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 14, 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 August 14, 2023, Humacyte, Inc. issued a press release regarding its financial results for its fiscal second quarter ended June 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 August 14, 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: August 14, 2023

By: /s/ Dale A. Sander

Name: Dale A. Sander

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

Exhibit 99.1

Humacyte Second Quarter 2023 Financial Results and Business Update

– Completed Enrollment in Phase 2/3 V005 Trial of HAV™ in Vascular Trauma Repair; Top-Line Results on Track for Q3 2023 –

– Results from Vascular Trauma Humanitarian Program in Ukraine Highlighted at 2023 Military Health System Research Symposium –

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

DURHAM, N.C., August 14, 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 second quarter ended June 30, 2023, and highlighted recent corporate accomplishments.

“Humacyte has made significant strides in the first half of 2023 in advancing our universally implantable Human Acellular Vessel™ (HAV) across our clinical development programs,” said Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte. “Notably, we are excited that enrollment in the V005 trial in vascular trauma repair is now complete, and activities to report results are underway. We remain on track to report topline clinical trial outcomes in the third quarter of 2023, followed by a planned Biologics License Application (BLA) filing for the vascular trauma indication with the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2023. We are also proud that our humanitarian efforts in Ukraine have resulted in successful outcomes to date, saving lives and limbs in a wartime setting. Finally, we are pleased that the potential of the HAV to resist infection was featured in a recent publication in *Journal of Vascular Surgery – Vascular Science*, adding to the growing body of literature supporting HAV use in multiple indications. We look forward to building our momentum throughout the second half of 2023 as we advance toward the expected regulatory submission in our first indication.”

Second Quarter 2023 and Recent Corporate Highlights

Clinical and Regulatory Updates

- **Completed enrollment of Phase 2/3 clinical trial of HAV in vascular trauma repair** – In July 2023, the Company announced enrollment completion in its Phase 2/3 trial of the HAV in vascular trauma repair (V005). The V005 trial is a single-arm, open-label, pivotal study of patients suffering from vascular trauma injuries, conducted at Level 1 Trauma Centers in the U.S. and Israel. The primary efficacy assessment is based on a 30-day HAV patency in patients who have vascular trauma of the extremity, as compared to historic benchmarks reported in literature. The completion of the V005 trial enrollment comes on the heels of Humacyte receiving the FDA's Regenerative Medicine Advanced Therapy (RMAT) designation for the HAV in urgent arterial repair following extremity vascular trauma in May 2023. At the time of completion of target enrollment in V005, a total of 68 patients in the trial had received the HAV, of which 51 comprise the primary efficacy analysis. Results from the V005 trial are expected in the third quarter of 2023 and are intended to support a BLA filing for the vascular trauma indication with the FDA planned for the fourth quarter 2023.

- **Completion of enrollment in Phase 3 trial of HAV in Hemodialysis Access** – In April 2023, Humacyte also announced enrollment completion of a Phase 3 trial of the HAV in hemodialysis access. The Phase 3 trial, conducted in the U.S., is designed to assess the safety and efficacy of the HAV in establishing vascular access for hemodialysis patients with end-stage kidney disease, as compared to autogenous arteriovenous (AV) fistulas. Efficacy assessments include conduit patency and useability of the conduit for dialysis during the first year, with top-line results expected in 2024. The rate of dialysis-related infections in both HAV and fistula subjects will also be tracked as a secondary endpoint.

Presentations and Publications

- **Presentation of success in treating wartime injured in Ukraine** – Results of the use of the HAV under our humanitarian aid program to treat war-induced vascular trauma injuries in Ukraine are being presented today 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 (presence of blood flow) 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.

- **Publication supporting infection resistance of HAV** – In July 2023, a preclinical study providing a scientific basis for the low rates of infection observed in clinical trials of the HAV was published in the *Journal of Vascular Surgery – Vascular Science*. This work compared the infection resistance of the HAV to expanded polytetrafluorethylene (ePTFE) grafts. The preclinical results showed that the bioengineered human tissue of the HAV had superior compatibility with the body's own neutrophil (immune) cells as compared to ePTFE, which may improve the ability of the HAV to fight dangerous infections.

Advancement in Type 1 Diabetes Research

- In April 2023, Humacyte and JDRF International (JDRF), the leading global organization funding type 1 diabetes research, announced a collaboration to advance the development of Humacyte's Biovascular Pancreas (BVP) product candidate. Humacyte's BVP is designed to use the HAV to enable the delivery and survival of insulin-producing islets as a treatment for type 1 diabetes. During 2023, the Company has been testing the BVP in primates. In recent experiments, the Company has observed that insulin-producing cells in the BVP survive for multiple weeks after implantation into the animal, and continue to make insulin after implantation. Humacyte considers these results to be extremely encouraging as they support the potential ability of the BVP to deliver a curative number of insulin-producing islets into diabetic subjects. Additional work in large animals is planned going forward, including using the BVP in diabetic large animals.

