Movano Health
Fourth Quarter 2023 Earnings
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Presenters
John Mastrototaro, CEO
J. Cogan, CFO
Michael Leabman, CTO
David Barnard, LHA Investor Relations
Michael Soule, VP Business Development
Tyla Bucher, CMO
Stacy Salvi, VP Strategy

Operator
Greetings and welcome to the Movano Health Fourth Quarter 2023 Earnings Call. At this time all participants are in a listen-only mode. A brief question and answer session will follow a formal presentation. If anyone should require operator assistance during the conference, please press star, zero, on your telephone keypad. As a reminder, this conference is being recorded.

It is now my pleasure to introduce your host, David Barnard, with LHA Investor Relations. Thank you, David, you may begin.

David Barnard
Thanks, Paul. Good afternoon, everyone. And thank you for joining us today. Movano Health's CEO, John Mastrototaro, will open today's call with prepared remarks about the progress the company made during the fourth quarter of 2023 and in recent weeks. Today's guest speaker will be Michael Soule, Vice President of Business Development, who will provide some remarks on the company's B2B activities, followed again by John and then CFO, J. Cogan, will provide highlights of the company's quarterly operating results and current financial position. Then we'll open the call for Q&A.

John, J., and Michael will be joined by our Chief Marketing Officer Tyla Bucher, and Vice President of Product Strategy, Stacey Salvi. Movano Health issued a news release this afternoon detailing both fourth quarter and full-year 2023 financial results. Before we begin, I would like to remind everyone that the company will make forward-looking statements during today's call, based on current expectations.

Whether in prepared remarks or during the Q&A session, these forward-looking statements are subject to inherent risks and uncertainties and actual results may be materially different from such statements. These risks and uncertainties are detailed in the risk factors section of Movano Health's filings with the Securities and Exchange Commission, specifically in the

company's forms 10-Q and 10-K. Except as otherwise required by federal securities laws, Movano Health disclaims any obligation to update or make revisions to such forward-looking statements contained herein or elsewhere to reflect changes in expectations with regards to those events, conditions and circumstances.

With that, I'll turn the call over to CEO John Mastrototaro.

John Mastrototaro
Good afternoon, everyone. Movano Health is at a critical inflection point and I'm excited to speak with you today about our progress. First, we commercially launched the Evie Ring last November ahead of Black Friday, garnering strong reviews on the aesthetics, technology and form factor. Demand for the Evie Ring far exceeded our expectations. However, our ability to attain volume production to meet demand was hindered most significantly by capital constraints, and to a lesser degree, we experienced some operational challenges, so we paused our ring order intake.

I'm pleased to share our team has been diligently addressing the issues and are nearing resolution. During this time, in just six weeks, we have amassed a waitlist of over 8,000 potential buyers organically without any paid marketing. Our initial direct to consumer launch is providing incredibly valuable user feedback as we drive toward both continued D2C growth and multiple business to business opportunities.

This afternoon, we closed on a $24 million private placement, including a $3 million strategic seed investment from a tier-one multibillion dollar global medical device company. This is a pivotal moment in our company's journey. We're thrilled to partner with this leader in healthcare and look forward to potential future collaborations. As we highlighted in our press release earlier this week, this strategic investor is keenly interested in the Evie Ring and our proprietary millimeter wave radiofrequency technology, and this event underscores the vast potential of our innovative approach to delivering medical-grade data to both consumers and enterprises.

We're also fortunate to have had the broad participation in the private placement from Movano Health's management team and Board of Directors, totaling more than $3.6 million. Now, with the new financing, we are set up to scale commercial production, proceed further along the regulatory pathway and pursue multiple market opportunities that should deliver shareholder value. Our goal is to deliver both a consumer and FDA cleared wearable that combines accessibility, personalization and style with the recognized capabilities of a medical device.

Our highest priorities are as follows. One, to achieve our first FDA clearance for pulse rate and blood oxygen monitoring, which sets the stage for a brand expansion to Evie Med. Two, on the heels of this clearance to bring key B2B opportunities to fruition. And three, to accelerate our

clinical trials for cuffless blood pressure and non-invasive glucose monitoring, establishing the foundation to develop additional commercial products, leveraging our proprietary technology.

Movano Health is using Evie to set new standards for the possibilities of what wearable health technology can do. We plan to serve consumers through both D2C and B2B channels, where regardless of the access point, our user is ultimately always a consumer wearing a ring. As such, the Evie Ring wellness product is a valuable step on our path to broader commercialization. We're already learning what consumers like and want, and this critical information will help us achieve higher adoption and engagement from future users.

