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): May 10, 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** (Address of principal executive offices)	**27713** (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 May 10, 2024, Humacyte, Inc. issued a press release regarding its financial results for its fiscal first quarter ended March 31, 2024. 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 May 10, 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: May 10, 2024

By: /s/ Dale A. Sander

Name: Dale A. Sander

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

Exhibit 99.1

Humacyte First Quarter 2024 Financial Results and Business Update

-Biologics License Application (BLA) for HAV™ Accepted by FDA-

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

-Raised approximately $43 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., May 10, 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 first quarter ended March 31, 2024 and highlighted recent accomplishments advancing the investigational Human Acellular Vessel™ (HAV) closer to planned U.S. market launch.

"During the first quarter of 2024, we achieved a major milestone with the acceptance by the Food and Drug Administration (FDA) of our Biologics License Application (BLA) 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 decision to grant Priority Review sets a Prescription Drug User Fee Act (PDUFA) date of August 10, 2024, and the entire Humacyte team is working to support our planned U.S. market launch. Among our recent accomplishments is the completion of a Budget Impact Model illustrating the potential economic value of the HAV compared to current standard of care in vascular trauma. In addition, the FDA completed its Pre-Licensing Inspection of our manufacturing facilities in Durham, North Carolina as part of the BLA review process. We remain on track with our BLA review and commercial launch preparations and remain confident in the approvability of the HAV in vascular trauma."

First Quarter 2024 and Recent Corporate Highlights

HAV in Vascular Trauma

- **Biologics License Application for HAV Granted Priority Review by U.S. FDA for the Vascular Trauma Indication** – In February 2024, the FDA accepted and granted Priority Review to Humacyte's 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 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, or blood flow, and lower rates of amputation and infection, as compared to historic synthetic graft benchmarks.

- **Preparation for Planned U.S. Launch of HAV in Vascular Trauma** – Building upon the positive clinical results and the Priority Review grant by the FDA, Humacyte has implemented a company-wide, multi-disciplinary program designed to ensure U.S. launch readiness upon the anticipated approval of the HAV for the vascular trauma indication. Major recent milestones include the completion of a Budget Impact Model illustrating the potential economic value of the HAV compared to current standard of care. Presentations of clinical results and the Budget Impact Model are planned at upcoming medical meetings and in publications during the remainder of 2024. Other ongoing activities to build awareness include demonstrations of the HAV by Humacyte's Medical Affairs team at medical and military

conferences, and at meetings conducted across the U.S. at Trauma medical centers. The Company has also begun the process to procure an ICD-10 PCS code for the HAV with the Centers for Medicare & Medicaid Services (CMS). We have also commenced the recruiting of a high-quality sales team to support the planned market launch. Humacyte is pleased to announce that we have hired Morgan Rankin as Vice President of Sales, joining Humacyte after 12 years at Teleflex Medical. Morgan most recently served as Vice President of Sales, Trauma and Emergency Medicine at Teleflex where she led a team of approximately 100 sales professionals focused on vascular access and hemorrhage control.

Medical and Scientific Presentations

- **Presentation Highlighting Advancement of the HAV in Dialysis Access** – in April 2024, Humacyte completed one year of follow-up in our Phase 3 clinical trial in arteriovenous (AV) access for hemodialysis comparing the HAV to the current standard of care, autologous arteriovenous fistula. Top line results are expected in the third quarter of this year. In addition, in collaboration with our corporate partner Fresenius Medical Care and its subsidiary Frenova Renal Research, Humacyte conducted a study to review the outcomes of close to 180,000 adult patients who received in-center dialysis at Fresenius Kidney Care dialysis centers. Among the areas of study were the complications and cost of treatment by patient demographic. The objective of the study was to further define patient subgroups who could most benefit from the HAV. Results from the study were presented by clinicians at a virtual KOL event in March 2024 titled “Hemodialysis Access: A Crossroads of Care” (a replay of the webinar is available here https://lifescievents.com/event/humacyte-2/). In the study women, particularly obese and diabetic women, were observed to have higher complication rates, including infections and access failures, and that these factors drive substantially higher treatment costs. The cost of maintaining dialysis access in patients, including costs of infections and fistula failures, average approximately $22,000 to $55,000 per year. In addition, data indicate that vascular access costs for the upper quintile of patients exceed approximately $91,000 per year. Based on the results of this research, Humacyte has commenced a clinical study designed to demonstrate the anticipated clinical and health economic benefits of the HAV in female dialysis patients, a high-unmet-need population.

- **Advancement of Diabetes Program** – Results from ongoing preclinical studies support the potential of Humacyte’s BioVascular Pancreas (BVP™) product candidate to enable the delivery and survival of insulin-producing islets as a potential treatment for type 1 diabetes. In three-month studies conducted in non-human primates, researchers observed that insulin-producing cells in the BVP survive after implantation and continue to make insulin. In addition, Humacyte has advanced the manufacturing of islets from human stem cells and has observed that these islets can arrest diabetes in rodent models. These and other preclinical results will be presented at several upcoming scientific conferences, including the American Diabetes Association Annual Meeting 2024 to be held June 21-24, 2024.

