

Tivic Reports First Quarter 2025 Financial Results and Provides Updates on Business Transformation

Pre-recorded Conference Call to Follow at 1:30 p.m. PDT/4:30 p.m. EDT

FREMONT, Calif. - Tivic Health[®] Systems, Inc. (Nasdaq: TIVC), a diversified immunotherapeutics company, today announced financial results for the first quarter ended March 31, 2025 and outlined operational highlights based on its newly expanded clinical pipeline.

"This is a defining time for the company. During the quarter we initiated a significant strategic shift, dramatically expanding Tivic's clinical pipeline for restoring immune system health," stated Tivic CEO Jennifer Ernst.

"In February, we executed a comprehensive worldwide exclusive licensing agreement for the Phase III TLR5 agonist, Entolimod and its molecular derivative, Entolasta, with the agreement encompassing multiple indications. Phase III validation of Entolimod for treatment of acute radiation syndrome, or ARS, has been completed via the FDA's animal rule pathway and we have initiated manufacturing validation procedures that are required prior to regulatory filings.

"We have met with and provided briefings to senior leadership at the White House and FDA, securing positive interest in potential military and defense applications of Entolimod for treatment of ARS, for our country and our allies. We also discussed applications of our non-invasive vagus nerve stimulation, or VNS, program, which was of high interest to the defense community.

"Our ongoing study of non-invasive VNS continues to show noteworthy signs of its potential to improve outcomes in inflammatory, cardiac and neurologic disorders relative to current treatment options. As we have moved through the currently active optimization study for our non-invasive VNS, we have created new intellectual property. This includes IP captured in patent filings that cover potential breakthroughs in personalizing and optimizing the clinical effects of vagus nerve stimulation.

"Finally, we have entered into financing agreements that we expect will provide sufficient funding to take us through the manufacturing validation for Entolimod and the upcoming VNS data readouts. We believe that the advancements in and expansion of our clinical pipeline will position Tivic to increase shareholder value as we execute on our transformation strategy."

First Quarter and Subsequent Weeks Business and Operational Updates

In the first quarter of 2025 and subsequent weeks, the company announced the following developments:

- Provided briefings to senior leadership at the White House and at the FDA, which garnered significant positive interest in potential military and defense applications for the company's biologic and bioelectronic product candidates. The meeting with the FDA explored potential expedited pathways to approval for Entolimod and Entolasta. The company also discussed Tivic's ncVNS program, including the potential to treat post-traumatic stress disorder, one of several neurologic areas of strong interest to military and defense organizations globally.
- Secured a \$25 million equity line of credit and also entered into a purchase agreement that provides for the sale of up to \$8.4 million of company securities.
- Exercised the option to license the Phase II drug candidate Entolimod for the treatment of neutropenia. This is the second indication Tivic has licensed from Staterra and for which Phase II trials are expected to be initiated later this year.
- In collaboration with The Feinstein Institute for Medical Research, presented a poster at the Sixth Bioelectronic Medicine Summit showing that personalizing Tivic's ncVNS technology resulted in optimized effects on autonomic nervous system activity.

- Regained compliance with Nasdaq Minimum Bid Price Listing rule, which followed the 1-for-17 reverse stock split that took effect on March 7.
- Further expanded the scope of the optimization study currently underway for its ncVNS device following positive findings related to achieving enhanced effects on autonomic nervous system function.
- Following the quarter close, entered an agreement for GMP manufacturing process validation for Entolimod in advance of filing a Biologics License Application (BLA) with the FDA.

Financial Performance for the first quarter of 2025 compared with the first quarter of 2024:

- Revenue totaled \$70,000, compared with \$334,000 a year ago, reflecting lower unit sales of Tivic's ClearUP™ device to treat sinus pain and pressure. The lower sales are attributable to a 92% decrease in advertising expenses as the company focused resources on research and development programs, including securing the Entolimod and Entolasta license agreement.
- Gross profit was \$50,000, compared with \$167,000, for the year ago quarter.
- Gross margin was 72%, compared with 50% for the first quarter of 2024.
- Operating expenses totaled \$1.6 million and remained flat compared with \$1.6 million for the same period in 2024.
- Net loss of \$1.5 million remained flat compared to \$1.5 million in the first quarter of 2024.
- At March 31, 2025, cash and cash equivalents totaled \$669,000. Cash at year end 2024 totaled \$2.0 million. Subsequent to the quarter, the company raised net proceeds of \$1.7 million under its ATM. The company has no debt on its balance sheet.

