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): August 9, 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 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 August 13, 2024, Humacyte, Inc. (the "Company") issued a press release regarding its financial results for its fiscal second quarter ended June 30, 2024. A copy of this press release is furnished as Exhibit 99.2 to this Current Report on Form 8-K and incorporated herein by reference.

The information contained herein, including the exhibit 99.2 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 8.01. Other Events.

On August 9, 2024, the Company issued a press release announcing that the U.S. Food and Drug Administration will require additional time to complete its review of the Company's Biologics License Application seeking approval of the Company's acellular tissue engineered vessel in the vascular trauma indication. A copy of this press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release, dated August 9, 2024.
99.2	Press release, dated August 13, 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: August 13, 2024

By: /s/ Dale A. Sander

Name: Dale A. Sander

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

Humacyte Announces FDA Communication of Additional Time Required to Complete Review of acellular tissue engineered vessel (ATEV™) BLA for the Treatment of Vascular Trauma

– *2nd quarter conference call to be held Tuesday, August 13th, at 8:30 a.m. ET -*

DURHAM, N.C., August 9, 2024 **–** Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable, bioengineered human tissues at commercial scale, today announced that the U.S. Food and Drug Administration (FDA) will require additional time to complete its review of its Biologic License Application (BLA) for the acellular tissue engineered vessel (ATEV) in the vascular trauma indication. The ATEV trauma program BLA was submitted to FDA in December 2023, and the FDA granted a Priority Review in February 2024 and assigned a PDUFA date of August 10, 2024. In a phone call from FDA CBER leadership today, the Company was informed that the FDA required additional time to complete its review.

“We received a call from FDA CBER leadership this afternoon apologizing to us and stating that additional time was required for review.” said Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte. “FDA leadership noted that Humacyte’s ATEV is a first-in-class product, and that Priority Review had been granted, which allows only a six-month review cycle, as compared to the standard ten-month review cycle for most products. During the course of the BLA review, the FDA has conducted inspections of our manufacturing facilities and clinical sites and has actively engaged with us in multiple discussions regarding our BLA filing, including post-marketing and labeling discussions. Based on these interactions, we are confident in the approvability of the ATEV in treating vascular trauma. The FDA leadership expressed an apology for their inability to complete the review by the PDUFA date, and currently we do not yet have a revised action date.”

ATEV is a first-in-class bioengineered human tissue that is designed to be a universally implantable vascular conduit for use in arterial replacement and repair. While harvesting vein from a trauma patient takes valuable surgical time, ATEV is available off the shelf, and does not require further injuring the patient to obtain the needed vascular repair material. Humacyte’s BLA included positive results from the V005 pivotal Phase 2/3 clinical study, as well as real-world evidence from the treatment of wartime injuries in Ukraine under a humanitarian aid program. ATEV was used to repair many types of traumatic injuries including car accidents, gunshot wounds, blast wounds and industrial accidents. It was utilized by vascular and trauma surgeons in Level 1 Trauma centers throughout the U.S. and Israel to repair severe limb-threatening and life-threatening injuries, and in front-line hospitals in Ukraine to treat war injuries. In both the civilian and military clinical studies, ATEV was observed to have high rates of patency, or blood flow, and low rates of amputation and infection.

Conference Call Information

Management will be available during its 2nd quarter 2024 financial report and business update conference call, details ss follows:

Date:	August 13, 2024
Time:	8:30 AM Eastern Time
Conference Call Details:	1-877-704-4453 (U.S. Investors Dial) 1-201-389-0920 (International Investors Dial) 13747913 (Conference ID)
Call me™ Feature:	Click Here
Webcast:	Webcast Link - Click Here

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 product candidates, a portfolio of ATEVs, are currently in late-stage clinical trials targeting multiple vascular applications, including vascular trauma repair, arteriovenous (AV) access for hemodialysis, and peripheral artery disease. A Biologics License Application for the ATEV in the vascular trauma indication is currently under review by the FDA and was granted Priority Review with a PDUFA date of August 10, 2024. 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 ATEV 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 ATEV for urgent arterial repair following extremity vascular trauma and for advanced PAD also have received an RMAT designations. The ATEV received priority designation for the treatment of vascular trauma by the U.S. Secretary of Defense. For more information, visit www.Humacyte.com.

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

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, the expected PDUFA date for our ATEV in vascular trauma repair; the statements regarding the initiation, timing, progress, and results of our preclinical and

clinical trials, including our BVP program; the anticipated characteristics and performance of our ATEVs and the BVP; our ability to successfully complete, preclinical and clinical trials for our ATEVs and the BVP; the anticipated benefits of the BVP relative to existing alternatives; the anticipated commercialization of our ATEVs and our ability to manufacture at commercial scale; the implementation of our business model and strategic plans for our business; and the timing or likelihood of regulatory filings, acceptances and approvals. 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 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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Exhibit 99.2

Humacyte Second Quarter 2024 Financial Results and Business Update

-FDA requires additional time to complete its review of ATEV™ (acellular tissue engineered vessel) BLA for the Treatment of Vascular Trauma-

-Reported Positive Topline Results from Phase 3 Trial of ATEV in Hemodialysis Access-

-ATEV Received Third Regenerative Medicine Advanced Therapy (RMAT) Designation from FDA in Advanced Peripheral Artery Disease-

-Conference call and live webcast at 8:30 a.m. ET today-

DURHAM, N.C., August 13, 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 second quarter ended June 30, 2024 and highlighted recent accomplishments.

