

Transcript of
Tivic Health Systems
First Quarter 2023 Earnings Call
May 15, 2023

Participants

Jennifer Ernst - Chief Executive Officer, Tivic Health Systems, Inc.

Kimberly Bambach - Interim Chief Financial Officer, Tivic Health Systems, Inc.

Presentation

Operator

Welcome to the Tivic Health Systems Q1 2023 Shareholder Update Conference Call. All participants will be in listen-only mode. A question-and-answer session will follow the formal presentation. [Operator Instructions] Please note that this conference is being recorded.

Statements made during this call contain forward-looking statement about Tivic's business. You should not place undue reliance on forward-looking statement as these statements are based upon current expectations, forecasts and assumptions and are subject to significant risks and uncertainties. These statements may be identified by words such as may, will, should, could, expect, intend, plan, anticipate, believe, estimate, predict, potential, forecast, continue, or the negative of these terms or other words or terms of similar meaning.

Risks and uncertainties that could cause Tivic's actual results to differ materially from those set forth and any forward-looking statement include but are not limited to the matters listed under risk factors in the company's annual report on Form 10-K for the year-ended December 31, 2022, filed with the Securities and Exchange Commission on March 31 2023, and in its other filings with the Securities and Exchange Commission.

Statements and information including forward-looking statement speak only to the date that they are provided unless an earlier date is indicated and the company does not undertake any obligation to publicly update any statements or information, including forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

Now let me hand the call over to Jennifer Ernst, Tivic Health's Chief Executive Officer.

Jennifer Ernst - Chief Executive Officer, Tivic Health Systems, Inc.

Hello, everyone. And thank you for joining us today. I'm Jennifer Ernst, CEO of Tivic Health. As always, I am pleased to be here today to review the financial and business results with a focus on our first quarter of 2023.

Also joining me today to provide our financial overview is our interim CFO Kimberly Bambach. As we start, I want to highlight that this was a particularly important quarter for Tivic. We saw a number of our major initiatives began to bear fruit. In one dimension, we've had meaningful

commercial advancements, here's a new manufacturing partnerships have yielded a 4x improvement in our gross margin, a major initiative for last year.

Those improvements are materializing ahead of plan, with continuing improvements expected in the second quarter. Increased margins allow us to open new channels selling profitably in new areas. And one example is the recently announced business-to-business portal through the healthcare professionals.

For the first time this quarter, though, I'm also able to talk about one of our key innovation initiatives, expanding our footprint and bioelectronic medicine and expanding beyond ClearUP. Keep in mind Tivic's overall mission is to harness the power of bioelectronic medicine to fight disease, improve health and increased vibrancy of life.

We are using non-invasive approaches as a platform it's a core approach for targeting chronic and inflammatory diseases via different neural pathways. So as well as cellular and biologic response mechanisms. ClearUP works with the nerves in the facial region easily accessible non-invasively and linked to a host of the inflammatory conditions in the head and neck area.

We've also now begun growing the portfolio of product opportunities with additional nerve targets and specifically the vagus nerve. The vagus nerve is one of the most important structures in the body running from the brain through every major organ. However, because of this vagus nerve stimulation, it's often concerned with creating off target effects. We've had a small internal program addressing this exact problem.

Our internal program is piloting a new protocol by which we can more precisely target the signaling of the vagus nerve. And those efforts have served as the as the basis for new intellectual property filings. And I'm also thrilled that that internal program has now led us to work in with some of the leaders, the absolute leaders and bioelectronic medicine.

This quarter we announced a partnership with the Feinstein Institute for Medical Research at Northwell Health, specifically with the team at the institute for bioelectronic medicine. A successful pilot these new protocols has the potential to unlock a significant number of high value, high value product opportunities in neurology, cardiology, rheumatology and other areas. These represent both products and licensing opportunities for the company.

We also expanded our collaboration with another internationally renowned Northeastern Hospital. The medical system has been sponsoring a double-blind, randomized sham-controlled trial to evaluate the use of our handheld bioelectronic device as a way to manage pain following sinus surgery.

Well, that study is ongoing. It was also recently expanded to include additional cases in otolaryngology and facial plastic surgery patients. A successful outcome could accelerate offering the non-opioid, non-addictive alternative to traditional post-operative pain management, specifically for facial surgeries.

