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): March 24, 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:

☐ 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 March 24, 2023, Humacyte, Inc. issued a press release regarding its financial results for its fiscal fourth quarter and full year ended December 31, 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 March 24, 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: March 24, 2023

By: /s/ Dale A. Sander

Name: Dale A. Sander

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

Exhibit 99.1

Humacyte Announces Fourth Quarter and Year End 2022 Financial Results and Business Update

-- Enrollment Nearing Completion in Human Acellular Vessel™ (HAV™) Phase 2/3 Trial in Vascular Trauma and Phase 3 Trial in Arteriovenous (AV) Access in Hemodialysis Patients

-- Multiple publications and scientific meeting presentations highlighting clinical and preclinical HAV results –

-- Conference call and live webcast at 8:00 a.m. ET today –

DURHAM, N.C., March 24, 2023 – Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable bioengineered human tissues and advanced tissue constructs and organ systems at commercial scale, today announced financial results for the fourth quarter and year ended December 31, 2022, and highlighted recent corporate accomplishments.

"During 2022, we continued to make significant progress across all of our clinical programs and are poised to maintain this momentum throughout 2023," said Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte. "With enrollment approaching completion in our Phase 2/3 trial of the HAV in its vascular trauma indication, we have moved substantially closer to our anticipated filing of a Biologics License Application (BLA) in this indication. The potential of the HAV in vascular trauma was highlighted in a compelling key opinion webinar we hosted in December, featuring Ukrainian surgeons Drs. Oleksandr Sokolov, Vasyl Shaprynskyi, and Oleksandr Stanko. We extend our sincere thanks to our Ukrainian colleagues for sharing their experiences using the HAV to treat patients with wartime vascular trauma. In addition to our vascular trauma indication, we are excited to be nearing completion of enrollment in our Phase 3 trial of the HAV in arteriovenous access for hemodialysis patients, with topline results anticipated one year following completion of enrollment. Finally, we continue to be encouraged with the preclinical progress of our small diameter HAV in coronary artery bypass grafting (CABG), which we believe further supports the utility of our HAV as a vascular conduit across multiple indications."

Fourth Quarter 2022 and Recent Corporate Highlights

Clinical Updates

- **Enrollment nearing completion in Phase 2/3 V005 trial in vascular trauma** – A total of 63 patients have received the HAV in the Company's Phase 2/3 V005 trial in vascular trauma. In addition, 17 vascular trauma patients have been treated with the HAV under the humanitarian program in Ukraine. All patient results will be included in the BLA filing with the FDA. The primary efficacy assessment of the HAV in trauma will be based on a 30-day patency in 50 patients from the V005 trial who have suffered vascular trauma of an extremity. This primary efficacy analysis will not include patients with torso injuries and iatrogenic trauma enrolled in the V005 trial, though data from these patients will contribute to the safety database. Currently, 46 patients comprising the primary endpoint population have been treated with the HAV in the V005 trial, and the Company plans to enroll approximately six more patients to complete the study. Efforts to accelerate the enrollment of the remaining patients in V005 include the recent addition of clinical sites in Israel and ongoing efforts to expand the V005 trial to Ukrainian sites. The Company plans to file a BLA for accelerated approval with the U.S. Food and Drug Administration (FDA) for an indication in vascular trauma within approximately four months after the completion of the V005 trial. The Company plans to seek accelerated approval of the HAV for urgent arterial repair following extremity vascular trauma when synthetic graft is not indicated and when autologous vein is not feasible.

- **Enrollment nearing completion in Phase 3 V007 trial in arteriovenous (AV) access** – Currently, 238 patients have been enrolled in the Company's Phase 3 trial of the HAV for 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. Top-line results are anticipated one year after completion of enrollment of the final patients in the trial, based on the one-year follow-up period built into the study.

Publications and Presentations

- Six-year results from the Company's Phase 2 trial of the HAV in peripheral artery disease (PAD) were published in *Journal of Vascular Surgery – Vascular Science*. The article, entitled "6-Year Outcomes of a Phase 2 Study of Human-Tissue Engineered Blood Vessels for Peripheral Arterial Bypass," reports overall secondary patency rate of 60% at 72 months, as estimated by Kaplan Meier analysis. This patency compares well with outcomes from saphenous vein revascularization. There was no evidence of graft rejection or infection, and no patients underwent amputation of the affected limb out to six years.

- In December 2022, the Company hosted a key opinion leader (KOL) webinar on its HAV in the treatment of wartime vascular trauma, featuring presentations from Ukrainian surgeons Oleksandr Sokolov, M.D., Ph.D., Vasyl Shaprynskyi, M.D., Ph.D., and Oleksandr Stanko, M.D, who discussed the use of the HAV to treat war-induced traumatic injuries, including case studies from the first nine patients treated under the humanitarian program. Our Ukrainian colleagues observed 30-day patency and zero cases of infection in all patients treated with the HAV. A replay of the event can be accessed on the Humacyte website here.

- Also in December 2022, Ukrainian surgeons presented patient outcomes from the use of the HAV to treat wartime vascular trauma at two vascular conferences. Drs. Sokolov, Shaprynskyi and Stanko presented at the VI Congress of Vascular Surgeons, Phlebologists, and Angiologists of Ukraine in Kyiv, Ukraine. In addition, Dr. Sokolov presented at the 11th Munich Vascular Conference (MAC) 2022.

