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 22, 2024

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 22, 2024, Humacyte, Inc. issued a press release regarding its financial results for its fiscal fourth quarter and full year ended December 31, 2023. 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 22, 2024.
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 22, 2024

By: /s/ Dale A. Sander

Name: Dale A. Sander

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

Exhibit 99.1

Humacyte Fourth Quarter and Year End 2023 Financial Results and Business Update

-Biologics License Application (BLA) for HAV™ Accepted by FDA on February 8, 2024-

-BLA Granted Priority Review for Vascular Trauma Indication; PDUFA date set for August 10, 2024-

-Raised approximately $43.1 million in net proceeds from public offering of common stock-

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

DURHAM, N.C., March 22, 2024 **–** 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 fourth quarter and year ended December 31, 2023 and highlighted recent corporate accomplishments in advancing the investigational Human Acellular Vessel (HAV) closer to planned U.S. market launch.

“During 2023, we accomplished major goals across all of our clinical programs. In December 2023, we submitted our Biologics License Application (BLA) to the Food and Drug Administration (FDA) seeking approval of the HAV in the vascular trauma indication,” said Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte. “The FDA’s acceptance of our filing in February 2024 brings us another major step closer to our goal of providing an innovative regenerative medicine product for patients suffering traumatic vascular injury. We believe the FDA’s decision to grant Priority Review reflects their recognition that many patients with severe injuries are underserved by the current standard of care. We look forward to working with the agency toward their Prescription Drug User Fee Act (PDUFA) date of August 10, 2024.”

“During the year we were also pleased with the progress made in our broader HAV pipeline, including completion of enrollment of our V007 Phase 3 trial of the HAV for use in AV access for hemodialysis, presentation and publication of clinical trial results in severe peripheral artery disease (PAD), and publication of preclinical results for our small caliber HAV in a juvenile heart disease preclinical model. The coming year will be exciting, and we thank the medical professionals, patients, researchers and our employees for their contributions to the continued advancement of the HAV,” concluded Dr. Niklason.

Fourth Quarter 2023 and Recent Corporate Highlights

Clinical and Regulatory Updates

- **Biologics License Application for HAV Granted Priority Review by U.S. FDA for the Vascular Trauma Indication** – In February 2024, the Company announced that the FDA had accepted and granted Priority Review to its BLA seeking approval of the HAV in urgent arterial repair following extremity vascular trauma when synthetic graft is not indicated, and when autologous vein use is not feasible. The BLA submission is supported by positive results from the V005 Phase 2/3 clinical trial, as well as real-world evidence from the treatment of wartime injuries in Ukraine under a humanitarian aid program. The HAV was observed to have higher rates of patency (blood flow), and lower rates of amputation and infection, as compared to historic synthetic graft benchmarks in both the V005 Phase 2/3 clinical trial and the Ukraine humanitarian program.

The PDUFA date, the FDA action date for their regulatory decision regarding the BLA, is August 10, 2024. The Priority Review designation is a mechanism reserved by FDA for products that, if approved, would significantly improve the treatment, diagnosis, or prevention of serious conditions. Priority Review applications have a six-month review time instead of ten months for a standard review. The Priority Review aligns with the Regenerative Medicine Advanced Therapy (RMAT) designation granted by the FDA in May 2023 for urgent arterial repair following extremity vascular trauma. The Priority Review is also consistent with the priority designation given by the Secretary of Defense under Public Law 115-92, which was enacted to expedite the FDA's review of products that are intended to diagnose, treat or prevent serious or life-threatening conditions facing American military personnel.

Presentations and Publications

- **Presentations at a Major Vascular Surgery Symposium** – Two presentations were made at the VEITH Symposium, a major vascular surgery meeting, held in New York City on November 15-18, 2023. These include an expanded presentation of positive results of the V005 vascular trauma trial, with the HAV observed to have higher rates of patency and lower rates of amputation and infection as compared to historic synthetic graft benchmarks.

