

Transcript of
Tivic Health Systems, Inc.
Second Quarter 2023 Earnings Release Call
August 14, 2023

Participants

Jennifer Ernst - Chief Executive Officer & Co-Founder, Tivic Health Systems, Inc.
Kimberly Bambach - Interim Chief Financial Officer, Tivic Health Systems, Inc.

Presentation

Operator

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

Statements made during this call contain forward-looking statements about our business. You should not place any 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, 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 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 the risk factors in our company's annual report on Form 10-K for the year-ended December 31, 2021, filed with the Securities and Exchange Commission on March 31, 2022. As updated by the risk factors included in the registration statement on Form S-1 filed by the company equal with the Securities and Exchange Commission on October 26, 2022, and in our other filings with the Securities and Exchange Commission.

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 statement 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 the call over 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. My name is Jennifer Ernst. I'm the CEO of Tivic Health. This is usually the part of the call where I will say I'm pleased to have this opportunity to review the business results with you. As you've seen from our advanced announcements and recent transactions, this has been a particularly challenging quarter, a particularly challenging time period for the company.

So what this call today will focus on primarily is some of the steps that we've been taking to move the company forward and to position the company better as we move into the next coming quarters and year. I also am joined today by our interim CFO, Kimberly Bambach, who will be reviewing the financial performance and some of the internal restructuring steps that we've taken.

Now, when I prepare for these calls, I always find myself reflecting on both the current quarter on recent transactions and on the underpinnings of the business. I'd like to take a step back with our investor community in that light. In Q1 of this year, we entered the year with an open S-1, a failed transaction in an acquisition. And we had a real gut punch, one in February, a very challenging environment. We were looking to close a transaction of \$10 million. We ended up well below that with a transaction that netted only \$3.6 million to the company. Now, since that time, we have actually closed that gap. Additional transactions have brought in net proceeds to the company of approximately \$4.8 million.

The Q2 has been a particularly hard time, one that came with some very tough decisions, decisions necessary to move the company forward. As part of being that, going through that period, we held back on our marketing investments to retool, to realign the marketing initiatives, to segments that have the strongest likelihood to purchase the highest willingness to pay.

We implemented a pricing increase. We increased the pricing to reflect durable increases in electronic component parts. Things that are now part of a new economic reality for us and for many companies. And these price increases, while making the product sales more profitable, directly impacted the Q2 sales top-line revenue.

As I discussed in the Letter to Shareholders a few weeks ago, we've also been battling through the compliance issues with our Nasdaq listing. These issues are now on the verge of being resolved, in fact, based on recent vote. But we also brought additional capital into the company, an area I'll address further in our Q&A section.

We downsized the team in certain areas. We performed an internal reorganization to bring more focus to critical work efforts. We also determined some areas in which we needed increased strength and experience. One of those is in the area of finance, having brought in an interim CFO, Kim Bambach, as well as in our marketing leadership, having retained Elizabeth Jackson on a consulting agreement, both of whom have turnaround track records in the public markets.

Kim in particular brings over 30 years of financial leadership experience in both public and private industries. Her background includes financial leadership in medical, retail markets, manufacturing, wholesale distribution, licensing, digital media and broadcasting. And importantly, she's participated in the roll up process to be able to bring new value into investors through M&A processes.

We also added an advisor to the board, Christina Valauri. She is a 30-year Wall Street veteran, who is well respected by The Street and ranked as the number one biotech/biomedical analyst in Wall Street Journal's "Best of Wall Street". She has extensive experience identifying and analyzing the commercial potential for breakthrough innovation, something that we think is going to be very valuable as we assess our next steps as a company.

So she's also had the experience mentoring and advising C-suites of private and public early stage healthcare companies through product development regulatory, go-to market strategies, potential mergers and acquisitions, and IPOs. So I am deeply grateful for Christina Valauri's experience coming to the board as an advisor. Each of these team members has successfully developed and executed transformational business strategies to drive growth, enhance operating performance and execute turnaround.

So with this newly added talent and expertise, we are a very different team than we were just even 6 months ago, certainly very different than we were 2 years ago. One thing has not changed, though, our goal to build a diversified health tech company anchored in novel therapeutics and specifically in the area of bioelectronic medicine. Therefore, the development pipeline is as important to the company as the commercial traction and the outlets we are building and, in fact, potentially more so.

So with that lens, I'd like to go into looking at a few of the updates on our research and development programs from this quarter. Earlier this year, we announced a research collaboration with The Feinstein Institute for Medical Research to conduct a small pilot clinical study on a novel non-invasive bioelectronic device.

This device targets the vagus nerve and we are utilizing a new stimulation approach that is expected to enable more precise targeting of vagus nerve activity. This is important, because one of the areas that have held Vagus nerve back from broader adoption is the potential for unintended side effects. With more precise targeting, we expect to be able to open up applications in neurologic, cardiac and autoimmune areas.

