Movano
Q1 2023 Earnings Call
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Presenters
John Mastrototaro, CEO
J. Cogan, CFO
Michael Leabman, CTO
Tyla Bucher, Chief Marketing Officer
Stacy Salvi, Vice President of Strategy

Operator
Greetings and welcome to Movano's First Quarter 2023 Earnings Call. At this time, all participants are in listen-only mode. A question and answer session will follow the 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, J. Cogan, Chief Financial Officer. Thank you. You may begin.

J. Cogan
Thank you, operator. Good morning, everyone, and thank you for joining us today. Our CEO John Mastrototaro will open today's call with prepared remarks about the progress we've made during the first quarter of 2023, and in recent weeks. Our Chief Marketing Officer, Tyla Bucher, will join us to give an update on the upcoming launch of the Evie Ring. Afterward, I'll cover the highlights of our quarterly operating results and provide a perspective on our financial position. Finally, Movano Health's Founder and Chief Technology Officer Michael Leabman, and Stacy Salvi, our Vice President of Strategy, will join John, Tyla and me for the Q&A session.

Movano Health issued a news release earlier this afternoon, detailing our first quarter financial results. The news release and today's presentation are available on our website at Movanohealth.com. Before we begin, I would like to remind everyone that we will make forward-looking statements during today's call based on our 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 our 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.

Now, I'd like to turn the call over to our CEO John Mastrototaro.

John Mastrototaro
Welcome, everyone. Thank you for joining us for Movano Health's first quarter earnings call. It's been 18 months since we made the strategic decision to commercialize a smart ring design for women. To go from ideation to a well-designed wearable solution at such a rapid pace has been no small feat, especially when considering all the macro forces at play. We're in the final stages of development before the commercial launch, and today, we're excited to announce publicly for the first time that we plan to make the Evie Ring available for purchase in September of this year for $269 with no subscription.

We carefully considered the right time for a commercial launch, balancing product quality, speed to market and seasonality. We believe a September launch will set us up for success for several reasons.

First and foremost, there's no better time to be launching a health device for women. The global wearable health industry is exploding and projected to be worth $145 billion by 2027. This demand is driven by consumers heightened awareness and desire to build healthier habits following the pandemic. This, in combination with the rise of femtech and a focus on women's health initiatives, has created a massive opportunity for a women-first wearable.

From a seasonal standpoint, we believe a September launch is the perfect time to capture an engaged audience. Consumers are transitioning away from a vacation mindset and are settling back into their day-to-day routines. The back-to-school timeframe often comes with a desire to get organized and start fresh habits. In addition, people are starting to plan for holidays and gifting season, which will be just around the corner from our launch and a great opportunity for sales.

By September, we will have also completed two beta programs with multiple strategic partners, enabling hundreds of consumers to test our solution. With usability data, and enhancements to the product driven by feedback from potential customers, we believe our initial product will be primed for our target audience.

The timing of the launch may or may not be in sync with an FDA clearance, which is consistent with our previous commentary. We announced today that we plan to file our first 510(K) in June for heart rate and blood oxygen. And whether or not we have a decision from the FDA in September, we are prepared to launch Evie as a wellness device and then transition to a medical device when the time comes. I'll talk more about where we are with the FDA filing in just a moment.

All in all, we remain very bullish on the market potential for Evie and believe our strategy will position the company for a successful launch and beyond. Our CMO, Tyla Bucher, will join us

later on to provide more details around our launch plans. In the meantime, I want to provide an update on a variety of important company initiatives.

As it relates to the FDA submission in June, over the past two years, we've worked to ensure there is an established pathway through the regulatory approval process, but bringing a medical device to the market can be very challenging.

One of the most critical aspects of the FDA submission is clinical performance. We previously presented the results of our hypoxia study, where the Evie Ring demonstrated exceptional performance for both SpO2 and heart rate. Recently, we completed a more comprehensive heart rate evaluation on the bench for FDA guidelines to evaluate the system and measuring heart rates from 40 to 240 beats per minute. The results demonstrated excellent accuracy, with errors of less than one beat per minute. Not only does the FDA submission require detailed reports on the performance of the device, but we also need to prepare thousands of pages of documentation regarding the design, safety, reliability, software, biocompatibility, labeling and more, with many verification reports generated by external certified test laboratories. And before the submission, we must ensure the organization is structured as a medical device company. This requires a quality management team and system to assess the risk of every vendor and component we use, an FDA compliant contract manufacturer and design control and risk management features, among other things.