"We were surprised to be notified by the FDA that they will require additional time to complete their review of the BLA for our ATEV (acellular tissue engineered vessel) in vascular trauma," said Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte. "FDA leadership noted that Humacyte's ATEV is a first-in-class product, and that Priority Review had been granted, which involves only a six-month review cycle, as compared to the standard ten-month review cycle for most products. During the course of the BLA review, the FDA has conducted inspections of our manufacturing facilities and clinical sites and has actively engaged with us in multiple discussions regarding our BLA filing, including post-marketing and labeling discussions. Based on these interactions, we are confident in the approvability of the ATEV in treating vascular trauma, although we currently do not yet have a revised action date."

"The ATEV continues to make significant progress in its other investigational indications, including in hemodialysis access," continued Dr. Niklason. "We were pleased to announce positive top-line results from the V007 Phase 3 clinical trial in patients with end-stage renal disease, in which the ATEV was observed to have superior functional patency over current standard of care. In addition, the ATEV received its third RMAT designation from the FDA, specifically in advanced peripheral artery disease. This serves as a recognition from the Agency that Humacyte's ATEV may provide an important therapeutic option for patients with advanced arterial disease in their legs, who are facing potential amputation. We are proud that the ATEV's broad potential continues to be recognized and look forward to presenting additional results across our pipeline at upcoming medical meetings."

Second Quarter 2024 and Recent Corporate Highlights

ATEV (acellular tissue engineered vessel)

- **FDA extension of time to complete review of BLA for ATEV in the Treatment of Vascular Trauma**– On August 9, 2024, in a phone call, Center for Biologics Evaluation and Research (CBER) leadership from the U.S. Food and Drug Administration (FDA) notified the Company that the FDA will require additional time to complete its review of the Company's Biologics License Application (BLA) for the ATEV in the vascular trauma indication. The ATEV trauma BLA was submitted to FDA in December 2023, FDA granted a Priority Review in February 2024, and assigned a PDUFA date of August 10, 2024.

- **Positive Topline Results of ATEV in Hemodialysis Access** – In July 2024, Humacyte reported positive topline results from the V007 Phase 3 clinical trial (NCT03183245) of the ATEV in arteriovenous (AV) access for patients on hemodialysis. The V007 trial is prospective, multi-center, randomized clinical study in 242 hemodialysis patients in the United States. Participants were randomly assigned to receive either the ATEV or an AV fistula for hemodialysis access and are being followed for up to 24 months. In the trial, the ATEV was observed to provide superior functional patency at six and 12 months (co-primary endpoints; p=0.0071) compared to autogenous fistula, which is the current standard of care for hemodialysis patients. Patients on ATEV also achieved a significantly longer duration of hemodialysis using the ATEV over the first 12 months, as compared to autogenous fistula (p=0.0162). Humacyte anticipates that detailed results from the trial will be presented at upcoming medical meetings.

- **ATEV Received Third Regenerative Medicine Advanced Therapy (RMAT) Designation from FDA** – In July 2024, the FDA granted RMAT designation of the ATEV for patients with advanced peripheral artery disease (PAD). This RMAT designation is granted at the same time as FDA cleared a new Investigational New Drug (IND) application for the PAD indication. This is the third RMAT designation granted by the FDA for Humacyte's ATEV, in addition to previous RMAT designations for vascular trauma repair and AV access in hemodialysis.

Medical and Scientific Publications and Presentations

- **PAD Publication:** In June 2024, Dr. Todd Rasmussen and colleagues at the Mayo Clinic in Rochester MN published outcomes of arterial bypass using the ATEV in patients with chronic limb ischemia (severe PAD). In this paper, appearing in the *Journal of Vascular Surgery* in June, all patients treated with the ATEV for severe PAD had no suitable vein of their own for bypass, and were treated under an investigator-sponsored protocol. Outcomes for ATEV patency (or blood flow) and limb salvage in patients with severe PAD and no vein were compared to historical control patients, having similar disease but receiving a bypass using their own vein at the Mayo Clinic. Mayo investigators reported that patency and limb salvage were similar for patients receiving ATEV, and patients receiving bypass with their own vein. This result highlights the potential impact that Humacyte's ATEV may have on patients suffering from severe PAD and having no vein of their own to perform a bypass operation.

- **Presentations Highlighting Advancement of Diabetes Program** – In June 2024, Humacyte presented positive results from ongoing preclinical studies supporting 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:

    - At a presentation at the Breakthrough T1D (formerly, JDRF) Beta Cell Consortium Meeting in New York City, scientists presented data in which stem cell-derived islets, manufactured at Humacyte, were observed to restore normal blood sugar in diabetic mice. In the mice, the stem cell-derived islets survived and continued to produce insulin, with no evidence of adverse safety events from the stem cell-derived islets. These experiments were performed in collaboration with the Diabetes Research Institute (DRI) at the University of Miami.

