Humacyte Announces Third Quarter 2025 Financial Results and Provides Business Update

- Total revenues of $753,000 for third quarter, and $1,571,000 for first nine months of 2025, from sales and collaborative research agreement -

- Major advances in pipeline as Humacyte moves closer to planned BLA filing in dialysis and first-in-human studies in cardiac bypass graft surgery –

– IND submitted to the FDA for the CABG indication –

- Symvess™ and pipeline programs highlighted in multiple scientific publications and presentations -

- Conference call today at 8:00 am ET -

DURHAM, N.C., Nov. 12, 2025 (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 third quarter ended September 30, 2025, and provided a business update.

“During the third quarter of 2025 we continued to execute on our U.S. commercial launch of Symvess with sales increasing substantially, totaling $703,000 for third quarter compared to $100,000 in second quarter,” said Laura Niklason, M.D., Ph.D., Founder and Chief Executive Officer of Humacyte. “This significant ramp-up is due to an increased number of individual hospital and healthcare system Value Analysis Committee (VAC) approvals, our recent inclusion in the U.S. Defense Logistics Agency’s Electronic Catalog (ECAT), and the tireless work of our commercial and medical teams in educating the vascular surgery community about the benefits of Symvess.”

“The launch of Symvess in the vascular trauma indication is just the first of the many planned products emerging from our proprietary bioengineering platform, and the advancement of our broader pipeline was supported by multiple events during the quarter,” continued Dr. Niklason. “The acellular tissue engineered vessel (ATEV™) is moving closer to our planned supplemental Biologics License Application (BLA) filing in dialysis access. This planned dialysis indication is supported by positive two-year results from the V007 Phase 3 trial presented last weekend at *Kidney Week 2025,* which is the world’s largest nephrology meeting. For coronary artery bypass grafting (CABG), we published positive results of a preclinical study evaluating our coronary tissue engineered vessel (CTEV) in non-human primates. These results support our plans to advance the CTEV into a human study in CABG in 2026. If successful, the CTEV would be the first novel conduit tested in CABG in the US in decades. Lastly, we expanded our intellectual property estate with the grant of a new U.S. patent for our bioengineered esophagus, complementing our existing intellectual property in urinary conduits and tracheas, all of which can be produced using our proprietary regenerative tissue engineering platform.”

Third Quarter 2025 and Recent Corporate Highlights

Symvess Market Launch and Expanded Clinical Results

- **VAC Approval Process and Sales**: There are now a total of 25 VAC approvals of the Symvess product compared to 13 as of the date of the August 2025 quarterly report. As these VAC approvals include multi-hospital networks, 92 civilian hospitals are now eligible to purchase Symvess. Furthermore, an additional 45 VAC committees are currently conducting their review processes. To date, 16 hospitals have ordered Symvess, with the majority placing re-orders.

- **Publication of Outcomes for Patients with Hospital-Acquired Vascular Complications Treated with Symvess:** A September 2025 publication in the J*ournal of Vascular Surgery* reported that Symvess was observed to have high levels of patency, 100% limb salvage, and zero cases of conduit infection in 12 patients with hospital-acquired iatrogenic injuries or complications of vascular surgical procedures. Complications of surgery and vascular procedures, including iatrogenic injuries, planned oncological tumor resections, and steal syndrome following arteriovenous access placement, are increasingly common in modern medical care, and are reported to comprise close to 30% of patients requiring vascular injury repair.

- **Long-term Results for Ukrainian Patients Published**: 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 publication, titled "Evaluating the Safety and Efficacy of Humacyte Acellular Tissue-Engineered Vessel in a Real-World Combat Setting: A Retrospective Observational Multicenter Study,” 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 patency rate of 87.1%, along with 100% limb salvage, and zero cases of conduit infection, showing 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 experienced similar short-term outcomes for patency, limb salvage, and infection.