Based on early feedback, we've made several software updates to improve the overall experience, including minimizing use of the green LED light, and improving the accuracy of our sleep tracking. In March, we launched our Insights Engine, which is the first step to offering our customers personalized insights, which leveraging AI-based framework correlate disparate data types. We plan to be judicious with our capital position, and methodical in our approach to build out our direct-to-consumer and business-to-business market opportunities.

In preparation for our B2B launch, we must secure FDA clearance and improve our scale and volume production capabilities. We also plan to execute several initiatives in the next few months, developing an android version of the app, building sufficient finished inventory to ensure quick order fulfillment, and bolstering our customer service capacity.

Regarding the FDA pathway, we've been strategically focused on pulse rate and blood oxygen saturation monitoring, often referred to as SpO2. In the first quarter of 2024, we used our commercial ring in a second hypoxia trial with UCSF, in which each subject wore four Evie Rings, two on fingers and two held on fingertips. When evaluating accuracy versus arterial blood gas levels, the four Evie Rings achieved a root mean square error of 2.46%, well within the FDA guidance of 3.5%. In addition, our rings accuracy also exceeded that of two commercially available hospital-grade reference pulse oximeters, one of which failed to meet the FDA standard for accuracy.

Later this month, we plan to present this confirmatory data and address the outstanding FDA comments from our prior submission. We believe taking these steps will put Movano Health on track to receive a decision regarding the 510-K clearance in July 2024. We look forward to continuing to work closely with the FDA throughout the review process.

In preparation for a positive FDA decision, we have been planning the launch of Evie Med, the medical device version of the ring. It's important to note that because the Evie Ring and Evie Med will be the same physical ring, production costs remain the same. The primary differences that Evie Med will include labeling for the FDA cleared features, as well as some modifications to the app experience. As mentioned earlier, our Evie user base and customer feedback support sizable B2B opportunities.

I'll now hand the call over to Michael Soule, our VP of Business Development, to discuss our efforts.

Michael Soule
Thank you, John. As noted, there are numerous B2B opportunities for Evie Med. We are actively engaged with potential partners that are performing various beta tests with Evie to assess form and function. Today, I will review three of the distinct market segments beyond the medical device partnership that we announced earlier this week.

First, the clinical trials market consists of pharmaceutical companies that need to gather data from FDA-cleared devices as part of their drug trials for FDA and other regulatory submissions. We are poised to dominate the $2 billion market annually of FDA-cleared wearables with minimal competition. Currently, trials are in person, cumbersome, expensive, and sub-optimal as they don't capture the subjects in actual real-life situations.

We believe Evie Med would improve compliance, lower cost significantly and enable quicker enrollment, better data and improved quality of results. Presently, we are in discussions with five top-tier pharma companies, one of which has beta tested Evie. All of these potential partners are excited about the prospects for an FDA-cleared, low-cost and convenient wearable to take the place of other devices presently used.

Second, the payer market consists of insurers that represent more than 130 million patients with chronic diseases, often with comorbidities who have poor and/or unreliable monitoring options. Evie Med would provide an easy to implement solution for early detection of dangerous health risks, and for the prevention that could greatly reduce costly disease interventions. Already, we have traction with one of the top three U.S. payers, that covers approximately 50 million lives. If Evie Med is used by just 1% of this insurer's population, that equates to more than a half a million rings.

The third market I wanted to highlight is the rapidly growing remote patient monitoring channel, or RPM. This market barely existed four years ago. However, COVID unlocked the reality that healthcare can reduce the need for in-office visits, expand access and reduce costs. We believe Evie Med will be able to automate more complete and accurate data, resulting in an RPM solution with meaningful advantages over RPM products in the market today. Our wearable technology is in beta testing with a leading us RPM company that serves over 450 healthcare organizations as the exclusive platform for one of the largest medical device companies in the world.

This is just the tip of the iceberg. Other large B2B opportunities include applications and condition management for cardiovascular, metabolic, obesity, and pulmonary patients. Which in aggregate, we've identified as a $20 billion per year market opportunity and corporate wellness with an identified TAM of $14 billion. Additionally, we fully anticipate the Evie Med introduction will drive more consumer awareness leading to greater D2C adoption.

I'll now turn the call back to John.

John Mastrototaro
Thanks, Michael. Our product development plan extends far beyond Evie and Evie Med. We're deeply invested in multi-analyte sensing and pursuing additional FDA clearances with further research in respiration rate, core temperature and a solution to address sleep disturbances. Some of these metrics may only require a software update, while others may require new hardware components or potentially different form factors.

