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HeartBeam

Virtual Retail Roadshow

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CORPORATE PARTICIPANTS

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Jon Hunt, Ph.D., *Chief Business Officer*

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PRESENTATION

Operator

Greetings, and welcome to the HeartBeam Virtual Roadshow webinar.

As a reminder, this conference is being recorded.

Before we begin the formal presentation, I would like to remind everyone that statements made on the call and webcast may include predictions, estimates or other information that might be considered forward-looking. While these forward-looking statements represent our current judgement on what the future holds, they are subject to risks and uncertainties that could cause actual results to differ materially. You are cautioned not to place undue reliance on these forward-looking statements, which reflect our opinions only as of the date of this presentation. Please keep in mind that we are not obligating ourselves to revise or publicly release these results of any revision to these forward-looking statements in light of new information or future events. Throughout today's discussion, we will attempt to present some important factors relating to our business that may affect our predictions. You should also review our most recent Forms 10-K and 10-Q for a more complete discussion of these factors and other risks, particularly under the heading Risk Factors.

Your hosts today are Branislav Vajdic, Chief Executive Officer and founder; Jon Hunt, Chief Business Officer; and Rick Brounstein, Chief Financial Officer.

At this time, I would like to turn the call over to HeartBeam's Chief Executive Officer, Branislav Vajdic, you may proceed with your presentation.

Branislav Vajdic, Ph.D.

Thank you, Operator. Good afternoon, everyone. I am pleased to welcome you to today's Virtual Roadshow webinar. We would like to start this event with a recently introduced video presentation. It summarizes key points about our product and our market in less than three minutes. While we are playing the video, for our call-in participants unfortunately it will be about three minutes of silence. But I'd like to remind you that this same video is available on our website, heartbeam.com.

Today, there are many ECG technologies that are offered to consumers and patients outside of a medical facility. What they have all in common is that they do not offer a standard of care, a 12 lead ECG. That means that they are not capable of detecting a heart attack. In great majority of cases, it is a single-lead ECG that may be adequate for some arrhythmias, but is certainly not capable of detecting a heart attack.

Shown in this slide is the actual message from Apple Watch warning the user of its inability to detect a heart attack. Similarly AliveCor, with their cardio products, prominently features on their website the same disclaimer about inability to detect a heart attack.

Our technology, we believe, solved the problem of heart attack detection outside of a medical institution. In the next slide, we shed a bit more light on the problem of heart attack and its detection.

Many medical studies have shown, over and over again, that the chest pain patient that is potentially experiencing a heart attack delays reaction to that episode of chest pain for about three hours. There are many reasons for that, and they have to do with human nature that tends to be in denial of something seriously happening, but also about the high cost in dollars and time if one goes to emergency room. Three-hour delay means an increase in mortality of about 40%. That mortality rate goes close to zero if the intervention is performed within first hour of the onset of chest pain.

The flipside of the same problem is that about 80% of people that go to the emergency room thinking that they be in the middle of a heart attack actually do not have a heart attack, should not be in emergency room, as they have something benign as pulled muscle or indigestion. These unnecessary visits cost the health care system well over $10 billion each year.

In summary, the problem of chest pain detection outside of the medical facility results in many lives lost and also in the great cost and unnecessary cost to the health care system.

I will now ask our Chief Business Officer Jon Hunt to take over the presentation and indeed talk about markets and the products that we have and plan to have. Jon?

Jon Hunt, Ph.D.

Thank you, Branislav.

On this slide you can see the current arrhythmia market for a-fib detection is currently a prevalence pool of about three million patients, and you can see a lot of companies, one of which I was the founding CEO of, Bardy Diagnostics, all play in this same space of remote cardiac monitoring for arrhythmia detection. That is about a $2 billion market in the U.S., anticipated to expand to approximately $5 billion by the year 2030.

On the flipside, if you look at the U.S. coronary artery disease patients, the prevalence pool is currently 18 million patients. Of those 18 million, about 8 million are prior patients with a heart attack, so very large prevalence pool, totally underserved market, and we estimate to be about a $10 billion market just in the U.S. alone. Next slide?

For our AIMIGo telehealth product, we have engaged with Triple Ring Technologies, which is a pro-development company, to assist in the design and development of our AIMIGo device for remote heart attack monitoring. The project is on schedule and on budget, and this joint partnership is a five-phase expedited device development project, scheduled to be completed in the fourth quarter of 2022, in time for our 510k submission to the FDA.

The AIMIGo product incorporates the hardware design and development efforts of Triple Ring and the software, firmware and RPM platform development efforts of Livmor. We recently acquired the source code access for the HeartBeam-branded version of Livmor's FDA-cleared remote patient monitoring platform to connect physicians and patients. Management is confident we'll meet our project timelines for a Q4 2022 FDA submission.

