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BioStem Technologies Inc

Second Quarter 2024 Earnings Call

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CORPORATE SPEAKERS:

Adam Holdsworth
BioStem Technologies; Managing Director of Investor Relations
Jason Matuszewski
BioStem Technologies; Chief Executive Officer
Michael Fortunato
BioStem Technologies; Chief Financial Officer

PARTICIPANTS:

Bradley Sorensen
Zacks; Analyst
Unidentified Participant
Unknown; Analyst
Howard Gostfrand
American Capital Ventures; Analyst
Kevin Bennett
Davenport; Analyst

PRESENTATION:

Operator^ Hello. And thank you for standing by. (Operator Instructions) At this time I would like to welcome everyone to the BioStem Technologies Second Quarter Earnings Conference Call. (Operator Instructions)

I would now like to turn the conference 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 second quarter 2024 financial results and corporate highlights.

Leading the call today will be Jason Matuszewski, Chief Executive Officer; 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 and may change at any time in the future.

Although we 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.

This 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 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 section of BioStem's website.

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

Jason Matuszewski^ Thanks, Adam. And I appreciate you all joining this call.

I'm happy to share that BioStem has reached a new milestone by achieving a second consecutive record quarter, making the highest revenue and profitability reported in our company's history.

Our strong financial results reflect the positive momentum we are experiencing across our business, which has been driven by the strong commercial performance of our BioRetain Allograft across multiple sites of service. These key successes significantly contributed to our results and reinforce our commitment to driving continued growth and profitability.

First, let's discuss second quarter highlights and then I'll update you on our progress towards achieving our strategic priorities.

For the second quarter, revenue grew year-over-year by several orders of magnitude to $74.5 million, setting an all-time record for quarterly revenue. 2024 is trending strongly. With the first half reaching $116.4 million in revenue, a complete 180 from the $1.6 million reported for the same period last year.

Our gross margin continues to be strong in the mid-90 percentile, and we strengthened our cash position, ending the quarter with $6.6 million in cash, a healthy increase of $6 million in the quarter.

Additionally, BioStem is making notable achievements with our strategic priorities.

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In January, we set the bar high to substantiate our BioRetain processing technology.

We are working diligently to launch multiple clinical trials and publish peer review papers on our retrospective data accumulated from all of our Allografts used on our various wound types.

We are committed to completing these studies to proactively address potential updates to the reimbursement landscape.

We agree the future coverage requirements for skin substitutes VENDAJE AC will necessitate clinical data to support product efficacy, which we are addressing through these trials and have high confidence, our allografts manufactured with our BioRetain processing technology will do just that.

Some of the work we are doing on retrospective data has demonstrated exceptional results in a wound care study recently published in the industry leading peer-reviewed Journal, Health Science Reports.

The study compared the effectiveness of AmnioWrap2 processed using our proprietary BioRetain technology with a leading competitor's product. The results were overwhelmingly favored for BioStem, with AW2 requiring fewer applications in achieving a significantly higher percent area reduction in diabetic foot ulcers compared to the competitor's product. This tremendous validation of the BioRetain technology and the clinical utility of our allografts, improving wound care outcomes underscores our commitment to innovation and patient care.

On the clinical trial front, we have also received IRB approval for the clinical study evaluating AmnioWrap2 in diabetic foot ulcers. This study aims to demonstrate the efficacy of AW2 in treating DFUs and preventing complications such as lower limb amputation.

The primary endpoint of the study is the percentage of subjects whose target ulcer achieve complete wound closure within 12 weeks.

Secondary end points comparing differences between treatment groups include the time to closure, percentage change in wound area and volume at 12 weeks, total number of applications used to achieve complete enclosure and time to closure for subjects that cross over. The safety endpoint will evaluate spontaneously reported an elicited adverse events and an exploratory endpoint will assess the differences between treatment groups and clinical signs and symptoms of infection.

We are optimistic that with positive study data, similar to our retrospective paper and data set, these study results will lead to product commercial advancements with expanded payer insurance coverage within the advanced wound care market. Given the substantial economic burden diabetic foot ulcers placed on the U.S. health care system, where estimated annual treatments can cost up to $13 billion, we are confident that our allografts will deliver a meaningful impact.

