Humacyte Announces First Quarter 2025 Financial Results and Provides Business Update

- Commenced market launch and first commercial sales of Symvess™ (acellular tissue engineered vessel-tyod) for the treatment of extremity vascular trauma -

- Total revenues of $517,000 for quarter from sales and collaborative research agreement –

- Completed public offering raising $46.7 million in net proceeds -

- Implemented cost reduction to extend cash runway -

---Conference call today at 8:30am ET -

DURHAM, N.C., May 13, 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 first quarter ended March 31, 2025, and provided a business update.

"The U.S. commercial launch of Symvess this quarter was a major milestone for Humacyte, and we are excited to provide this transformative product to surgeons and patients in need of a new option to save limbs and lives," said Laura Niklason, M.D., Ph.D., Founder and Chief Executive Officer of Humacyte. "Supporting the launch is our number one priority and we are pleased by the traction gained in our interactions with hospitals, despite the current volatile economic environment. Only a few months after commercial launch, we are excited that 45 hospitals have already commenced an evaluation of Symvess as part of their Value Analysis Committee (VAC) approval process – approximately one quarter of all Level 1 trauma centers nationwide."

"We also appreciate the strong support we have received from surgeons who have treated patients with Symvess, and the resiliency of our team members, in the face of some unfounded negative press regarding Symvess and Humacyte." continued Dr. Niklason. "Through our March 2025 financing and some recent cost reductions, we have taken steps to extend Humacyte's cash runway. With this extended runway we will continue to aggressively expand our commercial launch, while creating value from our bioengineering pipeline. Upcoming major value drivers we anticipate include publications of additional clinical results in trauma and in dialysis access, and filing an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) later this year to enable first-in-human clinical testing of the small-diameter ATEV™ in coronary artery bypass grafting (CABG). As a result of reaching a major enrollment milestone in our V012 Phase 3 trial in dialysis, we are also on track for filing a supplemental Biologics License Application (BLA) for ATEV in dialysis in 2026.

First Quarter 2025 and Recent Corporate Highlights

Symvess Market Launch

- **First Commercial Sales**: Humacyte commenced its commercial launch of Symvess in late February 2025 after the first commercial batch was released by the FDA. The first commercial shipments containing multiple units of Symvess were made during the first quarter to three Level 1 trauma centers.

- **VAC Approval Process**: Commencement of sales to hospitals for new products typically requires review and approval by a VAC, which is a centralized decision-making body within each institution. Forty-five hospitals have already initiated the VAC approval process, with additional hospitals expected to commence the process in the near term. The VACs of five hospitals have already approved the purchase of Symvess and we expect this number to increase throughout the second quarter based on current discussions with hospitals.

- **Military Treatment Facilities**: Multiple military treatment facilities have expressed interest in purchasing Symvess. To enable these purchases, Humacyte expects shortly to be listed in the Electronic Catalog (ECAT), an internet system that provides the Department of Defense and other Federal agencies with access to manufacturers' and distributors' products.

- **Economic Value of Symvess:** The Company's Budget Impact Model was published in March 2025 in the *Journal of Medical Economics*. Based on the model, the per-patient cost of treating patients with Symvess is estimated to be less than the cost of treating trauma patients with synthetic grafts, cryopreserved allografts, or xenografts. Major drivers of cost savings were attributed to reductions in the rate of amputation and vascular conduit infection.

- **Manufacturing Patent**: In January 2025, Humacyte was issued a new U.S. patent covering key aspects of its biomanufacturing platform. The newly issued patent provides protection into 2040 and complements a family of existing patents and patent applications encompassing the design and composition of Symvess and Humacyte's other product candidates, and their methods of manufacture.

ATEV Earlier-Stage Pipeline

- **Major Enrollment Milestone in V012 Phase 3 Study in Dialysis**: A total of 84 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 arteriovenous (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 BLA in the second half of 2026, that includes data from V012 and the V007 Phase 3 pivotal studies, to add AV access for hemodialysis as an indication for the ATEV.

- **Planned IND Filing in CABG**: During the quarter Humacyte announced plans to file an IND application with the FDA to enable first-in-human clinical testing of the small-diameter (3.5mm) acellular tissue engineered vessel in CABG.

Corporate Update

- **Cost Reduction Actions**: In March 2025 Humacyte completed a public offering that provided $46.7 million in net proceeds. In April and May 2025 Humacyte implemented a plan to reduce its workforce by approximately 31 employees, defer additional planned new hires, and reduce other operating expenses. These reductions have been done thoughtfully, and Humacyte has retained key personnel, resources and initiatives to meet our key corporate goals and milestones. Humacyte is undertaking cost reductions to extend its cash runway and to better align its organizational structure with its top business objectives. These objectives include 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 IND to commence human study of the small-diameter ATEV in CABG. The Company estimates that it will incur aggregate charges representing one-time cash expenditure for severance and other employee termination benefits of approximately $0.8 million, of which the majority is expected to be incurred during the second quarter of 2025. Humacyte estimates a net savings due to the 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.