An added benefit of our partnership with Triple Ring is that they have an established relationship with an OEM device manufacturer able to manufacture the AIMIGo device at scale. In addition, that OEM manufacturer is capable of handling both logistics and distribution for their customers. We are in active discussions with this manufacturing partner to manufacture at scale to support the market release of our telehealth product in Q2/Q3 of 2023.

The HeartBeam AIMIGo solution provides an end-to-end closed loop solution for the patient for their physician. The patient activates an app on their phone, this in turn wakes the device automatically, and the patient places the device on their chest over their heart and records their cardiac activity. The ECG recording is streamed to the HeartBeam cloud via the phone, and then a comparative ECG for the patient are displayed to the physician via the physician portal on their mobile device or computer. If the physician is concerned by what they see, obviously they can contact the patient directly.

The AIMIGo device has the footprint of a credit card, it weighs approximately an ounce, and is about one eighth of an inch or four millimeters thick. Placed on the patient's chest, it records a 3D vector cardiogram, including the sagittal or front-to-back plane of the patient's cardiac activity. The device is placed over the patient's heart to record. It's portable, credit card footprinted, easy for a patient to have with them at all times. It is personalized and allows the patient to easily record an ECG at any time and when experiencing symptoms such as shortness of breath or chest pain. Data from the system provides three key data streams to the physician, which they use to determine their treatment course for the patient. It provides comparative ECGs, the clinical history of the patient, and reported symptoms.

To date, HeartBeam has completed three key studies, and the one on the left here demonstrates the accuracy of the HeartBeam algorithm, showing it outperformed a panel of cardiologists in detecting a heart attack, in a study conducted in Europe. The algorithm we found was agnostic to the physical location of vessel occlusion, identifying both lateral and posterior locations, which are typically difficult for a cardiologist to diagnose just from an ECG. Triage of heart attack, also the algorithm performed comparably to a cardiologist, as you see in the middle sensitivities slide here, and is as accurate as a cardiologist in diagnosing from an ECG. Also reassuringly from our perspective is that specificity is very high here. There were no false positives in ambulatory patients taking almost 1500 recordings outside of a medical facility.

HeartBeam is partnered with some key medical contributors from both large academic centers, which many people will recognize here, Harvard, Cleveland Clinic, Stanford, University of Tennessee, but also some large regional health care systems, Piedmont Health Care in Atlanta and Wellstar in Atlanta, as well as cardiologists that have played a prominent role in various societies, like Tom Deering is a past president of the Heart Rhythm Society for example.

This slide shows several companies in the cardiac monitoring market that you are very familiar with. While each product offers some of the capabilities of the HeartBeam telehealth product, the 12 lead ECG capability, integration of patient history and symptoms, and the presentation of comparative ECGs, so a baseline and symptomatic ECG to the physician, differentiate the AIMIGo device significantly from other products on the market.

Important to note, while AliveCor's KardiaMobile product, recently introduced, shown on this slide, it's only a single lead ECG recording, and it does not contain the vector information recorded by the AIMIGo device.

As we move toward commercialization, we have also continued to build a substantial moat of protection that will provide distinct competitive advantage for our products. To date we now have a fortified IP portfolio of three issued U.S. patents, six patent applications in advance or in near term commercialization

initiatives. We believe our products offer substantial capabilities beyond existing offerings, and we continue to engage with potential customers and partners in anticipation of FDA clearance and commercial launch for our products.

The HeartBeam AIMIGo is a 510k regulatory pathway. We've already identified a predicate device to demonstrate substantial equivalence with a simple validation study. Importantly, the clearance of the Gen 1 device allows HeartBeam to collect 3D vector cardiogram data and use these data for developing advanced features for a Gen 2 product.

Other good news from our perspective is the technology has a clear reimbursement pathway with existing CPT codes, and these are highlighted on this slide, and we're planning on using a subscription model where HeartBeam bills a practice on a per patient per month basis, and the discussions my commercial team have had with cardiology practices indicate this is an attractive business model, because they can use existing codes, and it provides enhanced level of care for high-risk patients that they currently do not monitor.

Just briefly, there's a derivative product we've produced from the telehealth AIMIGo platform, and that is software as a medical device solution for use in acute care settings, and our first target will be emergency departments, where this will just be a software licensing business model, on a subscription basis of $0.1 million per year per emergency department, and the high-volume emergency departments we've discussed this with, this turns out to be about 85 patients per day that goes through the emergent department requiring a 12 lead ECG, so it works out at an amortized cost of between $3–4 per use. There are 5000 emergency departments in the U.S., total addressable market about $500 million.