Our allografts offer significant potential to improve patient outcomes while reducing health care costs.

Looking ahead, we plan to continue pulling many levers and launch additional clinical studies in 2024 and beyond to further demonstrate the effectiveness of our allografts. These studies will provide valuable insights and reinforce the clinical benefits of our BioRetain method, driving continued innovation in the wound healing segment. Turning to the next steps as a public company.

I'm excited to announce that we have made strategic decision to become a fully reporting entity with the SEC and to uplift to the NASDAQ stock market.

We have worked diligently to meet NASDAQ's stringent uplisting requirements and recognize the importance of BioStem trading on a national exchange for our current and future shareholders as we advance as a high-growth company. Listing on NASDAQ will provide investors with a global trading platform, increased visibility and the liquidity opportunities, particularly for institutional investors worldwide. This process will depend on the successful completion and review of our Form 10 filing with the SEC as well as the approval of our NASDAQ listing application. This step is crucial to our commitment to financial growth and expanding our presence in the capital market.

We strongly believe these strategic initiatives will position BioStem for continued success and unlock greater value and shareholder opportunities.

I thank you for believing in us as we embark on this exhilarating new journey to manufacture products that change lives. With that, I'll hand the call over to Mike for a review of our Q2 2024 financial results.

Michael Fortunato^ Thank you, Jason. And good afternoon to everyone on today's call and thank you for joining us.

I am pleased to share our 2024 Q2 results with you today.

As a reminder, some of our measures on today's call will be non-GAAP measures. 2024 has become a transformative period of growth for the company compared to 2023 when the company was in the early stages of commercialization of its allografts.

Our net revenue reached $74.5 million, reflecting an increase of $73.4 million compared to the same period in 2023.

This growth was primarily driven by strong market demand for AmnioWrap2. Higher gross profit for the quarter was $70.7 million, representing 95% of revenue compared to $0.8 million

or 81% of revenue in Q2 2023. This $69.9 million increase in gross profit was primarily due to higher sales volume of AmnioWrap2.

Additionally, our gross profit margin improved to 95% as a result of enhanced operational efficiencies.

Operating expenses for Q2 '24 totaled $61.9 million, an increase of $58.3 million for the same period in '23.

The rise in operating expenses is attributable to workforce expansion, bona fide service fees related to our partnership with Venture Medical, distributor of AmnioWrap2 and higher share-based compensation.

We began making investments in R&D study assets such as software and equipment in the second quarter and expect to recognize the expense associated with these costs over the study period. With our AmnioWrap2 and VENDAJE RCT underway, we continue to expect our R&D spend to modestly increase on a relative basis compared to 2023 to mid-single digits as a percentage of net revenue.

Our GAAP income from operations for the second quarter was $8.7 million compared to a loss from operations of $2.9 million in the prior year period. Net income for the quarter was $6.4 million or $0.39 per share compared to a net loss of $3.9 million (sic) [$2.8 million] or $0.22 per share in the prior year.

Turning to liquidity.

Our adjusted EBITDA income for Q2 2024 was a record $10 million or 13% of net sales compared to an adjusted EBITDA loss of $1.3 million or 60% of net revenue in the previous year. This strong performance boosted our net cash balance to $6.6 million by quarter end. With this strengthening balance sheet, we will now have the flexibility to make strategic investments that we believe will drive shareholder value.

In summary, we are experiencing positive financial momentum as this quarter marks the second consecutive period of positive GAAP net income for BioStem.

We remain committed to driving growth, enhanced profitability and delivering shareholder value. Thanks.

Now back to Jason.

Jason Matuszewski^ Thank you, Michael, and to all of you for joining this afternoon, my thanks as well.

Looking ahead, we remain highly optimistic about BioStem's future.

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Our strategic initiatives and growth plans are progressing well and we are confident we'll achieve robust results throughout the remainder of the fiscal year.

As the industry moves towards requiring clinical evidence to prove efficacy as products come to market, this plays into BioStem's strengths given our long-term commitment to evidence-based medicine. The clinical trials we are executing on AW2 and VENDAJE for diabetic foot ulcers, combined with the accumulation of real-world data that has been presented in peer-reviewed journals, demonstrate our commitment to enhancing patient outcomes.

