Humacyte Announces First Quarter 2026 Financial Results and Provides Business Update

- Appointed Jim Mercadante as Chief Commercial Officer and Dr. Todd Rasmussen as Chief Surgical Officer -

- First quarter sales of Symvess® were $0.5 million in 2026 compared to $0.1 million in 2025 -

- Purchase commitment received for a minimum of $1.475 million for a clinical evaluation and outreach program in the Kingdom of Saudi Arabia -

- Announced Israeli Ministry of Health Acceptance of Marketing Authorization Application for Symvess for Vascular Injury Repair -

- U.S. Department of Defense funding for procurement of bioengineered blood vessels -

- Major milestone upcoming: Top-line interim results from V012 Phase 3 study in hemodialysis access -

-Conference call today at 8:00 am ET -

DURHAM, N.C., May 13, 2026 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a commercial-stage biotechnology platform company developing universally implantable, bioengineered human tissues at commercial scale, today announced financial results for the first quarter ended March 31, 2026, and provided a business update.

"We have seen expansion in the commercial uptake of Symvess. We also recognize that more rapid growth and expansion of sales is necessary and warranted, based on this innovative product's potential," said Laura Niklason, M.D., Ph.D., Founder and Chief Executive Officer of Humacyte. "Therefore, as recently announced, we have made substantial hires in senior commercial and surgical leadership positions including industry veteran James Mercadante as Chief Commercial Officer and Dr. Todd Rasmussen as Chief Surgical Officer. Jim is an accomplished medtech commercial leader with an extensive track record of field-specific success in vascular and cardiothoracic surgery markets. Dr. Rasmussen is one of the trailblazers of modern vascular surgery and will be instrumental in guiding scientific strategy and real-world implementation of Symvess going forward. We look forward to working with both of our new leaders to accelerate and expand patient access to Symvess."

"We are nearing one of the most exciting milestones in Humacyte's history, the presentation of top-line interim results of our Phase 3 trial in hemodialysis access June 11, 2026 at the Society of Vascular Surgery's (SVS) Vascular Annual Meeting (VAM) in Boston. We also continue to work toward commencement of our Phase 1/2 trial of the CTEV in coronary artery bypass surgery in the second half of 2026. We have accomplished multiple important tasks in the scientific, technical and clinical arenas over the past year, and this has allowed us to streamline operations and re-structure our personnel to focus resources on commercialization and late-stage clinical development. Over the past two months, we have reduced our expected spending by $14.3 million for the remainder of 2026 and have reorganized our team, resulting in a reduction of total headcount by approximately 25%. We have done this while continuing to invest even more heavily in personnel with specialized expertise in clinical education, sales, marketing, as well as those who perform the clinical development work necessary to secure follow-on clinical indications for Symvess," concluded Dr. Niklason.

First Quarter 2026 and Recent Corporate Highlights

Symvess U.S. and International Commercialization

- **Appointed Industry Veteran James Mercadante as Chief Commercial Officer:** Mr. Mercadante is a seasoned commercial executive with a track record of successful leadership across medical devices, diagnostics, and healthcare technology. Over his career, he and his teams have launched over 50 new products and delivered millions of dollars in growth for multiple technologies, including high-end peripheral vascular and aortic devices. Mr. Mercadante will oversee all aspects of the Company's commercial strategy, including sales, marketing, and market access, as Humacyte continues to expand the U.S. launch of Symvess and prepares for potential future commercial indications.

- **Appointed Renowned Vascular Surgeon Dr. Rasmussen as Chief Surgical Officer:** Dr. Rasmussen joins Humacyte with extensive expertise as a vascular surgeon, including a 28-year career in the U.S. Air Force during which he deployed multiple times during the Iraq and Afghanistan Wars. A recognized leader in peripheral vascular surgery and trauma repair, at Humacyte he will focus on providing peer-to-peer scientific support, medical education, and technical insights to surgeons and other healthcare providers. He will bring an experienced surgical perspective and leadership to the development of education and clinical support materials aligned with regulatory guidance to optimize the safe, appropriate, and effective implantation of Humacyte products.

