

**VALION BIO REPORTS FIRST QUARTER 2026 FINANCIAL RESULTS**

First Reporting Quarter as Valion Bio Marked by Continued Advancement of the Entolimod Platform, Broader Government Engagement, and Continued Integration of Velocity Bioworks

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

SAN ANTONIO , May 14, 2026 /PRNewswire/ -- Valion Bio, Inc. (formerly Tivic Health Systems, Inc.) (Nasdaq: VBIO), a clinical-stage immunotherapeutics company, today reported financial results for the three months ended March 31, 2026 - the company's first full reporting quarter under its new corporate identity - and provided a business update on the continued advancement of its Entolimod platform, ongoing engagement with U.S. government agencies, and continued integration of wholly owned manufacturing subsidiary Velocity Bioworks.

**First Quarter 2026 Highlights and Subsequent Events**

- Completed corporate transformation, including the change of the company's legal name from Tivic Health Systems, Inc. to Valion Bio, Inc. and the change of the company's Nasdaq listing symbol from TIVC to VBIO, consolidating the company's identity as a focused clinical-stage immunotherapeutics platform.
- Advanced engagement with U.S. government agencies, including BARDA, the National Institute of Allergy and Infectious Diseases (NIAID), and the Department of War, regarding the development, procurement, and stockpiling of Entolimod as a medical countermeasure for Acute Radiation Syndrome (ARS).
- Continued integration of Velocity Bioworks, the company's wholly owned contract development and manufacturing organization (CDMO) subsidiary acquired in December 2025, with operational workstreams advancing across both internal pipeline manufacturing support and third-party CDMO business development.
- Reinforced regulatory pathway for Entolimod under the FDA's Animal Rule, supported by the program's Fast Track and Orphan Drug designations and the previously demonstrated 200-fold manufacturing scale-up at 50-liter fermentation, equivalent to approximately 1.3 million human doses.
- Continued advancement of Entolasta, the company's next-generation TLR5 agonist, designed to support broader therapeutic applications including oncology supportive care, longevity, and immunosenescence.
- Maintained domestic biologics manufacturing footprint through Velocity Bioworks' San Antonio, Texas operations, addressing both the company's internal pipeline manufacturing requirements and a structurally underserved Phase I and Phase II domestic biologics manufacturing market.

The first quarter of 2026 was, by design, a quarter of execution rather than announcement: the first full quarter operating with Velocity Bioworks integrated, the first quarter following the previously demonstrated 200-fold manufacturing scale-up, and the first quarter under the Valion Bio identity. The transition follows the divestiture and discontinuation of the legacy consumer bioelectronics business completed in 2025 and consolidates the company's focus on the development and potential commercialization of its TLR5 platform.

"The transition to Valion Bio is more than a change of name and ticker. It reflects the institutional identity we have built - a clinical-stage immunotherapeutics company anchored by a differentiated TLR5 platform, an in-house biologics manufacturing capability through Velocity Bioworks, and increasing visibility within the federal agencies responsible for national medical countermeasure preparedness," said Michael K. Handley, Chief Executive Officer of Valion Bio. "Each of those pillars advanced through the first quarter, and we believe the company enters the balance of 2026 with sharper focus, deeper engagement, and broader optionality than at any point in our history."

Government engagement broadened across multiple agencies during the quarter. Building on the previously disclosed non-clinical evaluation agreement with NIAID, Valion Bio further advanced Entolimod toward potential procurement and stockpiling under the FDA's Animal Rule pathway. Engagement with BARDA, the Department of War, and additional

federal stakeholders progressed in scope and depth over the same period. Entolimod's profile - dual gastrointestinal and hematopoietic protection, repeat-dose tolerability supported by a deletion-variant design that reduces immunogenicity, Fast Track and Orphan Drug designations, and a domestic manufacturing footprint - represents a meaningful point of differentiation from currently fielded countermeasures, and one that aligns with both Strategic National Stockpile modernization priorities and allied-government preparedness initiatives.

Integration of Velocity Bioworks advanced on multiple fronts during the quarter. The San Antonio facility continued to support internal Entolimod manufacturing capability while active business development discussions with third-party biotech sponsors progressed in parallel. Velocity addresses a structurally underserved domestic Phase I and Phase II biologics manufacturing market and is expected to function both as a cost and timeline accelerant for Valion Bio's internal pipeline and, increasingly, as a stand-alone source of revenue and operating leverage.

"Beyond Entolimod's role in radiation defense, the most significant commercial opportunity in front of us is oncology supportive care," Mr. Handley continued. "Neutropenia and related conditions affect a meaningful proportion of patients undergoing chemotherapy and radiation therapy, and the mechanistic profile of Entolimod - together with the broader applicability of our second-generation molecule, Entolasta - positions us to address that market with a differentiated entry. Velocity Bioworks accelerates our path on both fronts: it compresses our internal development timelines, structurally lowers our manufacturing cost base, and creates a stand-alone CDMO revenue stream serving the broader biotech industry. The first quarter was a quarter of execution, and we are building."

Pipeline development advanced across both molecules during the quarter. Entolimod continued progressing toward potential approval under the FDA's Animal Rule, with regulatory and clinical development workstreams positioned to support both medical countermeasure and oncology supportive care applications, including neutropenia. Entolasta, the company's next-generation TLR5 agonist, continued to advance as a strategic platform extension - engineered to support broader therapeutic applications including longevity, immunosenescence, and additional oncology supportive care indications, areas where the underlying TLR5 mechanism is mechanistically suited and the addressable markets are substantial.

### **Financial Results for the Three Months Ended March 31, 2026**

Operating expenses for the three months ended March 31, 2026 were \$5.6 million, compared with \$1.4 million for the three months ended March 31, 2025. The year-over-year change reflects the inclusion of Velocity Bioworks operating costs following the December 2025 acquisition, continued advancement of the Entolimod regulatory and development program, and one-time costs associated with the corporate rebrand and Nasdaq symbol change.

