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BioStem Technologies

Q1 2024 Earnings Call

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CORPORATE SPEAKERS:

Jason Matuszewski

Biostem Technologies; Chief Executive Officer

Mike Fortunato

Biostem Technologies; Chief Financial Officer

PARTICIPANTS:

Jeff Ramson

PCG Advisory Group; Chief Executive Officer

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PRESENTATION:

Operator^ Thank you for standing by. (Operator Instructions) At this time, I would like to welcome everyone to the Biostem Technologies first quarter 2024 Earnings Call. (Operator Instructions) I would now like to turn the call over to Jeff Ramson, CEO PCG Advisory. Please go ahead.

Jeff Ramson^ Good afternoon, everyone. Thank you for joining our conference call to discuss BioStem's first quarter 2024 financial results and corporate highlights. Leading the call today is Jason Matuszewski, Chief Executive Officer. We're also joined by Mike Fortunato, 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 including the risks and uncertainties described in the company's filings with the over-the-counter market.

You are cautioned not to place any undue reliance on any forward-looking statements, which speak only as of the date made and may change at any time in the future.

Although it may voluntarily do so from time to time, the company undertakes no commitment to update or revise forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by applicable securities laws.

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This call will also include 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 those non-GAAP financial measures to the most comparable measures calculated and presented in accordance with GAAP are available in the earnings press release on the Investor Relations portion of BioStem's website. With that, I'm now pleased to turn the call over to Jason Matuszewski.

Jason Matuszewski[^] Thank you, everyone for joining today's call. I'm pleased to share that BioStem technology had a phenomenal start to 2024.

As we embark on BioStem 2.0, we are starting to see the fruits of our labor and hard work the team has put in over the last 18 months to transform the business.

Our first quarter revenue rose to \$41.9 million, nearly 71 times higher than the \$600,000 reported on the same period last year.

Our growth was primarily fueled by the continued successful commercialization of AmnioWrap2 into the private office setting. This led to an increase of gross margin of 95% compared to 82% in the first quarter of 2023. The improvement in margin is a direct result of our enhanced sales strategies and the ongoing benefits from our partnership with Venture Medical.

This quarter also marks a historic moment for BioStem as we report positive net income for the first time on a US GAAP basis.

We successfully transitioned from a net shareholders' deficit position into a net positive equity position as well. Another exciting development this quarter was the prioritized examination for our patent application with the United States Patent and Trademark Office, USPTO. This patent is critical as it covers our proprietary BioREtain processing technology. This technology is at the core of our product offerings, distinguishing us from competitors and supporting advanced wound care treatments.

We eagerly anticipate working with the USPTO as our application undergoes priority examination.

Once granted, it will significantly enhance our intellectual property protections. BioREtain processing technology currently has five patents, four in provisional status and one in the granted phase.

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Additionally, we've taken a major step forward in our clinical capabilities by engaging McCoy Clinical Consulting to lead our Diabetic Foot Ulcer and Venous Leg Ulcer clinical trials. Nick McCoy's extensive experience in clinical research across various therapeutic areas will be invaluable as we aim to accelerate our trial processes and demonstrate the real-world benefits of our BioREtain products. His leadership will be crucial and facilitate product adoption across hospitals, wound care clinics and inventory surgery centers nationwide.

On the regulatory and corporate governance front, we have completed a rigorous two-year audit, a significant achievement that aligns with our strategic goals for uplisting to a senior stock exchange.

This step not only enhances our transparency and regulatory compliance, but it also sets a solid foundation for our next phase of growth in BioStem 2.0. The successful completion of these audits and our plans to become a fully reporting company with the SEC are designed to solidify our market position, attract a broader investor base and ultimately enhance shareholder value. With that I will turn the call over to Mike for a review of our Q1 2024 financial results.

Mike Fortunato[^] Thank you, Jason. For the first quarter of 2024, our net revenue reached \$41.9 million up from \$600,000 in the same quarter of the previous year, an increase of \$41.3 million. This growth is primarily due to the market demand for MBO route to which was introduced in the fourth quarter of 2023.

Our gross profit for this period was \$39.7 million or 95% of revenue compared to \$500,000 or 18% of net revenue in the first quarter of 2023. This increase of \$39.2 million in gross profit mainly results from the higher sales volume of our MBO route to product line.

Operating expenses for the first three months of 2024 were \$35.1 million, an increase of \$32 million over the same period in 2023. The increase in operating expenses is due to the expansion of our team, the Bona fide service fees resulting from our partnership with venture medical, the distributor for AmnioWrap2 and increases in share-based compensation.

In summary, the first quarter of 2024 marks the first time Biostem has reported positive GAAP net income.

Our financial foundation is strong setting us up for further advancement and expansion in our market segments. Thank you. And I'll turn the call back over to Jason.

