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 12, 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 May 12, 2023, Humacyte, Inc. issued a press release regarding its financial results for its fiscal first quarter ended March 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 May 12, 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: May 12, 2023

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 2023 Financial Results and Business Update

- Human Acellular Vessel™ (HAV™) granted second RMAT designation by the FDA, for Vascular Trauma -

- Completion of enrollment in Phase 3 trial of HAV in Hemodialysis Access in End-Stage Renal Disease Patients -

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

DURHAM, N.C., May 12, 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 first quarter ended March 31, 2023, and highlighted recent corporate accomplishments.

"We are off to a fast start in 2023 and have moved closer to our planned filing of a Biologics License Application (BLA) for accelerated approval with the U.S. Food and Drug Administration (FDA) of our Human Acellular Vessel (HAV) for an indication in extremity vascular trauma," said Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte. "We were pleased to receive our second RMAT designation from the FDA, for use of the HAV in urgent arterial repair following extremity vascular trauma. The RMAT designation provides a higher likelihood for priority review of our planned BLA filing. We were delighted to see the potential benefits of the HAV reflected in two recent publications, *The Lancet Regional Health - Europe* and the *Journal of Trauma and Acute Care Surgery*. Lastly, I wanted to acknowledge JDRF International for their support of our Biovascular Pancreas (BVP) preclinical program in Type 1 diabetes."

First Quarter 2023 and Recent Corporate Highlights

Clinical Updates

- **Progress toward planned BLA filing of HAV in vascular trauma** – In May 2023, Humacyte was granted the FDA's Regenerative Medicine Advanced Therapy (RMAT) designation for the HAV for urgent arterial repair following extremity vascular trauma. The RMAT designation allows for more interactions with the FDA and expedited development and review of regenerative medicine products within the U.S., including the potential for priority review process for a BLA. The RMAT designation comes as Humacyte is nearing the anticipated completion of enrollment in its Phase 2/3 V005 clinical trial of the HAV in the repair of civilian vascular trauma, a study being conducted at Level 1 Trauma Centers in the U.S. and Israel. Currently, a total of 66 patients have received the HAV in the V005 trial, including 49 patients comprising the primary endpoint population. Humacyte plans to file a BLA with the FDA later in 2023 for the treatment of extremity vascular trauma when synthetic graft is not indicated and when autologous vein is not feasible.

- **Completion of enrollment in Phase 3 trial of HAV in Hemodialysis Access** – In March 2023, Humacyte completed enrollment of a Phase 3 trial 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 renal disease as compared to autogenous arteriovenous (AV) fistulas in 240 patients. 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.

Publications and Presentations

- In May 2023, a publication in *The Lancet Regional Health - Europe* described how Ukrainian surgeons have used the HAV to save life and limb in treating battlefield and other vascular trauma injuries suffered in Ukraine-Russia conflict. Since June 2022, 19 patients (13 at time of publication submission) in Ukraine have been treated under a humanitarian program with the HAV to repair vascular trauma.

- In April 2023, publication of a preclinical study in the *Journal of Trauma and Acute Care Surgery* compared the use of the HAV to expanded polytetrafluorethylene (ePTFE) grafts for vascular repair following arterial trauma in a porcine model. The data observed in this preclinical study indicate that the HAV performed better than ePTFE on multiple indices, including recovery of limb function after six hours of ischemia and conduit patency. In addition, the HAV showed no incidence of infection, degradation, aneurysm or mechanical failure. Host recellularization of the HAV conduits was observed to be greater than that for ePTFE grafts.

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

Corporate Updates

- 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 BVP product candidate. Humacyte's BVP is designed to enable the delivery and survival of insulin-producing islets using the HAV, as a treatment for type 1 diabetes. JDRF will provide Humacyte with funding to support the preclinical development and testing of the BVP.