On the flipside, AIMIGo again, we're going to use existing CPT codes for remote patient monitoring, and if we look at the average monthly reimbursement per practice per patient, it's about $1300 per year per patient, about $110 per month, and HeartBeam will bill the practice a technical fee of $50 per month per patient or $600 per year. Again, this is to monitor a currently underserved high-risk patient population. We estimate this to be about a $10 billion a year market in the U.S. alone.

The regulatory pathway for both products, as it mentioned in the previous slide, is a 510k, the 510k submission for the software as a medical device HeartBeam AIMI product was submitted in August, last month, August 15, and we budgeted about a 90 day review cycle and clearance in Q4 2022, so we plan on doing a limited market release towards the end of the year for the AIMI product in the acute care setting, with a product launch in Q1, and then the AIMIGo telehealth platform, as I said earlier, anticipated regulatory submission, 510k submission, is Q4 2022. Again, we've budgeted about 90 days for a review and clearance, with a limited market release in Q2 and a full product launch in Q3 of 2022.

Now I'd like to turn it over to Rick Brounstein, our Chief Financial Officer, to discuss some operational updates and financials.

Rick Brounstein

Thank you, Jon.

I'd like to, here, the slides you're looking at, briefly discuss our sample financial model at scale, for HeartBeam AIMI and HeartBeam AIMIGo solutions, which shown, even capturing a very modest percentage of the total addressable market results in a significant reoccurring revenue base. See, it's those existing insurance codes, that Jon reviewed on a couple of his previous slides, that really are going to drive the AIMIGo revenue.

This telehealth is a much larger market, probably about 20 times or so our market opportunity compared to the side of the ED market, and over time we expect that it will be the primary source of revenue.

I would also like to highlight that our solutions also generate high gross margins under either base case assumptions, with gross margins above 80%, and finally, as the Company scales, operating margins can be in excess of 30%, even as we increase our investment in R&D. This R&D opportunity is most evident by taking a look at our platform technology, so let me now turn it back over to Branislav to do just that. Branislav?

Branislav Vajdic, Ph.D.

Thank you, Rick.

Indeed, our technology is a true platform technology. So far, we have developed two products that are going through the process of either already submitted to the FDA, for the case of AIMI, or soon to be submitted to the FDA, for AIMIGo product.

The AIMIGo product will be introduced as generation one product, with somewhat limited features, to be upgraded to generation two after we get initial data from the field.

Beyond that, looking at the product pipeline, we think that application of artificial intelligence will be of huge value to us. We have a very unique data set, or we will have very unique data set, of patients who actually have recorded their ECG on a perhaps daily or weekly or monthly basis. That longitudinal data for our patient population will be of huge value. Applying artificial intelligence to this data set that is extremely data-rich, much richer than the standard 12 lead ECG, will yield, we strongly believe, additional insight into cardiovascular disease and help further the cardiovascular patients.

Last, on the right hand side is shown the 12 lead patch. We have recently received a patent that basically assigns this whole 12 lead patch category to HeartBeam. We are very pleased with that development, because it addresses a large market, very large market of about $4.8 billion projected to be by 2030. It is an disruptive technology that has potential to really have major influence on the patch industry as a whole.

Lastly, I'd like to share our team, which is comprised of very experienced individuals with high tech experience as well as med tech experience. We are all very enthusiastic about what we are doing here, and indeed you rarely see such a mix of experience and past successes in this microcap space.

Not only that we have expected and believe in that this will be a great success for our shareholders and our employees, but we are all super excited about the prospect of helping millions and millions of cardiovascular patients, initially heart attack patients but in general our technology will basically address all cardiac disease out there that are detectable by a 12 lead ECG. So that's very exciting prospect for us, as well, great motivator to be helping those millions of patients throughout the world.

I look forward to providing our shareholders with further updates in the near term, as we move forward with our commercialization.

I thank you all for attending. Now I would like to answer the questions and ask our team members to answer the questions. Please, Operator.

Operator

Q&A will be taken from the webcast viewers only at this time.

Moderator

The first question from a webcast viewer is: When are you expecting 501 clearances from the FDA?

Branislav Vajdic, Ph.D.

Jon, please comment.

Jon Hunt, Ph.D.

The 510k for the AIMI product, which is a software as a medical device, acute care solution, was submitted August 15. FDA has statutory times in which they have to respond, and typically any review goes through a questions that FDA have, they turn back to the Company, there's a response time from the Company, so that's pretty standard. The 90 days that we've budgeted in are from submission to clearance is to address exactly that. We've budgeted one term of questions, based on FDA's response time, so it's actively in review and we're waiting to hear from them. As soon as we do, obviously, if there are questions for us, we'll respond to them, but that's where the 90 day budget is in the timeline that we've already outlined in the presentation, so. We're currently just waiting to hear from the FDA.