As a result of these types of advancements, and in recognition of Tivic's world-advancing bioelectronic medicine into first line therapeutics, Tivic was named to fast company's annual list of the World's Most Innovative Companies 2023, specifically in the medical device category. And the company was also named The Most Pioneering Bioelectronic Medicine Company by Global Health and Pharma Magazine.

I particularly want to underscore for our investors that these programs are product-oriented in nature. When we invest in innovation, we are pursuing meaningful high value commercial opportunities, solutions that we believe can contribute significantly to the bottom line as they mature. So if you can't tell, I am beyond excited to finally be able to talk about some of what's been happening behind the scenes.

Importantly, though, also are the advancements in our commercial product line. I cannot underscore strongly enough that we have hit a critical turning point for profitable revenue growth for ClearUP. In 2022, last year, we were significantly impacted by the global supply chain issues and electronics, by surging shipping costs by the extraordinarily high cost of component parts. These are all significant factors that negatively impacted company performance. High purchase price variances and increases that translated into our standard cost.

In 2023, we've now changed our PCB manufacturer, a fulfillment vendor and our assembly partners in an effort to decrease our costs and streamline our manufacturing and fulfillment processes. To achieve price stability, we opportunistically made advanced purchases in late-2022 that helps secure improved pricing and should provide protection against that type of erratic supply chain events we saw before. We're tightening we are hardening our supply chain, our inventory management, and our overall cost structure.

We are now seeing those results pay off. This quarter we have experienced an increase in margins from 10% to 40% as older high costs inventory sold through. Going forward, we expect further gross margin improvements within the second quarter as that older inventory continues to flush out and also as we replenish at lower cost.

Additionally, we conducted new price sensitivity testing and as a result, we have supported an increased pricing by over 60% over the past few quarters. That combination lower cost of goods 60% increase in pricing, we are now have margins. So although we are expecting to see some drop in the unit sales, due to the price increases the pricing structure on the underlying COGS improvements are expected to more than offset more than offset any negative impact of the pricing increase.

So finally, some of the other important commercial developments include we completed product line expansion studies identifying new unmet needs for ClearUP that we believe are addressable by the existing product. These are in areas such as sleep, expanded headaches, migraine, beyond allergies, and among other symptoms that affect over 85 million consumers in the U.S. We invested in product improvements to enhance customer experience and to support cost effective product line expansion into those high value areas we described.

And based on our market studies, we are completing a two-year product versioning plan to increase sales through additive market segments, many with a greater willingness to pay a higher price tolerance and a greater likelihood to purchase, than the core markets that we have already attacked. We also obtained a successful recertification of our ISO-1345 Quality Management System and the European medical device CE mark, keeping an open the alternatives for international markets.

So with that, I'd like to hand over to Kimberly Bambach, Tivic Health Interim CFO, to go over the financial results for the quarter ended March 31, 2023 in more detail.

Kimberly Bambach - Interim Chief Financial Officer, Tivic Health Systems, Inc.

Thanks, Jennifer. And good afternoon, everyone. I'm very pleased to be working with the team. We posted first quarter revenue of 376,000, a decrease of 52,000 or 12%, compared to the same quarter last year, primarily due to a 27% decrease in unit sales offset by a 70% increase in the per unit average sale price. Unit sales in our direct-to-consumer channels decreased 34% while unit sales in our wholesale channels decreased by 9%.

Average sales price and our direct-to-consumer and wholesale channels increased by 23.6% and 4.8% respectively. Going forward, we expect to see some continued variability in sales due to reduction in marketing spend and price point positioning for target market with the net impact resulting in a higher gross profit and a lower loss from operations.

For the three months ended March 31, 2023, cost of sales decreased by \$95,000 or 27% compared to the same period in 2022, primarily driven by lower cost per unit and the decrease in sales volume. Variable cost was \$192,000 or \$0.6981 cents per unit for the three months ended March 31 2023, compared to \$310,000 or at \$0.8193 per unit for the same period in 2022. The decrease in variable costs is primarily driven by lower manufacturing and fulfillment costs.

Fixed costs were \$71,000 or \$0.2561 per unit for the three months ended March 31 2023. Compared to \$48,000 or \$0.1257 cents per unit for the same period in 2022. The increase in the fixed costs was primarily due to lower sales volume to absorb those costs.

