Movano Health
First Quarter 2024 Earnings Call
May 15, 2024

Presenters
John Mastrototaro, Chief Executive Officer
Michael Soule, Vice President of Business Development
Jeremy Cogan, Chief Financial Officer
Stacy Salvi, Vice President of Products and Strategy
Tyla Bucher, Chief Marketing Officer
Michael Leabman, Founder and CTO

Operator
Greetings, and welcome to the Movano Health Q1 2024 Earnings Call. At this time, all participants are in a listen-only mode. A brief question-and-answer session will follow the formal presentation. If anyone should require operator assistance during the conference, please press star and zero on your telephone keypad. As a reminder, this conference is being recorded.

It is now my pleasure to introduce your host, Jay Cogan. Thank you. You may begin.

Jeremy Cogan
Thanks, operator. Good afternoon, everyone, and thank you for joining us today. Movano Health CEO, John Mastrototaro, will open today's call with prepared remarks about the progress the company has made during the first quarter of 2024 and recent weeks. I will then provide highlights of the company's quarterly operating results and current financial position. Then, we'll open up the call for Q&A.

John and I will be joined by our Chief Marketing Officer, Tyla Bucher; our Vice President of Business Development, Michael Soule; and Vice President of Product and Strategy, Stacy Salvi. Movano Health issued a news release this afternoon detailing first quarter 2024 financial results. Before we begin, I'd 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.

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

John Mastrototaro
Good afternoon, everyone. As you are aware, we reported our Q4 2023 earnings just over a month ago on April 4. We were very excited to share the news of our recent $24 million private placement, which included a strategic seed investment from a tier one multibillion dollar medical device company. While we plan to be judicious with our capital spend and methodical in our approach to build out our Evie Ring direct-to-consumer and Evie Med business-to-business market opportunities, we are committed to establishing a solid foundation for both our D2C and B2B businesses, so we can successfully our customers.

As such, our priorities are threefold, one, to prepare to take D2C orders again for the Evie Ring, two to secure FDA 510(k) clearance for its pulse oximeter feature under the Evie Med brand, and three, to refine our wrist-worn prototype with the millimeter wave RF system on a chip in preparation for additional blood pressure and glucose studies.

As to the first priority, we are laser-focused on preparing to take orders again for the Evie Ring, which requires that we deliver an excellent product experience, ensure a seamless delivery timeline for all orders, and provide an improved customer service response to any issue. From a product standpoint, we are diligently working to improve the customer experience across both hardware and software.

We are developing more robust hardware, with improved chemical, environmental, and physical resistance. In software, we are improving our heart rate and motion and sleep algorithms, implementing a more comprehensive AI-driven suite of insights, and are initiating the process to develop an Android version of the app.

On the production side, we are enhancing our automation, tooling and assembly, and test processes to increase yield and throughput as we prepare for re-launch. We are also in conversations with our key production partner to implement a turnkey solution which would further increase our efficiencies.

We have bolstered our customer service capacity and have implemented an AI-powered customer response chatbot on our site as well as onboarded a new Head of Customer Service, with over 25 years of experience in the D2C space. All these efforts will ensure an enhanced customer experience, whether users reach us through D2C or B2B channels.

Regarding our second priority, we are working closely with the FDA in anticipation of the 510(k) clearance on the medical device version of the ring, which we will launch under the brand name Evie Med. We announced last week that we successfully submitted exemplary clinical trial results from a Q1 hypoxia trial to the FDA on April 22, 2024, which is a significant milestone for our organization.

During the trial, each subject wore four Evie Med Rings, two on fingers and two held on fingertips. When evaluating accuracy versus arterial blood gas levels, the four Evie Med Rings achieved a root mean square error of 2.46 percent, well within the FDA guidance of 3.5 percent. In addition, our ring's accuracy exceeded that of the two commercially available hospital-grade reference pulse oximeters, one of which failed to meet the FDA standard for accuracy. We continue to expect an FDA decision regarding our 510(k) in July 2024.