Moderator

The next questioner asks: Is the AIMI product expected to go live in Q4 2020 still?

Branislav Vajdic, Ph.D.

Jon, please continue.

Jon Hunt, Ph.D.

Assuming the 90 day estimate from us is correct and we get FDA clearance in August, 90 days, September, October, November timeframe, we already have some pilot sites that we have spoken to, and they have indicated they are anxious to get to use the product. Assuming we hit that 510k clearance as we've estimated, then yes, we will go live with some pilot site. It'll be limited, but yes, that's the plan.

Moderator

The next question is: Please tell us why you think BEAT was the number one most actively traded stock on the NASDAQ a few days ago, on a day when AAPL was number two.

Branislav Vajdic, Ph.D.

The high trading volume was in response to our announcement of our newly issued patent for the 12 lead ECG patch. It is a patent that describes a very novel technology that could be disruptive, as we said, in a well-established market for ECG patch products. It is a significant market, again, projected to be at $4.8 billion by 2030. The market leader in this ECG space is iRhythm Technologies, and they command a market cap about $4.5 billion today. We believe that the investor community realized what the value of our game-changing, in our opinion, patent is.

Also, it serves as a reminder that our technology is truly a platform technology, with AIMI and AIMIGo products to be introduced shortly, and more to come.

Moderator

The next question is: Your latest 10Q filing indicated you would file AIMIGo for FDA approval this year. How is that going?

Branislav Vajdic, Ph.D.

Jon, please.

Jon Hunt, Ph.D.

As I indicated in the presentation, actually everything is on schedule. The hardware development that we're conducting with Triple Ring, we're on schedule as I said and on budget, so we still expect to submit the 510k for AIMIGo in Q4 and most likely in early December.

Moderator

The next questioner asks: On your newly issued patent, is this something you are considering licensing to medical device manufacturers?

Branislav Vajdic, Ph.D.

We are exploring the best available options for us, and certainly we have a spectrum of options there that we will consider and are considering, and as soon as we reach a decision we will be announcing that.

Moderator

The next question is: Supply chain is such a big issue these days throughout the U.S. How is HeartBeam planning to deal with that, now that AIMIGo has a hardware component?

Branislav Vajdic, Ph.D.

We are keenly aware of supply chain issues that are still very much present in many industries. We have been closely working with our product development partner, Triple Ring Technologies, to address this issue.

In fact, we are at this time already procuring all hardware components that should be sufficient for our 2023 production plans. We are very proactive and we believe that we have everything that will take for that production to happen in 2023.

Moderator

The final question is: Once you receive FDA approval for HeartBeam AIMI, how long a process is it to commercialization, and what steps are you planning or have you taken so far to prepare?

Branislav Vajdic, Ph.D.

Jon?

Jon Hunt, Ph.D.

We do plan to commercialize, obviously. We will run a pilot. Most of the sites we have spoken to want to run a pilot. Depending on the size of the hospital system, they have varying levels of sign-off to get a new product into the system. We'll plan on running a pilot, and most physicians we've spoken to that can run from two to four weeks. We have to put a business arrangement in place with them, and that varies also on the number of sign-offs. That process varies, depending on the size of the health care system, typically. But we're planning on doing pilots in a variety of health delivery systems, because I think that's very important for us to demonstrate to the community at large that it can be used in very different types of health care delivery systems, and we will look at that very carefully and that will vary depending on each center. Some may go quickly and others will take longer just because it's a large system that you're dealing with and the sign off on getting it into a health care system just takes longer. That varies depending on the health care system, as I said.

Moderator

We have one last question, and that is: Is the AIMIGo product disposable or reusable?

Branislav Vajdic, Ph.D.

AIMIGo product, the hardware component of it which is credit card size device, is very much reusable. It will have the lifetime similar to a cell phone. It has rechargeable battery, and indeed it has the potential to last for multiple years.

Moderator

We have no more questions.

Operator

I would now like to turn this call back over to Mr. Vajdic for closing remarks.

Branislav Vajdic, Ph.D.

Thank you, Operator.

I would like to thank each of you for joining our webinar today. We look forward to continuing to update you on our ongoing progress and growth. If we were unable to answer any of your questions today, please reach out to our IR firm, MZ Group, who would be more than happy to assist.

Thank you again.

Operator

This concludes today's conference. You may disconnect your lines at this time. Thank you for your participation. Enjoy the rest of your day.