Enrollment has begun for that study and we will be looking forward to sharing results and the outcomes of that as we move forward. We've continued expanding our IP portfolio and that includes expanding the clinical targets as well as the issuance of new patents on our previously filed patents. So as a company, we're looking not only at the platform we have today, but how we take the bioelectronic expertise we have and create a broader portfolio of offerings.

We expanded our collaboration with a renowned international hospital on a sham-controlled clinical trial that's evaluating our bioelectronic medicine one of our devices for post-surgical pain relief. This 60-person study is currently ongoing and this year it was broadened to go beyond the otolaryngology department to also include the facial plastic surgery area. Now, this study aims to investigate potential benefits of a drug-free alternative to traditional postoperative pain management, which the traditional method is to use opioids. So our collaborator on this is looking specifically for opportunities to reduce dependence on opioids as part of the treatment regimens.

In Q2 2023, we also advanced our commercial roadmap. We launched our B2B portal. Now, that portal increases the streamlining for the ordering and fulfillment process for professional customers and reduces our company's logistical complexity. We implemented a price increase this quarter after completing marketing research that indicated customers would be willing to pay more for the unit.

In this quarter, we also expanded the target market for ClearUP to include consumers that link their allergy and congestion issues to deprivation of sleep, exercise and concentration. Now, at the end of Q2, we signed a distribution agreement with Cardinal Health, the first of one of – several that we expect with a healthcare oriented focus. Cardinal Health is the leading distributor of medical products worldwide. Execution of this agreement is one of our key steps in expanding distribution and marketing targeted at the healthcare professional networks.

In short, from a business standpoint, this quarter was all about ensuring cost-cutting measures were implemented and processes were streamlined. We reduced our operating overhead. We reset our marketing programs to drive efficiency and to begin repositioning our products. This resulted in a significant revenue dip this quarter, but we expect to see growth and improved targeting in the second half of 2023.

Now, let me hand over the call to Kimberly Bambach, the Tivic Health interim CFO, to go over the specifics of the financial results for the quarter ended June 30, 2023.

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

Thanks, Jennifer, and good afternoon, everyone. As Jennifer stated, the second quarter was a challenging one for the company and is reflected in the financial results for the quarter ending June 30, 2023. We posted second quarter revenues of \$161,000, a decrease of \$367,000, or 69.5%, compared to the same quarter last year, primarily due to significant reductions in a profitable marketing expense. This resulted in an 82% decrease in unit sales, offset by a 69% increase in the per unit average sales price.

For the 3 months ended June 30, cost of sales decreased by \$303,000, or 75%, compared to the same period in 2022, primarily driven by the decrease in sales volume. Variable cost was \$64 per unit for the 3 months ended June 30, compared to \$80.10 per unit for the same period in 2022. The decrease in variable costs was primarily driven by lower manufacturing and fulfillment costs.

Fixed costs were \$60.48 per unit for the 3 months ended June 30, compared to \$10.16 per unit for the same period in 2022. The increase in the fixed costs was due to the lower sales volume to absorb the fixed expenses. We expect to see that improve as sales increase.

Our second quarter gross margin was 37.5% as compared to first quarter of 30.1% and 23.4% in the same quarter last year. We expect our gross margin to increase with increasing sales volume over which fixed and semi-fixed costs are allocated.

Research and development expenses decreased by \$29,000 compared to the same period in 2022. Research and development activities in 2023 are related to the Feinstein vagus nerve stimulation study, the segmentation study to identify additional incremental market segments for our products, product design for our next generation device, as well as enhancements of our intellectual property protection.

Sales and marketing expenses decreased by \$673,000 compared to the same period in 2022. The decrease was due to discontinuing unprofitable advertising and causing other campaigns to reset messaging, positioning and creative within the second quarter, whereas third quarter will be

focused on optimization and expansion of campaigns with improved performance and conversion efforts, while bringing new distribution partners online.

General and administrative expenses decreased by \$255,000 compared to the same period in 2022. The overall decrease was attributable to a decrease in personnel costs, professional fees and other overhead costs offset by onetime severance expense. As a result, our second quarter net loss was \$2.1 million compared to \$3 million in the same quarter last year. Lastly, our cash balance at the end of the quarter was \$2.7 million and we continue to maintain a no debt balance sheet.

From July 11, 2023 to August 9, we sold an aggregate of 116,923,000 shares of common stock to certain investors at prices ranging from \$0.055 to 0.040 per share in a series of registered public offerings, resulting in aggregate proceeds to the company of approximately \$5.2 million. Aggregate net proceeds to the company, after expenses was approximately \$4.8 million, for a total of \$7.5 million in cash now available.

