volumes from the launch of VENDAJE AC and the continued growth of AmnioWrap2.

Operating expenses for the 12 months of 2024 were $256.9 million compared to $23.2 million for the same period last year, an increase of $233.7 million. The increase is primarily due to higher costs related to scaling our operations, including workforce expansion, higher bona fide service fees driven by an increase in sales through our partner, Venture Medical, and increases in share-based compensation.

Net income for fiscal 2024 was $31.9 million or $1.95 per share with an adjusted EBITDA of $39.4 million. In addition, our cash balances increased from $14.6 million from the previous quarter to $22.8 million in the fourth quarter, an increase of $8.2 million.

During the fourth quarter of 2024, we completed a detailed deferred tax study, including a Section 382 analysis and confirmed that there were no limitations existing in our ability to use prior accumulated net operating loss carryforwards. As a result, we utilized 100% of our federal and Florida net operating loss carryforwards totaling approximately $54.7 million. The utilization of these loss carryforwards fully offset our income tax expense in the amount of $5.8 million recognized through September 30 and resulted in additional income tax benefit of $7.1 million for the fourth quarter of 2024. The full year income tax benefit as a result of fully utilizing our net operating loss carryforwards was $1.3 million.

As we look ahead to 2025, we are confident that the strong fourth quarter results, combined with the successful execution of our strategic initiatives, positioned BioStem for sustained growth and success. We remain focused on driving expansion, increasing profitability and maximizing value for our shareholders.

I'll now turn the call back over to Jason for an update on operational highlights.

Jason V. Matuszewski
CEO, President, Director & Secretary

Thank you, Mike. As we close this record-breaking year, I want to briefly highlight 4 key pillars driving BioStem's continued success and what we are really excited about in 2025.

First, our strong financial performance has positioned us exceptionally well. Additionally, our increased cash position has further strengthened our balance sheet, providing a solid financial foundation to support our ongoing strategic initiatives and future growth. Our cash balance has increased to $22.8 million at the end of Q4, up from $14.6 million in the previous quarter, reflecting an improvement of $8.2 million.

Second, our nationwide launch of VENDAJE AC, alongside the continued market strength of AmnioWrap2 represents a critical milestone in our commercial strategy. The CMS national pricing approval effective from Q4 has significantly expanded patient access across the U.S., further accelerating our growth trajectory in the chronic wound care market.

We are strategically focused on transitioning more customers to VENDAJE AC for enhanced brand continuity within the VENDAJE product family, while simultaneously reducing our SG&A expenses by eliminating licensing fees associated with AmnioWrap2, which we believe will ultimately improve our bottom line.

Third, our commitment to clinical excellence remains strong. we are currently conducting 3 randomized controlled clinical trials, our first trial evaluating our BioREtain Amnion Chorion allograft for diabetic foot ulcers has enrolled 75% of the patients to date with enrollment to complete in the coming months. Our second trial assessing Amnion allograft for diabetic foot ulcers began enrollment in January and has enrolled over 30% of the patients to date. Our third trial recently IRB approved in enrolling patients focuses on the nonhealing venous leg ulcers. 37 sites comprising of large institutions, academia and clinical research sites are currently participating in these studies with several more in process. These trials are progressing as planned with early data readouts expected by mid to late 2025 and final results anticipated in early 2026.

Fourth, we remain actively engaged with CMS, Congress and industry stakeholders regarding CMS' local coverage determination policy through Project EPIC. Efficiency provides improved care. Project EPIC proposes a national framework designed to bring standardized regulatory and reimbursement regulation, improve patient access and sustainable innovation to Wound Care. It seeks recision of restrictive LCDs and stabilization through temporary payment freezes anchored to Q4 2024 ASP and the eventual introduction of a national coverage in termination and evidence-based reimbursement model that recognizes the benefits of superior products driving improved patient outcomes.

Notably, recent analysis published in the peer-reviewed Journal of Wound Care indicates that the proposed restrictive LCD could inadvertently increase Medicare trust fund expenditures significantly. Restricting treatments to an arbitrary number of applications over a fixed period could lead to higher rates of treatment failure, increased hospitalizations, amputations, emergency visits and overall health care resource use, ultimately increasing Medicare expenditures by potentially hundreds of millions of dollars annually.

