Humacyte Announces Second Quarter 2026 Financial Results and Provides Business Update

– Breakthrough results from V012 dialysis access Phase 3 study, where ATEV was observed to outperform AV fistula; supplemental Biologic License Application (sBLA) for dialysis access to be filed with the Food and Drug Administration (FDA) during the second half of 2026 –

– FDA accepted IND for first-in-human clinical study of CTEV for CABG with Phase 2a study expected to start Q3 2026 –

– Second quarter sales of Symvess® were $0.4 million in 2026 compared to $0.1 million in 2025 –

– Conference call today at 8:00 am ET –

DURHAM, N.C., Aug. 12, 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 second quarter ended June 30, 2026 and provided a business update.

“Our second quarter and recent weeks have been a transformative period for Humacyte and our pipeline expansion, led by the presentation of breakthrough top-line interim results from our V012 Phase 3 trial in female dialysis access patients at the Society of Vascular Surgery’s (SVS) *Vascular Annual Meeting (VAM)* in Boston,” said Laura Niklason, M.D., Ph.D., Founder and Chief Executive Officer of Humacyte. “Results from this trial exceeded our expectations, and our acellular tissue engineered vessel (ATEV) outperformed autologous arteriovenous (AV) fistula, the current standard of care for patients on dialysis. We look forward to using this data to file a supplemental BLA with the FDA later this year. We are also pleased that the FDA recently accepted our Investigational New Drug (IND) application for our coronary tissue engineered vessel (CTEV), and plan to initiate a Phase 2a study in coronary artery bypass grafting (CABG) during the third quarter. No new off-the-shelf conduits have been introduced for CABG in the past 40 years, and our preclinical results suggest that the CTEV may be a promising off-the-shelf alternative to saphenous vein grafts in CABG.”

The Company’s operational progress was highlighted by Jim Mercadante, Humacyte’s recently appointed Chief Commercial Officer, who said, “We intentionally focused our second quarter on rebuilding our commercial effort for Symvess, along with implementing an enterprise-wide transformation. Our goal was to drive hospital product adoption and product usage, and to better position Humacyte for sustained growth.” He then addressed the Company’s evolution, “We have remodeled our commercial team to ensure members have relevant longstanding relationships in the vascular surgery space. Beyond team capabilities, we have refined introductory pricing incentive programs, professional-to-professional education, and streamlined our value analysis committee process to drive Symvess adoption. These combined initiatives are creating a growth platform to drive approvals, utilization and revenue growth for this category-defining product. As we move into the second half of 2026, we are already seeing results from this approach with influential hospitals adopting Symvess and utilization strengthening across the board.”

Second Quarter 2026 and Recent Corporate Highlights

Breakthrough Phase 3 Results of ATEV in Dialysis Support Planned BLA Filing

- **Superior Results Reported from V012 Phase 3 Study in Women:** In June 2026, breakthrough results from the V012 Phase 3 trial in female dialysis patients were presented at the Society for Vascular Surgery's *Vascular Annual Meeting*. In a pre-specified interim analysis of the first 80 patients from the study, the ATEV was observed to outperform AV fistula, the current standard of care, significantly reducing usage of infection-prone catheters. Women who received the ATEV achieved an average of 91 more catheter-free days than those receiving AV fistula and the difference was statistically significant (p=0.00070), meeting the primary efficacy endpoint of the study. Infections were also less common in patients receiving the ATEV, and patients receiving the ATEV had 6 infections per 100 patient years compared with 23 per 100 patient years for patients who received an AV fistula. Women experience up to two times the rate of fistula maturation failure compared to men, leaving many reliant on infection-prone catheters. The V012 study, focused on female dialysis patients, demonstrates that a biologic conduit has the potential to address this longstanding disparity.

