Humacyte Announces Fourth Quarter and Year End 2024 Financial Results and Provides Business Update

- Received U.S. Food and Drug Administration (FDA) approval of Symvess™ (acellular tissue engineered vessel-tyod) for the treatment of extremity vascular trauma -

- Commenced market launch and first commercial sales of Symvess -

- Budget Impact Model for Symvess published in Journal of Medical Economics -

- IND filing planned in 2025 to support first-in-human clinical study of small-diameter ATEV™ for coronary artery bypass grafting -

- Conference call today at 8:30am ET -

DURHAM, N.C., March 28, 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 fourth quarter and year ended December 31, 2024, and provided a business update.

“The past year has been a landmark time for Humacyte, highlighted by the FDA’s approval of Symvess for the treatment of extremity vascular trauma,” said Laura Niklason, M.D., Ph.D., Founder and Chief Executive Officer of Humacyte. “Symvess is a biologic product that went through more than 20 years of research and development, and we believe that this first-in-class approval marks an important new era in vascular surgery. We are thrilled to deliver this transformative innovation to surgeons and patients in need of a new option to save limbs and lives. Results from our clinical studies suggest that there are patients walking on their own legs today who would not be doing so if Symvess were not available.”

“Our commercial launch of Symvess is proceeding at full speed and we are excited by the response to date from hospitals and healthcare providers,” continued Dr. Niklason. “So far the market has responded well, and 34 hospitals have already initiated the Value Analysis Committee (VAC) approval process. We are also excited that just 16 days after having the commercial inventory availability, we made our first shipments of Symvess. The potential health economic benefits of Symvess are supported by our Budget Impact Model that was just published in the *Journal of Medical Economics*, which concludes that the avoidance of vascular infections and amputations drive cost reduction with the use of Symvess in traumatic injury. Our commercial team will continue to work closely with health care providers to make Symvess available to patients in need nationwide.”

Fourth Quarter, Year End 2024 and Recent Corporate Highlights

Symvess FDA Approval and Market Launch

- **FDA Approval**: The FDA granted full approval for Symvess on December 19, 2024 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.
- **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 the institution. Thirty-four hospitals have already initiated the VAC approval process, with additional hospitals expected to commence the process in the near term. These hospitals are a mix of leading trauma centers that were participants in Humacyte clinical studies, combined with institutions that have been newly introduced to Symvess. VACs have been engaged from individual institutions, and from larger hospital networks, meaning that individual VAC approvals could apply to multiple hospitals. Although the VAC process often takes three to six months to complete, three hospitals have already approved the purchase of Symvess.
- **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 last week to two Level 1 trauma centers.
- **Economic Value of Symvess:** The Company’s Budget Impact Model was published several weeks ago 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.
- **NTAP Reimbursement**: In October 2024, Humacyte submitted a New Technology Add-On Payment (NTAP) application for Symvess to the Centers for Medicare and Medicaid Services (CMS). Humacyte presented the Symvess data at a public town hall with CMS in December 2024. If successful, NTAP reimbursement will begin on October 1, 2025, offering hospitals additional payment to cover a portion of the costs associated with purchasing Symvess.
- **Manufacturing Patent**: In January 2025, Humacyte was issued a new U.S. Patent covering key aspects of our 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 product candidates, and their methods of manufacture.

