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 12, 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 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 2.02. Results of Operations and Financial Condition

On November 12, 2021, Humacyte, Inc. issued a press release regarding its financial results for its fiscal third quarter ended September 30, 2021. A copy of this press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

The information contained herein, including the exhibit attached hereto, 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 of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description
99.1	Press release, dated November 12, 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 12, 2021

By: /s/ Dale A. Sander

Name: Dale A. Sander

Title: Chief Financial Officer and Chief Corporate Development Officer

Exhibit 99.1

Humacyte Reports Third Quarter 2021 Financial Results and Provides Business Highlights

-- Completed business combination with Alpha Healthcare Acquisition Corp. and raised $242M in proceeds --

-- Progressed advanced-stage clinical- and early-stage programs of the human acellular vessel (HAV™) and other engineered tissue platform applications --

DURHAM, N.C. – Nov. 12, 2021 – Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable bioengineered human tissue at commercial scale, today announced financial results for the third quarter ended September 30, 2021, and highlighted recent corporate accomplishments.

"Humacyte has made great strides advancing our bioengineered tissue platform to create novel human acellular tissues and organs. This quarter was marked with significant corporate progress, including the closing of our business combination agreement with Alpha Healthcare and our debut on Nasdaq. We are excited about our transition to a public company, and we are laying a strong foundation of clinical, technical and infrastructure progress to support our continued advancement toward commercialization," said Laura Niklason, M.D., Ph.D., Founder, President and Chief Executive Officer of Humacyte. "This month we will be sharing late-breaking data on the performance of HAVs manufactured with our commercial-scale LUNA200^{TM} platform. We look forward to continued progress of our HAV for vascular trauma, AV access and peripheral arterial disease toward late-stage clinical readouts, while advancing our earlier stage work in treatments for heart disease and diabetes."

Third Quarter 2021 and Recent Corporate Highlights

Pipeline Updates

- Published laboratory and preclinical data in the *Journal of Tissue Engineering* demonstrating the potential to engineer a biovascular pancreas as a method to transplant pancreatic islet cells for the long-term treatment of type 1 diabetes.

- Continued enrolling the HAV Expanded Access Program (EAP) which improves access for patients with critical vascular issues while also further demonstrating the utility and versatility of the HAV, and completed the 15th implant in the U.S. under this program. Researchers reported on one recent EAP case in a patient suffering from severe peripheral arterial disease (PAD) and at risk of losing a leg due to poor blood flow where the HAV was used to successfully restore perfusion to the leg in a bypass operation.

- Last month, the Mayo Clinic in Rochester, Minn. received acceptance of a first-of-its-kind investigator-sponsored Investigational New Drug (IND) application to allow surgeons' access to the investigational HAV for treatment of patients with severe PAD. Patients with PAD who have no options for surgical bypass meeting the criteria outlined in the IND may now be treated under this new investigational program. By enabling enrollment of as many as 25 subjects, the IND will allow the utilization of the HAV for the treatment of severe limb ischemia, a condition that if left untreated could result in limb loss.

- Presented five-year data from the Phase 2 clinical trial of patients who received Humacyte's HAV for arteriovenous access in hemodialysis, which suggest long-term durability and functional hemodialysis access of the HAV in patients with end-stage renal disease who dialyze three times per week, at the American Society of Nephrology Kidney Week 2021.

- Delivered scientific presentations covering the HAV clinical and preclinical applications during the third quarter, including a keynote on laboratory and preclinical findings and notable criteria for engineering functional air sacs in the lungs, which support the potential to create engineered lung tissue organ, at the virtual Janelia R3 – Replace, Repair, Regenerate Planning Workshop.

- Announced the issuance of three additional U.S. patents covering Humacyte's proprietary universally implantable bioengineered human tissue platform, and the issuance of 23 additional patents in international markets. The Company now owns or licenses 119 patents covering its proprietary platform.

Corporate Updates

- Completed the business combination with Alpha Healthcare Acquisition Corp., a special purpose acquisition company, on August 26, 2021, and commenced trading of its shares of common stock and warrants on the Nasdaq Global Select Market® under the ticker symbols "HUMA" and "HUMAW," respectively. As a result of the Business Combination, the Company received proceeds of $242.4 million net of offering costs, including a $175 million PIPE financing.
    - Participating PIPE investors included Fresenius Medical Care, OrbiMed, Monashee Investment Management, Alexandria Venture Investments, UBS O'Connor, Morgan Creek Capital, Maven Investment Partners, and a number of other health care focused funds.
    - Fresenius Medical Care, the world's leading provider of products and services for individuals with renal diseases, made an additional investment of $25 million in Humacyte as the lead investor in the PIPE financing.

