Humacyte Announces Fourth Quarter and Year End 2025 Financial Results and Provides Business Update

- Total revenues from sales and research collaborations were $0.5 million for fourth quarter and $2.0 million for full year -

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

- Submitted of a Marketing Authorization Application with the Israel Ministry of Health -

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

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

- Conference call today at 8:00 am ET -

DURHAM, N.C., March 27, 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 fourth quarter and year ended December 31, 2025, and provided a business update.

“We continued to execute our U.S. market launch of Symvess, and in parallel have taken major steps to expand the commercialization of the product to international markets,” said Laura Niklason, M.D., Ph.D., Founder and Chief Executive Officer of Humacyte. “Awareness and usage among surgeons continue to grow, with product sales totaling $0.4 million for fourth quarter and $1.4 million for the full year. We are pleased that the U.S. Department of Defense has dedicated funding for evaluation and incorporation of new biologic vascular repair technologies, and we look forward to working with leaders in our military and the Pentagon to ensure that American service personnel will have access to Symvess. International interest in Symvess is highlighted by a $1.475 million purchase commitment to enable the education of surgeons and the evaluation of Symvess by hospitals within the Kingdom of Saudi Arabia. We have also submitted a Marketing Authorization Application with the Ministry of Health of the State of Israel for Symvess for arterial trauma repair.”

“We are also close to reaching an exciting milestone, and in the second quarter of 2026 expect to announce the top-line interim result from our V012 Phase 3 study of the acellular tissue engineered vessel (ATEV) in hemodialysis access in women,” continued Dr. Niklason. “This milestone moves us closer to our planned BLA filing for the ATEV in the hemodialysis indication in the second half of 2026. In addition, our earlier-stage pipeline continues to advance, highlighted by our plans to progress the coronary tissue engineered vessel (CTEV) into a human trial in CABG in the second half of 2026. To support this planned trial, we initiated the first large-scale manufacturing lot of CTEV in our commercial-scale production facilities during the first quarter of 2026.”

Fourth Quarter 2025 and Recent Corporate Highlights

Symvess U.S. and International Commercialization

VAC Approval Process and Sales: There are now a total of 27 Value Analysis Committee (VAC) approvals of the Symvess. Furthermore, an additional 43 VACs are currently conducting their review process. To date, 27 hospitals have ordered Symvess, with the majority placing re-orders.

- **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 enable the education of surgeons and the evaluation of Symvess by 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 (DoD) 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.

- **Submitted Marketing Authorization Application for Symvess in Israel:** In March 2026 Humacyte submitted a Marketing Authorization Application (MAA) with the Ministry of Health of the State of Israel for approval of Symvess for arterial trauma repair. In response to requests from surgeons, Humacyte is also pursuing a mechanism for making Symvess available in Israel on a hospital-by-hospital basis in advance of MAA approval.

Symvess Expanded Results

- **Durability of Symvess Highlighted in Two Long-Term Efficacy and Safety Publications:** Long-term data from the V005 Phase 2/3 study were published in December 2025 in the *Journal of Vascular Surgery Cases, Innovations and Techniques.* Symvess was observed to maintain long-term structural integrity, exhibit low infection rates, and support high

rates of limb salvage in patients who were followed for up to 36 months in data from the Company's V005 trial. In addition, an October 2025 publication in Oxford Academic's *Military Medicine* described positive long-term results from a humanitarian program using Symvess to treat wartime vascular injuries in Ukraine. The paper reported on 17 trauma patients with wartime extremity injuries who were treated with Symvess and were followed for up to 18 months. These wartime patients were observed to have a high Symvess patency rate of 87.1%, along with 100% limb salvage, and zero cases of conduit infection, pointing to the durability of Symvess in treatment of real-world combat injuries.

- **New Data Comparing Symvess to Autologous Vein Published in *Trauma Surgery & Acute Care***: A new study comparing clinical outcomes of Symvess to autologous vein in the treatment of extremity arterial trauma was published in the American Association for the Surgery of Trauma (AAST)'s *Trauma Surgery & Acute Care Open Journal* in October 2025. In comparison to pre-existing patients in a trauma registry who were treated with autologous vein, patients treated with Symvess were observed to experience similar short-term outcomes for patency, limb salvage, and infection.