Over the second half of 2024, we will continue building upon our strong first half. The market demand for our advanced wound care solutions remains robust, fueled by the increasing prevalence of chronic wounds.

We continue to receive feedback from the medical community for innovation, new solutions, and this trend presents significant opportunities for BioStem as we continue to set ourselves apart through our proprietary technology and commitment to delivering superior [perinatal] tissue allografts to the market.

We are prioritizing the development of new products to meet the needs of hospital settings and are developing resources to support our products getting on to GPO, IDN, regional purchasing and local agreements.

We're also planning to expand our presence in the VA, DoD, IHS and federal sites as areas of Blue Ocean with the support of our service and sales veteran-owned small business partner, Level Government Services.

We are also continuously looking for expansion opportunities through M&A and evaluating companies that could strengthen BioStem's growth through product synergy and diversification across the continuum of care. The wound care industry is rapidly evolving, which has been driven by technology events such as BioStem's BioRetain technology. A few weeks ago, CMS published a proposed 2025 physician fee schedule.

It does not include proposed changes to the pricing methodology for skin substitutes in a private office away from ASP. That being the case, the implementation of the LCD in a format similar to what has been proposed, is the most likely near-term mechanism for Medicare to make changes in coverage policy.

If the proposed LCD goes into effect, the changes will likely cause some level of short-term disruption in the marketplace.

However, through BioStem's clinical trial initiative and commitment to bring proven evidence-based products to the market, we feel we would meet the proposed Medicare LCD requirements for coverage. With our strengthened financial position and the ability to fund these needed

clinical trials, I believe we are well positioned to navigate any changes in the LCDs and expect the results to benefit the company in the end. To summarize, BioStem is well positioned to capitalize on the opportunities within the wound care market.

We will continue to advance our innovative products, adhere regulatory approvals and pursue our strategic initiatives, our commitment to driving growth, enhancing profitability and delivering value to our shareholders remains unwavering.

We look forward to updating you on the coming quarters. And in closing, my deep appreciation and heartfelt thanks to our team of professionals for their continued commitment to our mission and their relentless focus on driving growth.

We are on the precipice of a mountain of success.

And I'm eager to reach the summit with a year of strong top line growth and solid operational execution.

With that, I invite questions from the audience.

Operator, please open the line.

QUESTION & ANSWER:

Operator^ (Operator Instructions) Our first question will come from the line of Brad Sorensen with Zacks.

Bradley Sorensen^ Yes. Jason, great quarter. You guys keep blowing it away. Good to hear.

I just wanted to touch on, if you could, real quick, the -- your supply, is there any concern because the demand is clearly increasing in a great degree, and that's awesome to hear.

Is there any problems of the supply chain, getting the raw material that you need or the manufacturing constraints that you may have as you go forward? Is there going to be investments in that? Or do you feel like you have enough capacity at this point?

Jason Matuszewski^ Yes. Brad, thanks for the compliments. And to answer your question, we've been working diligently with our recovery partners, specifically two or three that really have been engaged on kind of forward forecasting what we think our demand is going to need and working with them to kind of start the process of getting them positioned for recovery on their side, working with their hospital networks and systems. And for right now we strongly feel like we've got a good handle on getting materials, specifically raw materials and working with those recovery partners.

In regards to the manufacturing side, we actually have been continuing to build out at our site here in Pompano Beach.

We just initiated another project where we're going to add an additional eight clean rooms onto our facility and bringing our total clean room footprint to 17 biosafety cabinets or hoods within our facility. That should get us to a pretty nominal amount of material manufactured on a monthly and frankly, quarterly basis.

But we do anticipate demand increasing and at some point, looking at possibly a separate site or a larger facility in the near term.

Operator^ Our next question will come from the line of Kevin Peterson with Petersen Capital.

Unidentified Participant^ Nice quarter.

Could you give us a little bit of like an overview on why you're experiencing rapid growth for the AmnioWrap2 and where you see this kind of going?

Jason Matuszewski^ Yes. No problem. Thank you.

We've been really fortunate of being able to partner with a group call Venture Medical. They've really kind of really developed the narrative around BioRetain and really have latched on and been able to communicate that outward to the providers that are using our products. And then ultimately, the success of those products on patients kind of highlighted in our retrospective data that we published around heads up against a competitor product.