In preparation for a positive FDA decision, we remain bullish on the enterprise opportunities that we believe a clearance will unlock for our organization, and as we get closer to securing this distinction, we are already engaged with our strategic partners in the pharmaceutical, medical device, and payor channels.

These partners have all expressed the immediate challenge they face in obtaining continuous and secure medical grade data and see our solution as an integral part of their future initiatives. We see opportunistic applications in chronic management of cardiovascular, metabolic, obesity, and pulmonary patients, which, in aggregate, we've identified as a $20 billion per year market opportunity.

And finally, we continue to focus on the breakthrough technology of our ultra-compact and efficient health monitoring system on a chip, which measures just 4 x 6.7 mm and has yielded breakthrough advances in blood pressure monitoring, enabling accurate, cuff-less, and automated tracking.

As you'll recall, we previously 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 mmHg below the 7 mmHg MAD required for an FDA recognized standard for wearable, cuff-less blood pressure measuring devices.

We have been making enhancements to this prototype we evaluated in that study, and we expect that our next blood pressure study will take place this June and will be the first study we've done with an arterial line, which is the precursor to an FDA pivotal study. Unlike a cuff, which provides only one blood pressure value, an arterial line will provide continuous data on a number of patients.

In addition, we are also evaluating AI-based individual calibration methods to further enhance the future performance of our platform. Ultimately, we expect blood pressure monitoring will be a significant addition to the suite of analytes we current offer in Evie as over half the adults in the U.S. over age 20 are pre-hypertensive or have hypertension. Continuous monitoring of blood pressure holds the promise of dramatically enhancing the management of these conditions.

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

Jeremy Cogan
Thanks, John. We shipped 5,305 Evie Rings in the first quarter of 2024 and reported $852,000 in revenue in the period. The company reported an operating loss of $5.8 million in the first quarter of 2024 versus an operating loss of $7.2 million in the year-ago period. We launched the Evie Ring during the Black Friday 2023 holiday period, and we are reporting revenue for the first time, as revenue is tied to the timing of ring shipments, which commenced in January of this year.

You'll recall that, given capital constraints, we ceased all paid marketing as of December 1, 2023, and temporarily halted taking orders in February of 2024. From December of 2023 through March of this year, we prioritized capital preservation and actions to meet production and customer service needs.

Not surprisingly, given the limited initial launch, there were some operating inefficiencies and learnings early on. For example, our launch generated a great deal of excitement, and consumers were anxious to receive their rings. Delays that we experienced with delivery timelines generated a number of cancellations and impacted the top and bottom line results of our initial launch.

We intend to avoid this issue, going forward, as John noted earlier, by ensuring ample inventory prior to taking orders again. We are already making important strides and additional operational improvements across products, manufacturing, and customer service that should position us well for both an expanded launch of the Evie Ring in direct-to-consumer and eventual launch of Evie Med in B2B upon an FDA clearance decision.

Following our successful private placement in April, where the company raised $24 million in gross proceeds, including a strategic seed investment from a tier one multibillion dollar medical device company, we believe we have the resources to judiciously drive our D2C business, launch Evie Med, target B2B, and accelerate clinical trials related to our proprietary RF technology.

Importantly, and as noted before, with these funds now on our balance sheet, we are in conversations with our production partner about a turnkey solution, which should free up both working capital and people resources for Movano Health.

A few other financial highlights, our cash burn in the first quarter of 2024 was $4.1 million, which was inclusive of costs for the Evie Ring launch and expenses related to our FDA submission as well as other quarter-to-quarter timing considerations. Whereas we had $2.1 million of cash and cash equivalents on our balance sheet at March 31, pro forma for the early April private placement, we had $24.8 million of cash and cash equivalents at that time.

Now, I'll turn it back over to John for final remarks.

John Mastrototaro
Thanks, J. This past quarter has been a significant one for the company, marked both by valuable lessons from our D2C launch as well as significant progress in our organizational milestones. We are encouraged on all fronts and look forward to a successful D2C re-ignition, continued positive momentum around our expected 510(k) clearance, and advancing to the next phase of our blood pressure clinical studies.