Fortunately, we're nearing completion of all the required documentation, and plan to make the formal submission by the end of June. This first submission will set the stage for future FDA clearances on Evie and our future wearables. The effort associated with becoming a medical device company presents significant opportunities with healthcare and other enterprises, and we believe it's a highly competitive differentiator, as well as an underappreciated asset when compared to existing wellness solutions. In fact, it's been an influential factor in attracting partners to our beta programs.

Since we last updated you in mid March, we've completed our first round of beta programs with four partners including Novant Health, Stanford University, a major global pharmaceutical company, and a leading patient focused medical device company. These programs have proven to be a critical exercise in readying the Evie ring for commercialization. Throughout the five to six week programs, beta participants were given a ring and access to a beta version of our app. Each week, participants were asked to complete a series of activities, and then answer questions related to their experience with the ring.

As a result, we gained a greater understanding about how and when people interact with and wear the ring, and we are now armed with real usability data that showcased our strengths and presented us with opportunities to fine tune the Evie Ring and app experience. We're looking forward to incorporating our learnings into the next set of beta programs, which are set to commence in early July. During this round of betas, we'll be testing our technology with a global athletic apparel company, and two additional leading global medical device companies. And as

we've highlighted in prior calls, there are many more enterprises across healthcare, consumer and tech that we're in discussions with, given the high interest in a solution like Evie, which combines the best of consumer wearables with the quality of an FDA cleared device.

During our last earnings call in March, we also shared that we were getting our single chip solution ready for its first blood pressure clinical trial, which has now effectively been completed. Over the course of three weeks, ending tomorrow, we will have brought in over 50 volunteers from our local community to the Movano Health clinical lab to participate in an IRB-approved clinical study. Each participant wore a Movano Health wrist worn wearable, as well as a hospital-grade blood pressure system to compare the measurements. We've been very encouraged by the quality of the data signals that have been collected in the study with our single chip solution, and we will continue to analyze the results over the next few weeks. We remain optimistic that our single chip solution positions us to make further progress on algorithms development given the smaller size of the prototype. We plan to use the same single chip prototype in a glucose clinical trial in the June/July timeframe.

We continue to file patents to protect and validate our innovative approach to RF enabled glucose and blood pressure monitoring. During the first quarter of this year, we were issued six new U.S. patents, including multiple foundational patents, extending our IP portfolio to 21 patents issued in the U.S., one patent issued in China and 37 patents pending.

Now, I'd like to turn it over to our CMO, Tyla Bucher, for an update on our launch plans for the Evie Ring.

Tyla Bucher
Thanks, John. So, in addition to building a great product, another critical component to the successful launch of Evie this September is the establishment of a strong follower base, which is already well underway. CES 2023 ignited significant interest in Evie, and now we're building on that earned awareness with a strategic multi-channel paid and organic social campaign that leverages targeted messaging to engage prospective consumers. The level at which our product is resonating with consumers is well beyond our expectations.

In the four months since we announced Evie, we have received almost half a million visitors to our site, and over 80,000 people have signed up to receive regular updates about our product, including, of course, our launch plans. These numbers tell an important story and are a signal of the strong demand for our product. We've cultivated an engaged audience of early adopters on our social channels who are providing valuable feedback, as well as helping us shape our look-alike audience pool as we grow our base pre-launch. This impressive lead list, combined with an above average engagement rate on social media is a very positive sign for conversion potential once the device is ready for sale.

Additionally, we are certain that consumers will be very excited to hear about our $269 price point without a subscription, that John just announced. We believe this is a highly competitive

and attractive price point for such a comprehensive solution, and we're looking forward to sending out an email following this call to let everyone know about these exciting updates.

In preparation for September's launch, we're building out a marketing campaign that blends influencer partnerships, celebrity endorsements, PR, paid advertising and content. Our September launch timing positions as well to execute against this campaign from the seasonality, media and customer awareness standpoint. As John noted, many are returning from vacation and turning their attention to the fall.

