Humacyte Announces Second Quarter 2025 Financial Results and Provides Business Update

- Total revenues of $301,000 for quarter, and $818,000 for first six months of 2025, from sales and collaborative research agreement -

- 82 civilian hospitals now have VAC approval to purchase Symvess™ -

- ECAT approval makes Symvess available to 35 Military Treatment Facilities and 160 U.S. Department of Veterans Affairs hospitals -

- Conference call today at 8:00 am ET -

DURHAM, N.C., Aug. 11, 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 second quarter ended June 30, 2025, and provided a business update.

“During our second quarter of 2025, we continued to execute on our U.S. commercial launch and now have 82 civilian hospitals eligible to purchase Symvess,” said Laura Niklason, M.D., Ph.D., Founder and Chief Executive Officer of Humacyte. “This is a substantial increase from the five hospitals that were eligible to purchase at our last quarterly update in May. This tremendous increase is due to a combination of individual hospital and healthcare system Value Analysis Committee (VAC) approvals. In addition, our recent inclusion on the Electronic Catalog (ECAT) means that approximately 190 Military Treatment Facilities and U.S. Department of Veterans Affairs (VA) hospitals are also eligible to purchase Symvess. While we encountered some headwinds during the second quarter of 2025 due to unsubstantiated attacks by detractors, we have moved forward and seen an acceleration in VAC approvals in late June and July. Indeed, our July product sales exceeded the total sales recorded during the first half of the year. We were also pleased to achieve our first commercial sale to a U.S. military treatment facility in July, and this facility has since re-ordered the Symvess product. We have great interest in improving the medical options available to healthcare professionals treating military personnel and their families and look forward to advancing our discussions with additional Department of Defense (DOD) hospitals.”

“We were also gratified to see that our V007 trial data was one of only three presentations selected for special mention by the Society of Vascular Surgery in June, and that the Society chose to highlight the strength of the results in their own announcement,” continued Dr. Niklason. “In our V007 trial, the ATEV was observed to have superior functional patency during the first year over the autologous fistula control group not only in the overall study population but in two important subgroups: women, and men with diabetes and obesity. These two groups make up more than half of the dialysis access market and are underserved by the current standard of care, representing a high unmet medical need. We look forward to publication of the results from the V007 Phase 3 clinical trial in a major peer-reviewed medical journal this year.”

Second Quarter 2025 and Recent Corporate Highlights

Symvess Market Launch

- **VAC Approval Process and Sales**: To date, a total of 13 VACs have approved the Symvess product. Since these VAC approvals include multi-hospital networks, 82 civilian hospitals are now eligible to purchase Symvess. Furthermore, an additional 40 VACs are currently conducting their review process. Humacyte has experienced an acceleration in VAC approvals in late June and July 2025, and July product sales of $0.3 million exceeded the sales recorded during the first half of the year. To date, 12 hospitals have ordered Symvess, with multiple facilities re-ordering additional product during the month of July.

- **ECAT Approval**: In July 2025, Symvess was granted ECAT listing approval from the U.S. Defense Logistics Agency. ECAT is an internet system that provides the DOD and other federal agencies with access to manufacturers’ and distributors’ products. The ECAT approval makes Symvess available to healthcare professionals treating military service members, veterans, and other patients receiving care at approximately 35 Military Treatment Facilities and approximately 160 VA hospitals.

- **First Military Treatment Facility Sale**: Following the ECAT approval, the first sale of Symvess to a U.S. Military Treatment Facility was completed in July. The facility is a state-of-the-art medical complex located on a major U.S. military base that provides healthcare to approximately 200,000 active-duty service personnel, retirees, and their family members. Subsequent to the initial shipment, the facility has re-ordered Symvess. We are in active discussions with additional DOD facilities that are expressing interest in purchasing Symvess.