Project EPIC provides a thoughtful alternative aimed at balancing cost containment, clinical flexibility and optimize patient outcomes. Since publicly introducing Project EPIC, we have received overwhelming positive feedback from industry peers, policymakers, health care providers and patient advocacy groups, all recognizing the potential of this balanced approach to improve patient access and accelerate innovation in Wound Care.

There are 2 additional matters that I would like to provide further clarity on. First, I want to address our announcement last November of the signing of a letter of intent to acquire commercial stage products and development technologies from ProgenaCare Global. Following due diligence, we decided to pause the acquisition process. And as a lender, we are continuing to follow their progress. Moving forward, we remain actively engaged in evaluating opportunities for acquisitions, joint ventures or other agreements that we will expand our product portfolio and our market penetration.

Secondly, I want to address the FDA warning letter we received data in January 17, 2025 related to FDA's September 2023 inspection of our manufacturing facility in Pompano Beach, Florida. The warning letter cited observations considering 4 injectable-based products, namely OROPRO, PROVISCUS, NEOFYL and RHEO. After inspection, but before the warning letter, we had already ceased manufacturing and distribution of these 4 products as of late February 2024, which represented less than [1/4] of 1% of our 2024 net revenue.

In the warning wetter, FDA explained that the agency determined these products did not qualify for regulation solely under Section 361 of the Public Health Service Act as tissue products, but were instead subject to regulation as a biological product.

In response to the warning letter, we submitted a comprehensive written response to the FDA on February 10, 2025, outlining our plan for addressing all identified concerns. We reiterated our decision to discontinue the manufacturing and distribution of the 4 products and detailed corrective actions, enhancements to our quality management systems and compliance measures aligning with FDA regulations for our current tissue product portfolio.

More importantly, our current products have received written confirmation from the Tissue Reference Group at the FDA and -- that they meet Section 361 criteria, confirming the regulatory pathway for the current portfolio is considered a tissue product, while the observations cited in the warning letter on the

other hand, were issued under the regulations applicable to the manufacturing of drugs and biologic products.

The warning letter citations are, therefore, not directly relevant to the products that we currently manufacture and distribute. However, we recognize that there are some similarities between the processing and regulations for tissue products and manufacturing regulations for drug and biological products, and our corrective actions are designed to address these commonalities and opportunities for improvement. We continue to provide regular updates to the FDA on our progress and we remain fully committed to maintaining the highest standards of product quality, safety and regulatory compliance.

On public company front, our pathway to uplisting to NASDAQ is clear and defined and progressing. We are actively addressing the SEC comments and finalizing the amended Form 10 filings required for NASDAQ listing. We believe achieving this milestone will significantly enhance BioStem's visibility, credibility and access to broader institutional investment, creating long-term shareholder value.

Looking ahead to 2025, we are confident that the strategic initiatives we have established will sustain our strong momentum. We expect continued financial growth, further clinical validation expanded payer coverage and ongoing market penetration of our core products AmnioWrap2 and VENDAJE AC.

We are also actively exploring opportunities to expand our Advanced Wound Care portfolio and to launch our platform technology into complementary market sectors.

I want to express my gratitude to our exceptional team at BioStem as well as our trusted partner, Venture Medical. Our shareholders and all our stakeholders who contribute daily to our vision of improving outcomes in patients with chronic loads.
With that, operator, please open the line for questions.

Question and Answer

Operator

[Operator Instructions]. We'll take our first question today from Swayampakula Ramakanth with H.C. Wainwright.

Swayampakula Ramakanth
H.C. Wainwright & Co, LLC, Research Division

This is RK from H.C. Wainwright. So a couple of quick questions. So the first 1 regarding trying to get the resolution on the bona fide service payments that you need to do to Venture. What sort of payments are these? And then -- and how much is it going to impact your reported revenue lines? And I know it's not easy to figure out with the regulatory bodies. But in general, what is your expectation in terms of timing for the placement?

Michael A. Fortunato
Chief Financial Officer

Jason, do you want me to take that?

Jason V. Matuszewski
CEO, President, Director & Secretary

Yes, go for it. Mike.