ATEV in Dialysis Progresses Toward Planned BLA Filing

- **Positive V007 Phase 3 Study Two-Year Results in Dialysis Highlighted at *Kidney Week 2025* Conference**: Positive two-year results from the V007 Phase 3 trial of the ATEV in dialysis patients were presented in November 2025 at the American Society of Nephrology's *Kidney Week 2025*, which is the premier nephrology meeting. The ATEV was observed to have superior duration of use over 24 months compared to autogenous fistula in high-need subgroups having historically poor outcomes with arteriovenous (AV) fistula procedures. The significantly longer duration of ATEV use could greatly reduce reliance on catheters for dialysis access, a major cause of complications, morbidity and costs for dialysis patients in these high-need subgroups.

- **ATEV Progresses Toward Planned Supplemental BLA Filing**: A total of 109 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 dialysis in comparison to AV fistulas in female patients. An interim analysis is planned when the first 80 patients reach one-year of follow up, and this enrollment threshold was achieved in April 2025. Subject to these interim results, Humacyte's plans to submit a supplemental BLA in the second half of 2026, including data from V012 and the V007 Phase 3 pivotal studies, to add dialysis as an indication for the ATEV.

Pipeline Progress

- **Coronary Tissue Engineered Vessel (CTEV) Progresses Toward First Human Study**: Positive results of a preclinical study evaluating the CTEV as a coronary artery bypass graft conduit in a non-human primate model were published in September 2025 in *JACC: Basic to Translational Science*, which is a specialist journal launched by the Journal of the American College of Cardiology (JACC). In the study, 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 in 2026. In preparation for the trial. Humacyte has submitted an Investigational New Drug (IND) application to the Food and Drug Administration (FDA) for the CABG indication.

- **New U.S. Patent for Bioengineered Esophagus**: Humacyte announced the expansion of its intellectual property for its pipeline products with the grant of a new U.S. Patent covering the composition of a bioengineered esophagus. The patent, titled "Tubular Prostheses (Esophagus)," provides protection into 2041 of key structural and mechanical attributes for its designed use as an esophageal replacement including size, strength, and methods of production. Humacyte's Tubular Prostheses patent family now encompasses claims granted for the composition and methods for engineered trachea, engineered urinary conduit, and engineered esophagus.

Third Quarter 2025 Financial Highlights

- There was $0.8 million in revenue for the three months ended September 30, 2025, of which $0.7 million related to U.S. sales of Symvess. 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 nine months ended September 30, 2025 was $1.6 million, of which $0.9 million related to U.S. sales of Symvess and $0.6 million resulted from the research collaboration. There was no revenue for either the three or nine months ended September 30, 2024.

- Cost of goods sold was $0.3 million and $0.6 million for the three and nine months ended September 30, 2025, respectively, which includes 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 or nine months ended September 30, 2024.

- Research and development expenses were $17.3 million for the three months ended September 30, 2025 compared to $22.9 million for the three months ended September 30, 2024, and were $54.7 million for the nine months ended September 30, 2025 compared to $67.9 million for the nine months ended September 30, 2024. The decrease in research and development expenses for the third quarter of 2025 compared to 2024 primarily related to the capitalization of material and overhead costs associated with the commercial manufacturing of Symvess, and cost reductions implemented during the quarter ended June 30, 2025. The decrease in research and development expenses for the nine months ended September 30, 2025 compared to 2024 resulted primarily from decreased materials costs as the Company began capitalizing expenditures for inventory following the commercial launch of Symvess and the winding down of certain clinical trial programs, partially offset by higher non-commercial production runs.

- Selling, general and administrative expenses were $7.6 million for the three months ended September 30, 2025 compared

to $7.3 million for the three months ended September 30, 2024, and were $23.6 million for the nine months ended September 30, 2025 compared to $18.4 million for the nine months ended September 30, 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 September 30, 2025 was net income of $6.9 million compared to net expense of $9.0 million for the three months ended September 30, 2024, and other net income was $61.3 million for the nine months ended September 30, 2025 compared to other net expense of $41.5 million for the nine months ended September 30, 2024. The increase in other net income for the three and nine months ended September 30, 2025 compared to the prior year periods resulted primarily from the non-cash remeasurement of the contingent earnout liability associated with the Company's August 2021 merger with Alpha Healthcare Acquisition Corp.