We are currently in conversation with a number of influencers and expect them to be a significant piece of our marketing campaign, creating custom content by channel and driving brand awareness among their dedicated follower bases. Additionally, we're building a panel of expert medical advisors across key verticals, such as mental health, gynecology, cardiology, and sleep, to lend their expertise on product features and to help us create bespoke content.

And finally, we're also working closely with the customer success team to create a fully integrated customer experience that builds trust among consumers and drives the flywheel of recommendation, ambassadorship and positive brand awareness. We believe we have all the pieces in place to launch successfully and are very much looking forward to seeing the reception for Evie this September.

And with that, I'd like to turn it back to John.

John Mastrototaro
Thank you, Tyla. From an operational standpoint, we're in a strong position for the September launch. Our supply chain partners, and our FDA compliant contract manufacturing sites are preparing and are ready to flex on demand. We're driving final process and equipment automation, hard tooling, and packaging as we speak. Software integrations for order fulfillment and logistics will be ready and operational for launch.

From the outset, Movano health has had a vision to develop a more accessible medical device with a personalized, simple and smart experience. And now we are closer than ever to making this a reality. We're very excited to get the Evie Ring in the hands of consumers in September and are confident that our affordable price point and fresh, emotionally intelligent app experience will make it attractive for women at all stages of life. We look forward to sharing more details about our planned launch as September approaches.

With that, I'll turn it back to J. to go over the financials.

J. Cogan
Thanks, John. We detailed the financial results in today's first quarter earnings release, which you can find on our website, but I'll share a few key line items. Movano Health reported an operating loss of $7.2 million in the first quarter of 2023, compared to an operating loss of $6.9

million in the year ago period. The increase was primarily related to the accelerated R&D and commercialization initiatives described earlier in the call. Our cash burn in the period was $6.1, million in line with the prior five quarters.

In regards to capital, we raised $7.5 million in gross proceeds or $6.85 million net through an underwritten public offering of shares of Movano Health common stock and warrants in the period. In addition to the public offering, we also raised $2.8 million in net proceeds via our $50 million ATM facility. As you recall, we executed the ATM agreement in August of last year, and we raised more than $5 million in net proceeds at an average price of $1.75 per share since inception. We continue to view the ATM is an opportunistic source of capital, and we're pleased with the execution to date.

At the end of the first quarter of 2023, we had $14.3 million of cash, cash equivalents and short-term investments, and total assets of $16.8 million. We will not be providing specific financial guidance, but as you've heard in today's quarterly report, as well as through commentary on previous quarterly calls, we're making great progress toward the direct-to-consumer launch of the Evie Ring, as well as our other b2b and clinical initiatives, and doing so on a capital efficient basis. As that concludes our formal remarks, we'd be glad to take your questions.

Operator, we're ready to begin the Q&A section of the call.

Operator
Thank you. Ladies and gentlemen, at this time, we will be conducting a question and answer session. If you'd like to ask a question over the phone, you may 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. If you are joining us by the webcast, you may submit a question by hitting the question mark and clicking send. One moment while we pull for questions.

J. Cogan
Okay. Operator, I can see that there are a few questions in the webcast, so why don't we start there? Let's see, some questions about the Evie launch. John, I think you and Tyla and Stacy can join in on this one. Why'd you land on September for the right time to launch?

John Mastrototaro
Why don't we start with Tyla and then Stacy and myself for this one. Go ahead, Tyla.

Tyla Bucher
Sure, happy to. So typically, during the summer months, people tend to be on vacation. They're focused on activities with friends and family and not really paying attention to what's going on in the consumer space. And similarly, the media focus shifts to lighter fare and audiences are

thinner, so we really determined that in order to maximize our launch, this is really the most efficient way and September timing would provide a much more engaged audience. Stacy, I'll turn it over to you to add a little color on the product.