- **Marketing Authorization Application for Symvess in Israel Accepted for Review:** The Company's Marketing Authorization Application (MAA) for approval of Symvess for arterial injury repair has been accepted for approval by the Israel Ministry of Health. The Ministry of Health has set a 180-working-day review period for the MAA due to the existing Food and Drug Administration (FDA) approval of Symvess in extremity vascular injury.

- **Major Purchase Commitment for Clinical Evaluation and Outreach Program in the Kingdom of Saudi Arabia**: In March 2026 Humacyte received a minimum purchase commitment of $1.475 million of Symvess to facilitate a clinical

evaluation and outreach program in hospitals within the Kingdom of Saudi Arabia (KSA). The planned clinical evaluation program is to be conducted in parallel with ongoing negotiations with a KSA-based entity for establishment of a joint venture and license to commercialize Symvess within the country.

- **New U.S. Department of Defense Funding for Procurement of Bioengineered Blood Vessels:** The FY 2026 U.S. Department of Defense Appropriations Act includes dedicated funding to support the evaluation and incorporation of biologic vascular repair technologies for the warfighters suffering from traumatic vascular injuries. The Company is working with leaders in the military and the Pentagon to ensure that American service personnel will have access to Symvess.

ATEV in Dialysis Approaching Major Milestone

- **ATEV V012 Hemodialysis Interim Results**: A total of 120 patients have been enrolled to date in the V012 Phase 3 clinical trial, which is designed to assess the efficacy and safety of the ATEV for hemodialysis access in comparison to AV fistulas in female patients. An interim analysis on the first 80 patients to reach one-year of follow-up is being conducted now, and top-line interim results are expected to be available for reporting June 11, 2026 at the Society of Vascular Surgery's (SVS) Vascular Annual Meeting (VAM) in Boston. Subject to these interim results, Humacyte's plan is to submit a supplemental BLA in the second half of 2026, including data from V012 and the V007 Phase 3 pivotal studies, to add hemodialysis as an indication for the ATEV.

- **Hosted a Virtual KOL Event to Discuss ATEV for Arteriovenous (AV) Access for Hemodialysis:** The April 2026 event featured Prabir Roy-Chaudhury MD, PhD, FASN (University of North Carolina (UNC) Kidney Center, Salisbury VA Medical Center), and Mohamad A. Hussain, MD, PhD, RPVI, FAHA, FRCSC, FACS (Brigham & Women's Hospital, Center for Surgery and Public Health, Harvard Medical School), who joined company management to discuss the unmet need and current surgical access landscape for the nearly 500,000 U.S. patients currently on hemodialysis. A replay is available here.

Pipeline Progress

- **Coronary Tissue Engineered Vessel (CTEV) Progresses Toward First Human Study**: Humacyte plans to advance CTEV into first-in-human study in coronary artery bypass grafting (CABG) and submitted an Investigational New Drug (IND) application to the FDA. To support this planned study, Humacyte has completed the first large-scale manufacturing lot of CTEV in its commercial-scale production facilities, and plans to commence the study in the 2nd half of 2026 upon clearance by the FDA.

Corporate Update

- **Focus on Top Business Objectives While Reducing Spend in 2026**: In May 2026 Humacyte implemented a restructuring of its workforce by to reduce total headcount approximately 45 employees, by a reduction in force and by deferment of planned hires. Other operating expenses were also trimmed, reflecting the successful completion of multiple technical and clinical projects over the past year. These reductions have been done thoughtfully, and Humacyte has retained personnel, resources and initiatives to meet its key corporate goals and milestones. These key corporate goals include advancing the U.S. and global commercial launch of Symvess; completion of the V012 Phase 3 pivotal trial of the ATEV in hemodialysis; the planned filing of a supplemental BLA with the FDA in the hemodialysis indication; and the commencement of a human study of CTEV in CABG. The reorganization has maintained and grown the support for Humacyte's commercial mission, while taking advantage of successfully completed initiatives in the technical sphere that have allowed the Company to reduce operating costs while maintaining a key focus on medical education, sales and marketing. The Company estimates that it will incur aggregate charges of approximately $0.8 million representing one-time cash expenditure for severance and other employee termination benefits, of which the majority is expected to be incurred during the second quarter of 2026. Humacyte estimates net savings due to the workforce reductions and operating cost reductions, net of termination severance and benefits, totaling approximately $14.3 million during the remainder of 2026.