ATEV in Dialysis

- **V007 Phase 3 Study Results in Dialysis Highlighted at Major Vascular Surgery Conference**: Results from the V007 Pivotal Phase 3 clinical trial of the acellular tissue engineered vessel (ATEV™) in arteriovenous (AV) access were presented in a plenary session at the Society for Vascular Surgery Vascular Annual Meeting (VAM25) in June 2025. The V007 clinical trial enrolled a total of 242 patients, of which 110 were described as high-risk of fistula non-maturation – either women, or men having diabetes and obesity. Among this cohort, functional patency at six months and secondary patency at 12 months were significantly higher in ATEV recipients (85.7% and 76.8%, respectively), compared with AV

fistula (51.9% and 46.3%, respectively) (global p-value, p<0.0001). Duration of access usability over the first year was also significantly higher in the ATEV group (8.0 months vs. 4.5 months; p<0.0002).

- **Major Enrollment Milestone in V012 Phase 3 Study in Dialysis**: A total of 100 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 plan is to submit a supplemental Biologics License Application (BLA) in the second half of 2026, including data from V012 and the V007 Phase 3 pivotal studies, to expand the Symvess label to add AV access for hemodialysis as an indication, subject to FDA approval.

Second Quarter 2025 Financial Highlights

- There was $0.3 million in revenue for the three months ended June 30, 2025, of which $0.1 million related to U.S. sales of Symvess. The remaining $0.2 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 six months ended June 30, 2025 was $0.8 million, of which $0.2 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 six months ended June 30, 2024.

- Cost of goods sold was $0.2 million and $0.4 million for the three and six months ended June 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 six months ended June 30, 2024.

- During the three months ended June 30, 2025 Humacyte implemented a plan to reduce its workforce by 30 employees, defer additional planned new hires, and reduce other operating expenses. These reductions were done thoughtfully, and Humacyte retained key personnel, resources and initiatives to meet its key corporate goals and milestones. Humacyte undertook these cost reductions to extend its cash runway and to better align its organizational structure with its top business objectives. These objectives are the commercial launch of Symvess, including sales, marketing, and manufacturing; completion of the V012 Phase 3 pivotal trial of the ATEV in dialysis and the planned filing of a supplemental BLA with the FDA in the dialysis indication, and; the filing of an investigational new drug application to commence human study of the small-diameter ATEV for use in coronary artery bypass graft. The Company estimates that it has incurred and will incur aggregate charges representing one-time cash expenditure for severance and other employee termination benefits of approximately $0.7 million, of which the majority was incurred during the three months ended June 30, 2025. Humacyte estimates a net savings due to workforce reductions, operating cost reductions and reduced capital expenditures, net of termination severance and benefits, totaling approximately $13.8 million in 2025. Net savings are estimated to be up to approximately $38.0 million in 2026, for a total estimated savings of over $50 million in 2025 and 2026, relative to original budget forecasts. Due to the timing of the cost reduction plan, any anticipated savings are expected to occur after June 30, 2025.

- Research and development expenses were $22.0 million for the three months ended June 30, 2025 compared to $23.8 million for the three months ended June 30, 2024, and were $37.4 million for the six months ended June 30, 2025, compared to $45.0 million for the six months ended June 30, 2024. The decrease in research and development expenses for the second quarter of 2025 compared to 2024 primarily related to the capitalization of overhead costs associated with the commercial manufacturing of Symvess, offset by higher non-commercial production runs. The decrease in research and development expenses for the six months ended June 30, 2025 compared to the 2024 period resulted primarily from decreased materials costs as the Company began capitalizing expenditures for inventory following the commercial launch of Symvess, as well as the capitalization of overhead costs associated with the commercial manufacturing of Symvess.

- Selling, general and administrative expenses were $7.8 million for the three months ended June 30, 2025 compared to $5.7 million for the three months ended June 30, 2024 and were $15.9 million for the six months ended June 30, 2025, compared to $11.1 million for the six months ended June 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 June 30, 2025 was net expense of $7.9 million compared to net expense of $27.2 million for the three months ended June 30, 2024, and other net income of $54.4 million for the six months ended June 30, 2025, compared to other net expense of $32.5 million for the six months ended June 30, 2024. The decrease in other net expense for the three months ended June 30, 2025 and the increase in other net income for the six months ended June 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 $37.7 million for the three months ended June 30, 2025 compared to net loss of $56.7 million for the three months ended June 30, 2024, and net income was $1.5 million for the six months ended June 30, 2025, compared to net loss of $88.6 million for the six months ended June 30, 2024. The decrease in net loss for the three months ended June 30, 2025, and the increase in net income for the six months ended June 30, 2025 compared to the prior year periods was primarily due to the non-cash remeasurement of the contingent earnout liability described above.