- Appointed leadership to support public and commercial company efforts, including:
    - B.J. Scheessele as Chief Commercial Officer. Mr. Scheessele joined Humacyte from Quest Medical Imaging, Inc., where he served as Executive Vice President of Global Marketing, and will provide leadership, direction and strategic vision to drive the commercial launch of the HAV in its initial vascular indications and follow-on market expansion.
    - Expanded the Board of Directors, and added new board members including Gordon M. Binder, Dr. Emery N. Brown, Michael T. Constantino, Todd M. Pope, Rajiv Shukla and Dr. Susan Windham-Bannister. Prior legacy Humacyte board members continuing their service include Dr. Jeff Lawson, Max Wallace, Brady Dougan, Dr. Laura Niklason and Kathleen Sebelius, who was also appointed board chair.

Third Quarter Financial Highlights

- At September 30, 2021, Humacyte held $240.4 million in cash and cash equivalents, which the Company believes to be sufficient to fund operations at least through the first anticipated approval and market launch of the HAV in the treatment of vascular trauma.

- Research and development expenses were $15.4 million for the three months ended September 30, 2021, consistent with the $14.7 million incurred for the same period in 2020. Research and development expenses for both periods primarily related to advanced-stage clinical trials of the HAV, implementation of commercial-scale manufacturing, and advancement of earlier-stage pipeline programs, with the current-period increase primarily related to additional payroll and personnel expenses to support these initiatives.

- General and administrative expenses were $5.4 million for the three months ended September 30, 2021, compared to $3.4 million for the same period in 2020. The increase was primarily due to increased professional fees and other costs related to preparation for transition to public status and planned commercialization, and non-cash stock-based compensation related to expansion of the leadership team.

- Net total other expenses were $11.0 million for the three months ended September 30, 2021, compared to $0.5 million for the same period in 2020. The majority of the increase related to a $9.8 million non-cash expense resulting from quarterly remeasurement of the contingent earnout liability associated with the completed business combination.

- Net loss for the three months ended September 30, 2021, was $31.6 million, or $0.72 per share, compared to a net loss of $17.8 million, or $3.07 per share, in the same period in 2020. The increase was primarily due to the non-cash liability remeasurement mentioned above, combined with the increase in general and administrative expenses.

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-4 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.

Humacyte, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,	
	2021	**2020**
Grant revenue	$ 241	$ 914
Operating expenses:		
Research and development	15,386	14,692
General and administrative	5,398	3,435
Total operating expenses	20,784	18,127
Loss from operations	**(20,543)**	**(17,213)**
Other expenses, (net):		
Change in fair value of contingent earnout liability	(9,768)	-
Other income (expenses) (net)	(1,252)	(547)
Total other expenses, net	(11,020)	(547)
Net loss and comprehensive loss	**$ (31,563)**	**$ (17,760)**
Net loss per share, basic and diluted	$ (0.72)	$ (3.07)
Weighted-average shares outstanding, basic and diluted	43,950,856	5,788,130

Humacyte, Inc.
Condensed Consolidated Balance Sheets
(unaudited)
(in thousands)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 240,449	$ 39,929
Prepaid expenses and other current assets	3,730	1,520
Total current assets	244,179	41,449
Property, plant and equipment, net	36,499	40,978
Lease right-of-use assets, net	22,685	24,261
Total assets	**$ 303,363**	**$ 106,688**
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 5,830	$ 2,274
Accrued expenses	9,422	4,592
SVB loan payable, current portion	3,889	-
Other current liabilities	2,104	4,367
Total current liabilities	21,245	11,233
Contingent earnout liability	169,200	-
Finance lease obligation, net of current portion	21,627	23,090
SVB loan payable, net of current portion	14,038	-
Other long-term liabilities	1,392	1,693
Total liabilities	**227,502**	**36,016**
Redeemable convertible preferred stock	-	420,989
Stockholders' equity (deficit)		
Common stock and additional paid-in capital	533,019	37,779
Accumulated deficit	(457,158)	(388,096)
Total stockholders' equity (deficit)	75,861	(350,317)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	**$ 303,363**	**$ 106,688**

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