  Results of the V005 trial were presented by Charles J. Fox, MD, FACS, Director of Vascular Surgery at the University of Maryland Capital Region, a clinical investigator in the V005 trial, in a podium presentation titled "Phase 2/3 Study for the Evaluation of Safety and Efficacy of HAV for Vascular Reconstruction in Patients with Limb or Life-Threatening Vascular Trauma." Results from V005 and the Ukraine humanitarian program, with statistical comparison to historic benchmarks, were presented at a symposium titled "Vascular Trauma Repair Clinical Study Results with Humacyte Human Acellular Vessel (V005 & V017 Data)" by Dr. Moore, Dr. Fox, and Laura Niklason, MD, PhD, Chief Executive Officer of Humacyte.

- **Publication of Preclinical Results in Juvenile Heart Disease Study** – In October 2023, a publication in the *Journal of Thoracic and Cardiovascular Surgery* described a preclinical study showing the potential for the investigational small-diameter HAV to treat tetralogy of Fallot, a heart condition that affects one in every 2,000 babies born each year in the United States. In the preclinical study, researchers from Nationwide Children's Hospital (Columbus, OH) and Humacyte implanted 3.5mm diameter HAVs into a juvenile animal model of pediatric heart disease. The 3.5mm HAVs remained patent for up to six months, and evidence of HAV repopulation by host cells was observed, similar to what has been observed in human patients. In connection with the study, Humacyte produced 3.5mm vessels using the same manufacturing platform used to produce Humacyte's 6mm HAVs that are in current clinical use.

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

Fourth Quarter and Full Year 2023 Financial Highlights

- The Company reported cash and cash equivalents of $80.4 million as of December 31, 2023. In addition, Humacyte completed two transactions in early 2024 which added to its cash balance. On March 5, 2024, the Company closed an underwritten public offering of its common stock and raised net proceeds of approximately $43.1 million. Furthermore, on March 11, 2024, the Company received $20 million in proceeds from an additional draw under its previously disclosed funding arrangement with Oberland Capital Management. Total net cash used was $69.0 million for the year ended December 31, 2023, compared to $67.7 million for the year ended December 31, 2022. Humacyte believes that its cash and cash equivalents, including net proceeds from the March offering and additional draw under the Oberland funding arrangement, will be adequate to finance operations for at least 12 months from the date of this financial report, well past the currently anticipated timelines for FDA approval of commercialization of the HAV in the vascular trauma indication.

- There was no revenue for either the fourth quarter of 2023 or the fourth quarter of 2022, and there was no revenue for the year ended December 31, 2023. Revenue was $1.6 million for the year ended December 31, 2022, and was related to a grant supporting the development of the HAV that was completed during 2022.

- Research and development expenses were $20.2 million for the fourth quarter of 2023, compared to $15.0 million for the fourth quarter of 2022, and were $76.6 million for the year ended December 31, 2023, compared to $63.3 million for the year ended December 31, 2022. The 2023 increases resulted primarily from increased personnel, external services expenses and materials expenses to support expanded research and development initiatives and our clinical trials, including the completion of our V005 Phase 2/3 and V017 Ukraine Humanitarian trials for the use of the HAV in extremity vascular trauma, our BLA filing in December 2023, and expansion of clinical development of the HAV for use in AV access for hemodialysis.

- General and administrative expenses were $6.0 million for the fourth quarter of 2023, compared to $5.8 million for the fourth quarter of 2022, and were $23.5 million for the year ended December 31, 2023, compared to $22.9 million for the year ended December 31, 2022. The slight net increases in 2023 resulted primarily from increased personnel costs, primarily driven by preparation for the planned commercial launch of the HAV in the vascular trauma indication.

- Other net income (expense) was net income of $1.1 million for the fourth quarter of 2023, compared to net income of $17.1 million for the fourth quarter of 2022, and was net expense of $10.7 million for the year ended December 31, 2023, compared to net income of $72.6 million for the year ended December 31, 2022. The reduction in other net income for the fourth quarter of 2023, and the increase in other net expense for the year December 31, 2023, resulted primarily from the non-cash remeasurement of the contingent earnout liability associated with the August 2021 merger with Alpha Healthcare Acquisition Corp.

