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 10, 2022

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 2.02. Results of Operations and Financial Condition

On November 10, 2022, Humacyte, Inc. issued a press release regarding its financial results for its fiscal third quarter ended September 30, 2022. 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 10, 2022.
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 10, 2022

By: /s/ Dale A. Sander

Name: Dale A. Sander

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

Exhibit 99.1

Humacyte Third Quarter 2022 Financial Results and Business Update

-- Progress Continues in Clinical Development of Human Acellular Vessel™ (HAV™) for Vascular Trauma; BLA Filing Anticipated mid 2023 –

-- Experience with HAV in Ukrainian War Vascular Trauma Mirrors Clinical Experiences in Civilians in the U.S., High Patency and Low Rates of Amputation and Infection Observed –

-- Pre-Clinical Studies of Small Diameter HAV in Coronary Bypass Continue to be Promising –

-- Strengthened Board of Directors with Appointment of Lt. General C. Bruce Green, M.D., USAF-ret and Senior Management Team with Appointment of Yang (Cindy) Cao, Ph.D. as Chief Regulatory Officer –

-- Conference Call and Live Webcast at 8:00 a.m. ET Today –

DURHAM, N.C., November 10, 2022 -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable bioengineered human tissues, advanced tissue constructs and organ systems at commercial scale, today announced financial results for the third quarter ended September 30, 2022, and highlighted recent corporate accomplishments.

"The third quarter of 2023 proved to be highly productive for Humacyte, with continued progress across our clinical and preclinical programs and multiple data presentations at key medical meetings," said Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte. "We expect to file our Biologics License Application (BLA) for an indication in vascular trauma in mid 2023. We are pleased with the trial's progress and the positive results obtained to date. In addition, we are proud to be partnering with the Diabetes Research Institute to support our Biovascular Pancreas product development program in severe type 1 diabetes. The opportunity to work with the outstanding scientists and physicians at DRI is an exciting addition to our BVP program that we anticipate will accelerate our product development. Finally, we welcome to the Humacyte leadership team Dr. Lt. General Bruce Green and Dr. Cindy Cao, whose extensive expertise will be invaluable as our HAVs continue to progress toward approval."

Third Quarter 2022 and Recent Corporate Highlights

Clinical Updates

- The Company plans to file a Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA) for an indication in vascular trauma in mid 2023. As of October 31, 2022, 56 patients had received the HAV in the V005 Phase 2/3 clinical trial in vascular trauma. V005 is an open-label study and to date we have observed high rates of patency, low rates of amputation and only one case of HAV infection in the V005 trial. In addition, the preliminary results of the first nine patients treated under the humanitarian program in Ukraine have been shared with the FDA, and the Company expects to supplement the V005 data with these complementary results. The Company also plans to open a Clinical Trial Application in Ukraine and plans to enable enrollment of additional patients in the V005 clinical trial.

- Humacyte initiated a research partnership with the Diabetes Research Institute (DRI) in Miami, Florida, a global leader in pre-clinical studies of novel diabetic therapies, to facilitate development of the Biovascular Pancreas (BVP), a product candidate designed to treat patients with severe type 1 diabetes.

- Enrollment is nearing completion in our Phase 3 trial of the HAV for arteriovenous (AV) access in hemodialysis patients. The V007 trial is designed to assess the usability of the HAV for hemodialysis, in comparison to autogenous fistulas, in up to 240 patients with end stage renal disease. With 227 patients enrolled as of October 26, 2022, we anticipate that enrollment will be completed soon. Top-line results are anticipated one year after enrollment completion, based upon the one-year follow-up period built into the study.

Publications and Presentations

- In October 2022, the U.S. Army published an update affirming their support of the development of the HAV in trauma. In an article entitled "How an Army-funded 'bioengineered blood vessel' is saving lives in Ukraine," the Army reported that officials with the Defense Department encouraged Humacyte to collaborate with the Medical Technology Enterprise Consortium (MTEC), which helps identify new medical solutions for warfighters. MTEC has already provided more than $6.8 million in funding to Humacyte to develop the HAV.

- Ukrainian surgeons presented patient outcomes from the use of the HAV to treat wartime vascular trauma at the European Society for Vascular Surgery Annual Meeting in Rome in September 2022. The surgeons described long-standing limitations in vascular tissue repair and replacement as well as the injuries that they have observed during the Russian-Ukrainian conflict. Surgeons have utilized the HAV to treat patients with a multitude of wartime injuries including blast trauma, shrapnel injuries, and gunshot wounds. The surgeons observed that access to the HAV, a biologic conduit, has improved their ability to perform vascular reconstructions by eliminating the need to harvest a venous conduit.

