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): October 28, 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 8.01. Other Events.

On October 28, 2024, Humacyte, Inc. (the "Company") issued a press release announcing the presentation of positive results from its Phase 3 clinical trial (V007) of the acellular tissue engineered vessel (ATEV) in arteriovenous access for patients with end-stage renal disease at the American Society of Nephrology's *Kidney Week* 2024. A copy of this press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	**Description**
99.1	Press release, dated October 28, 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: October 28, 2024

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

Humacyte Announces Presentation of Positive Results from V007 Phase 3 AV Access Clinical Trial at the American Society of Nephrology's *Kidney Week 2024*

– ATEV™ demonstrated superiority at six and 12 months (co-primary endpoints) compared to autogenous fistula, the current standard of care for hemodialysis access –

- ATEV also showed superior function and patency in female, obese and diabetic patients, subgroups with historically poor outcomes with autogenous fistula procedures -

DURHAM, N.C., October 28, 2024 **–** Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable, bioengineered human tissue at commercial scale, announced the presentation of positive results from the V007 Phase 3 clinical trial of the acellular tissue engineered vessel (ATEV) in arteriovenous (AV) access for patients with end-stage renal disease at the American Society of Nephrology's (ASN) *Kidney Week 2024*, the premier nephrology meeting, in San Diego.

In the Phase 3 trial, the ATEV demonstrated superior function and patency at six and 12 months (co-primary endpoints) compared to autogenous fistula, which is the current standard of care for hemodialysis patients, and also showed superior function and patency in female, obese and diabetic patients, each of which is a high-need subgroup with historically poor outcomes with AV fistula procedures. The late-breaking podium presentation, titled "Prospective Randomized Trial of Humacyte's Acellular Tissue Engineered Vessel Versus Autologous Arteriovenous Fistula for Hemodialysis Access," was presented on Saturday, October 26, 2024 by Mohamad A. Hussain, MD, PhD, RPVI, FAHA, FRCSC, FACS, Vascular and Endovascular Surgeon-Scientist at Brigham and Women's Hospital, Core Faculty at the Center for Surgery and Public Health, and Assistant Professor of Surgery at Harvard Medical School.

"These results show that availability of the ATEV, a biologic conduit, could be game changing in improving arteriovenous access in many hemodialysis patients," said Dr. Hussain. "I was particularly pleased to see positive results in female, obese, and diabetic patients, groups which typically have poor outcomes with autogenous fistula procedures and historically limited treatment alternatives for hemodialysis access. The significantly higher duration of access over one year in these underserved patients could greatly reduce reliance on catheters for arteriovenous access."

The V007 Phase 3 trial (NCT03183245) is a prospective, multi-center, randomized clinical study in 242 hemodialysis patients in the United States. Enrolled individuals were randomly assigned to receive either the ATEV or an AV fistula for hemodialysis access and are being followed for up to 24 months. Under the statistical analysis plan for the trial, the primary efficacy assessment compared functional patency (usability for hemodialysis access) at six months and secondary patency (blood flow through the conduit) at 12 months, as co-primary endpoints. At six months, 81.3% of the patients implanted with the ATEV had functional patency compared to 66.4% of the patients receiving an AV fistula. At 12 months, 68.3% of the patients implanted with the ATEV had secondary patency, compared to 62.2% of the patients receiving an AV fistula. The joint test for superiority of the ATEV versus AV fistula at six and 12 months was statistically significant ($p=0.0071$). Patients receiving an ATEV also achieved a significantly longer duration of hemodialysis over the first 12 months, as compared to AV fistula ($p=0.0162$).

Sub-group analysis was also performed in patient groups that historically have poor outcomes with AV fistula procedures. In female patients (n=70), patients implanted with the ATEV had significantly higher six-month and one-year patency rates than female patients receiving an AV fistula ($p<0.0001$). Female patients receiving an ATEV also achieved a significantly longer duration of hemodialysis over the first 12 months compared to AV fistula, 8.3 months versus 5.0 months, respectively ($p=0.0011$). In obese patients (body mass index or BMI of at least 30) (n=93), patients implanted with the ATEV had significantly higher six-month and one-year patency rates than diabetic patients receiving an AV fistula ($p=0.0001$). Obese patients receiving an ATEV also achieved a significantly longer duration of hemodialysis over the first 12 months compared to AV fistula, 7.7 months versus 4.5 months, respectively ($p=0.0020$). In diabetic patients (n=165), patients implanted with the ATEV had significantly higher six-month and one-year patency rates than diabetic patients receiving an AV fistula ($p=0.0024$). Diabetic patients receiving an ATEV also achieved a significantly longer duration of hemodialysis over the first 12 months compared to AV fistula, 7.4 months versus 5.5 months, respectively ($p=0.0155$).

Rates of infection were low in both treatment arms, with 9.1% of patients implanted with the ATEV experiencing access-related infections (12 total events) compared to 9.9% of patients treated with AV fistula (14 total events). Treatment-Emergent Adverse Events (TAEEs) occurred in 98.3% of patients implanted with the ATEV (1,211 total events) compared to 96.7% of patients treated with AV fistula (828 total events). The largest area of difference in adverse events was in thrombosis, occurring in 52.1% of patients implanted with the ATEV (126 total events) compared to 9.1% of patients treated with AV fistula (12 total events). The majority of ATEV patients with thrombosis, 94%, were successfully treated.

The ATEV is an investigational product and has not been approved for sale by the FDA or any other regulatory agency.

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. Humacyte develops and manufactures acellular tissues to treat a wide range of diseases, injuries, and chronic conditions. Humacyte's initial product candidates, a portfolio of 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 is currently under review by the FDA and was granted Priority Review. 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.

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, the statements regarding the initiation, timing, progress, and results of our preclinical and clinical trials; the anticipated characteristics and performance of our ATEV; our ability to successfully complete preclinical and clinical trials for our ATEVs; the anticipated benefits of the our ATEVs 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, filed by Humacyte with the SEC, and in subsequent 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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