ATEV Earlier Stage Pipeline and Corporate Updates

- **V007 Results in Dialysis**: Positive results from the V007 Phase 3 clinical trial of the ATEV in arteriovenous (AV) access for patients with end-stage renal disease were presented in October 2024 at the *American Society of Nephrology's (ASN) Kidney Week 2024.* The Phase 3 study met the co-primary endpoints, and the ATEV was observed to have superior function and patency (blood flow) at 6 and 12 months compared to AV fistula, which is the current standard of care for hemodialysis patients. The ATEV was also observed to have superior function in female, obese, and diabetic patients, each of which is a high-need subgroup having historically poor outcomes with AV fistula.
- **Planned Supplemental BLA in Dialysis**: A total of 76 patients have been enrolled to date in the V012 Phase 3 trial, which is designed to assess the usability 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. 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 V007, to add AV access for hemodialysis as an indication for the ATEV.
- **Planned IND Filing in CABG**: Humacyte plans to file an Investigational New Drug (IND) application with the FDA to enable first-in-human clinical testing of the small-diameter (3.5mm) acellular tissue engineered vessel (sdATEV) in coronary artery bypass grafting (CABG). Results of a six-month preclinical study of the sdATEV in primates were presented in November 2024 at *The American Heart Association's Scientific Sessions 2024* meeting. In the preclinical CABG model, the sdATEV was observed to sustain patency, recellularized with the animals' host cells, and remodel so as to match the size of the animals' native coronary arteries.

Fourth Quarter and Full Year 2024 Financial Highlights

- There was no revenue for the fourth quarter of 2024 and 2023, and there was no revenue for the years ended December 31, 2024 and 2023.
- Research and development expenses were $20.7 million for the fourth quarter of 2024, less than the $22.9 million incurred for the third quarter of 2024. The decrease in expenses compared to the prior quarter was primarily attributed to a reduction in materials expenses due to the timing of manufacturing runs. Research and development expenses for the fourth quarter of 2024 were $20.7 million, a slight increase compared to the $20.2 million incurred in the fourth quarter of 2023. Research and development expenses were $88.6 million for the year ended December 31, 2024, compared to $76.6 million for the year ended December 31, 2023. The increase in expenses during the year ended December 31, 2024 resulted primarily from increased materials expense associated with manufacturing runs and personnel expenses. These increases supported expanded research and development initiatives and clinical trials, including the expansion of manufacturing activities and support of the FDA review of the BLA in extremity vascular trauma.
- General and administrative expenses were $7.4 million for the fourth quarter of 2024, consistent with the $7.3 million incurred for the third quarter of 2024. General and administrative expenses were $7.4 million for the fourth quarter of 2024 compared to $6.0 million for the fourth quarter of 2023, and were $25.8 million for the year ended December 31, 2024 compared to $23.5 million for the year ended December 31, 2023. The increases during 2024 resulted primarily from preparation for the planned commercial launch of Symvess, including increases in personnel expenses and professional fees. These increases were partially offset by a decrease in non-cash stock compensation expense during 2024.
- Other net income (expense) was net income of $7.1 million for the fourth quarter of 2024, compared to net expense of $9.0 million for the third quarter of 2024. The increase in other net income compared to the prior quarter was due to the non-cash remeasurement of the contingent earnout liability associated with the Company's 2021 merger with Alpha Healthcare Acquisition Corp. Other net income for the fourth quarter of 2024 was $7.1 million compared to other net income of $1.1 million for the fourth quarter of 2023, and other net expense of $34.3 million for the year ended December 31, 2024 compared to net expense of $10.7 million for the year ended December 31, 2023. The increase in other net income during the fourth quarter of 2024 compared to 2023, and the increase in other net expense during the year ended December 31, 2024 compared to 2023, resulted primarily from non-cash remeasurements of the contingent earnout liability.
- Net loss was $20.9 million for the fourth quarter of 2024, compared to $39.2 million for the third quarter of 2024 and to $25.1 million for the fourth quarter of 2023. The decreases in net loss for the fourth quarter of 2024 compared to the prior quarter and to the fourth quarter of 2023 resulted from the non-cash remeasurement of the contingent earnout liability described above. Net loss was $148.7 million for the year ended December 31, 2024 compared to $110.8 million for the year ended December 31, 2023. The year-over-year increase in net loss in 2024 compared to 2023 resulted from the non-cash remeasurement of the contingent earnout liability and operating expense increases, both described above.
- The Company reported cash, cash equivalents and restricted cash of $95.3 million as of December 31, 2024. Subsequent to December 31, 2024, in March 2025 the Company completed an underwritten public offering of common stock which provided approximately $46.6 million in net proceeds, with the potential for another $7.1 million in net proceeds subject to an underwriter option that is exercisable before April 26, 2025. Total net cash provided was $14.5 million for the year ended December 31, 2024, compared to total net cash used of $69.0 million for the year ended December 31, 2023. The increase in net cash provided resulted primarily from the receipt of approximately $43.0 million in net proceeds from an underwritten public offering of common stock in March 2024, $43.1 million in net proceeds from two registered direct offerings of common stock and warrants completed in October and November 2024, and $20 million in proceeds from an