As a result of both the Microart and Alon agreements signed within the fourth quarter of 2022, we have significantly reduced the cost per unit for the existing ClearUP product in the first quarter of 2023. We expect that the remainder of the ClearUP inventory previously built under the higher cost structure should sell through in the early second quarter of 2023, resulting in continued reduction of cost-of-goods sold as a percentage of revenue.

Our first quarter gross margin was 30.1% as compared to fourth quarter of 2022 of 10.4% and a 16.4% in the same quarter last year. We expect our gross margin to increase the future price increases continued optimization of our supply chain and product design, as well as increased sales volume over which fixed and semi-fixed costs are allocated.

Research and Development expenses increased by \$89,000 compared to the same period in 2022. The emphasis of research and development activities in 2023 has been primarily related to a large segmentation study to identify additional incremental market segments with high

willingness to pay product designs in new versions of the device as well as enhancement of our intellectual property protection. Sales and marketing expenses decreased by \$226,000 compared to the same period in 2022. The decrease was primarily due to more targeted sales and marketing efforts while bringing new distribution partners online and managing seasonal variability.

General and administrative expenses increased by \$55,000 compared to the same period in 2022. The increase was primarily attributable to hire staff costs offset by lower overhead costs. Our first quarter net loss was \$2.1 million compared to \$2.2 million in the same quarter last year.

On February 13, 2023, we issued and sold 20 million shares of our common stock at a public offering price of \$0.25 per share less underwriting discounts and commissions resulting in gross proceeds for the company of \$5 million and net proceeds of \$3.6 million. As of March 31, 2023, the company had \$5.2 million of cash and equivalents including proceeds from the offering closed in first quarter 2023. We also continue to maintain a no debt balance sheet.

I will now hand the call back to Jennifer to discuss this 2023 outlook.

Jennifer Ernst - Chief Executive Officer, Tivic Health Systems, Inc.

Thank you, Kim. I am definitely looking forward to 2023. Operationally last year involves significant expenses that carried over from the IPO a protracted offering associated with an unconsummated transaction, and all of the supply chain issues we've already talked about.

But now as I look forward into 2023, we are focused on high value target market segments for ClearUP and for our commercial product segments with higher return on marketing investment, and I'm able to start talking about our R&D pipeline, our initiatives to push through and to target breakthrough opportunities that can contribute meaningfully to the bottom line.

Moving forward, we are also focused on reducing our operational overhead, tightening our G&A spin, reducing the fixed overhead the fixed infrastructure, and optimizing our utilization of third party resources. We intend to selectively invest in advancing our product candidates, our marketing, and our distribution. That includes targeting the high incremental market segments with unmet needs, the high willingness to pay.

We've talked about increasing a retail price supported by a brand enhancement to increase gross margins. We are continuing to broaden our distribution channels with large commercial contracts, with a focus on penetrating the healthcare and wellness-centric channels, optimizing our marketing investment to focus on lowering the fixed infrastructure and creating a higher return on our ad spending, optimizing our total customer acquisition costs. And strategically broadening our intellectual property and our product pipeline.

Our portfolio is currently supported by -- currently supports our products with five issued U.S. patents 96 claims and 20 pending patents in the U.S. and abroad.

So across the board, Tivic has proven our ability to innovate by combining science and technology with our expertise in neuro immunology and medical device development, in

regulatory affairs and in product development. We have launched commercial product, and it is now gaining market traction.

As shared in our recent announcements we've also secured, engaged and broaden the academic research community, the community that supports our opportunities for being able to deliver breakthrough innovation. The FDA defines breakthrough innovation as areas that are life threatening, or irreversibly debilitating conditions. And these are the conditions. These are the conditions that create high-cost burdens for the healthcare system, and high life altering factors for the people that experienced them. Those opportunities that as they mature will contribute significantly to the company's bottom line.

Non-invasive bio electronics, the core of our platform and our ability to manipulate the system electronically has the potential to significantly benefit not only patients today with our commercial products, but to significantly benefit both the patients and healthcare systems with more effective solutions. These areas as well as the commercial traction that I continue to look forward to and I am excited about as we move into 2023. As we continue to move through this year. I will look forward to coming back and sharing more about our advancements in all of these areas through the coming year.