First Quarter 2023 Financial Highlights

- The Company reported cash, cash equivalents and short-term investments of $131.7 million as of March 31, 2023. Subsequent to March 31, 2023, Humacyte reported the completion of an up to $160 million funding arrangement with Oberland Capital. Humacyte believes that its cash, cash equivalents short-term investments and planned funding from the Oberland funding agreement are adequate to fund operations past the anticipated timelines for potential approval and commercialization of the HAV in vascular trauma.

- There was no revenue for the first quarter of 2023, compared to $0.2 million for the first quarter of 2022. Revenue for 2022 is related to a grant supporting the development of the HAV.

- Research and development expenses were $17.3 million for the first quarter of 2023, compared to $16.3 million for the first quarter of 2022. The current-period increase resulted primarily from increased personnel expenses to support expanded research and development initiatives and our clinical trials.

- General and administrative expenses were $5.2 million for the first quarter of 2023, compared to $5.7 million for the first quarter of 2022. The current-period decrease resulted primarily from reduced professional fees in 2023.

- Other net income (expense), was net expense of $14.5 million for the first quarter of 2023, compared to net income of $1.9 million for the first quarter of 2022. The current-period increase in other net expense resulted primarily from the remeasurement of the contingent earnout liability associated with the August 2021 merger with Alpha Healthcare Acquisition Corp.

- Net loss was $37.0 million for the first quarter of 2023, compared to $19.8 million for the first quarter of 2022. The current-period increase in net loss resulted from the increase in other net expense described above.

- Net cash used in operations was $18.6 million for the first quarter of 2023 compared to $18.8 million for the first quarter of 2022. Total net cash used was $20.2 million for the first quarter of 2023, compared to $19.3 million for the first quarter of 2022, with the current-year increase related to purchases of property and equipment to prepare for planned commercial launch of the HAV.

Conference Call and Webcast Details

Date:	Friday, May 12, 2023
Time:	8:00 a.m. ET
Conference Call Details:	Toll-Free: 1-877-704-4453 International: +1-201-389-0920 Conference ID: 13738048
Call me™ Feature:	Click Here
Webcast:	Q1 2023 Earnings Conference Call - 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. The forward-looking statements in this press release represent our views as of the date of this press release. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. 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,	
	2023	**2022**
Grant revenue	$ —	$ 233
Operating expenses:		
Research and development	17,278	16,314
General and administrative	5,234	5,682
Total operating expenses	22,512	21,996
Loss from operations	**(22,512)**	**(21,763)**
Other income (expense), net		
Change in fair value of contingent earnout liability	(14,191)	3,258
Other expense (net)	(266)	(1,327)
Total other income (expense), net	(14,457)	1,931
Net loss and comprehensive loss	**$ (36,969)**	**$ (19,832)**
Net loss per share, basic and diluted	$ (0.36)	$ (0.19)
Weighted-average shares outstanding, basic and diluted	103,263,528	103,004,088

Humacyte, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 129,570	$ 149,772
Short-term investments	2,107	2,107
Prepaid expenses and other current assets	2,178	2,329
Total current assets	133,855	154,208
Property, plant and equipment, net	29,593	30,039
Lease right-of-use assets, net	19,528	20,055
Total assets	**$ 182,976**	**$ 204,302**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,954	$ 1,595
Accrued expenses	6,411	7,108
SVB loan payable, current portion	12,857	8,571
Other current liabilities	2,379	2,306
Total current liabilities	23,601	19,580
Contingent earnout liability	42,084	27,893
SVB loan payable, net of current portion	16,410	20,336
Finance lease obligation, net of current portion	18,252	18,853
Other long-term liabilities	742	712
Total liabilities	**101,089**	**87,374**
Stockholders' equity		
Common stock and additional paid-in capital	545,394	543,466
Accumulated deficit	(463,507)	(426,538)
Total stockholders' equity	81,887	116,928
Total liabilities and stockholders' equity	**$ 182,976**	**$ 204,302**