Conference Call and Webcast Information

Management will host a webcast/conference call today, Thursday, May 15, at 1:30 p.m. PT / 4:30 p.m. ET to discuss the company's first quarter 2025 financial results and provide a business update. The company invites investors to submit questions in advance to ir@tivichealth.com.

Teleconference Details:

Toll Free: 1-877-407-0779

International: 1-201-389-0914

Conference ID: 13753498

Webcast Link

https://viaid.webcasts.com/starthere.jsp?ei=1717125&tp_key=322c3ca4f6

An audio replay of the call will be available for the next 90 days from the investor page on the Tivic Health website at <https://tivichealth.com/investor/>.

About Tivic Health Systems, Inc.

Tivic Health is a diversified immunotherapeutics company harnessing the power of the immune and autonomic nervous systems to fight disease and restore health. Tivic Health's bioelectronic program is focused on developing personalized non-invasive therapeutic devices for vagus nerve stimulation to improve clinical outcomes in inflammatory, neurologic and cardiac disease. The program also includes Tivic Health's first FDA approved product, ClearUP®, which has been proven to provide temporary relief of sinus pain, pressure and congestion and is available through top-tier online retail and distribution partners. The company's newly formed biopharmaceutical program is focused on commercial advancement of the toll-like receptor 5 drugs Entolimod™ and Entolasta™, including lead product candidate Entolimod for acute radiation syndrome. The company is also driving expansion into additional indications for Entolimod and Entolasta.

Forward-Looking Statements

This press release may contain "forward-looking statements" that are subject to substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this press release are forward-looking statements. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict," "project," "target," "aim," "should," "will" "would," or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on Tivic Health Systems Inc.'s current expectations and are subject to inherent uncertainties, risks, and assumptions that are difficult to predict. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate, including as a result of interactions with and guidance from the FDA and other regulatory authorities; changes to the company's relationship with the its partners; the failure to obtain FDA or similar clearances or approvals and noncompliance with FDA or similar regulations; the company's future development of its ncVNS treatment, Entolimod and Entolasta; changes to the company's business strategy; timing and success of clinical trials and study results; regulatory requirements and pathways for approval; consummation of any strategic transactions; the company's need for, and ability to secure when needed, additional working capital; the company's ability to maintain its Nasdaq listing; and changes in tariffs, inflation, legal, regulatory, political and economic risks. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors. Accordingly, you are cautioned not to place undue reliance on such forward-looking statements. For a discussion of risks and uncertainties relevant to the company, and other important factors, see Tivic Health's filings with the SEC, including, its Annual Report on Form 10-K for the year ended December 31, 2024, filed with the SEC on March 21, 2025, under the heading "Risk Factors," as well as the company's subsequent filings with the SEC. Forward-looking statements contained in this press release are made as of this date, and Tivic Health Systems, Inc. undertakes no duty to update such information except as required by applicable law.

Tivic Health Systems, Inc.

Condensed Balance Sheets

(in thousands, except share and per share data)

	March 31, 2025 (Unaudited)	December 31, 2024 (Audited)
ASSETS		
Cash and cash equivalents	\$ 669	\$ 2,002
Other current assets	592	637
TOTAL CURRENT ASSETS	1,261	2,639
PROPERTY AND EQUIPMENT, NET	118	119
NONCURRENT ASSETS	2,398	49
TOTAL ASSETS	\$ 3,777	\$ 2,807
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued expenses	\$ 741	\$ 272
TOTAL CURRENT LIABILITIES	741	272
TOTAL LONG-TERM LIABILITIES	-	-
STOCKHOLDERS' EQUITY		
Preferred stock	-	-
Common stock	1	1
Additional paid in capital	48,078	46,075
Accumulated deficit	(45,043)	(43,541)
TOTAL STOCKHOLDERS' EQUITY	3,036	2,535
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 3,777	\$ 2,807

Tivic Health Systems, Inc.
Condensed Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2025	2024
REVENUES	\$ 70	\$ 334
COST OF SALES	20	167
GROSS PROFIT	50	167
OPERATING EXPENSES		
Research and development	335	256
Sales and marketing	179	505
General and administrative	1,042	887
TOTAL OPERATING EXPENSES	1,556	1,648
NET OPERATING LOSS	(1,506) (1,481
Other Income	4	-
NET LOSS	\$ (1,502) \$ (1,481
NET LOSS PER SHARE - BASIC AND DILUTED	\$ (2.52) \$ (17.15
WEIGHTED-AVERAGE NUMBER OF SHARES - BASIC AND DILUTED	596,368	86,338

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