- Net loss was $17.5 million for the three months ended September 30, 2025 compared to net loss of $39.2 million for the three months ended September 30, 2024, and net loss was $16.0 million for the nine months ended September 30, 2025, compared to net loss of $127.8 million for the nine months ended September 30, 2024. The decrease in net loss for the three and nine months ended September 30, 2025 compared to the prior year periods was primarily due to the non-cash remeasurement of the contingent earnout liability described above combined with current-period decreases in operating expenses and loss from operations.

- The Company reported cash, cash equivalents and restricted cash of $19.8 million as of September 30, 2025. In addition, subsequent to September 30, 2025, the Company completed the sale of common stock and warrants that resulted in net proceeds of approximately $56.5 million. Total net cash used in operating activities was $78.9 million for the first nine months of 2025, compared to $71.5 million for the first nine months of 2024. The increase in net cash used in operating activities for the first nine months of 2025 compared to the prior year resulted primarily from the buildup in inventory associated with the commercial launch of Symvess, partially offset by a reduced loss from operations.

Conference Call and Webcast Details

Title:	Humacyte Third Quarter 2025 Financial Results and Corporate Update
Date:	November 12, 2025
Time:	8:00 AM Eastern Time
Conference Call Details:	1-877-704-4453 (U.S. Investors Dial) 1-201-389-0920 (International Investors Dial) 13754596 (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.

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.

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.

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 and our CTEVs 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 plans, anticipated timeline and ability to file applications for, and obtain marketing approvals from, the FDA and other regulatory authorities, including the European Medicines Agency, for our ATEVs, CTEVs and product candidates; 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 and our CTEVs; our ability to use our proprietary scientific technology platform to build a pipeline of additional product candidates; the implementation of our business model and strategic plans for our business; and 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. 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 September 30,		Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
Revenue:				
Product revenue, net	$ 703	$ —	$ 950	$ —
Contract revenue	50	—	621	—
Total revenue	753	—	1,571	—
Operating expenses:				
Cost of goods sold	260	—	620	—
Research and development	17,273	22,926	54,697	67,943
Selling, general and administrative	7,610	7,307	23,555	18,367
Total operating expenses	25,143	30,233	78,872	86,310
Loss from operations	**(24,390)**	**(30,233)**	**(77,301)**	**(86,310)**
Other income (expense), net:				
Change in fair value of contingent earnout liability	4,893	(8,489)	49,154	(38,653)
Other income (expense) (net)	1,987	(480)	12,118	(2,798)
Total other income (expense), net	6,880	(8,969)	61,272	(41,451)
Net loss and comprehensive loss	**$ (17,510)**	**$ (39,202)**	**$ (16,029)**	**$ (127,761)**

Net loss per share, basic and diluted	$ (0.11)	$ (0.33)	$ (0.11)	$ (1.10)
Weighted-average shares outstanding, basic and diluted	158,313,290	119,408,565	148,514,044	115,623,616

Humacyte, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands)

	September 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 19,488	$ 44,937
Inventory	18,418	—
Prepaid expenses and other current assets	3,445	2,922
Total current assets	41,351	47,859
Restricted cash	209	50,209
Property and equipment, net	19,857	23,063
Finance lease right-of-use assets, net	29,420	15,490
Other long-term assets	672	1,251
Total assets	**$ 91,509**	**$ 137,872**
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 9,575	$ 4,490
Accrued expenses	10,264	11,424
Revenue interest liability, current portion	3,072	885
Other current liabilities	2,670	3,155
Total current liabilities	25,581	19,954
Revenue interest liability, net of current portion	17,674	63,354
Contingent earnout liability	21,807	70,961
Finance lease obligation, net of current portion	27,155	13,620
Common stock warrant liabilities	3,234	19,254
Other long-term liabilities	809	3,398
Total liabilities	**96,260**	**190,541**
Stockholders' equity (deficit)		
Common stock and additional paid-in capital	697,293	633,346
Accumulated deficit	(702,044)	(686,015)
Total stockholders' equity (deficit)	(4,751)	(52,669)
Total liabilities and stockholders' equity (deficit)	**$ 91,509**	**$ 137,872**

Source: Humacyte, Inc