Michael A. Fortunato
Chief Financial Officer

Sure, sure. So thanks for the question. Yes. This -- the basic issue here is the payments we make to Venture Medical or classified currently as sales and marketing expense. The question that the SEC is asking is around whenever you make payments to a customer, the question becomes, is that a discount, or is it for bona fide services or some distinct services they're providing?

The way we're accounting for it, we believe there are distinct services, it's a sales and marketing engine for us and getting our goods to the end user customers. And so they're just going, there's -- it's highly technical. It's taking longer than I'd like, but we've just submitted a response back to the SEC staff, I want to say, a couple of days ago, so I'm looking forward to hearing from them.

So at the end of the day, it's really geography on the income statement the question -- essentially, the bona fide service fees you see in the sales and marketing expense. I think we actually haven't separately classified. Those would move, if the SEC says, "Look, you got to do this on a net revenue basis, essentially, they would go against revenue. " So revenue would come down by that amount, but also sales and marketing would come down.

So when we talk about net income and EBITDA, et cetera, not being affected. That's what we're talking about moving those costs up against revenue.

Swayampakula Ramakanth
H.C. Wainwright & Co, LLC, Research Division

Okay. So I say that we're going to hit the gross margin or the operating margin?

Michael A. Fortunato
Chief Financial Officer

So that's -- it hit the gross margin in the sense that revenue would be decreased by the amount of the bona fide service fees, yes. So it's not ideal, but the net income EBITDA would be the same stuff, roughly.

Swayampakula Ramakanth

H.C. Wainwright & Co, LLC, Research Division

Okay. Okay. I got it. And then in terms of the timing, do you have any idea?

Michael A. Fortunato
Chief Financial Officer

We don't. I mean I'd love to be able to tell you all. It's something I've been working on very hard, obviously. I think we're kind of at the backend call of the SEC at this point, but we've kind of put forth our final best argument for why we believe it's correct the way it currently is. We're just waiting to hear back from them.

I can tell you that the NASDAQ application has been submitted. There's a couple -- there were a couple of comments that we had that we cleared with them. And once this is -- we're clear with the SEC, one way or the other, then we should be good to go. I just don't have timing for you, I apologize.

Swayampakula Ramakanth
H.C. Wainwright & Co, LLC, Research Division

No issues. And then on the -- on the FDA letter itself, on the inspection letter and the clarifications that you have right now, because you are not really commercializing those products anymore, so is that relevant at all? In the sense, are there any of those processes that you're doing right now for your other products that could be impacted by the same letter? Or since you're not doing any production, so that letter is basically means nothing.

Jason V. Matuszewski
CEO, President, Director & Secretary

Yes. RK, I'll take that one. We just wanted to get it out and make sure everyone understood exactly what you just said that when the FDA came in and did the inspection -- site inspection, we already -- we're working towards discontinuing those products and their focus on those flowable, injectable based products are separate and distinct than our existing product line that we're commercializing today.

So -- but we just wanted to make sure everyone understood that there really is no impact to the manufacturing operation of our facility based on this warning letter and that they were solely focused on those 4 injectable products and looking at it in the lens of a 351 or BLA or drug and biologic product versus how we manufacture products today, which is good tissue practices via and towards AATB credit practices.

Swayampakula Ramakanth
H.C. Wainwright & Co, LLC, Research Division

Great. So you ended the fourth quarter with $108 million. So even those you exited the year at $300-odd million for the year, so can we annualize the fourth quarter number for 2025? Or do you think -- how sustainable is that in general? And if there is expectation for growth, what sort of expectation -- what's the push and pull on that annualization number basically?

Jason V. Matuszewski
CEO, President, Director & Secretary

Mike, do you want to speak to that?

Michael A. Fortunato
Chief Financial Officer

Yes, sure. I can speak to the revenue. So just to be clear, the product is still selling, there's still volume, there's still there's a lot of demand. The question then becomes, are we -- if we have to restate the revenue number, they'd probably be better to model on EBITDA versus revenue at this point only because what case would be the revenue number would come down by the same amount in the sales and marketing or bona fide service will be coming down.

So the economics are exactly the same. It's just the placement of the cost on the income statement. So I don't know if that helps you or not. That's the way I kind of think about it. At the end of the day, it's a question of does the color [indiscernible].

