

Transcript of  
Tivic Health Systems, Inc.  
Tivic Health First Quarter 2022 Earnings Release Call  
May 16, 2022

**Participants**

Jennifer Ernst - Chief Executive Officer & Co-Founder, Tivic Health Systems, Inc.  
Veronica Cai - Chief Financial Officer, Tivic Health Systems, Inc.

**Presentation**

**Operator**

Welcome to the Tivic Health Systems Q1 2022 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 the conference is being recorded.

Statements made during this call contain forward-looking statements about our business, you should not place undue reliance on forward-looking statements, as these statements are based upon our 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, intent, 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 our actual results to differ materially from those set forth in any forward-looking statements include but are not limited to the matters listed under risk factors in our annual report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission on March 31, 2022. Statements and information including forward-looking statements speak only to the date that they are provided unless an earlier date is indicated. And we do not undertake any obligation to publicly update any statements or information, including forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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

**Jennifer Ernst - Chief Executive Officer & Co-Founder, Tivic Health Systems, Inc.**

Hello, everyone. And thank you for joining us today for Tivic Health Q1 2022 Financial and Business Results. My name is Jennifer Ernst, and I'm the CEO of Tivic Health. So I will be walking you through some important updates from the first quarter. And also joining me on the call today is Veronica Cai, our CFO, she'll be walking us through some very exciting numbers from this first quarter.

So let's begin with the business update. We at Tivic Health could not be prouder of our accomplishments in Q1 2022. In November, I laid out for you a strategy for growing shareholder

value that started with two key points. The first is growing our direct-to-consumer sales as the linchpin of growing our overall revenue. The second is improving our gross margins. And I'm proud to say Tivic has delivered on both, on both elements of -- the first two elements of our strategy.

We've grown our overall revenue, we've grown our direct-to-consumer unit sales, and we've grown our gross margin. But more precise point on it 33% growth in revenue overall, 77% growth in our direct-to-consumer sales unit volume, and over 200% increase in gross margin. Those numbers say we have very good reason to be proud. And in many ways Q1 this quarter, and the coming will continue to be building the infrastructure and building the foundation.

For example, improvements to our e-commerce infrastructure are underway. We've been reducing or eliminating low margin contracts that we entered into in 2020, was then deploying component level cost improvement ahead of the Gen 2 plan that we outlined in November. We are expanding our advertising reach, improving flexibility in our parts sourcing. It has this kind of relentless focus on execution that is allowing us to build a balanced revenue mix with an improved cost structure supporting it.

So now I've touched on the first two legs of our strategy for building shareholder value. Increasing revenue, primarily through our DTC channel and driving down costs with improvements in manufacturing, procurement, and distribution. So the third leg of the strategy is to build shareholder value through expansion of our product and research pipeline. That is all with the objective of generating new platforms based on our patented monopolar nerve stimulation technology. So we have completed the internal post market data review from ClearUp users, indicating some relief from or some reduction in the number of migraine headaches that they experienced.

Based on the results of that evaluation, we began working with an experienced consulting group that has helping us define a winning market strategy, allowing us to enter the migraine research studies and clinical programs with a validated commercial pathway in line from the start. This quarter we're also proud to start our patient enrollment in an externally funded study with the Icahn School of Medicine at Mount Sinai. They are actively seeking non-addictive options for pain relief following sinus surgeries. And the product candidate that we are testing with them in a 60 patients study is an extension of Tivic Health monopolar architecture.

I underscore this because it demonstrates that this is a very powerful platform we have enhanced that can be programmed for different users. If a product candidate is successful, it will create a new indication a new product offering and yes, it would require a separate FDA approval, but still designed and developed around the same hardware architecture. So we are off to a very good start with the year. We will continue to maintain our focus on execution for the remainder of the year.

Now let me hand over the call to Veronica Cai, Tivic Health CFO to go over the financial results for the quarter ended March 31, 2022.

**Veronica Cai - Chief Financial Officer, Tivic Health Systems, Inc.**

Thanks, Jennifer and hello everyone. As Jennifer mentioned, we kicked off 2022 on a very positive note. Our revenue for Q1 2022 was \$0.43 million, compared to \$0.3 million for Q1 2021 a 33% increase year-over-year. This growth was driven by strong direct-to-consumer sales, which increased 77% in volume year-over-year. Amazon was our lead channel, it was responsible for 71% of this quarter's direct-to-consumer revenue.

