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): September 12, 2023

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:

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o 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 x

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. o

Item 8.01. Other Events.

On September 12, 2023, Humacyte, Inc. (the "Company") issued a press release announcing positive top line results from its Phase 2/3 Vascular trauma trial (V005) that are expected to support the planned Biologics License Application filing for the Company's human acellular vessel in extremity vascular trauma when a synthetic graft is not indicated and when an autologous vein is not feasible. 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 September 12, 2023.
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.

Date: September 12, 2023

By: /s/ Dale A. Sander

Name: Dale A. Sander

Title: Chief Financial Officer, Chief Corporate Development Officer and Treasurer

Humacyte Announces Positive Top Line Results from Phase 2/3 Trial of Human Acellular Vessel™ (HAV™) in Treatment of Patients with Vascular Trauma

-- Single-arm clinical trial was a success and showed the HAV had higher rates of patency, and lower rates of amputation and infection, compared to historic synthetic graft benchmarks --

-- BLA planned to be filed with FDA in 4th Quarter 2023 --

-- Conference call and live webcast with Key Opinion Leaders at 8:00 a.m. ET today -

DURHAM, N.C., September 12, 2023 – Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable, bioengineered human tissue at commercial scale, announced positive top line results from its V005 Phase 2/3 trial of the Human Acellular Vessel (HAV) in vascular trauma repair. The single-arm clinical trial was a success and showed that the HAV in this study had higher rates of patency, and lower rates of amputation and infection, compared to historic synthetic graft benchmarks. Humacyte plans to file a Biologics License Application (BLA) for the treatment of vascular trauma with the Food and Drug Administration (FDA) during the 4th quarter of 2023.

The V005 trial was a single-arm study conducted in the United States and Israel in patients with arterial injuries resulting from gun shots, workplace injuries, car accidents, or other traumatic events. Patients enrolled in the study did not have the standard of care, saphenous vein, available to use as a bypass graft. As a result, had the patients not received the HAV, they likely would have been treated with synthetic grafts, ligation of the bleeding artery, and/or amputation. Trauma injuries are commonly contaminated, and therefore patients are at a high risk of infection. As a single-arm study, the comparators for the HAV results were benchmark outcomes for treatment with synthetics grafts based on a systematic literature search. The principal means of evaluation was comparability of secondary patency (blood flow) at 30 days, with primary patency (blood flow without intervention) also evaluated. Secondary comparisons comprised of improvement in rates of amputation and rates of infection at 30 days. A total of 69 patients were enrolled in the V005 trial, of which 51 had vascular injury of the extremities and comprised the primary evaluation group for the study.

The V005 trial was a success, and the principal comparison of 30-day secondary patency for the HAV in the clinical trial was 90.2% for the extremity patients (89.9% for total patients) compared to 81.1% historically reported for synthetic grafts. Primary patency for total HAV patients and for extremity patients was 81.2% and 84.3%, respectively, although no comparison to synthetic graft primary patency was possible since this measure was not reported in the benchmark publications. For the secondary comparison of amputation rates, the HAV demonstrated an improvement with a rate of 9.8% for extremity patients (10.1% for total patients) compared to 20.6% historically reported for synthetic grafts. For the secondary comparison of infection rate, the HAV demonstrated an improvement, with a rate of 2.0% for the extremity patients (2.9% for the total patients) compared to 8.9% historically reported for synthetic grafts. There were no unexpected safety signals for the HAV in this study. An expanded presentation of the results of the V005 trial is expected to be made at the Veith Symposium, a major vascular surgery meeting, in New York City on November 16, 2023.

"We are elated that the V005 results support our expectation that the HAV may improve the treatment and outcome of patients suffering major traumatic Injuries," said Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte. "We are pleased to reach this major milestone, and thank the medical professionals, patients, advisors and our own team members who contributed to the success of this clinical trial. We now look forward to moving to completion of our BLA filing and planned commercial launch."

Humacyte is currently preparing a BLA for use of the HAV in urgent arterial repair following extremity vascular trauma when synthetic graft is not indicated, and saphenous vein is not feasible to the FDA before the end of the year. In May 2023, Humacyte's 6 mm HAV received the Regenerative Medicine Advanced Therapy (RMAT) Designation from the FDA for urgent arterial repair following extremity vascular trauma, which provides a basis for

priority review of the BLA by the FDA. Based on guidance from the FDA, Humacyte plans to pursue a traditional BLA approval which may eliminate the requirement for a post-approval confirmatory study.

The FDA has advised Humacyte to include patient outcomes from a humanitarian program conducted in Ukraine in its BLA submission. As a result, the Company is also reporting preliminary results for the 16 extremity patients from Ukraine who provided consent for use of their results. For this population, 30-day secondary patency for the HAV was 93.8% compared to 81.1% historically reported for synthetic grafts. The rate of amputation for the HAV was 0.0% compared to 20.6% historically reported for synthetic grafts. The rate of infection for the HAV was 0.0% compared to 8.9% historically reported for synthetic grafts.

The HAV, a bioengineered tissue, is under investigation as an infection-resistant alternative for revascularization. Designed to be ready off-the-shelf, the HAV has the potential to save valuable time for surgeons and to reduce discomfort and complications for patients. The HAV can be produced at commercial scale in Humacyte's existing manufacturing facilities, providing thousands of vessels for treating patients in need. The HAV has accumulated more than 1,000 patient-years of experience worldwide in a series of clinical trials in multiple indications, including vascular trauma repair, arteriovenous access for hemodialysis, and peripheral artery disease.

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

Conference Call and Webcast Details

Title:	Human Acellular Vessel (HAV) for Vascular Trauma Repair: Top Line Phase 2/3 V005 Results and KOL Perspectives
Date:	Tuesday, September 12, 2023
Time:	8:00 AM ET
Webcast:	Webcast Link - Click Here

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 with the potential to treat a wide range of diseases, injuries, and chronic conditions. Humacyte's initial opportunity, a portfolio of HAVs, is currently in late-stage clinical trials targeting multiple vascular applications, including vascular trauma repair, AV access for hemodialysis, and peripheral arterial disease. 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 HAV 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 HAV for urgent arterial repair following extremity vascular trauma also has received RMAT designation. The HAV 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, statements regarding the initiation, timing, progress, and results of our preclinical and clinical trials; the anticipated characteristics and performance of our HAVs; our ability to successfully complete, preclinical and clinical trials for our HAVs; the anticipated benefits of our HAVs relative to existing alternatives; the anticipated commercialization of our HAVs and our ability to manufacture at commercial scale; the implementation of our business model and strategic plans for our business; the timing or likelihood of regulatory filings and approvals; timing, scope, and rate of reimbursement for our HAVs; the outcome of our ongoing discussions with the FDA concerning the design of our ongoing V005 Phase 2/3 clinical trial, including determination of trial size, and the scope of any approved indication for our HAVs; and our estimated available market opportunity. 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 included under the header “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2022, 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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