Swayampakula Ramakanth
H.C. Wainwright & Co, LLC, Research Division

That's not the question at all I'm asking. I'm just talking about the expectations for 2025. Since you -- let's assume everything is as is, like what you're just reporting. So you reported like $104 million or so for the fourth quarter. So can we annualize it and expect somewhere north of $400 million for 2025? Or what's the push and pull on that?

Michael A. Fortunato
Chief Financial Officer

Yes. Unfortunately, we don't like to -- I mean I'm not in a position to give guidance around that. I mean, Jason, I don't know if you want to give any more color on it, but -- but I'm giving...

Jason V. Matuszewski
CEO, President, Director & Secretary

Yes, RK, I think, obviously, having the LCD pushed to implementation in Jan 1, 2026, I think that sets us up to continue our progress through 2025. And -- and we also mentioned that we are looking to have some data for our first DFU trial later this year as well.

And like Mike said, currently, we don't extend guidance around where we're going. But I think we're in a good position throughout 2025 to continue our progress.

Swayampakula Ramakanth
H.C. Wainwright & Co, LLC, Research Division

Okay. Perfect.

Operator

The next question is Erik Voss, Mission Vertical.

Erik Voss

Great. First of all, congratulations on a great year and a spectacular quarter, that was quite impressive. I'm wondering, just -- just to start off, again, just to reiterate, can you verify your earnings and EBITDA don't change in any of these scenarios that you're contemplating changing the top line too?

Michael A. Fortunato
Chief Financial Officer

Yes, yes, I can take that. Jay. I mean I think there could potentially be a small change if we go to net -- sorry, we say gross, there could be a small change in the revenue with respect to -- because currently, we're essentially recognizing revenue we sell to Venture Medical.

The question would become from the SEC would be, well, look, if -- if the end user is your customer should you essentially recognize revenue when that stuff is sold through? I can tell you that the turnover is very fast. That number, if there is a decrease in revenue would not be material. So I think it could change slightly. We're not talking magnitudes of tons of money. We're just talking in probably 2 weeks' worth of inventory or 2 weeks for the sales potential.

Erik Voss

Got it. But what you said is earnings don't change. Earnings are going to earnings you guys report of the earnings.

Michael A. Fortunato

Chief Financial Officer

Yes. I mean earnings would change only. But to the extent -- I don't think they've materially changed. I think it's what we said. So basically, they could shave a little bit, but I don't think they're going to materially change.

Erik Voss

Perfect. Okay. Can you help us with taxes then going forward. So that $0.94 was on 0 taxes or even a benefit. What should the effective tax rate be, Mike?

Michael A. Fortunato
Chief Financial Officer

Yes. That's [indiscernible], we're estimating around 24% tax rate at this point.

Erik Voss

Okay. And on the tax rate.

Michael A. Fortunato
Chief Financial Officer

Yes, go ahead, sorry.

Erik Voss

And the tax rate in this quarter was 0?

Michael A. Fortunato
Chief Financial Officer

Essentially it was -- I think we had a benefit, so it was like minus 2% or something like that because we had a little bit of an excess benefit that came through. So basically, the NOLs are all gone. We essentially use them all up for '24 earnings. So going forward, looking at ways and potentially reduce taxes, obviously, and make sure we're squared away there. So we actually just engage new tax advisers to help us in that regard.

Erik Voss

Okay. Perfect. Maybe going after the outlook for '25 in a little bit different way, Jason, can you kind of comment or give us a sense for how distribution looks right now versus midyear? I know that you guys were kind of focused on the West Coast and we're moving to the East Coast. But if you could talk maybe about penetration across the nation, penetration with podiatrists and if and when you're in hospitals, I would love to just get a sense for what inning you think this distribution story is in right now, Jason.

Jason V. Matuszewski
CEO, President, Director & Secretary

Yes. I mean I think right now, will you mentioned, Erik, we initiated with Venture Medical, and we have a more higher concentration specifically on the West Coast and then also specifically in what we call the mobile Wound Care segment, looking at long-term care, skilled nursing, physician office and smaller podiatry groups.

And so now as we kind of cascaded through 2024 and into early 2025, and frankly, now with this LCD overhang kind of pushed back until the beginning of 2026, I think there's an opportunity to just to really start looking at some larger organizations more on the East Coast, East in Mississippi.