- In September 2022, Todd E. Rasmussen M.D., FACS, (Col, ret. USAF MC) and Charles J. Fox M.D. provided a clinical update on the HAV for the treatment of vascular trauma at the 44th International Committee of Military Medicine (ICMM) World Congress in Brussels, Belgium. Speaking to an audience of NATO and other international surgeons, Drs. Rasmussen and Fox observed that injured service members and those with certain complex injuries in the civilian sector could benefit from the use of a readily available and infection resistant vascular conduit, such as the HAV, that would facilitate quick implantation, particularly in the setting of contaminated wounds.

- In July 2022, preclinical data on use of the small-diameter HAV in coronary artery bypass grafting (CABG) was presented at American Heart Association Basic Cardiovascular Sciences Scientific Sessions. Coronary bypass in a non-human primate model, with follow-up of 6 months, showed that the HAV maintained structural integrity and functioned well to conduct blood flow to the heart. In addition, the HAV had robust cell repopulation with vascular cells over time, becoming a living vascular tissue supplying the heart muscle. Updated data from this study, consistent with these findings, were also reported at the American Heart Association (AHA) Scientific Sessions annual meeting in Chicago on November 6, 2022.

Corporate Updates

- In September 2022, pharma industry veteran Yang (Cindy) Cao, Ph.D. joined as the Company's Chief Regulatory Officer. Dr. Cao brings over twenty years of drug discovery and development experience in pharmaceutical and biotech companies, including Bristol-Myer Squibb, Novartis, Novo Nordisk and Sanofi. Dr. Cao has extensive expertise in global and US regulatory strategy and policy on biologics, small molecules, and devices, and has provided guidance to development teams in various therapeutic areas. Dr. Cao holds a B.S. in genetics from Fudan University in Shanghai China, and a Ph.D. in biomedical sciences from University of New Mexico.

- Also in September 2022, Humacyte strengthened its Board of Directors with the appointment of Lt. General C. Bruce Green, M.D., USAF-ret., former Surgeon General of the U.S. Air Force. As command surgeon for three major commands, he planned joint medical response for operations Desert Thunder and Desert Fox, and oversaw aeromedical evacuation for operations Enduring Freedom and Iraqi Freedom. General Green earned a B.S. in chemistry at the University of Wisconsin-Parkside and an M.D. at the Medical College of Wisconsin.

- The Company is continuing to strengthen its relationship with its global partner and shareholder Fresenius Medical Care, the global market leader in kidney care services, products and value-based care. Humacyte is partnering with Frenova, a clinical research group owned by Fresenius Medical Care, to evaluate the complications and costs of hemodialysis access care for vulnerable patients in both the US and Europe. Data from more than 600,000 anonymized patients, concerning demographics, access complications and failures, infections, hospitalization and mortality is being analyzed to provide targeted information on those patients who may most benefit from the HAV.

Third Quarter 2022 Financial Highlights

- The Company reported cash, cash equivalents and short-term investments of $171.7 million as of September 30, 2022, compared to $225.5 million as of December 31, 2021. The $53.8 million net use of cash, cash equivalents and short-term investments for the first nine months of 2022 resulted from spending related to net operating activities for the period, including clinical and earlier-stage research and development programs, and preparation for the Company's anticipated commercial launch. The Company believes that its cash, cash equivalents and short-term investments are adequate to fund operations through 2024, past the Company's current expected timeline for potential approval of the HAV in vascular trauma.

- Revenue was $31 thousand for the third quarter of 2022, compared to $0.2 million for the third quarter of 2021, and was $1.6 million for the nine months ended September 30, 2022, compared to $1.1 million for the nine months ended September 30, 2021. Revenue in all periods related to grants supporting the development of the HAV.

- Research and development expenses were $17.3 million for the third quarter of 2022, compared to $15.4 million for the third quarter of 2021, and were $48.3 million for the nine months ended September 30, 2022, compared to $45.1 million for the nine months ended September 30, 2021. The current-period increases resulted primarily from increased personnel expenses to support expanded research and development initiatives and the support of clinical trials.