Having fully exhibit several low margin contracts, which were holdovers from our product discovery phase, our retail unit sales decreased 26% year-over-year. Our Q1 2022 cost of sales was \$0.36 million, compared to \$0.3 million for Q1 2021. This 19% increase year-over-year tracks with our 28% growth in the unit sales numbers.

Total operating expenses for Q1 2022 came in at \$2.3 million, compared to \$1.1 million in Q1 2021. This was primarily driven by the expansion of the customer focused areas in our organization, and operating as a public company. These increases resulted in a net loss of \$2.2 million for Q1 2022 compared to \$1.4 million in Q1 2021. Our cash and short term investments balance at the end of the quarter was \$10.8 million.

Lastly, it's important to know that Tivic has no debt.

I now hand the call back to Jennifer for final remarks and for the Q&A portion of the call.

**Jennifer Ernst - Chief Executive Officer & Co-Founder, Tivic Health Systems, Inc.**

Thank you, Veronica. So just to reiterate, we are very proud to see our strategy working this quickly. Direct-to-consumer business has increased that's driven both net revenue and gross margins. And compared to this time last year, we've increased sales volume, sales volumes were our highest margin channels. And I want to underscore this last point, we've managed the product cost structure, even in the face of economics supply chain challenges, driving a higher gross margin.

So with Q1 under our belt, we remain focused, and we remain diligent in our endeavors to increase customer value and shareholder value. Remain diligent and driving down costs and expanding awareness of a very novel therapeutic solution for sinus pain and congestion. And we are looking at the new users for our monopolar nerve stimulation platform, such as a promising indications in migraine. I can't tell you how much I'm looking forward to the future, quarter-by-quarter I see the opportunity for this company to grow and to continue to create shareholder value through a strategy we have outlined and a strategy we are executing.

And with that I would be delighted to start taking questions.

**Veronica Cai - Chief Financial Officer, Tivic Health Systems, Inc.**

Jennifer, before we get into the questions, I wanted to say thanks to the investors that provided their support and their questions. I picked some of the most common ones. Without further ado,

let's start with the first question. So Jennifer, you've talked before about ClearUp Gen 2, what's the status and has it received FDA approval?

**Jennifer Ernst - Chief Executive Officer & Co-Founder, Tivic Health Systems, Inc.**

Yes, so that as a potential juncture, I really want to be sure that I set some expectations appropriately. We've begun implementing some of the technical and board level changes that were originally meant for a Gen 2 product. Even today, we're already beginning to implement elements of the Gen 2 strategy. Some ways it's becoming more of a rolling program as we begin to implement some elements of the production designs now, we'll have some more coming out in the next two quarters, rebranding, refresh of the branding expected later in the year. So most of the plan Gen 2 program should be in place by the end of the year. That is, of course with the cooperation of all the global macroeconomic factors that play in the world at large.

Now, as the FDA approval, Gen 2 meets the criteria set out by the FDA in their own guidance documents, that is what called a line extension, the FDA does not see this being a new product. They see it as a natural extension under the prior approvals. So with the FDA guidance, a line extension, like Gen 2 does not require any new approvals, or even engagement, direct engagement with the FDA. It's covered by our existing de novo and 510(k). So again, that is based on guidance published by the FDA.

Similarly, we have all engaged with our regulatory agents overseas and for international clearances, who have rendered the same opinion for us related to a CE Mark, not needing additional approval for any new engagement around the CE Mark for Gen 2 product.

**Veronica Cai - Chief Financial Officer, Tivic Health Systems, Inc.**

Thanks, Jennifer. Our next question is, are you planning any acquisitions?

**Jennifer Ernst - Chief Executive Officer & Co-Founder, Tivic Health Systems, Inc.**

I love this question I get asked it often. The funny part is, you all know that if we were, I wouldn't be able to say anything on a call like this anyway. So what I'll say is we have been and we always will be evaluating opportunities. And when they make sense to pursue, we consider that to be if the product is sound, if the market needs are verified, the electoral property is there. And most importantly, the deal is priced right so that we're able to create shareholder value from it. We will always be looking, we are always evaluating and when we find those opportunities, we will certainly be sure the market knows.