ATEV in Hemodialysis Indication Progresses Toward Planned 2026 BLA Filing

- **Positive V007 Phase 3 Study Two-Year Results in Hemodialysis Highlighted at *Kidney Week 2025* Conference**: Positive two-year results from the V007 Phase 3 trial of the ATEV in hemodialysis patients were presented in November 2025 at the American Society of Nephrology's *Kidney Week 2025*, which is the world's premier nephrology meeting. The ATEV demonstrated superior duration of use over 24 months compared to autogenous fistula in high-need subgroups, such as women, having historically poor outcomes with AV fistula procedures. The significantly longer duration of ATEV use - six months greater than arteriovenous fistula during the first two years - could greatly reduce reliance on catheters for hemodialysis access, a major cause of complications, morbidity and costs for hemodialysis patients.

- **Major ATEV Hemodialysis Milestone Upcoming in 2nd Quarter 2026**: A total of 116 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 in comparison to AV fistulas in female patients. An interim analysis will be conducted when the first 80 patients reach one-year of follow up, and top-line interim results are expected to be reported by early June 2026. 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.

Pipeline Progress

- **Coronary Tissue Engineered Vessel (CTEV) Progresses Toward First Human Study**: In published studies, the CTEV was observed to sustain blood flow, recellularize with the animals' host cells, and remodel to bring the diameter of the CTEV in line with the animals' own native coronary artery. Humacyte plans to advance CTEV into first-in-human study in CABG and has submitted an Investigational New Drug (IND) application to the FDA. To support this planned study Humacyte initiated the first large-scale manufacturing lot of CTEV in its commercial-scale production facilities during the first quarter of 2026 and plans to commence the clinical trial in the second half of 2026 upon completion of manufacturing and clearance by the FDA.

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.

Fourth Quarter 2025 Financial Highlights

- There was $0.5 million in revenue for the three months ended December 31, 2025, of which $0.4 million related to U.S. sales of 25 Symvess units. The remaining $0.1 million resulted from a research collaboration with a large medical technology company to evaluate the potential use of Humacyte's bioengineered human tissue in specific cardiovascular and vascular applications. Revenue for the year ended December 31, 2025 was $2.0 million, of which $1.4 million related to U.S. sales of 61 Symvess units and $0.6 million resulted from the research collaboration. There was no revenue for either the three months or year ended December 31, 2024.

- Cost of goods sold was $9.1 million and $9.7 million for the three months and year ended December 31, 2025, respectively. Cost of sales for both periods includes a reserve of $8.9 million to reduce inventory to its net realizable value as a consistent sales history has not yet been established. Cost of sales also include overhead related to unused production capacity that was recorded as an expense in the applicable period. There was no cost of goods sold for either the three months or year ended December 31, 2024.

- Research and development expenses were $14.6 million for the three months ended December 31, 2025 compared to $20.7 million for the three months ended December 31, 2024, and were $69.3 million for the year ended December 31,

2025 compared to $88.6 million for the year ended December 31, 2024. The decrease reflects the transition from development activities to commercial operations following the FDA approval of Symvess in the vascular trauma indication in December 2024, including the current-year allocation of manufacturing costs to inventory and cost of sales, costs that in the prior year were included within research and development expenses. In addition, during 2025, clinical study costs decreased due to the completion or winding down of certain clinical programs, including the V005 study in trauma.

- Selling, general and administrative expenses were $7.6 million for the three months ended December 31, 2025 compared to $7.4 million for the three months ended December 31, 2024, and were $31.2 million for the year ended December 31, 2025 compared to $25.8 million for the year ended December 31, 2024. The increase in 2025 expenses compared to the prior year periods resulted primarily from the U.S. commercial launch of the Symvess in the vascular trauma indication, including increased personnel expenses.

- Other net income (expense) for the three months ended December 31, 2025 was net income of $6.0 million compared to $7.1 million for the three months ended December 31, 2024, and other net income was $67.3 million for the year ended December 31, 2025 compared to other net expense of $34.3 million for the year ended December 31, 2024. The increase in other net income for the year ended December 31, 2025 primarily resulted from a $98.2 million increase in non-cash gains consisting of a $59.5 million fair value remeasurement of the contingent earnout liability and $38.8 million fair value remeasurement of derivative liabilities, partially offset by $22.3 million loss on extinguishment of debt.