We are confident that this combination of positive developments will act as a catalyst for success through the balance of the year, and we look forward to keeping you updated as we continue to make headway.

As that concludes our formal remarks, we'd be glad to take your questions.

Operator
Thank you. We will now be conducting a question-and-answer session. If you would like to ask a question, please press star then one on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press star and then 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 keys. For those on the webcast, you can submit your questions via the webcast platform.

Jeremy Cogan
Okay, operator, it looks like--well, at least, while we're waiting for any questions from the phone lines, it looks like we have a few questions on the webcast. So, I can go ahead and begin asking those and directing them to the team.

The first one, John, I think this should be for you. Could you provide any updates as it relates to the 510(k) process beyond what you mentioned in the call today?

John Mastrototaro
Sure, J. Thanks for the question. As I mentioned in the call, we recently re-filed with the FDA some new clinical results for another hypoxia study, where we had four rings worn on four different locations for each subject. And we were really pleased with the results, which exceeded our expectations.

The rings not only exceeded--far exceeded the FDA benchmarks, but they provided more accurate results than two FDA approved hospital-grade control devices that were used during the study. And so, I think those results bode very well for us. We actually, since putting in the new data, have already had some back-and-forth communication with our reviewer, and thus far, things are going pretty well. So, we're going to continue to work closely with the agency along the path of ideally getting this product cleared for market.

Jeremy Cogan
I think Michael Soule can answer the next question, which is, can you provide some more detail on your plans for the launch of Evie Med with B2B partners?

Michael Soule
Hey, J. Sure. Yeah, that's a good question. So, we continue to engage with all of our beta partners and channels, ranging from medical device to pharma, who are looking forward to our FDA clearance in the July time frame. We expect a 510(k) clearance that unlocks a host of initiatives across clinical trials and remote patient monitoring. And we're currently building the back-end data systems required for these partnerships, so we can hit the ground running.

Coming off our recent announcement of cuff-less blood pressure clinical study results, we have another new group of large strategic partners wanting to work with us in channels ranging from pharma to medical devices.

Jeremy Cogan
Okay. Speaking of blood pressure, this next question could be for Michael Leabman or John. Do you want to comment on the progress you've seen with blood pressure?

Michael Leabman
Sure, I can take that. So, as John mentioned earlier, our next big step--there are two big steps, actually. One is to take our blood pressure design and make it more into a product as we get closer to our pivotal study and, as John said, really trying to improve the algorithm and do an arterial line test in June, which is similar to the test we would be doing for an FDA pivotal study, so really just trying to get everything ready in a form to really facilitate fast tracking blood pressure.

Jeremy Cogan
Okay. John, do you want to take this next question? I'll throw a couple of the questions together because they all relate to the shipping of the Evie Rings, some questions about when we'll start shipping Evie Rings and then also some questions about features related to Evie, including how far are we from an Android app?

John Mastrototaro
Sure, J. Thanks. Yeah, I've seen this question is coming up quite a bit. So, as J. had mentioned in the prepared remarks, we went through a pretty challenging capital situation the end of last year and into early this year, which kind of hamstrung us a little bit on what we were able to do.

However, launching the ring when we did and getting it out there in the marketplace where we could learn really provided a great opportunity for us. And so, now that we have the new funding, we are focused on optimizing our production processes and delivery times as well as working on overall ring improvements and, of course, the enhancements that we've already been making to our customer service.

We are currently working with our manufacturing vendors to order all the raw materials that we need to satisfy increased demand that we expect, moving forward. And we're going to hold on taking new ring orders until we've ensured that we can establish and maintain an ongoing inventory of about one to two months by SKU at all times.

Once we're confident in all these initiatives that we've set up, then we will announce a new ship start date, but we are under no huge urgency to do this earlier than when we feel really confident in our ability to fulfill orders. And so, having inventory built up and maintained before we turn on the spigot again is very important to us an organization.

Jeremy Cogan
Great. And John, I have another for you. Someone is asking if there's any update on the strategic investor and other potential partnerships.