On August 11, we held a Special Meeting to stockholders for the purpose of obtaining stockholder approval to authorize a reverse stock split. Our stockholders approved the proposal at the special meeting and we currently expect that we will implement a reverse stock split at a ratio within the approved range prior to the Nasdaq hearing date in order to regain compliance with the minimum bid price requirements.

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

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

Thank you, Kim. Now to recap, Q2 was a reset for the company. We have realigned the team, revamped the cost structure of the business, reduced overhead expenses, undertaken a more focused marketing strategy, and continued to see improvements in gross margin. We have taken the first steps in opening new healthcare focused channels and look to be increasing engagement with the healthcare community around uses of bioelectronic medicine, particularly in the management of inflammatory conditions.

Our research pipeline has begun moving forward at a brisker pace after delays in clinical enrollment in 2022 and early 2023, with a continued focus on new product outcomes and breakthrough opportunities. And we are continuing to evaluate M&A opportunities, but with an expanded lens to allow for stronger diversification. These measures involve some tough decisions, but they are important in setting the company on the track to rebuild shareholder value and trust.

So in that context, I'd like to move into the Q&A portion of the call.

Q: One of the key questions we've received in recent weeks has been around the series of back to back equity issuances. In one way, shape or form the question has been along these lines. The company has recently done an unusual series of back to back equity issuances. Why have you raised capital this way? And what should investors expect going forward?

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

So to answer this, I think it will be helpful for me to go back to earlier in the year, again, back to Q1. We entered the year with an open S-1 for a \$10 million capital raise, a transaction that ended up, as I said earlier, closing only \$5 million and netted the company only \$3.6 million of that at a share price value below the Nasdaq minimum listing price. This left us a bit of rock and a hard place, a place no CEO ever wants to be with not enough capital to spend on building a sales funnel, executing R&D to develop stronger products, and not particularly interesting yet as an acquisition target or as an acquirer, very difficult spot to be in.

So the series of transactions we've just completed brings us closer to the needs communicated at the start of the year. The new capital, plus our restructuring, our cost reduction measures, a realignment of the team gives us a foundation from which to start rebuilding and executing on three legs of a turnaround strategy. I'll go into that a bit more.

Now to the question of the structure, why did we do it in the format we did? That was really a multi-part format, was a result of various SEC and Nasdaq rules we've had to manage as we moved through the Nasdaq listing compliance measures. It was also dictated in part by the market appetite for smaller bytes. Where we could, we provided all investors, both early investors, new ones, the same information that was used by a maxim to market the deal. Some of our earliest supporters came in alongside new investors, actually seeing it as a great opportunity to do some dollar cost averaging.

And one of the critical issues in structuring all of the financing has been something I mentioned in a recent Letter to the Shareholders regarding Nasdaq listing compliance. I'm pleased to say that as of Friday, shareholders have voted and authorized the board to execute a reverse split that will bring us into compliance with all listing requirements within the very near-term. There's both price and common stock available in the public market float.

Q: Next question was does the company plan to delist?

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

No, it's not a consideration at this time. We have taken extraordinary measures to protect the listing. We believe that the company is better positioned to execute a turnaround with the public market vehicles as part of our toolkit. I was also asked to say more about our M&A strategy as well as how the company plans to regain shareholder value.

So, first and foremost, regaining listing compliance, something that I've discussed extensively in our recent communications, and I know it's not the flaxiest [ph] answer, but it's a critical first step. We have been doing repair work now with the share shortly to be back into a healthy price range. We have no outstanding warrants of any magnitude, we have no debt, and we have sufficient shares in the public float to meet our listing requirements and provide liquidity opportunity.

All of that, I hope, will be coming together to create a share vehicle that itself is a more attractive vehicle. That is separate from the company's growth strategy, which focuses on three areas, you've heard us talk about improving the profitability and the scalability of the line of business we have today, with strengthening our engagements in the healthcare field.

We are expanding the number of organically developed products through a strong clinical pipeline. And we are looking to diversify through acquisition, merger and licensing alongside those organic developments into high value therapeutic areas, particularly where chronic inflammatory mechanisms are a key driver of the disease. This is an area I'll look forward to sharing more details with you in each of these as over the remainder of the year and through next as we execute.

So to close out the call, let me say, as always, that I recognize and appreciate the support of the investment community of the internal and external team working so diligently through the recent matters and, frankly, the persistence and dogged determination of the Tivic team. I won't lie, it's been brutal in the public market and we have at the same time made important progress on the fundamentals of the business. And it is with that same dogged spirit that we will continue to embrace whatever challenges lie ahead.

So thank you for the time today and for your continued interest in Tivic.

Operator

Thank you, everyone. This concludes today's event. You may disconnect at this time and have a wonderful day. Thank you for your participation.