- Net loss was $24.8 million for the three months ended December 31, 2025 compared to net loss of $20.9 million for the three months ended December 31, 2024, and net loss was $40.8 million for the year ended December 31, 2025, compared to net loss of $148.7 million for the year ended December 31, 2024. The increase in net loss for the three months ended December 31, 2025 primarily resulted from the inventory reserve, partially offset by a decrease in operating expenses. The decrease in net loss for the year ended December 31, 2025 resulted primarily from the increase in other net income and the decrease in operating expenses, partially offset by the inventory reserve.

- The Company reported cash and cash equivalents of $50.5 million as of December 31, 2025. Subsequent to December 31, 2025, the Company raised an additional $18.4 million in net proceeds from a registered direct offering of common stock, and net proceeds of $4.6 million from the sale of common stock through its at-the-market facility. In December 2025 Humacyte entered into a credit facility with an affiliate of Avenue Capital Group, providing up to $77.5 million in principal amount of new financing. The credit agreement, which has a term of four years, includes an initial tranche of $40 million fully funded at close, and an additional two tranches of up to an aggregate of $37.5 million available to Humacyte, subject to the satisfaction of certain revenue, regulatory approvals, liquidity conditions. Proceeds from the initial $40 million tranche were used primarily to retire Humacyte's then-existing revenue interest purchase agreement. Total net cash used was $44.4 million for the year ended December 31, 2025, compared to total cash provided of $14.5 million for the year ended December 31, 2024. The increase in net cash used in 2025 compared to 2024 resulted primary from the termination of the revenue interest purchase agreement in 2025 and an additional debt draw during 2024 that did not occur in 2025.

Conference Call and Webcast Details

Title:	Humacyte Fourth Quarter 2025 Financial Results and Corporate Update
Date:	March 20, 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) 13758663 (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, including for our V007 and V012 Phase 3 clinical trials; the anticipated characteristics and performance of our ATEVs and the public perception thereof; the implementation of our business model and strategic plans for our business; 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, competitive and/or reputational 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, the Form 10-Q for the quarter ended September 30, 2025 and the Form 8-K dated March 19, 2026, 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		Year Ended December 31,	
	2025	**2024**	**2025**	**2024**
Revenue:				
Product revenue, net	$ 439	$ —	$ 1,389	$ —
Contract revenue	28	—	649	—
Total revenue	467	—	2,038	—
Operating expenses:				
Cost of goods sold	9,082	—	9,702	—
Research and development	14,605	20,656	69,302	88,599
General and administrative	7,616	7,432	31,171	25,799
Total operating expenses	31,303	28,088	110,175	114,398
Loss from operations	**(30,836)**	**(28,088)**	**(108,137)**	**(114,398)**
Other income (expense), net:				
Change in fair value of contingent earnout liability	10,315	5,608	59,469	(33,045)
Other income (expense) (net)	(4,283)	1,540	7,835	(1,258)
Total other income (expense), net	6,032	7,148	67,304	(34,303)
Net loss and comprehensive loss	**$ (24,804)**	**$ (20,940)**	**$ (40,833)**	**$ (148,701)**
Net loss per share, basic and diluted	$ (0.13)	$ (0.16)	$ (0.26)	$ (1.26)
Weighted-average shares outstanding, basic and diluted	186,785,182	126,983,464	158,160,468	118,479,097

Humacyte, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands)

	As of December 31,	
	2025	**2024**
Assets		
Current assets:		
Cash and cash equivalents	$ 50,497	$ 44,937
Inventory, net	13,589	—
Prepaid expenses and other current assets	3,709	2,922
Total current assets	67,795	47,859
Restricted cash	209	50,209
Property, plant and equipment, net	18,544	23,063
Finance lease right-of-use assets, net	29,146	15,490
Other long-term assets	672	1,251
Total assets	**$ 116,366**	**$ 137,872**
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 5,404	$ 4,490
Accrued expenses	10,540	11,424
Other current liabilities	2,428	4,040
Total current liabilities	18,372	19,954
Long-term debt	35,444	—
Contingent earnout liability	11,492	70,961
Revenue interest liability	—	63,354
Common stock warrant liabilities	19,392	19,254
Finance lease obligation, net of current portion	26,974	3,620
Other long-term liabilities	1,583	3,398
Total liabilities	**113,257**	**190,541**
Stockholders' equity (deficit)		
Common stock and additional paid-in capital	729,957	633,346
Accumulated deficit	(726,848)	(686,015)
Total stockholders' equity (deficit)	3,109	(52,669)
Total liabilities and stockholders' equity	**$ 116,366**	**$ 137,872**

Source: Humacyte, Inc