Tivic Reports Full Year 2025 Results

Completes Strategic Transformation into an Immunotherapy Company and Continues to Advance Entolimod Platform Toward Potential Funding Partnerships

Conference Call to be Held Today at 1:30 PM PT / 4:30 PM ET

SAN ANTONIO, TX / ACCESS Newswire / March 25, 2026 / Tivic Health Systems, Inc. (Nasdaq:TIVC), a development-stage immunotherapy company, today reported financial and operational results for the year ended December 31, 2025, and provided a business update highlighting the company's strategic transformation and focus on the development of its Entolimod™ platform.

"2025 was a defining year for Tivic as we marked our transformation into a focused immunotherapy company anchored by Entolimod and its next-generation molecule, Entolasta," said Michael K. Handley, chief executive officer of Tivic. "During the year, we secured global rights to Entolimod and advanced regulatory and development readiness, while initiating discussions with U.S. government agencies regarding its potential as a medical countermeasure. We believe that Entolimod's differentiated cytoprotective properties, immune-enhancing mechanism, and extensive development history make it a promising candidate for national preparedness programs. We are optimistic that our ongoing discussions with the BARDA, the Department of War, and the National Institute of Allergy and Infectious Disease will advance toward a potential funding or sponsorship arrangement."

Handley added, "While Entolimod for acute radiation syndrome remains our lead indication, its development is the first phase of a broader strategic roadmap to penetrate the multi-billion-dollar oncology supportive care market. Our immediate focus is on Neutropenia, where we are targeting the severe and often fatal side effects of chemo and radiation therapy. We are on track to advance this program into physician-sponsored clinical trials later this year.

"Simultaneously, the vertical integration provided by Velocity Bioworks has already significantly reduced our manufacturing timelines and costs. Beyond internal efficiencies, we have positioned Velocity Bioworks as a standalone contract development and manufacturing organization, or CDMO, to service third-party development projects. This creates an immediate opportunity for a new revenue stream and supports our long-term objective of transforming our manufacturing capabilities into a high margin profit center for the broader biotech industry."

2025 Corporate Highlights and Subsequent Events

- Acquired exclusive global rights to Entolimod™ for acute radiation syndrome, including a comprehensive clinical, regulatory, and nonclinical development package from Statera Biopharma, Inc. Statera's CEO Michael K. Handley joined Tivic in 2025, and in March 2026 was appointed CEO, succeeding Jennifer Ernst, who was Tivic's CEO since 2016

- Engaged with U.S. government agencies, including BARDA, Defense Threat Reduction Agency, National Institutes of Health, and NIAID, regarding potential development funding and Strategic National Stockpile procurement of Entolimod™

- Acquired biomanufacturing assets to establish Velocity Bioworks, a wholly owned CDMO subsidiary

- Discontinued ClearUP® operations and suspended the non-core neuromodulation, or VNS, program

- Relocated corporate headquarters to San Antonio, Texas

Financial Results for the Year Ended December 31, 2025, Compared to 2024

- Operating expenses for the year ended December 31, 2025 were $7.9 million, compared to $4.5 million for the year ended December 31, 2024. The increase was primarily due to the introduction of the biopharma business in February 2025, when the company licensed certain biologics assets and increased headcount and consultant services to support the development of Entolimod™. Additional increases occurred in December 2025 when we formed Velocity Bioworks and hired 45 employees to support the CDMO operations.

- Loss from discontinued operations decreased by $300,000 to $900,000 for the year ended December 31, 2025. Discontinued operations included all activities related to the consumer product business that Tivic exited in 2025.

- Net loss before discontinued operations for the year ended December 31, 2025 is expected to be in the range of $7.9 million to $8.1 million, compared with $4.5 million for the year ended December 31, 2024.

- Net loss for the year ended December 31, 2025 is expected to be in the range of $8.8 million to $9.1 million, compared with $5.7 million for the year ended December 31, 2024.

- The company is in the process of finalizing certain accounting matters related to the $16.3 million Senior Secured Convertible Note Payable dated December 10, 2025. All of the proceeds from the debt offering were used to acquire the assets now used by Velocity Bioworks.

- Cash and cash equivalents at December 31, 2025 totaled $12.6 million, compared with $2.0 million at December 31, 2024. The company had working capital of $12.4 million at December 31, 2025.

Conference Call and Webcast Information

Teleconference

Toll Free: 888-506-0062

International: 973-528-0011

Participant Access Code: 910220

Webcast Link

https://www.webcaster5.com/Webcast/Page/2865/53678

An audio replay of the call will be available for 90 days on the investor page of the company's website at https://tivichealth.com/investor/.

About Tivic

Tivic Health is developing biologics that activate innate immune pathways for cytoprotection and modulate immune responses in conditions driven by radiation, disease, and immune dysregulation. The company's lead candidate, Entolimod™ for acute radiation syndrome (ARS), has been extensively studied, having demonstrated survival benefits and improved tissue recovery in animal models under the FDA's Animal Rule.

Entolimod™ is a novel Toll-like receptor 5 (TLR5) agonist that activates NF-κB signaling pathways to protect cells from damage and stimulate immune responses. Entolimod™ has received Fast Track and Orphan Drug designations from the U.S. Food and Drug Administration.

Tivic is also advancing Entolasta™, a next-generation TLR5 agonist designed for potential broader therapeutic applications, including oncology supportive care. Tivic's clinical pipeline includes potential treatments for neutropenia, which is most commonly caused by chemotherapy, and a state of T-cell dysfunction known as lymphocyte exhaustion.

Tivic's wholly owned subsidiary, Velocity Bioworks, is a full-service CDMO offering biomanufacturing services to third-party biotech companies. Tivic also leverages Velocity Bioworks' manufacturing capabilities to advance its own drug pipeline with the expected benefits of lower costs, accelerated manufacturing outcomes, and supply chain security.

For more information, visit https://tivichealth.com/investors/.

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 the company's interactions with and guidance from the FDA and other regulatory authorities; the continued interest of BARDA and other U.S. government agencies in Entolimod™; the ability of the company to achieve the expected benefits from the acquisition of development and manufacturing assets within expected time frames or at all; changes to the company's relationship with its partners; expectations regarding the potential benefits of the leadership transition; failure to obtain FDA or similar clearances or approvals and noncompliance with FDA or similar regulations, including related to the Animal Rule; the company's future development of Entolimod™ or Entolasta; changes to the company's business strategy; timing and success of pre-clinical and clinical trials and study results; regulatory requirements and pathways for approval; the company's ability to successfully commercialize its product candidates in the future; changes in the markets and industries in which the company does business; 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. 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 the company undertakes no duty to update such information except as required by applicable law.

Investor Contact:
Hanover International, Inc.
ir@tivichealth.com

Media Contact:
DJ Freyman
DJ@FastrackPR.com

SOURCE: Tivic Health Systems

3/25/2026 4:05:00 PM