Stacy Salvi
Yeah, of course. Thank you so much. So, when we think about the device that we're bringing to market, we know that user expectations on what a wearable can do is relatively well-established. And we're coming out of the gate with not only a unique hardware form factor, but also building a device to be medical grade, because we really believe that people deserve data they can depend on. So, launching in September allows us to bake the app experience even further, and we're super excited about what we're bringing to market. I don't want to say too much at this time, but our solution was designed and built by women, and it really comes through in a meaningful way. And I'll hand it over to John.

John Mastrototaro
Thanks. Just an add on to this. There may be some questions about some of our risks related to launching in September. And of course, there's always risk in developing a new technology, and as we're working through the final phases of development, we want to continue to be very transparent with you about that. This being said, we've been focused on developing this product for 18 months, and we've been doing a lot of internal testing with the Evie Ring for months, and we'll continue to do so up to launch. And as well, we've got our beta evaluations, so we feel pretty good about the fact that we have identified and seen some of the areas where we can improve upon the product and are doing so right now. Overall, we feel really good about launching in September.

J. Cogan
Okay. We've got a few more questions on the Evie launch, so let's address those. On the price point, Tyla, can you talk a little bit about how we determined that $269 with no subscription was the optimal pricing strategy? And then there's also a question about the 80,000 people that have signed up for our email list, going to the website, clicking all the way through. What percentage, what conversion do you think we'll see in terms of buying the ring?

Tyla Bucher
Great. Yeah, happy to answer that. From a pricing standpoint, when we really thought about how to determine the right price, we started with research. We spoke to about 300 different women about their tolerance for subscription. And what we heard was, there's a lot of fatigue when it comes to having yet another monthly dollar commitment, and so we worked to come up with a price that satisfies our business needs without asking women to manage another bill. Additionally, we did look at the competitive landscape with an eye toward making Evie as accessible as possible relative to what else is out there, and that's how we netted out at the $269 price point, feeling that was really the right place to be able to accomplish this goal.

And to the question regarding the the 80,000 people who are signed up on the site, it's tough to put a conversion number against the when and the where. I think what we're seeing right now is that people are definitely interested and what we're not sure about is when they will convert. And I think we'll definitely see something in hopefully, the single digits, at launch in terms of conversion. And then following that, what we're hoping is that we'll see a lot more around holiday and in January. And specifically, these leads as an aggregate are much more efficient from a cost standpoint, because we're able to communicate with them directly, so there's an additional benefit there as we get closer to launch, and we continue to be able to reach out to them and cultivate that relationship and drive conversion versus starting from scratch. I hope that answers the question.

J. Cogan
Yeah, maybe I can also add that we think that we can be very successful with unit growth and revenue growth at the $269 price point with no subscription. We also think that our gross margins, while we don't provide formal guidance, we think that they should be very attractive. They should build to a very attractive level, allowing us to reinvest in the team, additional marketing, and our many other development initiatives, including B2B, our blood pressure and glucose work and other future devices and solutions that we have in mind. Also, we don't intend Evie to be a niche product, and we think that we've done a lot of research and feel very comfortable and very strongly about this price point and no subscription for the Evie Ring.

Let's go to the next question. John, do you want to take this one on the FDA clearance? Can you elaborate a little bit on the filing, including the data, what's involved in the process, and really, why is it a differentiator?

John Mastrototaro
Sure, J. Thanks. First off, as I've stated before, there's a multitude of documents that we have to create and provide to the agency when filing for a 510(K) for heart rate and SpO2. A couple of the most important ones relate to the clinical accuracy in heart rate and SpO2. And fortunately, in our clinical trials, and the bench studies that we have to conduct per the FDA guidance, we got exceptional accuracy. We achieved SpO2 with less than 2% average error, well within the three and a half percent standard. And our heart rate data was well below one beat per minute inaccuracy.

So really pleased with the clinical results, and obviously, those are some of the most important documents that the FDA looks at with a filing. However, in addition to that, there's many documents on electrical safety testing, cybersecurity testing, etcetera, biocompatibility, where we partner with third-party labs and vendors to help perform the assessments and provide us the reports and the feedback. And some of the reason why the filing is going to be in June is because we're waiting for some of those final reports be provided by those third-parties who we're partnering with on generating this evidence.