additional draw under Humacyte's funding arrangement with Oberland Capital Management.

Conference Call and Webcast Details

Title:	Humacyte Fourth Quarter and Full Year 2024 Financial Results and Corporate Update
Date:	March 28, 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) 13751524 (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 our ATEV in the United States under the brand name Symvess in vascular trauma repair; the statements regarding the initiation, timing, progress, and results of our preclinical and clinical trials; the anticipated characteristics and performance of our ATEVs; our ability to successfully complete preclinical and clinical trials for our ATEVs; the anticipated benefits of the ATEV relative to existing alternatives; the anticipated commercialization of our ATEVs and our ability to manufacture at commercial scale; the implementation of our business model and strategic plans for our business; and the timing or likelihood of regulatory filings, acceptances and approvals. We cannot assure you that the forward-looking statements in this press release will prove to be accurate. These forward-looking statements are subject to a number of significant risks and uncertainties that could cause actual results to differ materially from expected results, including, among others, changes in applicable laws or regulations, the possibility that Humacyte may be adversely affected by other economic, business, 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, 2023, and our Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, 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 Loss

(unaudited)

(in thousands except for share and per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2024	2023	2024	2023
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	20,656	20,180	88,599	76,550
General and administrative	7,432	6,002	25,799	23,497

Total operating expenses	28,088	26,182	114,398	100,047
Loss from operations	**(28,088)**	**(26,182)**	**(114,398)**	**(100,047)**
Other income (expense), net				
Change in fair value of contingent earnout liability	5,608	1,685	(33,045)	(10,023)
Other income (expense) (net)	1,540	(609)	(1,258)	(706)
Total other income (expense), net	7,148	1,076	(34,303)	(10,729)
Net loss and comprehensive loss	**$ (20,940)**	**$ (25,106)**	**$ (148,701)**	**$ (110,776)**
Net loss per share, basic and diluted	$ (0.16)	$ (0.24)	$ (1.26)	$ (1.07)
Weighted-average shares outstanding, basic and diluted	126,983,464	103,607,631	118,479,097	103,420,238

Humacyte, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands)

	As of December 31,	
	2024	**2023**
Assets		
Current assets:		
Cash and cash equivalents	$ 44,937	$ 80,448
Prepaid expenses and other current assets	2,922	2,830
Total current assets	47,859	83,278
Restricted cash	50,209	209
Property, plant and equipment, net	23,063	26,791
Finance lease right-of-use assets, net	15,490	17,313
Other long-term assets	1,251	632
Total assets	**$ 137,872**	**$ 128,223**
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 4,490	$ 6,490
Accrued expenses	11,424	9,340
Other current liabilities	4,040	2,613
Total current liabilities	19,954	18,443
Contingent earnout liability	70,961	37,916
Revenue interest liability	63,354	38,600
Common stock warrant liabilities	19,254	78
Finance lease obligation, net of current portion	13,620	16,293
Other long-term liabilities	3,398	3,347
Total liabilities	**190,541**	**114,677**
Stockholders' equity (deficit)		
Common stock and additional paid-in capital	633,346	550,860
Accumulated deficit	(686,015)	(537,314)
Total stockholders' equity (deficit)	(52,669)	13,546
Total liabilities and stockholders' equity (deficit)	**$ 137,872**	**$ 128,223**

Source: Humacyte, Inc