UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of

the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 19, 2024

Humacyte, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-39532**	**85-1763759**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification Number)

2525 East North Carolina Highway 54 Durham, NC	**27713**
(Address of principal executive offices)	(Zip code)

(919) 313-9633

(Registrant's telephone number, including area code)

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	**HUMA**	**The Nasdaq Stock Market LLC**
Redeemable Warrants, each whole warrant exercisable for one share of Common Stock at an exercise price of $11.50	**HUMAW**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On December 19, 2024, Humacyte, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (the "FDA") has granted a full approval for SYMVESS™ (acellular tissue engineered vessel-tyod) for use in adults as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and when autologous vein graft is not feasible. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

The information contained in this Item 7.01 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On December 19, 2024, the Company announced that the FDA has granted a full approval for SYMVESS for use in adults as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and when autologous vein graft is not feasible.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	**Description**
99.1	Press release, dated December 19, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

HUMACYTE, INC.

By: /s/ Dale A. Sander

Date: December 20, 2024

Name: Dale A. Sander
Title: Chief Financial Officer, Chief Corporate Development Officer and Treasurer

Exhibit 99.1

Humacyte Announces FDA Approval of SYMVESS™ (acellular tissue engineered vessel-tyod) for the Treatment of Extremity Vascular Trauma

– SYMVESS is a first-in-class bioengineered human tissue designed to be a universally implantable vascular conduit for use in arterial replacement and repair –

– In clinical testing SYMVESS was observed to have high rates of patency, or blood flow, and low rates of amputation and infection –

– Highly experienced sales team already recruited and trained in preparation for commercial launch –

DURHAM, N.C., December 19, 2024 **–** Humacyte, Inc. (Nasdaq: HUMA), a biotechnology platform company developing universally implantable, bioengineered human tissues at commercial scale, today announced that the U.S. Food and Drug Administration (FDA) has granted a full approval for SYMVESS (acellular tissue engineered vessel-tyod) for use in adults as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and when autologous vein graft is not feasible.

“We are very excited and proud to provide patients suffering from arterial injury with a novel treatment option. SYMVESS has been made possible by our innovative bioengineering science along with the contributions of many patients, healthcare providers and Humacyte team members.” said Laura Niklason, M.D., Ph.D., Founder and Chief Executive Officer of Humacyte. “SYMVESS approval in this first indication for arterial injury repair is a milestone for regenerative medicine overall, as well as for Humacyte. The FDA’s full approval of SYMVESS is a transformational event for the Company and our bioengineering technology platform. Even more importantly, we believe SYMVESS provides a new means of treating patients with devastating arterial injuries, which is a population that has not benefited from substantial innovation in decades. We look forward with great excitement to our upcoming commercial launch of SYMVESS, and we have recruited and trained a terrific team to execute on our sales and marketing missions.”

“The approval of a vascular conduit that resists infection and remodels into native arteries is an extraordinary technological advancement that will have a huge impact on the quality of trauma care around the world,” said Charles J. Fox, MD, FACS, Director of Vascular Surgery at the University of Maryland Capital Region, a clinical investigator in the V005 clinical trial. “SYMVESS is perfectly sized to treat most injuries, has excellent handling properties, and reduces time necessary to save both life and limbs. The Humacyte team has responsibly and scientifically solved a major clinical problem that I believe will reduce the amputation rate for traumatic vascular injury. They should be congratulated on an accomplishment that will undoubtedly advance our specialty to the next level.”

“I believe that SYMVESS will revolutionize vascular trauma care and be profoundly beneficial to our patients,” said Rishi Kundi, MD, Surgical Critical Care, Vascular Surgery, University of Maryland Medical System. “From my experience so far, SYMVESS will allow reconstructions that are currently impracticable because of contamination and infection. It will make reconstructions that we now perform with prosthetic or even biologic grafts more successful. I am most excited about the promise that SYMVESS holds for the long-term experience of our patients. I hope that, with SYMVESS, the 19-year-old patient with vascular reconstruction after trauma will no longer spend the six decades after their surgery anticipating disaster, but that their chances for reintervention will be no different than if they had autologous conduit.”