- Net loss was $25.1 million for the fourth quarter of 2023, compared to $3.7 million for the fourth quarter of 2022, and net loss was $110.8 million for the year ended December 31, 2023, compared to $12.0 million for the year ended December 31, 2022. The 2023 increases in net loss resulted from the non-cash remeasurement of the contingent earnout liability, and operating expense increases, described above.

Conference Call and Webcast Details

Title:	Humacyte Fourth Quarter and Year End 2023 Financial Results and Corporate Update
Date:	Friday, March 22, 2024
Time:	8:00 a.m. ET
Conference Call Details:	Toll-Free: 1-877-704-4453 International: 1-201-389-0920 Conference ID #: 13744046
Call me™ Feature (avoid waiting for operator):	Click Here
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 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 an 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 our plans and ability to execute product development, process development and preclinical development efforts successfully and on our anticipated timelines; our plans and ability to obtain marketing approval from the FDA and other regulatory authorities for the HAV and other product candidates; the outcome of the FDA’s review of our BLA seeking approval of the HAV in the vascular trauma indication; our ability to design, initiate and successfully complete clinical trials and other studies for our product candidates and our plans and expectations regarding our ongoing or planned clinical trials, including for our V007 Phase 3 clinical trial; the characteristics and performance of the HAV; our ability to manufacture HAVs and other product candidates in sufficient quantities to satisfy our clinical trial and commercial needs; our plans and ability to commercialize the HAV and other product candidates, if approved by regulatory authorities; and our anticipated cash runway. 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 described under the header “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2022 and in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, each 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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Humacyte, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(unaudited)

(in thousands except for share and per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	**2022**	**2023**	**2022**
Grant revenue	$ —	$ —	$ —	$ 1,565
Operating expenses:				
Research and development	20,180	14,957	76,550	63,260
General and administrative	6,002	5,833	23,497	22,883
Total operating expenses	26,182	20,790	100,047	86,143
Loss from operations	**(26,182)**	**(20,790)**	**(100,047)**	**(84,578)**
Other income (expense), net				
Change in fair value of contingent earnout liability	1,685	17,118	(10,023)	75,767
Other expense (net)	(609)	(48)	(706)	(3,154)
Total other income (expense), net	1,076	17,070	(10,729)	72,613
Net loss and comprehensive loss	**$ (25,106)**	**$ (3,720)**	**$ (110,776)**	**$ (11,965)**
Net loss per share, basic and diluted	$ (0.24)	$ (0.04)	$ (1.07)	$ (0.12)
Weighted-average shares outstanding, basic and diluted	103,607,631	103,162,219	103,420,238	103,051,366

Humacyte, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands)

	As of December 31,	
	2023	**2022**
Assets		
Current assets:		
Cash and cash equivalents	$ 80,448	$ 149,772
Prepaid expenses and other current assets	2,830	2,329
Short-term investments	—	2,107
Total current assets	83,278	154,208
Property, plant and equipment, net	26,791	30,039
Finance lease right-of-use assets, net	17,313	19,373
Other long-term assets	841	682
Total assets	**$ 128,223**	**$ 204,302**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,490	$ 1,595
Accrued expenses	9,340	7,108
Other current liabilities	2,613	2,306
SVB loan payable, current portion	—	8,571
Total current liabilities	18,443	19,580
Revenue interest liability	38,600	—
Contingent earnout liability	37,916	27,893
Finance lease obligation, net of current portion	16,293	18,853
Other long-term liabilities	3,425	712
SVB loan payable, net of current portion	—	20,336
Total liabilities	**114,677**	**87,374**
Stockholders' equity		
Common stock and additional paid-in capital	550,860	543,466
Accumulated deficit	(537,314)	(426,538)
Total stockholders' equity	13,546	116,928
Total liabilities and stockholders' equity	**$ 128,223**	**$ 204,302**