For uses other than the FDA approval in the extremity vascular trauma indication, the ATEV is an investigational product and has not been approved for sale by the FDA or any other regulatory agency. The CTEV is an investigational product and has not been approved for sale by the FDA or any other regulatory agency.

First Quarter 2026 Financial Highlights

- Commercial sales of Symvess were $0.5 million, or 29 units, in the first quarter of 2026 compared to $0.1 million, or five

units, in the first quarter of 2025. Contract revenue from a research collaboration with a large medical technology company was two thousand dollars in the first quarter of 2026 compared to $0.4 million in the first quarter of 2025, the decrease related to the completion of this phase of the collaboration.

- Cost of goods sold was $ 2.0 million for the first quarter of 2026, as compared to $0.1 million for the first quarter of 2025. In the first quarter of 2026, $0.2 million of cost of goods sold related to the cost of units recorded as sales revenue during the period, and the remainder was primarily comprised of a $1.6 million inventory reserve recorded to reduce certain inventory balances to their estimated net realizable value, as well as overhead related to unused production capacity which was recorded as an expense in the period.

- Research and development expenses for the first quarter of 2026 were $19.5 million, compared to $15.4 million for the first quarter of 2025. The increase related to $4.3 million in material costs, primarily from non-commercial manufacturing runs associated with the CTEV and process improvement designed to reduce cost of goods sold going forward.

- General and administrative expenses for the first quarter of 2026 were $7.9 million, consistent with the $8.1 million incurred for the first quarter of 2025.

- Other net income was $11.3 million for the first quarter of 2026, compared to $62.3 million for the first quarter of 2025. The decrease in 2026 of other net income compared to the prior year period resulted primarily due to a decrease in the non-cash income from the remeasurement of the contingent earnout liability associated with the Company's August 2021 merger with Alpha Healthcare Acquisition Corp.

- Net loss was $17.6 million for the first quarter of 2026, compared to net income of $39.1 million for the first quarter of 2025. The increase in 2026 net loss compared to the prior year period was primarily due to the decrease in the non-cash income from the remeasurement of the contingent earnout liability described above.

- The Company had cash, cash equivalents and restricted cash of $48.9 million as of March 31, 2026. Total net cash used was $2.0 million for the first three months of 2026, compared to net cash provided of $17.9 million for the first three months of 2025. The increase in net cash used for the first quarter of 2026 resulted from $47.0 million in net proceeds from a public offering completed in March 2025, partially offset by $23.3 million in net proceeds from sales of shares during 2026.

Conference Call and Webcast Details

Title:	Humacyte First Quarter 2026 Financial Results and Corporate Update
Date:	May 13, 2026
Time:	8:00 AM Eastern Time
Conference Call Details:	1-877-704-4453 (U.S. Investors Dial) 1-201-389-0920 (International Investors Dial) 13760221 (Conference ID)
Call me™ Feature:	Click Here
Webcast:	Click Here

A replay of the webcast will be available following the conclusion of the live broadcast and will be accessible on the investors section of the Company's website for at least 30 days.

INDICATION

Symvess is an acellular tissue engineered vessel indicated for use in adults as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and autologous vein graft is not feasible.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: GRAFT FAILURE

Loss of Symvess integrity due to mid-graft rupture or anastomotic failure can result in life threatening hemorrhage.

CONTRAINDICATIONS

DO NOT use Symvess in patients who have a medical condition that would preclude long-term antiplatelet therapy (such as aspirin or clopidogrel) after resolution of acute injuries.