Net loss for the three months ended March 31, 2026 was \$6.2 million, or \$2.23 per share, compared with a net loss of \$1.5 million, or \$2.52 per share, for the three months ended March 31, 2025. Cash and cash equivalents at March 31, 2026 totaled \$7.2 million, compared with \$12.6 million at December 31, 2025. The company continues to evaluate capital alternatives to support continued execution against pipeline, regulatory, and manufacturing milestones.

### **Conference Call and Webcast Information**

Valion Bio will host a conference call and webcast today, Thursday, May 14, 2026, at 1:30 PM PT / 4:30 PM ET to discuss the company's first quarter 2026 financial results and provide a business update. The webcast may be accessed at <https://www.webcaster5.com/Webcast/Page/2865/54024>. Participants may access the call by dialing 888-506-0062 (U.S. toll-free) or 973-528-0011 (international), with participant access code 118764. A replay of the webcast will be available on the Investors section of the company's website following the conclusion of the event.

### **About Entolimod for Acute Radiation Syndrome**

Entolimod (CBLB502) is a recombinant deletion variant of Salmonella FliC flagellin engineered to activate TLR5 selectively. Upon engagement, Entolimod triggers NF- $\kappa$ B-dependent signaling to stimulate G-CSF, PI3K, and IL-6

production, promote multi-tissue cytoprotection, and inhibit apoptosis in radiosensitive hematopoietic and gastrointestinal tissues. The compound has demonstrated survival benefit as both a radioprotectant and a radiomitigant in controlled non-human primate studies under the FDA's Animal Rule.

### **About Valion Bio, Inc.**

Valion Bio, Inc. (Nasdaq: VBIO), the new corporate identity of Tivic Health Systems, Inc., 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 and has 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- $\kappa$ B signaling pathways to protect cells from damage and stimulate immune responses. Entolimod for ARS has received Fast Track and Orphan Drug designations from the U.S. Food and Drug Administration. Valion Bio is also advancing Entolasta, a next-generation TLR5 agonist designed for potential broader therapeutic applications, including oncology supportive care. Valion Bio's wholly owned subsidiary, Velocity Bioworks, is a full-service contract development and manufacturing organization (CDMO) that provides biomanufacturing services to third-party biotech companies. Valion Bio 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 [www.valionbio.com](http://www.valionbio.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 Valion Bio, 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; 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 Valion Bio's filings with the SEC, including, its Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on March 30, 2026, 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 and Media Contact:**

Rich Cockrell  
CG Capital

Valion Bio, Inc. (formerly known as Tivic Health Systems, Inc.)  
Condensed Consolidated Balance Sheets  
(in thousands, except share and per share data)

	<b>December 31,</b>	
	<b>March 31, 2026</b>	<b>2025</b>
	(Unaudited)	(Audited)
<b>ASSETS</b>		
Cash and cash equivalents	\$ 7,215	\$ 12,645
Other current assets	1,437	361
<b>TOTAL CURRENT ASSETS</b>	<b>8,652</b>	<b>13,006</b>
PROPERTY AND EQUIPMENT, NET	12,644	12,641
ROU ASSETS	10,086	-
GOODWILL	3,457	3,457
OTHER NON-CURRENT ASSETS	3,376	2,503
<b>TOTAL ASSETS</b>	<b>\$ 38,215</b>	<b>\$ 31,607</b>
<b>LIABILITIES, TEMPORARY EQUITY AND STOCKHOLDERS' EQUITY</b>		
Accounts payable and accrued expenses	\$ 2,119	\$ 640
Operating lease liabilities, current	\$ 492	\$ -
Other current liabilities	\$ 4	\$ 6
<b>TOTAL CURRENT LIABILITIES</b>	<b>2,615</b>	<b>646</b>
DEBT, NET	6,899	6,454
OPERATING LEASE LIABILITIES	9,643	-
OTHER NON-CURRENT LIABILITIES	510	340
<b>TOTAL NON-CURRENT LIABILITIES</b>	<b>17,052</b>	<b>6,794</b>
TEMPORARY EQUITY	7,486	7,370
STOCKHOLDERS' EQUITY		
Common stock	2	2
Additional paid in capital	70,094	69,392
Accumulated deficit	(59,034)	(52,597)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>11,062</b>	<b>16,797</b>
<b>TOTAL LIABILITIES, TEMPORARY EQUITY AND STOCKHOLDERS' EQUITY</b>	<b>\$ 38,215</b>	<b>\$ 31,607</b>

Valion Bio, Inc. (formerly known as Tivic Health Systems, Inc.)  
Condensed Consolidated Statements of Operations  
(in thousands, except share and per share data)

	<b>Three Months Ended March 31,</b>	
	<b>2026</b>	<b>2025</b>
<b>OPERATING EXPENSES</b>		
Research and development	\$ 1,854	\$ 335
Selling, general and administrative	3,780	1,042
<b>TOTAL OPERATING EXPENSES</b>	<b>5,634</b>	<b>1,377</b>
NET OPERATING LOSS	(5,634)	(1,377)
OTHER INCOME (EXPENSE), NET	(591)	4
NET LOSS BEFORE DISCONTINUED OPERATIONS	(6,225)	(1,373)
INCOME (LOSS) FROM DISCONTINUED OPERATIONS	23	(129)
NET LOSS	\$ (6,202)	\$ (1,502)
NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED	\$ (2.23)	\$ (2.52)
WEIGHTED-AVERAGE NUMBER OF SHARES - BASIC AND DILUTED	2,883,650	569,368

SOURCE Valion Bio, Inc.