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

Second Quarter 2023 Financial Highlights

- The Company reported cash and cash equivalents of $114.6 million as of June 30, 2023. In May 2023, Humacyte reported the completion of an up to $160 million funding arrangement with Oberland Capital Management, of which it has received $40 million. Humacyte believes that its cash and cash equivalents and expected funding from the Oberland funding agreement are adequate to fund operations past the anticipated timelines for potential FDA approval and commercialization of the HAV in the vascular trauma indication.

- There was no revenue for the second quarter of 2023 and six months ended June 30, 2023. Revenue was $1.3 million for the second quarter of 2022 and $1.5 million for the six months ended June 30, 2022. Revenue for 2022 was related to a grant supporting the development of the HAV.

- Research and development expenses were $20.5 million for the second quarter of 2023, compared to $14.7 million for the second quarter of 2022, and were $37.8 million for the six months ended June 30, 2023, compared to $31.0 million for the six months ended June 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.

- General and administrative expenses were $6.2 million for the second quarter of 2023, compared to $5.2 million for the second quarter of 2022, and were $11.4 million for the six months ended June 30, 2023, compared to $10.9 million for the six months ended June 30, 2022. The current-period increases resulted primarily from increased personnel and external services 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 $4.0 million for the second quarter of 2023, compared to net income of $55.4 million for the second quarter of 2022, and other net expense of $10.4 million for the six months ended June 30, 2023, compared to other net income of $57.3 million for the six months ended June 30, 2022. The current-period decrease in other net income, and increase in other net expense, 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 $22.7 million for the second quarter of 2023, compared to net income of $36.9 million for the second quarter of 2022, and net loss was $59.7 million for the six months ended June 30, 2023, compared to net income of $17.0 million for the six months ended June 30, 2022. The current-period increase in net loss resulted from the non-cash increase in other net expense, and increased operating expenses, described above.

- Total net cash used was $35.2 million for the second quarter of 2023, compared to $36.5 million for the second quarter of 2022, with the current-year decrease in cash used related to proceeds from our Oberland funding agreement.

Conference Call and Webcast Details

Title:	Humacyte Second Quarter 2023 Financial Results and Corporate Update
Date:	Monday, August 14, 2023
Time:	8:00 AM ET
Conference Call Details:	Toll-Free: 1-877-704-4453 International: 1-201-389-0920 Conference ID #: 13739966
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 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; 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, 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, 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 Income (Loss)

(unaudited)

(in thousands except for share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Grant revenue	$ —	$ 1,301	$ —	$ 1,534
Operating expenses:				
Research and development	20,540	14,652	37,818	30,966
General and administrative	6,191	5,180	11,425	10,862
Total operating expenses	26,731	19,832	49,243	41,828
Loss from operations	**(26,731)**	**(18,531)**	**(49,243)**	**(40,294)**
Other income (expense), net				
Change in fair value of contingent earnout liability	3,627	56,353	(10,564)	59,611
Other income (expense) (net)	398	(954)	132	(2,281)
Total other income (expense), net	4,025	55,399	(10,432)	57,330
Net income (loss) and comprehensive income (loss)	**$ (22,706)**	**$ 36,868**	**$ (59,675)**	**$ 17,036**
Net income (loss) per share, basic	$ (0.22)	$ 0.36	$ (0.58)	$ 0.17
Weighted-average shares outstanding, basic	103,361,501	103,005,651	103,312,785	103,004,874
Net income (loss) per share, diluted	$ (0.22)	$ 0.35	$ (0.58)	$ 0.16
Weighted-average shares outstanding, diluted	103,361,501	103,908,440	103,312,785	103,923,138

Humacyte, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 114,604	$ 149,772
Prepaid expenses and other current assets	5,958	2,329
Short-term investments	—	2,107
Total current assets	120,562	154,208
Property and equipment, net	28,543	30,039
Lease right-of-use assets, net	19,001	20,055
Total assets	**$ 168,106**	**$ 204,302**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,362	$ 1,595
Accrued expenses	6,571	7,108
Other current liabilities	2,455	2,306
SVB loan payable, current portion	—	8,571
Total current liabilities	11,388	19,580
Contingent earnout liability	38,457	27,893
Revenue interest liability	36,248	—
Finance lease obligation, net of current portion	17,614	18,853
Other long-term liabilities	3,282	712
SVB loan payable, net of current portion	—	20,336
Total liabilities	**106,989**	**87,374**
Stockholders' equity		
Common stock and additional paid-in capital	547,330	543,466
Accumulated deficit	(486,213)	(426,538)
Total stockholders' equity	61,117	116,928
Total liabilities and stockholders' equity	**$ 168,106**	**$ 204,302**