WARNINGS AND PRECAUTIONS

- **Graft Rupture**

Vascular graft rupture has occurred in patients treated with Symvess. Advise patients that arterial bleeding can be life-threatening and to seek emergent medical evaluation for any signs or symptoms of graft rupture such as bleeding, pain and swelling in the extremity, or signs of extremity ischemia.

- **Anastomotic Failure**

Anastomotic failure has occurred in patients treated with Symvess. In clinical studies of Symvess, anastomotic failure occurred within the first 36 days post-implantation. Monitor patients for signs of anastomotic failure such as pain and swelling at the surgical site, decreasing hemoglobin or other signs and symptoms of bleeding. Advise patients to seek urgent medical evaluation if they have any signs or symptoms that may be indicative of anastomotic failure such as bleeding, swelling or worsening pain at the surgical site or changes in color of overlying skin.

- **Thrombosis**

Thrombosis has occurred in patients treated with Symvess. In clinical trials of Symvess, patients received antiplatelet therapy following implantation of Symvess to reduce the risk of thrombosis. The risk of thrombosis may increase in patients who discontinue antiplatelet therapy. Anti-platelet therapy is recommended following treatment with Symvess.

- **Transmission of Infectious Diseases**

Symvess is manufactured using cells and reagents that may transmit infectious diseases or infectious agents. The cells used in the manufacture of Symvess are derived from a donor who met the donor eligibility requirements for transmissible infectious diseases which includes screening and testing of risks associated with human immunodeficiency virus 1 (HIV-1), human immunodeficiency virus 2 (HIV-2), hepatitis B virus (HBV), hepatitis C virus (HCV), and syphilis (Treponema pallidum). The cell banks are tested negative for human and animal viruses, retroviruses, bacteria, fungi, yeast, and mycoplasma. While all animal-derived reagents are tested for animal viruses, bacteria, fungi, and mycoplasma before use, these measures do not eliminate the risk of transmitting these or other transmissible infectious diseases and disease agents. Fetal bovine serum is sourced to minimize the risk of transmitting a prion protein that causes bovine spongiform encephalopathy and the cause of a rare fatal condition in humans called variant Creutzfeldt-Jakob disease. No transmissible agent infections have been reported during clinical testing.

ADVERSE REACTIONS

The most common adverse reactions (occurring at ≥ 10%), were vascular graft thrombosis, pyrexia (fever) and pain.

Please see full Prescribing Information at www.symvess.com, including Boxed Warning, for Symvess.

About Humacyte

Humacyte, Inc. (Nasdaq: HUMA) is developing a disruptive biotechnology platform to deliver universally implantable bioengineered human tissues, advanced tissue constructs, and organ systems designed to improve the lives of patients and transform the practice of medicine. The Company develops and manufactures acellular tissues to treat a wide range of diseases, injuries, and chronic conditions. Humacyte's Biologics License Application for the acellular tissue engineered vessel (ATEV) in the vascular trauma indication was approved by the FDA in December 2024. ATEVs are also currently in late-stage clinical trials targeting other vascular applications, including arteriovenous (AV) access for hemodialysis and peripheral artery disease (PAD). Preclinical development is also underway in coronary artery bypass grafts, pediatric heart surgery, treatment of type 1 diabetes, and multiple novel cell and tissue applications. Humacyte's 6mm ATEV for AV access in hemodialysis was the first product candidate to receive the FDA's Regenerative Medicine Advanced Therapy (RMAT) designation and has also received FDA Fast Track designation. Humacyte's 6mm ATEV for urgent arterial repair following extremity vascular trauma and for advanced PAD also have received RMAT designations. The ATEV received priority designation for the treatment of vascular trauma by the U.S. Secretary of Defense. For more information, visit www.Humacyte.com.