And being able to actually articulate that narrative around the success of that product and then also just seeing it firsthand use cases on AW2.

On top of that, continuing to kind of look at the segment itself, heavily focusing on [MACs] in the West Coast of the United States and specifically in mobile wound care setting where there's a lot of patients that ultimately can't get into a facility and have regular, weekly or some sort of timely based care and ultimately, actually improving that cadence actually helps support getting wounds to closure. And the Venture team has done an amazing job of kind of communicating that plan, so.

Operator^ Our next question will come from the line of Howard Gostfrand.

Howard Gostfrand^ Jason, congrats on a blowout quarter, just tremendous. You touched on it, but with the strength in cash position and the growth that you're experiencing, what does M&A really look like in your mind over the next 12 months or so?

Jason Matuszewski^ Thanks, Howard.

We're kind of -- like I mentioned on the call earlier, we're looking at items that fit into our continuum of care. Right now our perinatal tissue products, service, I'll call it, one end of the spectrum. And we're looking at products that can support maybe upfront, maybe other types of products outside of the skin substitute realm that would support across the global continuum of care focusing on these patients.

We're kind of mining through opportunities at this time.

We haven't really identified anything as of yet but we're continuing to kind of look at opportunities as they come and kind of roll into 2025.

Operator^ Your next question comes from the line of Scott Hazelwood.

Unidentified Participant^ Congrats on the quarter. Really nice. And I know you mentioned it a bit earlier, but can you just go over some next steps and specifics on the Form 10 and NASDAQ uplisting process?

Michael Fortunato^ Sure.

Sir, this is Mike.

I'll take that. Basically, we're in the process of updating the registration table with the Q2 numbers as Q1 numbers are stale -- are becoming stale at this point. NASDAQ application has been filed and pending the review by the SEC in the Form 10.

We're hoping to get that done here in relatively short order.

So I'd say, in the near term.

So yes, that's kind of where we are.

So I would expect something in the next, say, 60, 90 days.

Operator^ Our next question comes from the line of Kevin Bennett.

Kevin Bennett^ I'm curious about the status of the patent that we have filed for. And also looking at the numbers, I mean it was -- total revenue was great, but the cost of the distribution of the AmnioWrap.

Is there any way that we could actually lower that cost? Or is there a set fee they charge us? Or I'm not sure how that's structured.

Just those two questions.

Jason Matuszewski^ Yes. Thanks, Kevin. Thanks for being a great shareholder over the many years that you've been a part of this journey.

In regards to the patents and IP portfolio, we continue to kind of expand that portfolio.

We're north of 65-plus patents in various phases currently around the use of the products within -- plus wound care and other facets.

And then also, I think we mentioned earlier this year, we acquired some IP through what's called Auxocell -- through Auxocell Technologies. The device is AC:Px unit and it's used to help support manufacture soft tissue products and minced tissue. And so we had a good pull-through of IP around that, but we're continuing to kind of develop IP around all kind of various forms of perinatal tissue and use cases on perinatal tissue. And we'll continue to kind of expand on that. These things don't happen overnight for sure.

So we'll continue to kind of work with our IP counsel and kind of continue to kind of build out a robust IP portfolio. Mike, do you want to -- I'll hand the question in regards to bona fide services and items that are kind of documented into the financial footnotes. They kind of highlight the means of the bona fide services and the work that we do with Venture Medical.

Michael Fortunato^ Yes. Sure, happy to try take this one on.

So as you think about the bona fide service arrangement with Ventures, it's more or less an outside services arrangement for an offsite sales force, if you will.

So instead of us -- think about it instead of us making an investment for that product into an internal sales force, we're essentially paying for sales force, for logistics, for customer education, for all the things that kind of would go into -- like an in-house sales force.

So the rate -- the rate is -- we pay market.

We pay a fair market value for the services they perform for us.

And we kind of look at -- it's a least (inaudible) decision, right? Do we buy -- do we make the investment in house? Or do we essentially outsource that and that's kind of where we landed.

Operator^ Our next question will come from the line of Charles Kinney.