- **Planned BLA Filing**: The above V012 results, combined with results from the V007 Phase 3 trial reported previously, suggest that the ATEV could represent the first major advance in dialysis access in decades, offering surgeons an alternative option for patients whose risk factors make AV fistula maturation difficult. Based on these results, Humacyte plans to submit a supplemental Biologics License Application to the FDA in the second half of 2026.

- **Appointed Key Nephrologists as Advisors to Prepare for Planned Dialysis Commercialization:** Robert J. (Rob) Kossmann, MD, FACP, FASN and Prabir Roy-Chaudhury, MD, PhD, FASN have been appointed as advisors to Humacyte. These leading nephrologists will help prepare for the planned commercialization of the ATEV in dialysis access, if approved by the FDA, contribute to the development of health economic, reimbursement and market access strategies as well as provide peer-to-peer scientific support and medical education.

- **Virtual KOL Event Highlights Need for ATEV in AV Access:** 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 Humacyte management to discuss the unmet need and current surgical access landscape for the nearly 500,000 U.S. patients currently on dialysis.

First Human Study in CABG

- **Coronary Tissue Engineered Vessel (CTEV) Progresses Toward First Human Study**: The FDA has accepted the IND application for a first-in-human clinical study of the CTEV in coronary artery bypass grafting. Humacyte plans to initiate a Phase 2a study of the CTEV in CABG patients during the current quarter. To support this planned study, Humacyte has completed the first large-scale manufacturing lot of CTEV in its commercial-scale production facilities.

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 is overseeing 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. Todd E. Rasmussen as Chief Surgical Officer:** Dr. Rasmussen joined 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 is focusing on providing professional-to-professional scientific support, medical education, and technical insights to surgeons and other healthcare providers. He brings 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 was accepted for review by the Israel Ministry of Health in April 2026. The Ministry of Health set a 180-working-day review period for the MAA due to the existing FDA approval of Symvess in extremity vascular injury.

- **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.

Corporate Update

- **Public Offering**: In June 2026 Humacyte raised aggregate gross proceeds of $57.5 million from a public offering of its common stock. Humacyte intends to use the net proceeds from the offering to fund the commercialization of Symvess, the planned filing of a Biologics License Application supplement in a dialysis indication, and related activities, the development of the product candidates in its pipeline, and for working capital and general corporate purposes.

- **Cost Reduction**: In May 2026, Humacyte implemented a restructuring of its workforce to reduce total headcount by approximately 45 employees through a reduction in force and by deferment of planned hires. 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 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.

Second Quarter 2026 Financial Highlights

- Commercial sales of Symvess were $0.4 million in the second quarter of 2026 compared to $0.1 million in the second quarter of 2025. For the six months ended June 30 2026, commercial sales of Symvess were $0.9 million compared to $0.2 million for the six months ended June 30, 2025. There was no meaningful contract revenue in either the three or six months ended June 30, 2026 due to completion of a research collaboration project in the prior year, compared to $0.2 million and $0.6 million for the three and six months ended June 30, 2025, respectively.

- Cost of goods sold was $1.2 million for the second quarter of 2026 compared to $0.2 million for the second quarter of 2025. In the second 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 $0.7 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. Cost of goods sold was $3.3 million for the six months ended June 30, 2026 compared to $0.4 million for the six months ended June 30, 2025. During the six months ended June 30, 2026, $0.5 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 $2.3 million inventory reserve and expenses related to unused production capacity.

- Research and development expenses for the three months and six months of 2026 were $18.1 million and $37.6 million, respectively, compared to $22.0 million and $37.4 million for the same periods in 2025. The decrease in research and development expenses during the second quarter of 2026 was primarily due to a reduction in non-commercial manufacturing runs and reduced clinical trial expenses.

- General and administrative expenses were $8.0 million and $16.0 million for the three months and six months ended June 30, 2026, respectively, consistent with the $7.8 million and $16.0 million for the same periods in 2025.