SYMVESS, or the ATEV™, is a first-in-class bioengineered human tissue that is designed to be a universally implantable vascular conduit for use in arterial replacement and repair. While harvesting vein from a trauma patient takes valuable surgical time, SYMVESS is available off-the-shelf, and does not require further injuring the patient to obtain vascular repair material. Humacyte's BLA included positive results from the V005 pivotal Phase 2/3 clinical study, as well as real-world evidence from the treatment of wartime injuries in Ukraine under a humanitarian aid program. SYMVESS was used to repair many types of traumatic injuries including car accidents, gunshot wounds, blast wounds, and industrial accidents. It was utilized by vascular and trauma surgeons in Level 1 Trauma centers throughout the U.S. and Israel to repair severe limb-threatening and life-threatening injuries, and in front-line hospitals in Ukraine to treat wartime injuries. Results from these studies were published in *JAMA Surgery* on November 20, 2024. In the civilian and military clinical studies, SYMVESS was observed to have high rates of patency, or blood flow, and low rates of amputation and infection.

"Finally, we have an innovative technology for battlefield vascular injuries using a tissue engineered human arterial replacement that can resist infections that are so prevalent in modern combat zones," added Dr. Fox. "SYMVESS shows promise to reduce amputation rates since an alternative conduit for war injuries is often needed but up until now has not been a good option."

"The FDA approval of SYMVESS will make it the preferred conduit for complex vascular injuries, and particularly those at risk for infection." said Ernest E. Moore, MD, FACS, Director of Research at the Ernest E. Moore Shock Trauma Center at Denver Health, a clinical investigator in the V005 trial. "I look forward to using SYMVESS in my practice."

Arterial injuries resulting from vascular trauma are common in civilian and military populations, frequently resulting in the loss of life or limb. In civilian populations, trauma injuries are primarily caused by motor vehicle, workplace and sporting accidents, gun violence, mass casualty terrorist attacks, stabbings, blunt trauma, and iatrogenic injuries (injuries caused by medical treatment or examination). Autologous vein, which is harvested from the patient's body through a separate surgical incision, is the current preferred conduit for arterial repair. However, harvesting of autologous vein is not always feasible due to damage to veins or to the limbs. Harvesting autologous vein is also an invasive procedure that requires additional time and resources, delaying the time from injury to restoration of blood flow for the injured patient. In contrast, SYMVESS may be removed from its packaging and ready for implantation within minutes and does not involve creating additional incisions in already-injured patients.

The SYMVESS trauma program was granted Regenerative Medicine Advanced Therapy (RMAT) designation by the FDA in May 2023, a Biologic License Application (BLA) was submitted to the FDA in December 2023, and in February 2024 the FDA granted a Priority Review. On August 9, 2024, the FDA informed Humacyte that it needed additional time to complete its review of the BLA, although there were no outstanding pre-approval requirements for SYMVESS as of that date. The FDA completed its review today, granting full approval.

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, including Boxed Warning, for SYMVESS.

Humacyte filed the BLA with trauma clinical data based upon the accepted statistical analysis plan. These data were also peer reviewed and published in *JAMA Surgery* on November 20, 2024. In the package insert, the FDA elected to exclude the synthetic graft comparator that was in the statistical analysis plan. The FDA also applied a different imputing methodology for SYMVESS patients who did not have a day 30 assessment. Nine patients without day 30 data were imputed as failures of patency in the package insert, despite the fact that they had favorable patency results at the last assessment. In addition, multiple patients who never underwent an amputation were imputed as failures of limb salvage.

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 initial product candidates, a portfolio of acellular tissue engineered vessels (ATEVs), are currently in late-stage clinical trials targeting multiple vascular applications, including vascular trauma repair, arteriovenous (AV) access for hemodialysis, and peripheral artery disease. A Biologics License Application for the ATEV in the vascular trauma indication was approved by the FDA in December 2024. 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 an 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, 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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