Forward-Looking Statements

This press release contains forward-looking statements that are based on beliefs and assumptions and on information currently available. In some cases, you can identify forward-looking statements by the following words: "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements involve risks, uncertainties, and other factors that may cause actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this press release, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. Forward-looking statements in this press release include, but are not limited to, our plans and ability to commercialize Symvess and, if approved by regulatory authorities, our product candidates, successfully and on our anticipated timelines; the degree of market acceptance of and the availability of third-party coverage and reimbursement for Symvess and, if approved by regulatory authorities, our product candidates; our ability to manufacture Symvess and, if approved by regulatory authorities, our product candidates in sufficient quantities to satisfy our clinical trial and commercial needs; the anticipated benefits of our ATEVs relative to existing alternatives; our plans and ability to execute product development, process development and preclinical development efforts successfully and on our anticipated timelines; our ability to design, initiate and successfully complete clinical trials and other studies for our product candidates and our plans and expectations regarding our ongoing or planned clinical trials; the anticipated characteristics and performance of our ATEVs; the implementation of our business model and strategic plans for our business; our ability to execute and achieve the expected benefits of our cost-saving measures and whether our efforts will result in further actions or additional asset impairment charges that adversely affect our business; the timing and expected benefits of the commitment to purchase Symvess to facilitate a clinical evaluation and outreach program in the KSA; our ability to realize the benefits of the DoD's funding in the DoD Appropriations Act; and the timing or likelihood of regulatory filings, acceptances and approvals. We cannot assure you that the forward-looking statements in this press release will prove to be accurate. These forward-looking statements are subject to a number of significant risks and uncertainties that could cause actual results to differ materially from expected results, including, among others, changes in applicable laws or regulations, the possibility that Humacyte may be adversely affected by other economic, business, and/or competitive factors, and other risks and uncertainties, including those described under the header "Risk

Factors" in our Annual Report on Form 10-K for the year ended December 31, 2024 and Form 10-Q for the quarter ended June 30, 2025, each filed by Humacyte with the SEC, and in future SEC filings. Most of these factors are outside of Humacyte's control and are difficult to predict. Furthermore, if the forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. Except as required by law, we have no current intention of updating any of the forward-looking statements in this press release. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this press release.

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Humacyte, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

(unaudited)

(in thousands except for share and per share amounts)

	Three Months Ended March 31,	
	2026	**2025**
Revenue:		
Product revenue, net	$ 493	$ 147
Contract revenue	2	370
Total revenue	495	517
Operating expenses:		
Cost of goods sold	2,038	147
Research and development	19,462	15,418
General and administrative	7,930	8,136
Total operating expenses	29,430	23,701
Loss from operations	**(28,935)**	**(23,184)**
Other income, net:		
Change in fair value of contingent earnout liability	4,732	49,731
Other income, net	6,584	12,592
Total other income, net	11,316	62,323
Net (loss) income and comprehensive (loss) income	**$ (17,619)**	**$ 39,139**
Net (loss) income per share, basic	$ (0.09)	$ 0.28
Weighted-average shares outstanding, basic	197,846,786	131,496,877
Net (loss) income per share, diluted	$ (0.09)	$ 0.28
Weighted-average shares outstanding, diluted	197,846,786	131,759,302

Humacyte, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands)

	March 31, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 48,539	$ 50,497
Inventory, net	9,920	13,589
Prepaid expenses and other current assets	5,138	3,709
Total current assets	63,597	67,795
Restricted cash	209	209
Property and equipment, net	17,381	18,544
Finance lease right-of-use assets, net	28,698	29,146
Other long-term assets	672	672
Total assets	**$ 110,557**	**$ 116,366**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,082	$ 5,404
Accrued expenses	8,677	10,540
Other current liabilities	2,428	2,428
Total current liabilities	16,187	18,372
Long-term debt	35,871	35,444
Contingent Earnout Liability	6,760	11,492
Common stock warrant liabilities	10,836	19,392
Finance lease obligation, net of current portion	27,602	26,974
Other long-term liabilities	1,677	1,583
Total liabilities	**98,933**	**113,257**
Stockholders' equity:		
Common stock and additional paid-in capital	756,091	729,957
Accumulated deficit	(744,467)	(726,848)
Total stockholders' equity	**11,624**	**3,109**
Total liabilities and stockholders' equity	**$ 110,557**	**$ 116,366**

Humacyte

Source: Humacyte, Inc