Jason Matuszewski[^] Thanks, Mike. Before closing, let's turn our attention to the recent local coverage determinations or LCDs proposed by Medicare administrative contractors. This new framework is crucial as it shapes the reimbursement landscape for our industry.

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The proposed LCDs suggesting utilization cap of for skin substitute applications per case with allowances for additional applications based on medical necessity, which is a significant improvement from the previous stipulations. This flexibility is essential for treating complex cases where patients require extended care to achieve wound closure.

However that proposed LCDs would limit the number of covered products to 15 of the approximately 200 products currently used by clinicians.

We believe the proposed LCDs would severely limit patient access to well-established products. While these limits are still it also sets a high standard that aligns with our commitment to evidence-based medicine.

It's worth noting that a vast number of products nearly 180 do not meet this threshold and will not be reimbursed. This potential change would significantly alter the competitive landscape emphasizing the importance of solid clinical evidence in product validation.

BioStem is actively engaging in the dialogue surrounding the proposed LCDs.

We see the comment period as an opportunity to contribute constructively to the discussions that shape these policies.

Our aim is to ensure that these changes benefit patients by maintaining access to high quality effective products while curbing the misuse of resources. The finalization of those LCDs expected by October following a similar timeline as last year OneMarket critical pivot in our operational and strategic planning.

However we do think it's important to note that currently 60% to 80% of the private office volume is on the non-covered list.

Our response to these potential reimbursement changes is multifaceted.

Firstly, we are accelerating our clinical trial activities particularly around our BioRetain product enlisting the expertise of McCoy Clinical Consulting led by Nick McCoy, a seasoned veteran and clinical research to lead pivotal trials for our diabetic foot ulcer and venous leg ulcer treatment. The data generated from these studies would satisfy the proposed LCD requirements.

In parallel the significant milestone of the prioritized examination of our recent patent application for sterile human placental allograft protects our proprietary by routine processing technology, ensuring that our innovations remain at the forefront of the market distinguishing us from competitors and reinforcing our commitment to advance scientifically backed wound care solutions.

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Additionally, our recent completion of a comprehensive two year audit performed by Marcum and our strategic steps towards uplisting to a major stock exchange reflect our commitment to transparency and corporate governance. These efforts not only enhance our market position, but also solidify our financial foundations preparing us for sustained growth and success in a changing regulatory environment.

While the proposed LCDs introduced a new layer of complexity in the market they also present an opportunity for Biostem to lead with our strong product portfolio and clinical programs.

We are confident, in our strategy, our team and our technology, to navigate these changes effectively. Continuing to provide value to our stakeholders and improve patient outcomes in the wound care space.

We look forward to keeping you updated on our progress, and our ongoing contributions to shaping a responsible, and patient focused healthcare environment including biosimilars entering the most exciting and unprecedented phase of its journey to-date Biostem 2.0, with continued robust growth, advancing clinical programs, and a clear path to expanding into new markets in 2024.

We are committed to increasing our presence in a hospital wound care and other wound care settings, by broadening our product offerings and geographical footprint, we aim to meet the growing needs of wound care patients worldwide.

Looking ahead our focus remains on driving sustainable growth, and continuing to innovate within the MedTech industry. With that, I invite questions from the audience. Operator, please open the line.

Operator^ (Operator Instructions) Mr. Ramson, you may begin with the Q&A.

Jeff Ramson^ Thank you. First question we have is of can use from Brad from Zacks. Could you expand on how the margins were improved through the sales process?

And that can continue?

Mike Fortunato^ Jason, you want me to take that one?

Jason Matuszewski^ Yes. Go for it, Mike.

Mike Fortunato^ Sure.

So Brad, really the story here for the first quarter is really sales volume with the high.

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We have a high ASP, average selling price on the rep to that's really the driver.

Our cost structure continues to be relatively the same, with respect to inventory production. It's really just all top end of ASP. I would expect that to continue. I guess given Jason's comments around LCD, however we'll have to see how that happens with how that shakes out and sometime later this year.

Jeff Ramson^ Okay. Thanks Mike.

So another question we have is, can you address the status for any application on a national exchange?

Mike Fortunato^ Sure. Jason, let me handle that one.

Jason Matuszewski^ Yes. You go ahead, Mike.

Mike Fortunato^ Yes. Sure. So the plan -- as we mentioned in the remarks the plan here is to first register registered in current with the SEC.

We are planning on doing a Form-10 registration statement this year.

Once that's done our concurrent with that, we will be making an application to a national exchange so near-term.

Jeff Ramson^ Yes. Next question is, how soon do you think these proposed changes will take place in the -- sorry, three to make my mistake.

But that will go -- with forward-looking uses fuel product you see diversification into internal use or diversification of product line ones patents are obtained?

Jason Matuszewski^ Yes. I mean I can take that one.

