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 9, 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:

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o 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 x

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. o

Item 2.02. Results of Operations and Financial Condition

On November 9, 2023, Humacyte, Inc. issued a press release regarding its financial results for its fiscal third quarter ended September 30, 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 November 9, 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: November 9, 2023

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 2023 Financial Results and Business Update

– Positive top line results from the V005 Phase 2/3 trial of the Human Acellular Vessel™ (HAV™) in vascular trauma repair –

– BLA for an indication in vascular trauma planned to be filed with the FDA during the current quarter –

- **Conference call and live webcast at 4:30 p.m. ET today** -

DURHAM, N.C., November 9, 2023 **–** 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 third quarter ended September 30, 2023 and highlighted recent corporate accomplishments advancing the investigational, universally implantable Human Acellular Vessel (HAV) closer to planned U.S. market launch.

“The major milestones reached during the third quarter of 2023 set the stage for our planned Biologics License Application (BLA) filing of the HAV for the vascular trauma indication with the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2023,” said Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte. “A key event supporting the planned BLA filing was our announcement of positive top line results from the V005 trial in vascular trauma repair. We are also proud that our humanitarian efforts in Ukraine, which will supplement the V005 results in our BLA filing, have resulted in successful outcomes including saving lives and limbs in a wartime setting. Finally, we are pleased that the potential of the HAV pipeline has also been observed in other clinical studies this quarter, including the presentation of Phase 2 results in severe peripheral arterial disease (PAD). In addition, we recently published preclinical results of our small caliber HAV in a juvenile heart disease model. The remainder of 2023 will be exciting, and we thank the medical professionals, patients, researchers and employees for their contribution to the advancement of the HAV.”

Third Quarter 2023 Corporate Highlights

Clinical and Regulatory Updates

- **Positive Phase 2/3 Trauma Results** – In September 2023, Humacyte announced positive top line results from its V005 Phase 2/3 trial of the HAV in vascular trauma repair. In this single-arm clinical trial, the HAV had higher rates of patency, and lower rates of amputation and infection, compared to historic synthetic graft benchmarks. A total of 69 patients were enrolled in the V005 trial, of which 51 had vascular injury of the extremities and comprised the primary evaluation group for the study. The 30-day patency (presence of blood flow) for the HAV in the clinical trial was 90.2% for the extremity patients compared to approximately 81% historically reported for synthetic grafts. The HAV demonstrated lower amputation rates, with a rate of 9.8% compared to over 20% historically reported for synthetic grafts. The HAV also demonstrated lower rates of infection, with a rate of 2.0% compared to over 8% historically reported for synthetic grafts.

- **Planned BLA Filing this Quarter** – Humacyte plans to file a BLA for the HAV for the treatment of vascular trauma with the FDA during the current quarter.

Presentations and Publications

- **Upcoming Presentations at a Major Vascular Surgery Symposium** – Multiple presentations are expected to be made at the VEITH Symposium, a major vascular surgery meeting, in New York City on November 15-18, 2023. These include an expanded presentation of the results of the V005 vascular trauma trial, and the outcome of research which seeks to identify which dialysis patients experience the most difficulties with their dialysis access, and which patients may most benefit from an access that is durable and resists infection.

- **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 preclinical study, researchers from Nationwide Children's Hospital (Columbus, OH) and Humacyte implanted 3.5mm diameter HAVs into a juvenile large-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. This study also demonstrates the extension of Humacyte's manufacturing platform, adding production of the 3.5mm vessels in the same manufacturing platform used to produce Humacyte's 6mm HAVs that are in current clinical use.

- **Presentation of Results from Phase 2 Study in PAD** – In September 2023, results were presented from an FDA-regulated, investigator-sponsored clinical study conducted at the Mayo Clinic of the HAV in patients with chronic limb-threatening ischemia, the end stage of peripheral artery disease (PAD). In the presentation at the Midwestern Vascular Conference in Minneapolis, MN, researchers observed that in the clinical study the HAV was a safe, resilient, and effective conduit for arterial bypass and limb salvage. This is an important result since approximately 40% of patients requiring lower extremity bypass do not have saphenous vein available, which is the standard of care for treating this challenging disease state.

- **Presentation of Success in Treating Wartime Injured in Ukraine** – Results of the real-world use of the HAV under the humanitarian aid program to treat war-induced vascular trauma injuries in Ukraine were presented in August at the 2023 Military Health System Research Symposium (MHSRS) in Kissimmee, Florida. The 19 patients treated under the program suffered from a range of traumatic injuries, including gunshots, shrapnel, blast injuries and accidents. Clinicians reported that the rate of success in treating patients with the HAV was high, with an observed 30-day HAV patency of 95%, 30-day limb salvage of 100%, 30-day survival of 100%, and zero cases of infection of the HAV. Ukrainian clinicians concluded that the HAV has the potential to offer combat surgical teams an off-the-shelf and universally implantable therapy that is resistant to infection, potentially offering durable performance to military personnel and helping with limb salvage. Results from the Ukraine program will be included in Humacyte's planned BLA filing with the FDA.

- **Publication Supporting Infection Resistance of HAV** – In July 2023, a preclinical study demonstrated a possible scientific basis for the low rates of infection that have been observed in clinical trials of the HAV. The report was published in the *Journal of Vascular Surgery – Vascular Science*. This work compared the infection resistance of the HAV to synthetic polytetrafluorethylene (ePTFE) grafts, which are made of plastic. The laboratory results suggest that the bioengineered human tissue of the HAV may have superior compatibility with the body's own white blood cells as compared to ePTFE. While human white blood cells die when they come in contact with ePTFE, the cells survive and function in contact with the HAV material, which may improve the ability of the HAV to fight dangerous infections once implanted in the body.