Our commitment to innovation and improving health monitoring and intervention has fueled six years of intensive R&D work in millimeter wave radio frequency and AI technology. Through these efforts, we created our ultra-compact and efficient health monitoring system on a chip, or SOC, which measures just 4 by 6.7 millimeters in size. Use of this chip yielded breakthrough advances in blood pressure monitoring, enabling accurate, cuffless and automated tracking.

We announced the results of a blood pressure clinical study in October 2023, where our prototype achieved an overall mean absolute difference, or MAD, of 5.9 millimeters of mercury, well below the seven millimeters of mercury MAD required for an FDA recognized standard for wearable, cuffless blood pressure monitoring devices. The results of this clinical trial were a clear catalyst for investment by the tier one medical device company.

Looking ahead, we're also evaluating AI based individual calibration methods to further enhance the future performance of our prototype. Ultimately, we expect blood pressure monitoring will be a significant addition to incorporate into a new product that supplements the suite of analytes we currently offer in Evie. In addition, we believe our single chip technology can be implemented in products designed to aid in the treatment of patients with multiple chronic conditions, including diabetes, where our platform is being evaluated for non-invasive blood glucose monitoring.

Our studies demonstrated that our millimeter wave RF technology surpasses traditional optical sensors and provides high-fidelity data and reliable readings with the ease of continuous data collection. We look forward to additional clinical testing later this year leveraging the RF chip.

With that, I'll now hand the call over to J. for the financial review.

J. Cogan
Thanks, John. Earlier this afternoon we closed on a $24 million private placement, including a $3 million equity investment by a tier-one multibillion dollar global medical device company, and more than $3.6 million in investment by insiders, including members of the company's management team and board of directors. Going forward, we believe we now have the resources to judiciously drive our D2C business, launch Evie Med, target B2B and accelerate clinical trials and pre-commercial work related to our proprietary RF technology. Importantly,

with these funds now on our balance sheet, our production partner is committed to instituting a turnkey process, which would free up both working capital and people resources for Movano Health, as our manufacturing partner will now purchase an inventory of raw materials, parts and finished goods. We expect this will be a significant benefit for the company.

Moving to our financial commentary, while the launch of Evie Ring in late 2023 began Movano Health's transition to a commercial stage company, shipments commenced in January 2024 and revenue will be recognized as result in 2024. In our first quarter results, we will begin to report revenue, which we expect to be nominal as we paused order intake in mid-February.

That said, one of the things we've learned since launching Evie Ring in November is that there is significant demand for the product. The company generated over a million dollars in sales during a very efficient Black Friday holiday launch period, but given capital constraints, we curtailed paid marketing as of December 1st. Yet, we continued to see a steady flow of orders through mid-February when we pause taking new orders.

From December through March, we prioritized capital preservation and actions to meet production and customer service needs. Looking ahead, with an improved capital position and operational improvements across product, manufacturing and customer service, we will be building inventory in preparation for relaunching Evie. We'll also be moving with intention along the regulatory pathway as we work toward receiving our first FDA clearance and securing initial B2B contracts with healthcare partners.

In the fourth quarter of 2023, Movano Health reported an operating loss of $6 million and that compared to an operating loss of $8 million in the year ago period. Our cash burn in the fourth quarter of 2023 was $5.4 million, which was inclusive of costs for the Evie Ring launch and expenses related to our FDA submission, as well as other timing considerations. In November, we raised $4.1 million in gross proceeds in an equity financing that partially offset the cash burn.

At December 31, 2023, we had $6.1 million of cash and cash equivalents on our balance sheet. And as noted earlier, we closed on a $24 million private placement earlier this afternoon. As that concludes our formal remarks, we'd be glad to take your questions. Operator?

Operator
Thank you. We'll now be conducting a question and answer session. If you would like to ask a question, please press star, one, on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press star, two, if you would like to remove your question from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star key. Questions may also be submitted online through the webcast. One moment please while we poll for questions.

J. Cogan

It doesn't look like we have any questions on the phone lines yet, operator. Let's start with the webcast. And I have a few questions here which I can begin to ask. And maybe, John, if you can start with this first question. Are there any additional updates that you can provide as it relates to our first 510(K) application?

John Mastrototaro
Yes, first off, as I mentioned in the earlier remarks, we've made tremendous progress with the clinical work on the Evie Ring. The results from our latest trial were exceptional, and it was very interesting to see that one of the hospital devices actually did not meet the FDA accuracy criteria. In my experience in working with the FDA, obviously, the clinical results are critically important, and so we feel really good about that.