**Veronica Cai - Chief Financial Officer, Tivic Health Systems, Inc.**

Thanks, Jennifer. Our next question is, will the company release any news on how the study with Mount Sinai is progressing?

**Jennifer Ernst - Chief Executive Officer & Co-Founder, Tivic Health Systems, Inc.**

Yes, I want to dress a little bit of the progress on the Mount Sinai study. We kicked off the program officially in December. Patient enrollment began in January, we have somewhere on the order of a dozen enrollees. Now beyond that, the study itself was run by the Icahn School of Medicine, and they are following the highest clinical standards for research. Part of that it means but it does not include any interim data readouts. There's no point during the course of the study that we will learn anything because it is fully blinded, double randomized control. So with that, we will actually not be releasing any news until the study is completed.

And at that point, we may for some reasons for proprietary reasons around intellectual property, we might still hold back some of the information on the completion of the study in order to pursue appropriate intellectual property strategies. So as patient enrollment is proceeding, we are happy to see the program growing, but we won't be able to report any interim data.

**Veronica Cai - Chief Financial Officer, Tivic Health Systems, Inc.**

Thanks, Jennifer. Our next question is, can you speak about where you see the sales trending in the next 12 to 24 months, up?

**Jennifer Ernst - Chief Executive Officer & Co-Founder, Tivic Health Systems, Inc.**

Well, I certainly hope they are going down. No, actually parts availability isn't as likely to be for some period, really the gating factor on our sales volume. So with the global volatility, everything, I don't know how closely everyone is tracking it, but in everything from the chips to the copper that goes down on the board, even most recently, the issues around paper supplies. We haven't chosen not to issue any guidance, because we want to be certain that when we are issuing guidance, its guidance you can rely on, that is very hard to produce in a volatility of the situation. So right now, sales are trending up. I'm excited about what we're seeing in our numbers and parts availability, that whole macroeconomic condition is likely for the next period of time to be a part of the gating factor on the sales volumes.

**Veronica Cai - Chief Financial Officer, Tivic Health Systems, Inc.**

Great, thanks Jennifer. Our next question is, what is the company's plans for future funding and how do you plan to obtain it, capital raise or potential acquisition or both?

**Jennifer Ernst - Chief Executive Officer & Co-Founder, Tivic Health Systems, Inc.**

This point we're keeping all options open. These are the kinds of discussions we have with the board, we will be making the decisions across the line for the best long-term interest of our shareholders.

**Veronica Cai - Chief Financial Officer, Tivic Health Systems, Inc.**

Thanks, Jennifer. Our next question is, is the company still filling the global supply chain constraints? If so, will you have to increase the price point for the ClearUp product continually?

**Jennifer Ernst - Chief Executive Officer & Co-Founder, Tivic Health Systems, Inc.**

So there's really two questions embedded in that, one is the one about the global supply chain. And I have addressed that we're not immune, we have been able to manage it. And we are keeping very high on time delivery rates continuing. On the second half of those, about pricing an increase in a price point for ClearUp. I am very proud of the fact that we have managed to control our cost structure with very, very low increase in any of the cost of production quarter from last year to this year.

And then you'll see that in the numbers, even lowered some of the per unit production costs with the manufacturing implementations we've implemented. So we do see though a strategic opportunity in the area of pricing, we enter the market with what we consider our minimum viable product. And there is definitely opportunity as we begin to introduce new variants of the product line in the area of pricing to create even higher margin offerings.

I don't want to say anything specifically more than that, though, while negotiations continue and are ongoing with our suppliers and our retail partners. So I'm just going to hold off on saying anything more specific about pricing, other than we consider it a strategic discussion, not driven so much by increases in cost, which we've been able to manage, but driven by the strategic placement of the product and how we go-to-market.

**Veronica Cai - Chief Financial Officer, Tivic Health Systems, Inc.**

Great, thanks, Jennifer. I think now is a good time to wrap up.

**Jennifer Ernst - Chief Executive Officer & Co-Founder, Tivic Health Systems, Inc.**

Okay, she heard me say we are proud of the results this quarter. The team is working hard. We're all very excited about things that are underway. We're excited about what we have accomplished and what we're able to demonstrate now to the market. And with that, I'll say I look forward to speaking with you again on June 14 at the Annual General Shareholders Meeting.