# 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): November 15, 2021

# 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**<br>**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 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 November 15, 2021, Humacyte, Inc. (the "Company") issued a press release announcing data from a Phase 2 clinical trial of patients receiving the human acellular vessel (HAV) produced using the Company's cutting-edge, large-scale manufacturing systems, known as "LUNA200," for vascular access in hemodialysis. 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 November 15, 2021. |
| 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: November 15, 2021

By: /s/ Dale A. Sander

Name: Dale A. Sander

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

**Exhibit 99.1**

**Humacyte Presents New 12-Month Data from HAVs™ Produced Using Commercial-Scale Manufacturing System**

*-- Performance of HAVs produced in the LUNA200™ commercial-scale system demonstrated efficacy that is similar to prior HAV performance in dialysis access trials –*

*-- 83% secondary patency observed at 12 months post-implantation –*

*-- Data presented today in keynote presentation at 6th World Congress of the Tissue Engineering and Regenerative Medicine International Society (TERMIS2021) –*

**Durham, N.C. – Nov. 15, 2021 –** Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable bioengineered human tissue at commercial scale, today announced that data from a Phase 2 clinical trial of patients receiving the human acellular vessel (HAV) produced using its cutting-edge, large-scale manufacturing systems, known as "LUNA200", for vascular access in hemodialysis, demonstrated 12-month efficacy that is similar to trials of HAVs produced in the development-scale systems previously used in manufacturing the HAV.

The Phase 2, prospective, multicenter, open-label, single-arm study evaluated the safety, efficacy and immunogenicity of HAVs manufactured with the commercial-scale LUNA200 platform in 30 end-stage renal disease patients undergoing hemodialysis. One year after implantation, 83% of subjects still showed secondary, or functional, patency. Secondary patency rates of the HAVs produced using the prior, development-scale systems ranged from 82% to 89%. No instances of HAV rupture, aneurysm formation or acute mechanical failure were observed in the study. In addition, the HAV appears to resist infection as compared to synthetic conduits.

"Our LUNA200 commercial-scale manufacturing system is a groundbreaking bioengineering platform that represents the result of decades of work iterating our approach to be more modular, controlled and automated," said Laura Niklason, M.D., Ph.D., Founder, President and Chief Executive Officer of Humacyte. "We have demonstrated the LUNA200 functions comparably to our legacy systems, and this data demonstrates that manufacturing engineered tissues at commercial-scale is feasible, a critical milestone for our regenerative medicine platform and for Humacyte that supports our efforts toward commercialization of the HAV."

Each modular, automated LUNA200 system, with enhanced process controls, can grow 200 HAVs at a time. Humacyte's LUNA200 systems are housed in its 83,000-square-foot state-of-the-art bioprocessing facility in Durham, N.C., which has ample space to house enough systems to produce an annual capacity of approximately 40,000 HAVs per year. The Durham facility is fully operational, and in 2021 the FDA authorized the use of HAVs produced in the LUNA200 system to supply the Company's ongoing clinical trials in the United States. The facility also achieved compliance with EU good manufacturing practices (GMP) and Qualified Person Certification to allow product to be supplied to ongoing studies in Europe and Israel.

The 12-month data were presented at the 6th World Congress of the Tissue Engineering and Regenerative Medicine International Society (TERMIS2021). The secondary objective of this study is to evaluate the long-term safety and efficacy of the HAV manufactured with the LUNA system for up to 36 months after implantation, and the study is ongoing.

**About HAV**

Human Acellular Vessels (HAV) are engineered off-the-shelf replacement vessels initially being developed for vascular repair, reconstruction and replacement. HAV is intended to overcome long-standing limitations in vessel tissue repair and replacement – it can be manufactured at commercial scale, it eliminates the need for harvesting a vessel from a patient, and clinical evidence suggests that it is non-immunogenic, infection-resistant, and can become durable living tissue. HAV is currently being evaluated in two Phase 3 trials in arteriovenous access and a Phase 2/3 trial for vascular trauma, and has been used in more than 460 patient implantations. It is the first product to receive Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food and Drug Administration (FDA), and has also received FDA Fast Track designation.

**About Humacyte**
Humacyte, Inc. (Nasdaq: HUMA) is developing a disruptive biotechnology platform to deliver universally implantable bioengineered human tissues and organs 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 opportunity, a portfolio of human acellular vessels (HAVs), is currently in late-stage clinical trials targeting multiple vascular applications, including vascular trauma repair, arteriovenous access for hemodialysis, and peripheral arterial disease. Pre-clinical 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 HAVs were the first product to receive the FDA's Regenerative Medicine Advanced Therapy (RMAT) expedited review designation and 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 clinical trials; the anticipated characteristics and performance of our HAVs; our ability to successfully complete, pre-clinical 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; our rights and obligations under our partnership with Fresenius Medical Care; the scope of protection we are able to establish and maintain for intellectual property rights covering our HAVs and related technology; the timing or likelihood of regulatory filings and approvals; timing, scope, and rate of reimbursement 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, the impact of COVID-19 on Humacyte's business, 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 the registration statement on Form S-1 filed by Humacyte with the SEC. 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. The forward-looking statements in this press release represent our views as of the date of this press release. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. 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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