In addition, we've had numerous discussions with the FDA. They have been working with us very collaboratively, and we're pleased with that. And we have addressed all of the questions that they have brought to our attention and so we will be filing the new information with the agency later this month. And as I mentioned, we do expect to have a decision from the agency in July, but I do feel pretty good about where we are based upon the discussions that we've had to this date and the clinical data that we achieved in the latest study.

J. Cogan
Okay. And there's another question here in the webcast about Evie Med, looking for a little bit more information about what Evie Med will be all about and how that compares to Evie Ring as a wellness product.

John Mastrototaro
So, the Evie Med hardware is essentially the same as the Evie wellness device that we launched already, but there are some differences. When you have a medical device, FDA reviews the labeling in detail. And obviously, for the medical device aspects of it, there are some differences between the two. And then secondly, beyond just the labeling, the app experience is different. We've separated out the wellness metrics from the medical metric of what a pulse oximeter would provide as part of the app experience and that's based upon some discussions that we've had with the agency as well.

So, we feel pretty good about that. Naturally, we do look forward to talking more about this in the future and certainly as we move forward and have more feedback from the agency. J., maybe you could spend a moment, though, and talk a little bit about some of the things that we're thinking about related to pricing and whatnot.

J. Cogan
Sure. I would say given that Evie Med will be an FDA-cleared device, we would expect it to be sold at a premium relative to the Evie Ring. And on top of that, across the B2B space, we see a variety of opportunities to have a recurring revenue stream, data revenue, for example.

Whereas with the Evie Ring, it's a product sale, and so we look forward to talking more about that in the future as well.

Okay, let's go on the next question. Either John or Michael, maybe you can give an update here. The question is related to other strategics, if you can talk a little bit about where things stand with potential partners at this stage.

John Mastrototaro
Go ahead. Michael.

Michael Soule
Sure. Thank you, John. Yeah. So that's a great question. Just this month, we've had two large strategic partners, one in the RPM channel, the other in the payer channel, wrapping up their beta tests. We continue to engage our first set of beta partners from last year, in channels ranging from medical device to Pharma, and they are all very much looking forward to our FDA clearance coming up in the July timeframe. And then most recently, coming off our announcement of our cuffless blood pressure clinical study results, we have a whole new tranche, large strategic partners wanting to work with us in channels ranging from pharma to medical device to everything in between. John?

John Mastrototaro
No, that's fine. I think we should move on to the next question. Go ahead, J.

J. Cogan
Great. Maybe this is for Tyla and Stacy. What has been the customer response to the Evie Ring thus far? Can you tell us how users are engaging with the app about their broader user experience?

Tyla Bucher
Sure. Yeah. I can kick us off. So as John already mentioned, we face a number of operational and customer service challenges at launch, which was obviously frustrating for our customers and very frustrating for us as well, as our goal has always been to provide a best-in-class user experience across the board. But despite these initial setbacks, we're still committed to fulfilling this goal and we have received a tremendous amount of invaluable feedback and support from our early adopters, all of which we are implementing in our go-forward planning.

Additionally, the media does continue to review us very positively, which is driving organic traffic and awareness for the Evie brand. And as John noted, we have over 8,000 people signed up for updates since we paused the site, with no paid marketing at all. So, this coupled with our planned media efforts, our influencer program and our upcoming launch on a new social channel will set us up for success once we're ready to start taking orders again. In addition to opening the store back up, our ongoing focus, now that we're resourced, will be to shore up our

customer service and delivery response times, expand our engagement strategy for our existing members, and build out our product offering to include new features and insights.

And with that, I will turn that over to Stacy.

Stacy Salvi
Thanks, Tyla. So, from a strategic product perspective, we're really pleased to see our users highly engaged with the app, and using the ring and app as expected. Of course, we're focused on delivering the high-quality experience our users deserve, with attention paid to improving sleep and the activity feature first. We're also rolling out the insights experience as we speak and excited to develop this important feature, which really personalizes and contextualize this the data from the ring in the coming months.

J. Cogan
Great. Thank you, Tyla and Stacy. Seeing that there are still no questions on the phone lines, I'm going to ask a few more questions here from the webcast Q&A. And either John, or maybe Tyla, there's a few questions about when we're going to start shipping Evie Rings again, what do we need to see before we start taking new orders going forward?

John Mastrototaro
Yeah. First off, with the new funding, we're focused on optimizing our production processes and delivery times, as well as ordering raw materials components, and working on the overall ring improvements. We're currently working with our vendors to order the materials we need to satisfy increased demand, but we're going to continue to hold on taking new orders until we ensure that we can establish and maintain an ongoing inventory of about a month or two by SKU at all times. We want to be able to move forward to be able to fulfill orders almost immediately when they come in.