First Quarter 2025 Financial Highlights

- There was $517 thousand in revenue for the first quarter of 2025, of which $147 thousand related to the initial U.S. commercial launch of Symvess. The remaining $370 thousand 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. There was no revenue for the first quarter of 2024.

- Cost of goods sold was $147 thousand for the first quarter of 2025 and includes overhead related to unused production capacity which was recorded as an expense in the period. There was no cost of goods sold for the first quarter of 2024.

- Research and development expenses for the first quarter of 2025 were $15.4 million compared to $21.3 million for the first quarter of 2024. The decrease in 2025 expenses compared to the prior year period resulted primarily from decreased materials costs as the Company began capitalizing expenditures for inventory during the three months ended March 31, 2025, following the commercial launch of Symvess, as well as a reduction in clinical study costs.

- General and administrative expenses for the first quarter of 2025 were $8.1 million compared to $5.3 million for the first quarter of 2024. The increase in 2025 expenses compared to the prior year period resulted primarily from the U.S. commercial launch of the Symvess in the vascular trauma indication, including increased personnel expenses.

- Other net income for the first quarter of 2025 was $62.3 million compared to net expense of $5.3 million for the first quarter of 2024. The increases in 2025 of other net income compared to the prior year period resulted primarily due to an increase in the non-cash remeasurement of the contingent earnout liability associated with the Company's August 2021 merger with Alpha Healthcare Acquisition Corp.

- Net income was $39.1 million for the first quarter of 2025 compared to net loss of $31.9 million for the first quarter of 2024. The increase in 2025 net income compared to the prior year period was primarily due to the increase in the non-cash remeasurement of the contingent earnout liability described above.

- The Company reported cash, cash equivalents and restricted cash of $113.2 million as of March 31, 2025. Total net cash provided was $17.9 million for the first three months of 2025, compared to net cash provided of $35.1 million for the first

three months of 2024. The net cash provided for the first three months of 2025 included $46.7 million in net proceeds from a public offering completed in March 2025. The decrease in net cash provided during 2025 compared to the prior year period resulted primarily from 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 First Quarter 2025 Financial Results and Corporate Update
Date:	May 13, 2025
Time:	8:30 AM Eastern Time
Conference Call Details:	1-877-704-4453 (U.S. Investors Dial) 1-201-389-0920 (International Investors Dial) 13753487 (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, 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, filed by Humacyte with the SEC, and in future SEC filings. Most of these factors are outside of Humacyte's control and are difficult to predict. Furthermore, if the forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. Except as required by law, we have no current intention of updating any of the forward-looking statements in this press release. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this press release.

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Humacyte, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

(unaudited)

(in thousands except for share and per share amounts)

	Three Months Ended March 31,

	2025	2024
Revenue:		
Product revenue, net	$ 147	$ —
Contract revenue	370	—
Total revenue	517	—
Operating expenses:		
Cost of goods sold	147	—
Research and development	15,418	21,264
General and administrative	8,136	5,314
Total operating expenses	23,701	26,578
Loss from operations	**(23,184)**	**(26,578)**
Other income (expense), net:		
Change in fair value of contingent earnout liability	49,731	(4,593)
Other income (expense) (net)	12,592	(725)
Total other income (expense), net	62,323	(5,318)
Net income (loss) and comprehensive income (loss)	**$ 39,139**	**$ (31,896)**
Net income (loss) per share, basic	$ 0.28	$ (0.29)
Weighted-average shares outstanding, basic	131,496,877	108,246,008
Net income (loss) per share, diluted	$ 0.28	$ (0.29)
Weighted-average shares outstanding, diluted	131,759,302	108,246,008

Humacyte, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands)

	March 31, 2025	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 62,847	$ 44,937
Inventory	8,020	—
Prepaid expenses and other current assets	2,838	2,922
Total current assets	73,705	47,859
Restricted cash	50,209	50,209
Property and equipment, net	22,436	23,063
Finance lease right-of-use assets, net	14,966	15,490
Other long-term assets	1,237	1,251
Total assets	**$ 162,553**	**$ 137,872**
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 5,572	$ 4,490
Accrued expenses	9,701	11,424
Revenue interest liability, current portion	1,690	885
Other current liabilities	3,066	3,155
Total current liabilities	20,029	19,954
Contingent earnout liability	21,230	70,961
Revenue interest liability, net of current portion	64,672	63,354

Finance lease obligation, net of current portion	12,844	13,620
Common stock warrant liabilities	3,320	19,254
Other long-term liabilities	4,415	3,398
Total liabilities	**126,510**	**190,541**
Stockholders' equity (deficit)		
Common stock and additional paid-in capital	682,919	633,346
Accumulated deficit	(646,876)	(686,015)
Total stockholders' equity (deficit)	36,043	(52,669)
Total liabilities and stockholders' equity (deficit)	**$ 162,553**	**$ 137,872**

Source: Humacyte, Inc