- The Company reported cash, cash equivalents and restricted cash of $88.4 million as of June 30, 2025. Total net cash used was $6.9 million for the first six months of 2025, compared to net cash provided of $13.1 million for the first six months of 2024. The net cash used for the first six months of 2025 included $46.7 million in net proceeds from a public offering of common stock completed in March 2025. The net cash provided for the first six months of 2024 included $43.0 million in net proceeds from a public offering of common stock completed in March 2024, and the receipt of $20 million in proceeds from a draw under its funding arrangement with Oberland Capital Management in 2024 that did not recur in 2025.

Conference Call and Webcast Details

Title:	Humacyte Second Quarter 2025 Financial Results and Corporate Update
Date:	August 11, 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.

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.

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 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; 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 and Form 10-Q for the quarter ended March 31, 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 June 30,		Six Months Ended June 30,	
	2025	**2024**	**2025**	**2024**
Revenue:				
Product revenue, net	$ 100	$ —	$ 247	$ —
Contract revenue	201	—	571	—
Total revenue	301	—	818	—
Operating expenses:				
Cost of goods sold	213	—	360	—
Research and development	22,006	23,753	37,424	45,017
Selling, general and administrative	7,809	5,746	15,945	11,060
Total operating expenses	30,028	29,499	53,729	56,077
Loss from operations	**(29,727)**	**(29,499)**	**(52,911)**	**(56,077)**
Other income (expense), net:				
Change in fair value of contingent earnout liability	(5,470)	(25,571)	44,261	(30,164)
Other income (expense) (net)	(2,461)	(1,593)	10,131	(2,318)
Total other income (expense), net	(7,931)	(27,164)	54,392	(32,482)
Net income (loss) and comprehensive income (loss)	**$ (37,658)**	**$ (56,663)**	**$ 1,481**	**$ (88,559)**
Net income (loss) per share, basic	$ (0.24)	$ (0.48)	$ 0.01	$ (0.78)
Weighted-average shares outstanding, basic	155,437,281	119,174,681	143,533,212	113,710,344
Net income (loss) per share, diluted	$ (0.24)	$ (0.48)	$ 0.01	$ (0.78)
Weighted-average shares outstanding, diluted	155,437,281	119,174,681	143,664,424	113,710,344

Humacyte, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands)

	June 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 38,032	$ 44,937
Inventory	11,067	—
Prepaid expenses and other current assets	2,631	2,922
Total current assets	51,730	47,859
Restricted cash	50,209	50,209
Property and equipment, net	21,191	23,063

Finance lease right-of-use assets, net	14,443	15,490
Other long-term assets	1,222	1,251
Total assets	**$ 138,795**	**$ 137,872**
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 6,629	$ 4,490
Accrued expenses	9,186	11,424
Revenue interest liability, current portion	2,116	885
Other current liabilities	3,154	3,155
Total current liabilities	21,085	19,954
Revenue interest liability, net of current portion	66,425	63,354
Contingent earnout liability	26,700	70,961
Finance lease obligation, net of current portion	12,030	13,620
Common stock warrant liabilities	4,358	19,254
Other long-term liabilities	4,145	3,398
Total liabilities	**134,743**	**190,541**
Stockholders' equity (deficit)		
Common stock and additional paid-in capital	688,586	633,346
Accumulated deficit	(684,534)	(686,015)
Total stockholders' equity (deficit)	4,052	(52,669)
Total liabilities and stockholders' equity (deficit)	**$ 138,795**	**$ 137,872**

Humacyte

Source: Humacyte, Inc