Tivic Reports Third Quarter 2025 Financial Results

Continues Execution of Strategic Transformation and Advancement of Biologics Pipeline

FREMONT, CA / ACCESS Newswire / November 14, 2025 / Tivic Health® Systems, Inc. (Nasdaq:TIVC), a diversified immunotherapeutics company, today announced financial results for the third quarter and nine months ended September 30, 2025 and provided a business update.

"Following our discussions at the Military Health System Research Symposium and continued engagement with key government agencies, we are encouraged by the interest in our lead product candidate, Entolimod for acute radiation syndrome (ARS), as a military medical countermeasure and stockpile drug," stated Tivic CEO, Jennifer Ernst. "This quarter, we continued the advancement towards commercial readiness. Starting the cGMP manufacturing process with successful cell line verification was a critical first step to establishing reproducibility and scalability in our drug manufacturing."

Tivic also completed the transfer of two INDs to Tivic from Statera Biopharma. These two INDs allow Tivic to initiate clinical trials for the use of Entolimod in the treatment of neutropenia and cancer-related conditions.

"Subsequent to the quarter's end, we also reported the compelling findings from Tivic's VNS Optimization Trial. These findings uncovered new insights into vagus nerve stimulation and have led to additional patent filings intended to protect Tivic's prescription device development for commercialization and licensing," added Ernst.

Corporate Highlights from the Third Quarter and Subsequent Weeks:

- Successfully completed the transfer of two INDs to Tivic from Statera Biopharma, which allows Tivic to conduct clinical trials in neutropenia and lymphocyte exhaustion, and to explore Entolimod's anti-tumor activity to potentially treat certain other cancer-related conditions.
- Completed the cell line verification, a key step to enable Current Good Manufacturing Practices (cGMP), required prior to filing a biologics license application (BLA) with the U.S. Food & Drug Administration (FDA).
- Moved forward with the wind down of Tivic's consumer health tech business, including discontinuing the
 allocation of any significant resources toward ClearUP sales, and the write-off of inventory, which was completed
 during the third quarter. As part of this progression, Tivic launched a new corporate website that emphasizes its
 transformed mission and expanded clinical pipeline.
- Advanced discussions of potential pathways to deploying Entolimod™ as a military countermeasure and stockpile drug through participation in the 2025 Military Health System Research Symposium (MHSRS) in August. The Department of Defense holds this annual scientific meeting to bring together military, academic, and industry experts to discuss innovations in health and medical research for warfighters.
- Closed the second, third and fourth tranches of Tivic's \$8.4 million financing for a total of \$3.8 million in net proceeds during the third quarter.

- Revenue totaled \$146,000, compared with \$126,000 a year ago. While unit sales of ClearUP™ to treat sinus
 pain and pressure rose slightly, the third quarter was the final quarter that Tivic will sell ClearUP directly to
 consumers, and we discontinued all advertising and marketing initiatives on October 1, 2025. We will continue to
 fulfill orders from our resellers through the fourth quarter to support their holiday promotions.
- Gross loss was \$145,000, compared with gross profit of \$44,000, for the year-ago quarter. The gross loss in 2025 was a result of \$230,000 of inventory reserves recorded in the third quarter in connection with the wind down of the consumer business. Gross margin, excluding the \$230,000 inventory reserve, was 42%, compared with 35% for the third quarter of 2024.
- Operating expenses totaled \$2.3 million, compared with \$1.5 million for the same period in 2024. The increase
 was due to the addition of the biopharma business in February 2025 as well as increased corporate costs and
 advertising as we pushed to sell through our remaining ClearUP inventory prior to exiting the consumer
 business.
- During the quarter, executed the write-down of the ClearUP inventory and equipment, which resulted in \$230,000 of cost of goods sold and \$117,000 of other expenses as part of the exit from the consumer business and the focus on our transformation plan that seeks to advance the clinical pipeline for licensed Entolimod and Entolasta indications.
- Net loss of \$2.6 million compared to \$1.4 million in the third quarter of 2024.
- At September 30, 2025, cash and cash equivalents totaled \$3.5 million, compared with \$2.0 million at December 31, 2024. The company has no debt on its balance sheet. Approximately \$3.5 million remained available at September 30 as a committed investment in Tivic through a preferred equity purchase agreement. The company believes the current and committed funding is sufficient to make meaningful progress toward manufacturing validation for Entolimod.

Conference Call and Webcast Information

Management will host a webcast/conference call today, November 14, at 1:30 p.m. PT / 4:30 p.m. ET to discuss the company's third quarter 2025 financial results and provide a business update.