So, all in all, we are really happy with where we are right now with the generation of all the documentation to the FDA. There are a few documents that we're still finishing up to get ready, and then putting the package together is obviously the last step. I think it's a huge differentiator for the company. This has been a lot of effort, both in terms of training every employee on the quality management system and then, of course, putting together everything that's part of the design control processes as a medical device, but it has been well worth the effort. The number of companies from healthcare, for example, who are coming to us wanting to discuss partnerships has been really more than maybe we could have expected.

And although we've got a couple of med device companies, for example, in the beta two trial, looking to work with us, there are several others who we're talking to because everyone is seeing an opportunity to help transition healthcare and chronic disease management to the home and try to collect more data from people from the home and transition healthcare in general, to the home, where it can be done in a much more timely fashion and for much lower costs. So, for all those reasons, we're really excited about where we are with the FDA filing.

J. Cogan
Okay. We've got a few more on the webcast here. Stacy, maybe you can jump in. There's a question about the features that we're offering with the Evie ring. And maybe talk a little bit about both in terms of the ring itself, and some of the analytes, as well as what we're going to see in the app.

Stacy Solvi
Sure. It's my favorite topic, so happy to talk about it. So, the Evie Ring comes with the sensor suite that you would come to expect in this day and age of wearables. It's going to have an accelerometer, heart rate sensor, blood oxygen, and skin temperature sensors. From those sensors, we can derive numerous different data points in the app experience, from sleep and sleep stages, all the way to the way we're cutting up activity, and of course, the various heart rate measurements that that one might take over time.

I don't want to give away too much about how these features are going to manifest within the app. I think we'll want to save some of that great, juicy storyline for launch and for Tyla. But suffice it to say that we do meet the bar of what's on the market, which is pretty incredible for our first device.

J. Cogan
Okay. Michael Leabman, how about on the blood pressure clinical study? Can you maybe talk a little bit more about what we've seen in the study to date, our expectations for algorithm development and maybe thoughts on glucose going forward too?

Michael Leabman
Sure. I think, as we noted before, that our hope in getting to our single chip was to improve the signal quality. And we've seen that come to fruition in our latest study, which concludes soon.

And that means the cleanliness of the signal, how reliable we get that signal on a variety of patients for blood pressure. So, over the next couple of weeks to months, we'll be refining our algorithm, running it on the latest set of data and seeing how our blood pressure measurement improves.

Similarly, as we conclude this study, we'll begin our glucose study, which we've been doing in the lab with our current chip. And again, seeing the accuracy has improved going to a single chip, primarily for several reasons. One, because we don't have signals wandering around between chips. It's all located in one small package, as well as the heat and temperature has gone down significantly by integrating into a single chip, which has helped the performance, as well. So definitely excited to start analyzing the data as we finish the current study and as we embark on the next one.

J. Cogan
Great. And then John, on the betas, have we been pleased with the results of beta one? Were there any surprises? And again, are there any more details we can provide about beta two?

John Mastrototaro
Sure, J. Yeah, we're really pleased with the results of the first beta, the purpose of which was really to test the hardware and the wearability. I can tell you that the response to the ring and wearing the ring was very positive overall, and we were pleased to see that the majority of reported issues were ones we were already aware of. There were no real surprises, which is a good thing. And it really means that the way we've been testing the ring has been a good indicator of what we can expect to see when it's out more broadly to external parties.

As we prep for beta two, there's a lot of interest. As I mentioned earlier, we've already got a few beta partners. We've discussed a global athletic apparel company, two more med device companies, and there's others who are talking to us right now about participating in one form or another, which is very exciting. And then during beta two, we're going to be testing the system more broadly. Stacy talked about some of the enhancements to the app experience that have been designed to address women's needs, and really filling out the rest of the functionality beyond what we did in beta one, so we're very excited about the start of that process in the early July timeframe.

J. Cogan
Okay. Operator, are there any questions on the phone lines?

Operator
There are no questions over the phone lines at this time.

J. Cogan

Okay. Well, I think with that, then we can conclude the conference call. We thank everybody for your time today. As a reminder, you can stay connected and up to date on Movano Health news and events by checking out our investor website at ir.movano.com.

Operator
Ladies and gentlemen, this does conclude today's teleconference. Thank you for your participation. You may disconnect your lines at this time and have a wonderful day.