- In November 2022, Alan P. Kypson, M.D., FACS, thoracic surgeon at UNC Rex Hospital and lead investigator in Humacyte's large animal pre-clinical development of vessels for coronary artery bypass grafting, provided a six-month patency update of the HAV in a baboon coronary artery bypass grafting (CABG) model in an oral presentation at the annual American Heart Association (AHA) Scientific Sessions meeting, held in Chicago, Illinois. Dr. Kypson highlighted that the HAV was observed to maintain structural integrity for up to six months and functioned as intended to conduct blood flow to the heart. In addition, the HAV showed evidence of robust cell repopulation with vascular cells over time, which suggests the potential for the HAV to become a living vascular tissue supplying blood to the heart muscle.

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

Fourth Quarter and Year Ended 2022 Financial Highlights

- There was no revenue for the fourth quarter of 2022 compared to $177.0 thousand for the fourth quarter of 2021, and revenue was $1.6 million for the year ended December 31, 2022, compared to $1.3 million for the year ended December 31, 2021. Revenue in all periods related to grants supporting the development of the HAV.

- Research and development expenses were $15.0 million for the fourth quarter of 2022, compared to $16.3 million for the fourth quarter of 2021, and were $63.3 million for the year ended December 31, 2022, compared to $61.3 million for the year ended December 31, 2021. The decrease for the quarter ended December 31, 2022 compared to the prior-year quarter resulted primarily from a decrease in non-cash stock-based compensation expense. The increase during the year ended December 31, 2022 compared to 2021 resulted primarily from increased personnel and materials expenses designed to support expanded research and development initiatives and the support of clinical studies.

- General and administrative expenses were $5.8 million for the fourth quarter of 2022, compared to $5.6 million for the fourth quarter of 2021, and were $22.9 million for the year ended December 31, 2022, compared to $21.1 million for the year ended December 31, 2021. The 2022 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, external services and insurance costs.

- Other net income was $17.1 million for the fourth quarter of 2022, compared to $64.2 million for the fourth quarter of 2021, and was $72.6 million for the year ended December 31, 2022, compared to $54.7 million for the year ended December 31, 2021. The reduction in other net income for the fourth quarter of 2022, and increase in other net income for the year December 31, 2022, resulted primarily from non-cash gains related to the remeasurement of the contingent earnout liability associated with the August 2021 merger with Alpha Healthcare Acquisition Corp.

- Net loss was $3.7 million for the fourth quarter of 2022, compared to net income of $42.6 million for the fourth quarter of 2021, and net loss was $12.0 million for the year ended December 31, 2022, compared to net loss of

$26.5 million for the year ended December 31, 2021. The increase in net loss for the current-year fourth quarter compared to 2021 resulted from a decrease in other net income described above. The decrease in net loss during the year ended December 31, 2022 compared to 2021 resulted from the increase in other net income described above, partially offset by operating expense increases also described above.

- The Company reported cash, cash equivalents and short-term investments of $151.9 million as of December 31, 2022, compared to $225.5 million as of December 31, 2021. The $73.6 million net use of cash, cash equivalents and short-term investments for the year ended December 31, 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 the end of 2024, past the Company's current expected timelines for potential approval of the HAV in its vascular trauma indication.

Conference Call and Webcast Details

Date:	Friday, March 24, 2023
Time:	8:00 a.m. ET
Conference Call Details:	Toll-Free: 1-877-704-4453 International: 1-201-389-0920 Conference ID#: 13736105
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 that have the potential 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 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, the impact of COVID-19 on Humacyte's business, 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, to be 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.

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Humacyte, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

(unaudited)

(in thousands except for share and per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	**2021**	**2022**	**2021**
Grant revenue	$ —	$ 177	$ 1,565	$ 1,263
Operating expenses:				
Research and development	14,957	16,250	63,260	61,341
General and administrative	5,833	5,554	22,883	21,130
Total operating expenses	20,790	21,804	86,143	82,471
Loss from operations	**(20,790)**	**(21,627)**	**(84,578)**	**(81,208)**
Other income (expense), net				
Change in fair value of contingent earnout liability	17,118	65,540	75,767	55,772
Other expense (net)	(48)	(1,328)	(3,154)	(1,041)
Total other income, net	17,070	64,212	72,613	54,731
Net (loss) income and comprehensive (loss) income	**$ (3,720)**	**$ 42,585**	**$ (11,965)**	**$ (26,477)**
Net (loss) income per share, basic	$ (0.04)	$ 0.41	$ (0.12)	$ (0.66)
Weighted-average shares outstanding, basic	103,162,219	103,003,506	103,051,366	39,970,398
Net (loss) income per share, diluted	$ (0.04)	$ 0.41	$ (0.12)	$ (0.66)
Weighted-average shares outstanding, diluted	103,162,219	104,743,854	103,051,366	39,970,398

Humacyte, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands)

	As of December 31,	
	2022	**2021**
Assets		
Current assets:		
Cash and cash equivalents	$ 149,772	$ 217,502
Short-term investments	2,107	8,000
Prepaid expenses and other current assets	2,329	3,838
Total current assets	154,208	229,340
Property, plant and equipment, net	30,039	35,034
Lease right-of-use assets, net	20,055	22,159
Total assets	**$ 204,302**	**$ 286,533**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,595	$ 2,094
Accrued expenses	7,108	6,757
SVB loan payable, current portion	8,571	—
Other current liabilities	2,306	2,199
Total current liabilities	19,580	11,050
Contingent earnout liability	27,893	103,660
SVB loan payable, net of current portion	20,336	27,361
Finance lease obligation, net of current portion	18,853	21,109
Other long-term liabilities	712	1,179
Total liabilities	**87,374**	**164,359**
Stockholders' equity		
Common stock and additional paid-in capital	543,466	536,747
Accumulated deficit	(426,538)	(414,573)
Total stockholders' equity	116,928	122,174
Total liabilities and stockholders' equity	**$ 204,302**	**$ 286,533**