And we are in constant dialogue with the venture team on how do we penetrate that the geography of Northeast and Southeast regions. And then also to how do we expand our access to some of the groups that are in their, I'll call it, more hometown geography out on the West Coast and looking at some of the larger mobile wound care providers, et cetera.

Mobile wound care is an expansive -- it's had a lot of expansion over the last few years. It's definitely the largest revenue generator in regards to the pie of where our end physicians are located and then kind of looking at where our organization seeks new opportunities is definitely getting into the hospital segment and also the ambulatory surgery center segment and hospital outpatient segment. And then last but not least, into the VA and Federal segment.

So I think there's a lot of greenfield for us compared to our competitors, where I think there's a lot of opportunity that we have to tap into areas where, yes, it would be head-to-head competition, but at the same time, a lot of opportunity for us to really articulate our story about our BioREtain products and the product differentiation there.

Erik Voss

Yes. That's fantastic. That's my final question. Congratulations again.

Operator

[Operator Instructions]. We'll go to Mitchell Sacks Grand Slam.

Mitchell Lester Sacks
Grand Slam Asset Management, LLC

Two questions. One is, if we look at your revenue where you go with kind of the worst-case scenario with the SEC saying the costs are going to be removed from revenue. What does your gross margin look like then on a percentage basis?

Michael A. Fortunato
Chief Financial Officer

Yes. Thanks for the question. Let me just look at some of it here really quick and add something prepared for that. Let me -- I think the easiest way to do this would be if you think about the revenue, roughly 78% -- say 72% to 78% of that's going to go into -- come out of sales and marketing into gross margin. to the gross margin line.

Let me see if I have something around that. I don't think I have it off the top of my head, but I can definitely -- if you wanted to connect with me offline, I can definitely think about that. Hang on one second.

Mitchell Lester Sacks
Grand Slam Asset Management, LLC

Sure.

Jason V. Matuszewski
CEO, President, Director & Secretary

Yes, maybe the easier way to answer your question, Mitchell, is to look at -- like Mike just said, we would just be moving up the bona fide Services SG&A and netting it against top line revenue in a worst-case scenario and then ultimately, then calculating gross margin from there.

Michael A. Fortunato
Chief Financial Officer

Yes. I'm sorry, I don't have the number off the top of my head, but we can definitely -- to Jason's point, you just simply take the sales, the bona fide service fee out of the OpEx have damned into as an offset to revenue and then rerun it.

Mitchell Lester Sacks
Grand Slam Asset Management, LLC

Okay. And then my second question comes with respect to the revenue that was generated in the fourth quarter. And I know you're not giving guidance. When I think about just sort of more simplistically, is

there any seasonality or anything that occurred in the quarter that skewed revenues to that quarter that would not be reappearing in future quarters? I don't know how to think about like onetime stocking kind of stuff? Or is that -- is it just sort of a normal course of business for the fourth quarter? And is there any seasonality?

Jason V. Matuszewski
CEO, President, Director & Secretary

Yes. I mean we get this question quite a bit, actually. Sadly, any sort of chronic wound doesn't have a season to it. I think we continue to push the Venture teams continue to push on getting product commercialized.

I think maybe some uncertainty around the market in regards to where things go, if you guys don't know the original LCD implementation date was February. And so I don't -- does that push providers to look at the use of skin substitutes prior to that date, and make sure patients are getting treated with their appropriate products before they come off the ability to have them may or may not address why the -- why was there a broader adoption of the product.

But we do continue to kind of grow our customer base and kind of to my answer back to Erik, I think there's areas in which we didn't have tapped into at the beginning or middle of last year where we started to get in access into later in the half of the year more geographically on the East Coast versus the West Coast.

Mitchell Lester Sacks
Grand Slam Asset Management, LLC

Okay. So -- but with respect to like with your customers, is there any kind of stocking or is stuff just ordered as needed. In other words, like how does that flow?

Jason V. Matuszewski
CEO, President, Director & Secretary

Yes. Kind of as Mike mentioned earlier, a lot of the material has flowed through. We don't have a situation where Venture takes possession and holds inventory for long periods of time. So a lot of the material is sold through in a very rapid pace through to the end customer, which would be the physician.

Mitchell Lester Sacks
Grand Slam Asset Management, LLC

Okay. And again, the -- so in that situation, then if we think about sales, what occurred in the fourth quarter, hopefully, you would be able to build on that in 2025. That would be your goal?