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

Third Quarter 2023 Financial Highlights

- The Company reported cash and cash equivalents of $100.0 million as of September 30, 2023. In May 2023, Humacyte reported the completion of a funding arrangement of up to $160 million with Oberland Capital Management, $40 million of which has been received. Total net cash used was $49.4 million for the first nine months of 2023, compared to $53.8 million for the first nine months of 2022. Humacyte believes that its cash and cash equivalents and expected funding from the Oberland arrangement are adequate to finance operations past the currently anticipated timelines for FDA approval and commercialization of the HAV in the vascular trauma indication.

- There was no revenue for the third quarter of 2023 and nine months ended September 30, 2023. Revenue was $31 thousand for the third quarter of 2022 and $1.6 million for the nine months ended September 30, 2022. Revenue for 2022 was related to a grant supporting the development of the HAV.

- Research and development expenses were $18.6 million for the third quarter of 2023, compared to $17.3 million for the third quarter of 2022, and were $56.4 million for the nine months ended September 30, 2023, compared to $48.3 million for the nine months ended September 30, 2022. The current-period increases resulted primarily from increased personnel and external services expenses to support expanded research and development initiatives and our clinical trials, including preparation for the HAV vascular trauma trial completion and planned BLA filing for the vascular trauma indication, and expansion of clinical development of the HAV in AV access for hemodialysis.

- General and administrative expenses were $6.1 million for the third quarter of 2023, compared to $6.2 million for the third quarter of 2022, and were $17.5 million for the nine months ended September 30, 2023, compared to $17.1 million for the nine months ended September 30, 2022. The increase during the nine months ended September 30, 2023 compared to the prior-year period resulted primarily from increased personnel costs, primarily driven by preparation for the planned commercial launch of the HAV in the vascular trauma indication. The slight decrease during the third quarter of 2023 compared to 2022 resulted primarily from a decrease in external services and professional fees, partially offset by an increase in personnel expenses.

- Other net income (expense) was net expense of $1.4 million for the third quarter of 2023, compared to net expense of $1.8 million for the third quarter of 2022, and other net expense of $11.8 million for the nine months ended September 30, 2023, compared to other net income of $55.5 million for the nine months ended September 30, 2022. The decrease in other net expense for the third quarter of 2023 compared to 2022 resulted primarily from an increase in interest income due to rate increases. The increase in other net expense for the nine months ended September 30, 2023 compared to 2022, 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 $26.0 million for the third quarter of 2023, compared to $25.3 million for the third quarter of 2022, and net loss was $85.7 million for the nine months ended September 30, 2023, compared to $8.2 million for the nine months ended September 30, 2022. The current-period increases in net loss resulted from the non-cash remeasurement of the contingent earnout liability, and increased operating expenses, described above.

Conference Call and Webcast Details

Title:	Humacyte Third Quarter 2023 Financial Results and Corporate Update
Date:	Thursday, November 9, 2023
Time:	4:30 p.m. ET
Conference Call Details:	Toll-Free: 1-888-999-5318 International: 1-848-280-6460 Conference ID #: 13741924
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 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 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; the timing or likelihood of regulatory filings and approvals, including the BLA for our V005 clinical trial; timing, scope, and rate of reimbursement 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, 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 June 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Grant revenue	$ —	$ 31	$ —	$ 1,565
Operating expenses:				
Research and development	18,552	17,337	56,370	48,303
General and administrative	6,070	6,188	17,495	17,050
Total operating expenses	24,622	23,525	73,865	65,353
Loss from operations	**(24,622)**	**(23,494)**	**(73,865)**	**(63,788)**
Other income (expense), net:				
Change in fair value of contingent earnout liability	(1,144)	(962)	(11,708)	58,649
Other expense (net)	(229)	(825)	(97)	(3,106)
Total other income (expense), net	(1,373)	(1,787)	(11,805)	55,543
Net loss and comprehensive loss	**$ (25,995)**	**$ (25,281)**	**$ (85,670)**	**$ (8,245)**
Net loss per share, basic and diluted	$ (0.25)	$ (0.25)	$ (0.83)	$ (0.08)
Weighted-average shares outstanding, basic and diluted	103,444,246	103,031,980	103,357,087	103,014,009

Humacyte, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 99,986	$ 149,772
Prepaid expenses and other current assets	2,865	2,329
Short-term investments	—	2,107
Total current assets	102,851	154,208
Property and equipment, net	27,851	30,039
Finance lease right-of-use assets, net	17,828	19,373
Other long-term assets	855	682
Total assets	**$ 149,385**	**$ 204,302**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,018	$ 1,595
Accrued expenses	9,586	7,108
Other current liabilities	2,533	2,306
SVB loan payable, current portion	—	8,571
Total current liabilities	15,137	19,580
Contingent earnout liability	39,601	27,893
Revenue interest liability	37,286	—
Finance lease obligation, net of current portion	16,960	18,853
Other long-term liabilities	3,408	712
SVB loan payable, net of current portion	—	20,336
Total liabilities	**112,392**	**87,374**
Stockholders' equity		
Common stock and additional paid-in capital	549,201	543,466
Accumulated deficit	(512,208)	(426,538)
Total stockholders' equity	36,993	116,928
Total liabilities and stockholders' equity	**$ 149,385**	**$ 204,302**