And with that, I would love to turn to the Q&A section.

Jennifer Ernst - Chief Executive Officer, Tivic Health Systems, Inc.

Hey, we've had a couple of questions come in ahead of time. And this is the point where I transitioned into our Q&A session. The first one was is the company planning on making budget cuts since it is burning so much money. I think I've actually addressed during my comments, quite a number of the areas where we are looking to reduce. First of all, I've already highlighted the manufacturing costs, increase the store average selling price, which increase the profit back into the company and increased advertising effectiveness.

We are also focused on reducing fixed infrastructure cost to be able to allocate to commercial spend with high returns. And we believe that the structural improvements, along with streamlining the administrative costs of the business should serve to improve the overall run-rate.

You've recently increased prices at a time when inflation concerns dominate the news. Are you worried about how this will impact sales?

The point you're making is obviously something we considered. When we evaluated the price increases. Yes, we did look at this question. And what I've what we observed in our pricing studies, though, is that a lot has changed over the last few years in how we all of us as consumers think about health and devices, whether that's Apple Watch or Google or the integrated health applications in our smart devices.

There's a growing preponderance of consumer focus monitors and different types of therapies. And in that context, we've seen a definite shift in consumer price tolerance. So we believe that the price increases are well supported. And that is what we are seeing early indications of as we are getting into this new quarter.

I had a question come in about migraine. You've previously spoken about the migraine area, didn't hear it mentioned today. Is that still an area you're focused?

Thank you. Yes, yes, briefly. That is an area we have ongoing activity. There is significant overlap between sinus pain and inflammation and the migraine triggers. Also, congestion, which is also a sign of inflammation is one of the onset symptoms with migraine. So quite a bit of overlap. It's definitely an area we are evaluating the marketing, evaluating the market and our clinical strategy. So this is an area where we are defining the go-to-market, looking at several alternatives as well as the regulatory milestones that are associated with it.

I did not speak to this today, because we did not have a specific milestone to report on, but definitely an area where we are still looking to build out the business.

Question, I believe you receive notice from NASDAQ about the company's stock price. What are you doing to address that?

Yes, we and many other companies received notice from the NASDAQ stock market. Ours came on January 26, 2023. We have 180 days to regain compliance, which may be subject to extension by NASDAQ as well. We are continuing of course to monitor the closing bid price of the common stock. And we'll be considering all options to resolve that non-compliance. That includes considering a reverse stock split, which to this end, we have included a proposal in our recent proxy statement for shareholder approval at our 2023 Annual Meeting.

If approved by our shareholders, that would enable us to move forward quickly with a reverse stock split if we determine the business necessary in order to regain compliance with the NASDAQ rules and to maintain our listing. So I am the board are committed to taking all steps necessary to maintain compliance.

Question, after the termination of the Reliefband acquisition last fall, is the company's still acquisition minded?

Absolutely. It's simply what we remain committed to our growth strategy, which includes both organic and inorganic opportunities. Today, I had the opportunity for the first time to speak about some of the organic development activities, not only around the hardware or product design of ClearUP but beyond, moving beyond the facial nerve stimulation and into the vagus nerve area. So we will continue to evaluate strategic acquisition, licensing and partnerships, both inbound and outbound.

And finally, what are your going forward plans to rebuild shareholder value? Okay, this is a great closing question. So thank you. So I hope that you've heard today, a number of the steps we are taking to build the shareholder value. With increased margins on ClearUP enabling profitable growth through both direct and indirect channels, we're pushing our marketing dollars harder and harder to get more out of them.

We're focused internally and with our third-party partners on reducing our operational overhead. And was strategically and selectively filtering opportunities for inorganic growth, while investing in our organic growth opportunities with a lean precision.

So with all that we are navigating some narrow pathways and it is a very challenging market. So I can't say that success is inevitable. But we have hit an important turning point. We have a small strong team, a powerful blend of short, medium and long-term catalysts, and committed partners working with us to propel the company forward.

So I am excited about where we are proud of what we've accomplished. And I look forward to reporting even more progress in Q2, and more questions at that time.

Operator

This concludes today's conference. And you may disconnect your lines at this time. Thank you for your participation.