- Other net income (expense) was net expense of $9.8 million and net income of $1.5 million for the three months and six months ended June 30, 2026, respectively, compared to net expense of $7.9 million for the three months ended June 30, 2025 and other net income of $54.4 million for the six months ended June 30, 2025. The increase in other net expense for the three months ended June 30, 2026 and the decrease in other net income for the six months ended June 30, 2026 compared to the prior year periods resulted primarily from the non-cash remeasurement of the contingent earnout liability and other derivative liabilities.

- Net loss was $36.8 million and $54.4 million for the three months and six months ended June 30, 2026, respectively, compared to a net loss of $37.7 million for the three months ended June 30, 2025 and net income of $1.5 million for the six months ended June 30, 2025. The increase in net loss for the six months ended June 30, 2026 compared to the prior year period was primarily due to the non-cash remeasurement of the contingent earnout liability described above.

- The Company had cash, cash equivalents and restricted cash of $80.3 million as of June 30, 2026. Total net cash provided was $29.4 million for the first six months of 2026, compared to total net cash used of $6.9 million for the first six months of 2025. The increase in total net cash provided for the six months ended June 30, 2026 resulted from higher proceeds from sales of common stock and a reduction in net cash used in operations.

Conference Call and Webcast Details

Title:	Humacyte Second Quarter 2026 Financial Results and Corporate Update
Date:	August 12, 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) 13761781 (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, 2025 and Form 10-Q for the quarter ended March 31, 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 June 30,		Six Months Ended June 30,	
	2026	**2025**	**2026**	**2025**
Revenue:				
Product revenue, net	$ 406	$ 100	$ 899	$ 247
Contract revenue	—	201	2	571
Total revenue	406	301	901	818
Operating expenses:				
Cost of goods sold	1,231	213	3,269	360
Research and development	18,144	22,006	37,606	37,424
General and administrative	8,027	7,809	15,957	15,945
Total operating expenses	27,402	30,028	56,832	53,729
Loss from operations	**(26,996)**	**(29,727)**	**(55,931)**	**(52,911**
Other (expense) income, net:				
Change in fair value of contingent earnout liability	(2,718)	(5,470)	2,014	44,261
Other (expense) income, net	(7,088)	(2,461)	(504)	10,131
Total other (expense) income, net	(9,806)	(7,931)	1,510	54,392
Net (loss) income and comprehensive (loss) income	**$ (36,802)**	**$ (37,658)**	**$ (54,421)**	**$ 1,481**
Net (loss) income per share, basic	$ (0.16)	$ (0.24)	$ (0.25)	$ 0.01
Weighted-average shares outstanding, basic	234,182,284	155,437,281	216,114,910	143,533,212
Net (loss) income per share, diluted	$ (0.16)	$ (0.24)	$ (0.25)	$ 0.01
Weighted-average shares outstanding, diluted	234,182,284	155,437,281	216,114,910	143,664,424

Humacyte, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands)

	June 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 79,903	$ 50,497
Inventory, net	6,985	13,589
Prepaid expenses and other current assets	5,899	3,709
Total current assets	92,787	67,795
Restricted cash	209	209
Property and equipment, net	16,170	18,544
Finance lease right-of-use assets, net	28,249	29,146
Other long-term assets	672	672
Total assets	**$ 138,087**	**$ 116,366**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,157	$ 5,404
Accrued expenses	9,273	10,540
Other current liabilities	1,518	2,428
Total current liabilities	14,948	18,372
Long-term debt	36,324	35,444
Contingent Earnout Liability	9,478	11,492
Common stock warrant liabilities	15,651	19,392
Finance lease obligation, net of current portion	28,338	26,974
Other long-term liabilities	2,087	1,583
Total liabilities	**106,826**	**113,257**
Stockholders' equity:		
Common stock and additional paid-in capital	812,530	729,957
Accumulated deficit	(781,269)	(726,848)
Total stockholders' equity	**31,261**	**3,109**
Total liabilities and stockholders' equity	**$ 138,087**	**$ 116,366**

Source: Humacyte, Inc