    - At the American Diabetes Association annual meeting in Orlando, Florida, Humacyte reported successful implantation of BVPs into non-human primate recipients. In the study, also performed in collaboration with the DRI, primate BVP implants showed islet survival and continued insulin production throughout the three-month duration of the study. Islets also developed capillaries to support survival of the insulin-producing cells.

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

Corporate Updates

- **Strengthened Board of Directors** – In July 2024, Humacyte announced the addition of pharmaceutical industry veteran Dr. John P. Bamforth and distinguished health system and academic physician Dr. Keith Anthony (Tony) Jones to the Company's Board of Directors.

Second Quarter 2024 Financial Highlights

- There was no revenue for either the second quarter of 2024 or the second quarter of 2023, and there was no revenue for the six months ended June 30, 2024 and 2023.

- Research and development expenses were $23.8 million for the second quarter of 2024, compared to $20.5 million for the second quarter of 2023, and were $45.0 million for the six months ended June 30, 2024, compared to $37.8 million for the six months ended June 30, 2023. The current-period increases resulted primarily from increased materials and personnel expenses to support expanded research and development initiatives and our clinical trials, including the expansion of manufacturing activities and support of the FDA review of the BLA in vascular trauma.

- General and administrative expenses were $5.7 million for the second quarter of 2024, compared to $6.2 million for the second quarter of 2023, and were $11.1 million for the six months ended June 30, 2024, compared to $11.4 million for the six months ended June 30, 2023. The slight decreases during 2024, resulted primarily from a decrease in non-cash stock compensation expense, partially offset by increased personnel expenses and increased professional fees.

- Other net income (expense) was net expense of $27.2 million for the second quarter of 2024, compared to net income of $4.0 million for the second quarter of 2023, and other net expense of $32.5 million for the six months ended June 30, 2024, compared to other net expense of $10.4 million for the six months ended June 30, 2023. The increase in other net expense for the second quarter of 2024 and the six months ended June 30, 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 $56.7 million for the second quarter of 2024, compared to $22.7 million for the second quarter of 2023, and net loss was $88.6 million for the six months ended June 30, 2024, compared to $59.7 million for the six months ended June 30, 2023. The current-period increase in net loss resulted primarily from the non-cash remeasurement of the contingent earnout liability, and operating expense increases, described above.

- The Company reported cash and cash equivalents of $93.6 million as of June 30, 2024. Total net cash provided was $13.1 million for the first six months of 2024, compared to net cash used of $35.2 million for the first six 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 funding arrangement with Oberland Capital Management.

Conference Call and Webcast Details

Title:	Humacyte Second Quarter 2024 Financial Results Corporate Update
Date:	Tuesday, August 13, 2024
Time:	8:30 a.m. ET
Conference Call Details:	Toll-Free: 1-877-704-4453 International: 1-201-389-0920 Conference ID #: 13747913
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

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Forward-Looking Statements

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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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	23,753	20,540	45,017	37,818
General and administrative	5,746	6,191	11,060	11,425
Total operating expenses	29,499	26,731	56,077	49,243
Loss from operations	**(29,499)**	**(26,731)**	**(56,077)**	**(49,243)**
Other income (expense), net:				
Change in fair value of contingent earnout liability	(25,571)	3,627	(30,164)	(10,564)
Other income (expense) (net)	(1,593)	398	(2,318)	132
Total other income (expense), net	(27,164)	4,025	(32,482)	(10,432)
Net loss and comprehensive loss	**$ (56,663)**	**$ (22,706)**	**$ (88,559)**	**$ (59,675)**
Net loss per share, basic and diluted	$ (0.48)	$ (0.22)	$ (0.78)	$ (0.58)
Weighted-average shares outstanding, basic and diluted	119,174,681	103,361,501	113,710,344	103,312,785

Humacyte, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands)

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 93,563	$ 80,448
Prepaid expenses and other current assets	2,547	2,830
Total current assets	96,110	83,278
Property and equipment, net	24,820	26,791
Finance lease right-of-use assets, net	16,536	17,313
Other long-term assets	815	841
Total assets	**$ 138,281**	**$ 128,223**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,005	$ 6,490
Accrued expenses	8,950	9,340
Other current liabilities	2,802	2,613
Total current liabilities	17,757	18,443
Contingent earnout liability	68,080	37,916
Revenue interest liability	60,078	38,600
Finance lease obligation, net of current portion	15,123	16,293
Other long-term liabilities	5,530	3,425
Total liabilities	**166,568**	**114,677**
Stockholders' equity		
Common stock and additional paid-in capital	597,586	550,860
Accumulated deficit	(625,873)	(537,314)
Total stockholders' equity	(28,287)	13,546
Total liabilities and stockholders' equity	**$ 138,281**	**$ 128,223**