We are actively looking at other use cases. I mean right now our core concentration is in the wound care space, specifically looking at treating diabetic foot ulcers, pressure ulcers, and venous leg ulcers.

But we are looking at other use cases.

We do have a partnership with NovaBay Pharmaceuticals in the optic space, using our product as a barrier covering in the overall space.

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But we also are looking at surgical opportunities in regards to the use case of these products. Jeff, I'm open to taking the question that you also just started to ask as well?

Jeff Ramson^ Yes, correct.

So I'll read that again.

So how soon do you think these proposed changes will take place?

And do you have any products that don't qualify?

Jason Matuszewski^ Yes. Currently, like I mentioned on the call there's about roughly over 180 products that are considered in the non-covered category.

We are currently working through what's called the commenting or in the LCD or local coverage determinations in the proposed status, actively throughout the next few months will sit and have discussions with the MAC med directors as an individual company.

But then also, as a group -- in a group setting, there's planned meetings to meet with those folks and have open form dialogue from not just us as an organization, as a company but other physicians, providers, et cetera.

Those meetings are happening throughout the month of May.

Then, there's formal written comments that are due by June 8.

We don't know what the timeline in the sense of after all of those med directors and those MACs received all of these comments in regards to the current proposed LCD, but our -- like we mentioned in the call today in regards to worst case scenario, which would be sometime in October that this proposed LCD would then be converted to a effective LCD.

I think just the sentiment within the industry and also from our viewpoint and perspective, these proposed LCDs have a large on detriment to the patient population. They're looking to use these types of innovative technologies to treat diabetic foot ulcers, venous leg ulcers and pressure ulcers.

I think what we see is a very limited number of products on the 'covered list' and I think not only from a manufacturing perspective but then also from a physician and provider perspective, there's been a very large concern about the impact that this proposed LCD is going to have against Medicare beneficiaries.

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Jeff Ramson^ Got it.

Okay. Few more so, a follow-up from an earlier question, where do you see the company on it, I mean international distribution as the US market picks up?

Jason Matuszewski^ And I think we are having active dialogue in regards to international. I know this was a question that was asked on the last -- on the annual for 2023.

We're looking at opportunities and kind of taking them in and kind of really analyzing what opportunities we want to pick and choose, and look at going forward with. Right now we have a lot of greenfield here in the United States, like we mentioned in the call a large portion of our revenue is right now focused solely on the private office segment.

We're moving forward with Nick McCoy on the clinical trials and getting that data to support getting commercial payer coverage for our products, and then ultimately give us an opportunity to actually have direct dialogue with some of the Group Purchasing Organizations or GPOs, and then really focus on commercializing our products inside the hospital systems throughout the United States here.

I think when we look at peers and competitors to our organization, there's a lot of opportunity, a lot of greenfield in that space and I think for us from a diversification perspective, I think that's it lends itself to that as well as you know kind of diversifying from just solely in the private office skilled nursing long-term care center markets, but then also expanding into more hospital in stickier business in that area.

Jeff Ramson^ Okay. Another question Jason, are you currently using AI or do you see how it might and the company moving forward?

Jason Matuszewski^ I mean I think there's a lot of opportunities to use AI in a lot of the things that we're doing. We're starting to see just feedback from physicians and some of those things on charting and note taking.

Since we are currently core focus on selling into the private office segment, a lot of those physicians you really need to make sure that they're documenting and noting properly in regards to the use case of these products as well as where the patient is at so that they actually qualify for the use case of advanced skin substitute.

So I think there's probably going to be iterations and use cases of using artificial intelligence within our industry.

I think near term that might be something that not only we adopt, but others adopted within our industry.

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Jeff Ramson^ One more question what's the company doing to create buzz in the hospital market to encourage faster adoption?

Jason Matuszewski^ Yes.

I mean I think one of the big things is this week we actually have kind of what we call the Super Bowl of wound care conferences at SAWC.

SAWC spring specifically in Orlando. We're actively engaging with key opinion leaders, physicians that are currently using our products to speak on behalf from a peer-to-peer perspective about our product lines.

Then also two, like I mentioned earlier, getting that clinical data around our products and working on these clinical trials both in diabetic foot ulcer indication as well as the base leg ulcer indication, really getting robust data to demonstrate that our buyer retain process is unique and has an advantage in regards to the competition on how we actually process our peritoneal tissue allografts. That messaging on top of like I said interacting and building rapport with KOLs within the industry, I think are two areas in which we can the leverage to hopefully like you mentioned get a buzz in the hospital system.

Jeff Ramson^ I think that covers everything, Jason.

Jason Matuszewski^ So Operator, I believe no question.

Sorry.

Operator^ All right. That concludes our Q&A session. And ladies and gentlemen. that concludes today's call. Thank you, everyone for joining. You may now disconnect.