John Mastrototaro
Sure. Well, as it relates to the current strategic investor, it's actually been a very, really collaborative relationship that's only a little more than a month old since we did the fundraise. And already, I've had multiple meetings with their team. They've actually offered us some support in a couple of areas where they have more experience and expertise than us, which has been very valuable to us for moving forward.

And we've discussed some further opportunities where our ring, in its current embodiment, could potentially be beneficial to some of the work that they're doing with customers and where they see the market trends going. And lastly, of course, there's continued interest in what we're doing with our proprietary millimeter wave RF technology and the future that that hold, as I mentioned, as it relates to blood pressure and/or glucose, which are the two big granddaddies of metrics that we could be monitoring, so a lot of excitement there as well.

So yeah, since this engagement started, it's been nothing but positive, I think, both on our side as well as theirs. And we've shared with them our strategic plan for the rest of this year and going into next, then gotten some feedback from them about what our plans are and our focus, and we're in complete alignment.

Jeremy Cogan
That's great. And then, a couple quick ones here. Blood pressure, do we see the first commercial device being a wristband or a ring? And then, for Evie Med, will that also be for men?

John Mastrototaro
Michael, why don't you do the first part of that, and I'll do the second part.

Michael Leabman

Sure. So, I mean, our chip, as John mentioned, is 4 x 6 mm, so it does have the ability to eventually go into a ring as well. I think in this first go around, given all of our great data so far that we did in our previous clinical studies, we want to make sure that we get through the FDA as quick as possible with what we've already been testing for the last year and a half. And I think once we take that a little bit further along, then we'll start looking at putting it into the ring as well.

John Mastrototaro
And then, as it relates to Evie Med, I can tell you a couple of things that are very important. When we've run our clinical trials for SpO2, for example, and heart rate, that was done both men and women. We looked at the entire population as well as, very importantly, people with different skin tones because there are optical sensors for SpO2. And so really, that was not limited to only women. It's for all.

And in the discussions that we've had, and Michael Soule perhaps can elaborate on this--but, the discussions that we've had with potential partners in the healthcare space, I mean, some of them are developing female-focused solutions, so obviously that would apply to them, but many others are looking at this for both men and women.

And the ring today is worn by some men, albeit a much, much smaller number of men than women, but nothing prohibits the ring from being used by either men or women. And certainly, the men on this call and out in the field are using Evie Rings today. And as the medical device comes to market, we will certainly use it on both men and women.

And Michael Soule, I don't know if you have anything you'd like to add.

Michael Soule
No, John, you covered it well, just that all of our beta partners, while they see what we're doing in the direct-to-consumer world and think it's a really great strategy, in the clinical trial areas and medical device areas, the folks, the large strategics that we're dealing with, see this as a unisex device, so I just want to add that.

Jeremy Cogan
Okay. And then, it looks like our last question for the webcast, and it doesn't look like we have any on the phone lines, so this will be our last question for this call today. We sold $1 million of rings in the first 10 days of your launch but netted $852,000 after a full quarter. Can you elaborate on the difference?

Sure. As we mentioned on the call, we had a lot of demand at launch, and we were very committed to fulfilling all the orders as quickly as possible, but we did have a series of unexpected delays on the manufacturing side, which caused some frustration to consumers, and they grew tired of waiting and subsequently canceled their orders.

So, while that was disappointing, it was excellent learning for us as an organization. We've since modified our processes and our inventory controls, so that when we begin taking orders again in the future, we will have plenty of inventory and be able to deliver all sizes and colors within five to seven business days.

Okay, operator. That looks like the end of the Q&A. I will turn it back to you.

Operator
Thank you, sir. Do you have any closing remarks you would like to say?

Jeremy Cogan
Yes. Thanks for reminding me. Just one. We appreciate you all being on the call today, and if you'd like to continue to follow Movano Health for news and events, please stay tuned to our website at ir.movano.com.

Operator
Ladies and gentlemen, that concludes this conference. Thank you for joining us. You may now disconnect your lines.