Tyla, do you have anything you'd like to add?

Tyla Bucher
No, I think it's good. I think the key is we're continuing to focus on this goal of making sure that it is a best-in-class customer experience when people do order the ring. And in the interim, we're going to be focused really heavily on driving engagement with the consumers that we do have, so then when we're opened up, there's really strong word of mouth.

J. Cogan
Okay. We've got a few here about blood pressure and prototypes for blood pressure and the glucose initiatives. So John, maybe these are for you. Can you tell us a little bit more about what the blood pressure clinical trial that we've been referring to from last fall, what do the results really mean? And how long will it be before a blood pressure product could potentially make it to the market?

John Mastrototaro
Yeah. First off, that was one thing that was really critical about the work on blood pressure was that we demonstrated that the chip that we produced, working in concert with Global Foundries was fully functional and able to provide higher resolution signals that we could use to determine blood pressure values, and so that was a real key for us. And the fact that we were able to gain an accuracy in the study that was commensurate with what the FDA guidelines request of a product like this, was really important to us and it really formed the basis for the investment by this tier one, multibillion dollar medical device company, because blood pressure is such a huge problem. It's probably, if you could out one analyte that you could be measuring continuously at home, blood pressure is first up. Half of people over the age of 20 suffer from hypertension or are pre-hypertensive, and it's the leading cause of heart disease and stroke and other things. So, it's the granddaddy of them all.

Glucose is a bit behind that and of course, we're making progress there as well, but this is critical. And then in terms of how long to the market, we just completed that feasibility trial with a prototype system. We have already made some enhancements in the layout of the components on the board to optimize it for a next round of studies. And so throughout the course of this year, we'll be conducting more clinical work, we'll be evaluating the product in more like consumer type form factor moving forward.

We have done all of our initial studies on the wrist versus the finger, and we will continue to do so but we may do some experimental work looking at our ability to monitor blood pressure on the finger. And through the course of this time, we will continue to develop what's the overall consumer-oriented form factor would look like, as well as continue to not only generate clinical evidence but look at longitudinal tracking of blood pressure. So, we look forward to updating you more over time now that we have the resources that allow us to really put more behind these efforts for blood pressure, because it is one of our top initiatives in the company.

J. Cogan
And John, I don't think you mentioned it in those comments there, but there's another question here regarding blood pressure and also regarding glucose monitoring and wondering if we would expect the first product to be in a ring or possibly a band or some other form factor?

John Mastrototaro
We have not evaluated for blood pressure anywhere but the wrist at this point. We basically focused the RF energy at the radial artery of the wrist for the measurements. We get really clean, very nice pulse pressure waveforms using that. We're going to have to look at whether or not we could do it on the finger. We know the chip is small enough to fit inside a ring that can be used on the finger, but we have not evaluated that site. But we do know that we want to be able to assess a waveform that's coming from an arterial source.

As it relates to glucose, it's a little bit more open. Quite frankly, if you know you're aware of the existing CGMs and something I worked on for a lot of my career, they're done looking at the

interstitial fluid. And really, we're looking at interstitial changes in signals based on the RF signature for glucose. So we are also looking at whether we could for glucose monitoring, use other sites of making the measurement. I think there's more flexibility with glucose than there is for blood pressure.

J. Cogan
Great. And maybe Stacy or Tyla, there's a question about Apple Health and when Evie is planning on connecting to Apple Health in the future.

Stacy Salvi
I can take this one. Thank you so much for the question. This is certainly near the top of our list. We know that our users are also likely Apple product users, of course. And so as we consider the kind of landscape of opportunity out there and where we want to focus our attention, this one is on the shortlist. I can say that. I can't give an exact date, but certainly something that we are looking at.

J. Cogan
Great. And I think the last question for today will be one that I can actually answer. How long will the cash you just raised last? And what we would first want to say is we're incredibly pleased with the results of the $24 million capital raise that we closed earlier this afternoon. As we've mentioned, we got a $3 million strategic seed investment by a tier-one multibillion dollar global medical device company and we also saw very strong demand from existing shareholders and new institutional investors and clearly had significant participation from insiders, including members of the management team and Board of Directors.

The capital is going to be able to provide us with the ability to proceed along our major initiatives, including the regulatory pathway to the FDA clearance, help us accelerate our blood pressure clinical studies and work around non-invasive glucose monitoring, and as we've also been discussing, begin to scale commercial production.

Okay. With that, operator, I think we are ready to end today's call. Thank you.

Operator
This concludes today's conference. You may disconnect your lines at this point. Thank you for your participation.