Jason V. Matuszewski
CEO, President, Director & Secretary

That is correct.

Operator

And we'll move to [indiscernible].

Unknown Analyst

Jason. Congratulations on a really good quarter and year. I have a question as it relates to the percent of revenues that stem from Medicare currently. Do you have information on that?

Jason V. Matuszewski
CEO, President, Director & Secretary

Yes. I mean a majority of our revenue is predicated on Medicare reimbursement at this time.

Unknown Analyst

Okay. And Jason, I get that couple of the approved items for treatment for lower extremity wounds currently are under $200. What is the cost per patient for treatment utilizing your products?

Jason V. Matuszewski
CEO, President, Director & Secretary

Most of the prices that can be found in the marketplace are subject to ASP price reporting. And so VENDAJE AC as well as AmnioWrap2 both have published ASPs that you can go on CMS' website and find them.

Unknown Analyst

I find it interesting, my another 4 years ago, Medicare picked up the expense for 30 bariatric chamber treatments to heal a wound and it cost about $75,000 where the infections were antibiotic resistant and could not -- and it was being healed. And I just find it amazing that -- they wouldn't look to expand several thousand dollars versus [indiscernible] and that bariatric chamber ran 18 hours a day and was fully booked for for 9 months. I mean it was a pretty amazing process to go through, but Medicare picked up all of the expense of that. It just seems to me given cost-efficient alternatives that they wouldn't be wanting to take more extreme measures than a couple of hundred dollar expenditures that seem to be working currently in the market are not working that well in the market.

Jason V. Matuszewski
CEO, President, Director & Secretary

Yes. I mean I think it's an interesting point. Dr. Tettelbach actually just drafted and you can look at online and Journal Wound Care, they did an analysis of actually what is the cost, specifically in the skin substitute space, the cost of Medicare and the cost of the Medicare Trust Fund for the use of these products. And it was actually a fascinating discovery that even moving these products up to where they are today from an ASP price reporting perspective actually saved the Medicare Trust Fund dollars.

Why? Because ultimately, patients aren't having amputations, patients aren't getting sepsis, which will drive a significant amount of cost to the system if these patients ultimately get brought back into the hospital system and frankly, those wounds and amputations have to be treated.

There is a really bad statistic around the mortality rate of patients that ultimately end up losing a limb and it's very high in a very short period of time. And hopefully, our goal is with utilizing our bio retained technology that we have the ability to actually save those patients, save their limbs and frankly, hopefully, save their lives.

Unknown Analyst

Well, I can't believe that the government wouldn't consider it because I don't think they give full consideration meaning, but it seems like to me that we might give consideration to the fact that, hey, it does increase the mortality and therefore, remove all those patients from being on Medicare to we shift that to the state and Medicaid cost because 90% of people there live last [15] -- on average 15 months of their life there and hey, you can shift the cost from Medicare to Medicaid if we continue with treatments that result in amputations and higher mortality rates. Anyway, that is a political commentary you're going to need to get into. But thanks for your time.

Operator

And everyone, that was our final question for today. I'd like to hand the call back to Mr. Jason Matuszewski for any additional or closing remarks.

Jason V. Matuszewski
CEO, President, Director & Secretary

All right. Well, first and foremost, I want to thank everybody for joining the call. As we close out this call, I want to take a moment to reflect on how far we've come and where we're going. 2024 was a transformative year for BioStem, one defined by record financial performance, commercial execution,

clinical progress and strategic clarity. We launched new products, expanded our national footprint, advanced our trials and brought forward a policy vision for the future of Wound Care.

What excites me most about 2025 is the momentum we're carrying into it. With a clear strategy, a powerful platform in BioRetain and a passionate team committed to improving the lives of patients. We're focused on execution, advancing our clinical data, expanding payer access, launching new initiatives and completing our uplisting to NASDAQ.

But evolve, we remain committed to delivering value to our patients, our providers and to you, our shareholders. Thank you for your continued trust and support, and we look forward to keeping you updated throughout the rest of this year. Thank you all.

Operator
And once again, ladies and gentlemen, that does conclude our conference. We would like to thank you all for your participation today. You may now disconnect.