Unidentified Participant^ Jason, as we look at growth and diversification beyond AmnioWrap2, what initiatives are underway?

Jason Matuszewski^ Yes. It's a great question.

So as we mentioned earlier in the call we're looking to launch several other product lines, specifically our VENDAJE, VENDAJE AC products. And we're looking to target, as I mentioned, GPO, IDN, regional purchasing coalition, things of that nature on the hospital side.

I think that diversification of not only on the private office segment, but then also into the hospital system once on a GPO contract will help support and diversify kind of our sales channel. And then also looking at different use cases of perinatal tissue and other sites of service in the sense of other applications.

Like I mentioned, hospital surgical use burn things of that nature.

So outside of just specific wound care.

Operator^ Next question will come from the line of [Paige Taggart] with [APT Consulting].

Unidentified Participant^ Great quarter. Just wanted to ask if you could speak more on how we should view the clinical trial initiative. And I guess, the impact to the company on revenue maybe our market expansion and some of the product coverage?

Jason Matuszewski^ Yes. The -- we've kind of early phases of getting these clinical trials kicked off, specifically the DFU study for AW2. This is a multisite RCT style trial.

We think that, that could be accelerated pretty quickly here, maybe 12 to 18 months timeframe just to get everything kind of kicked off and more towards the finish line.

I think this allows us to have opportunities, like I mentioned in the call earlier, the data to support any sort of potential LCD concern or -- excuse me, proposed LCD concern in regards to some data supporting the products for specifically diabetic foot ulcers.

I also -- like I mentioned earlier in the call we also are looking at other specific wound types, VLU and pressure ulcer near term and be able to kind of kick those trials off later in this year.

Operator^ Our final question will come from the line of [Peter Stoddard] with [Stoddard Investments].

Unidentified Participant^ Congrats on the quarter. With your comments on CMS and the publishing of a proposed 2025 position fee schedule, can you highlight what -- how this impacts BioStem and how you're well positioned for changes in LCD?

Jason Matuszewski^ Yes.

I think just recently, CMS announced that the physician fee schedule for 2025 is not going to be changed.

So ASP methodology is going to still stay within the physician office side.

Obviously there is a bucketed or bundled rate on the ASC and hospital outpatient side.

So with that knowledge, we don't feel like there's going to be some sort of change in regards to pricing mechanisms.

But in regards to the proposed LCDs they -- like we mentioned earlier in the call there may be some pressure in regards to consolidation of products or products either covered or noncovered, et cetera.

But really, with all the clinical data that we are collecting not only in our RCT but then also retrospectively, actively at the same time, that we'll be having data to support coverage for our products. All right. Do we have any other questions? Joseph Brown?

Operator^ We do have a question from the line of Joseph Brown.

Unidentified Participant^ I've been looking at it from -- my background is in biology, and I know this is all about the way this is going forward economically, but I'm thinking about the AmnioWrap. And is that coming specifically from just the (inaudible) the placenta material. And can you make that material artificially by PCR extension? That's kind of what I'm getting at.

Can it only come from live material?

Or can you guys manufacture that material in the future?

Jason Matuszewski^ I mean right now we're focused on utilizing perinatal tissue as our source material for making these products.

I think that would require a pretty substantially different regulatory framework, either device or a BLA or a drug development process. The uniqueness of these products are they're classified as [361] or tissue transplant allografts.

So what the product does in the donors, equivalents in the recipient.

So in this case, placental tissue is considered a recovery and barrier ultimately.

And so that's the use case for it in the current environment. Continuing to kind of look at unique opportunities outside of placental tissue is always on our mind. And as I mentioned earlier in the call in regards to M&A activity and looking at the continuum of care, those are things that we're always kind of constantly looking for near term, whether it be an R&D pipeline initiative or -- and M&A initiatives.

Operator^ I'll hand the call back for any final closing remarks at this time.

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Jason Matuszewski^ So thank you, everyone, for joining the call today.

Mike and I thank everyone, especially all of the team members here at BioStem for all their hard work and dedication.

Amazing Q2. And on to Q3 and Q4 and the rest of the year.

Thank you, everyone.

Michael Fortunato^ Thank you.

Operator^ That will conclude our call today. Thank you all for joining.

And you may now disconnect.