Teleconference Details:

Toll Free: 888-506-0062 International: 973-528-0011

Participant Access Code: 230582

Webcast Link:

https://www.webcaster5.com/Webcast/Page/2865/53145

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/investors/corporate-presentations/.

About Entolimod

Entolimod is a novel Toll-like Receptor 5 (TLR5) agonist that triggers NF-kB signaling, activating antiapoptotic and cell protective mechanisms. Under the FDA's Animal Rule, Entolimod™ has been the subject of extensive trials for the treatment of acute radiation syndrome (ARS), and has demonstrated robust survival, enhanced GI tract recovery and improved hematopoiesis in animal models. Entolimod has been granted Fast Track Designation for ARS.

About Tivic Health Systems, Inc.

Tivic's dual platform utilizes the body's biopharmaceutical and bioelectronic systems to treat unmet medical needs through targeting the immune system.

Tivic's biologics compounds activate an innate immune pathway to prevent cell death in the bone marrow and epithelial tissues across systems impacted by radiation and age. The company's lead drug candidate, Entolimod™ for acute radiation syndrome, is a novel TLR5 agonist that has been granted Fast Track and Orphan Drug designations and is in late-stage development. In addition to Entolimod™ for ARS, Tivic's pipeline includes and Entolimod™ for the treatment of neutropenia, and lymphocyte exhaustion, and Tivic has the exclusive option to license additional indications, including Entolasta to treat immunosenescence, and chronic radiation syndrome.

Tivic's bioelectronic program has been developing a novel, non-invasive medical device designed to target the neural pathways implicated in many prevalent and debilitating diseases. Early trials show promising signals that Tivic's approach may regulate specific biologic responses, and the company believes its early-stage vagus nerve stimulation device has the potential to deliver clinical outcomes similar to or better than those of surgically implanted devices.

To learn more about Tivic, visit: https://ir.tivichealth.com.

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; timing and success of clinical trials and study results; the failure to obtain FDA or similar clearances or approvals and noncompliance with FDA or similar regulations; the company's ability to secure orders for its product candidates, if regulatory approvals are obtained; the company's future development of its ncVNS treatment, Entolimod and Entolasta; changes to the company's business strategy, regulatory requirements and pathways for approval; changes to the company's relationship with its partners, including its manufacturing partners and other third-party providers; consummation of any strategic transactions; the company's need for, and ability to secure when needed, additional working capital; unexpected costs or expenses that the company may incur, or other issues that may arise, in connection with the wind down of its consumer health business; 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.

Investor Contact:

Hanover International, Inc.

ir@tivichealth.com

Tivic Health Systems, Inc.

Condensed Balance Sheets

(in thousands, except share and per share data)

	September 30, 2025	December 31, 2024
	(Unaudited)	(Audited)
ASSETS		
Cash and cash equivalents	\$ 3,450	\$ 2,002
Other current assets	290	637
TOTAL CURRENT ASSETS	3,740	2,639
PROPERTYAND EQUIPMENT, NET	12	119
NONCURRENTASSETS	2,477	49
TOTAL ASSETS	\$ 6,229	\$ 2,807
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued expenses	\$ 638	\$ 272
TOTAL CURRENT LIABILITIES	638	272
TOTAL LONG-TERMLIABILITIES STOCKHOLDERS' EQUITY	-	-
Preferred stock	-	-
Common stock	2	1
Additional paid in capital	55,206	46,075
Accumulated deficit	(49,617) (43,541)
TOTAL STOCKHOLDERS' EQUITY	5,591	2,535
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 6,229	\$ 2,807

Tivic Health Systems, Inc.

Condensed Statements of Operations
(in thousands, except share and per share data)

	Three Mon Septembe		Nine Months Ended September 30,	
	2025	2024	2025 2	2024
REVENUES	\$ 146	\$ 126	\$302	600
COST OF SALES	291	82	343	359
GROSS PROFIT OPERATING EXPENSES	(145) 44	(41)	241
Research and development	858	422	1,848	980
Sales and marketing	415	234	1,020	946
General and administrative	1,065	819	3,014	2,493
TOTAL OPERATING EXPENSES	2,338	1,475	5,882	4,419
NET OPERATING LOSS	(2,483) (1,431) (5,923)	(4,178)
OTHER EXPENSE, NET	(113) -	(106)	-
NETLOSS	\$ (2,596) \$(1,431) \$(6,029) \$	S(4,178)
NET LOSS PER SHARE - BASIC AND DILUTED	\$ (1.97) \$(3.93) \$(6.49) \$	S (18.22)
WEIGHTED-AVERAGE NUMBER OF SHARES - BASIC AND DILUTED	1,320,778	8 364,184	928,971	229,291

SOURCE: Tivic Health Systems

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