- **CABG Preclinical Remodeling Results** – Preclinical six-month studies have been conducted in non-human primates to support the planned advancement of the small-diameter HAV into human clinical trials in cardiac bypass graft surgery (CABG). Humacyte has observed remodeling of the HAV to a diameter that closely matches that of the native coronary vessels, which is an outcome not observed with any other conduit. These promising results of HAV patency and remodeling will be presented at the Tissue Engineering and Regenerative Medicine (TERM-2024) Conference on June 11-12, 2024.

The HAV and BVP are investigational products and have not been approved for sale by the FDA or any other regulatory agency.

First Quarter 2024 Financial Highlights

- The Company reported cash and cash equivalents of $115.5 million as of March 31, 2024. Total net cash provided was $35.1 million for the first three months of 2024, compared to net cash used of $20.2 million for the first three months of 2023. The increase in net cash provided resulted primarily from the receipt of approximately $43.0 million in net proceeds from an underwritten public offering of Humacyte's common stock in March 2024, and $20 million in proceeds from an additional draw under its previously disclosed funding arrangement with Oberland Capital Management. Humacyte believes that its cash and cash equivalents 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 first quarter of 2024 or the first quarter of 2023.

- The overall operating expense run rate for the first quarter of 2024 is virtually identical to the fourth quarter of 2024. Total operating expenses, which includes non-cash expenses, were $26.6 million for the first quarter of 2024, largely unchanged compared to $26.2 million incurred for the 4th quarter of 2023.

- Research and development expenses were $21.3 million for the first quarter of 2024, compared to $17.3 million for the first quarter of 2023. The current-period increase resulted primarily from increased materials and personnel expenses to support expanded research and development initiatives and our clinical trials, including the expansion of clinical development of the HAV for use in AV access for hemodialysis.

- General and administrative expenses were $5.3 million for the first quarter of 2024, compared to $5.2 million for the first quarter of 2023. The slight increase during the three months ended March 31, 2024 compared to the prior-year period resulted primarily from increased professional fees and external services costs.

- Other net income (expense) was net expense of $5.3 million for the first quarter of 2024, compared to net expense of $14.5 million for the first quarter of 2023. The decrease in other net expense for the first quarter of 2024 compared to 2023 resulted primarily from the non-cash remeasurement of the contingent earnout liability associated with the Company's August 2021 merger with Alpha Healthcare Acquisition Corp.

- Net loss was $31.9 million for the first quarter of 2024, compared to $37.0 million for the first quarter of 2023. The current-period decrease in net loss resulted primarily from the non-cash remeasurement of the contingent earnout liability described above.

Conference Call and Webcast Details

Title:	Humacyte First Quarter 2024 Financial Results Corporate Update
Date:	Friday, May 10, 2024
Time:	8:00 a.m. ET
Conference Call Details:	Toll-Free: 1-877-704-4453 International: 1-201-389-0920 Conference ID #: 13746046
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, 2023 filed 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 March 31,	
	2024	**2023**
Revenue	$ —	$ —
Operating expenses:		
Research and development	21,264	17,278
General and administrative	5,314	5,234
Total operating expenses	26,578	22,512
Loss from operations	**(26,578)**	**(22,512)**
Other income (expense), net:		
Change in fair value of contingent earnout liability	(4,593)	(14,191)
Other expense (net)	(725)	(266)
Total other expense, net	(5,318)	(14,457)
Net loss and comprehensive loss	**$ (31,896)**	**$ (36,969)**
Net loss per share, basic and diluted	$ (0.29)	$ (0.36)
Weighted-average shares outstanding, basic and diluted	108,246,008	103,263,528

Humacyte, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands)

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 115,505	$ 80,448
Prepaid expenses and other current assets	2,421	2,830
Total current assets	117,926	83,278
Property and equipment, net	25,653	26,791
Finance lease right-of-use assets, net	17,059	17,313
Other long-term assets	828	841
Total assets	**$ 161,466**	**$ 128,223**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,452	$ 6,490
Accrued expenses	7,917	9,340
Other current liabilities	2,718	2,613
Total current liabilities	14,087	18,443
Revenue interest liability	57,959	38,600
Contingent earnout liability	42,509	37,916
Finance lease obligation, net of current portion	15,850	16,293
Other long-term liabilities	4,909	3,425
Total liabilities	**135,314**	**114,677**
Stockholders' equity		
Common stock and additional paid-in capital	595,362	550,860
Accumulated deficit	(569,210)	(537,314)
Total stockholders' equity	26,152	13,546
Total liabilities and stockholders' equity	**$ 161,466**	**$ 128,223**