- General and administrative expenses were $6.2 million for the third quarter of 2022, compared to $5.4 million for the third quarter of 2021, and were $17.1 million for the nine months ended September 30, 2022, compared to $15.6 million for the nine months ended September 30, 2021. The current-period increases resulted primarily from the transition to being a public company and preparation for the anticipated U.S. commercial launch of the HAV, including increased personnel costs, professional fees and insurance costs.

- Other net expense was $1.8 million for the third quarter of 2022, compared to $11.0 million for the third quarter of 2021, and other net income was $55.5 million for the nine months ended September 30, 2022, compared to other net expense of $9.5 million for the nine months ended September 30, 2021. The current-period reduction in other net expense for the current-year third quarter, and increase in other current net income for the current-year nine months, resulted primarily from the remeasurement of the contingent earnout liability associated with the August 2021 merger with Alpha Healthcare Acquisition Corp.

- Net loss was $25.3 million for the third quarter of 2022, compared to $31.6 million for the third quarter of 2021, and net loss was $8.2 million for the nine months ended September 30, 2022, compared to $69.1 million for the nine months ended September 30, 2021. The current-period decreases in net loss resulted from the reductions in other net expense and increase in other net income described above, partially offset by operating expense increases also described above.

Conference Call and Webcast Details

Date:	Thursday, November 10, 2022
Time:	8:00 a.m. ET
Conference Call Details:	Toll-Free: 1-844-826-3033 International: 1-412-317-5185 Conference ID: 10171750
Webcast:	Webcast Link - Click Here

A replay of the webcast will be available following the conclusion of the live broadcast and will be accessible on the investors section of the Company's website for at least 30 days.

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 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. 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 arteriovenous (AV) access for performing 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. 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 benefits and risks related to our humanitarian efforts in the Ukraine; 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; the outcome of our ongoing discussions with the FDA concerning the design of our ongoing V005 Phase II/III 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, 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 our Annual Report on Form 10-K for the year ended December 31, 2021, 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. 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 Investor Contact:
Joyce Allaire
LifeSci Advisors LLC
+1-617-435-6602
jallaire@lifesciadvisors.com
investors@humacyte.com

Humacyte Media Contact:
Elizabeth Miller
LifeSci Communications
+1-704-299-6016
emiller@lifescicomms.com
media@humacyte.com

Humacyte, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(unaudited)

(in thousands except for share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Grant Revenue	$ 31	$ 241	$ 1,565	$ 1,086
Operating expenses:				
Research and development	17,337	15,386	48,303	45,091
General and administrative	6,188	5,398	17,050	15,576
Total operating expenses	23,525	20,784	65,353	60,667
Loss from operations	**(23,494)**	**(20,543)**	**(63,788)**	**(59,581)**
Other income (expense), net				
Change in fair value of contingent earnout liability	(962)	(9,768)	58,649	(9,768)
Other (expense) income (net)	(825)	(1,252)	(3,106)	287
Total other income (expense), net	(1,787)	(11,020)	55,543	(9,481)
Net loss and comprehensive loss	**$ (25,281)**	**$ (31,563)**	**$ (8,245)**	**$ (69,062)**
Net loss per share, basic and diluted	$ (0.25)	$ (0.72)	$ (0.08)	$ (3.69)
Weighted-average shares outstanding, basic and diluted	103,031,980	43,950,856	103,014,009	18,728,471

Humacyte, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 163,731	$ 217,502
Short-term investments	8,000	8,000
Prepaid expenses and other current assets	2,881	3,838
Total current assets	174,612	229,340
Property, plant and equipment, net	31,026	35,034
Lease right-of-use assets, net	20,581	22,159
Total assets	**$ 226,219**	**$ 286,533**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,255	$ 2,094
Accrued expenses	7,959	6,757
SVB loan payable, current portion	4,286	—
Other current liabilities	2,406	2,199
Total current liabilities	17,906	11,050
Contingent earnout liability	45,011	103,660
SVB loan payable, net of current portion	24,286	27,361
Finance lease obligation, net of current portion	19,442	21,109
Other long-term liabilities	902	1,179
Total liabilities	**107,547**	**164,359**
Stockholders' equity		
Common stock and additional paid-in capital	541,490	536,747
Accumulated deficit	(422,818)	(414,573)
Total stockholders' equity	118,672	122,174
Total liabilities and stockholders' equity	**$ 226,219**	**$ 286,533**