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 12, 2022

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 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 12, 2022, Humacyte, Inc. issued a press release regarding its financial results for its fiscal second quarter ended June 30, 2022. 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 12, 2022.
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 12, 2022

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 2022 Financial Results and Business Update

-- Human Acellular Vessels™ (HAVs™) successfully implanted in wounded Ukrainian citizens and reported to be functioning, saving limbs –

-- Hosted key opinion leader (KOL) webinar on HAV in the treatment of vascular trauma, featuring Ernest E. Moore, M.D and Gregory A. Magee, M.D. –

-- Strengthened Board of Directors with appointment of Diane Seimetz, Ph.D. and leadership team with appointment of Shamik Parikh, M.D. as Chief Medical Officer –

-- Multiple scientific meeting presentations and publications highlighting clinical HAV data in vascular trauma and arteriovenous access and preclinical small-diameter HAV data in coronary artery bypass grafting (CABG)–

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

DURHAM, N.C., August 12, 2022 -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable bioengineered human tissues, complex tissue systems, and organs at commercial scale, today announced financial results for the second quarter ended June 30, 2022, and highlighted recent corporate accomplishments.

"Humacyte has continued to make great progress throughout the second quarter of 2022, advancing our lead candidate, the HAV, in both our clinical and preclinical programs as well as our humanitarian effort in Ukraine," said Laura Niklason, M.D., Ph.D., Founder, President and Chief Executive Officer of Humacyte. "We are thrilled that the HAVs implanted in several Ukrainian patients are reported to be functioning and infection-free, providing further real-world evidence of the potential of HAV treatment for trauma. In addition, we are pleased with the progress of our small-diameter HAV program which we believe continues to show promise in preclinical CABG models, and we look forward to continued advancement as we move toward the clinic. Finally, we welcome Dr. Diane Seimetz to our Board of Directors, and we are excited to leverage her regulatory and commercial expertise as we move through our late-stage vascular clinical programs and approach potential approval and commercialization of the HAV."

Second Quarter 2022 and Recent Corporate Highlights

Clinical Updates

- Early in the second quarter, Humacyte launched an initiative to provide its HAVs to hospitals in Ukraine for the treatment of wounded civilians and soldiers with vascular trauma injuries. Reports from medical providers in Ukraine indicate that the first two Ukrainian patients treated under this humanitarian initiative are past their 30-day follow-up periods. One of the patients receiving the HAV was a gunshot victim at risk for limb loss following infection and failure of the initial synthetic graft used to treat his severed femoral artery. The HAVs implanted in both patients are reported to be functioning and infection-free, salvaging limbs in patients who were injured in this wartime conflict zone.

- In July 2022, Humacyte hosted a Key Opinion Leader (KOL) webinar on its HAV for the treatment of vascular trauma, featuring presentations from KOLs Ernest E. Moore, M.D. (trauma surgeon, Denver Health) and Gregory A. Magee, M.D. (vascular surgeon, Keck Medicine, University of Southern California). The KOLs discussed the current treatment landscape and unmet medical need in the vascular trauma field as well as case studies of trauma patients treated with the HAV. A replay of the webinar can be accessed on the Humacyte website here.

- Throughout the second quarter, the HAV was the subject of multiple presentations at scientific conferences and publications in scientific journals, including:

- Preclinical data on the small-diameter HAV in coronary artery bypass grafting (CABG) was presented at the American Heart Association Basic Cardiovascular Sciences Scientific Sessions (BCVS) in July 2022. In a non-human primate model, the HAV maintained structural integrity and patency for up to six months post-implantation and showed evidence of robust host cell repopulation and remodeling. The results were presented by Adam Williams, M.D., cardiothoracic surgeon, Duke University, and are also expected to be published in the September 2022 issue of *Circulation Research*.

- The potential of the HAV to expand vascular surgical treatment options was highlighted by clinical researchers in the June 2022 edition of *JAMA Surgery*. The HAV has been implanted in approximately 500 patients, with more than 1,000 patient-years of follow up across seven clinical trials and multiple compassionate use cases. Researchers described the potential advantages of the HAV over existing approaches, including clinical observation of the repopulation of the HAV with the patients' own cells, resistance to infection, maintenance of structural integrity, patency, uniform size and shape, and off-the-shelf availability that foregoes the time, technical requirements, and morbidity of vein harvest.

- Data on more than 500 patient-years of exposure in which clinicians observed that the HAV does not stimulate an increase in calculated panel reactive antibodies (cPRA) or show evidence of clinical rejection, were presented at the American Transplant Congress in June 2022. The results also showed that of the cohort of patients with end-stage renal disease who received an HAV or a synthetic expanded polytetrafluoroethylene (ePFTE) arteriovenous (AV) graft for hemodialysis access, HAV-implanted patients exhibited fewer instances of sensitization than patients receiving the ePFTE graft. These results are consistent with the absence of HAV rejection observed in the approximately 500 patients implanted with the HAV across all indications to date.

Corporate Updates

- In June 2022, Humacyte strengthened its Board of Directors with the appointment of Diane Seimetz, Ph.D. Dr. Seimetz has over 22 years of international drug development, partnering and managerial experience in the biopharmaceutical industry. In 2013, she co-founded Biopharma Excellence, serving as Chief Executive Officer until its acquisition in June 2021. Dr. Seimetz received a degree in Pharmaceutical Science from the University of Saarland, a Master's degree in Drug Regulatory Affairs from the University of Bonn, and a Ph.D. from the University of Heidelberg.

- In April 2022, Humacyte announced the appointment of Shamik J. Parikh, M.D., as Chief Medical Officer. In this role, Dr. Parikh leads the Company's global clinical development strategy, including oversight of the preclinical and clinical development, clinical operations, and medical affairs functions. Dr. Parikh brings more than two decades of leadership experience in academia and at global pharmaceutical companies, where he oversaw clinical and drug strategy, research and development, and product launches across multiple therapeutic areas, Including a 16-year tenure at AstraZeneca.

Second Quarter 2022 Financial Highlights

- The Company reported cash, cash equivalents and short-term investments of $189.0 million as of June 30, 2022, compared to $225.5 million as of December 31, 2021. The $36.5 million net use of cash, cash equivalents and short-term investments for the first six months of 2022 resulted from spending related to net operating activities for the period, including clinical and earlier-stage research and development programs, and preparation for the Company's anticipated commercial launch. The Company believes that its cash, cash equivalents and short-term investments are adequate to fund operations through 2024, past the Company's current expected timeline for potential approval of the HAV in vascular trauma.

- Revenue was $1.3 million for the second quarter of 2022, compared to $0.7 million for the second quarter of 2021, and was $1.5 million for the six months ended June 30, 2022, compared to $0.8 million for the six months ended June 30, 2021. Revenue in all periods related to grants supporting the development of the HAV.

- Research and development expenses were $14.7 million for the second quarter of 2022, compared to $14.6 million for the second quarter of 2021, and were $31.0 million for the six months ended June 30, 2022, compared to $29.7 million for the six months ended June 30, 2021. The current-period increases resulted primarily from increased personnel expenses to support expanded research and development initiatives and the support of clinical trials.

- General and administrative expenses were $5.2 million for the second quarter of 2022, compared to $5.4 million for the second quarter of 2021, and were $10.9 million for the six months ended June 30, 2022, compared to $10.2 million for the six months ended June 30, 2021. The increase during the six months ended June 30, 2022 compared to the prior-year period resulted primarily from the transition to being a public company and preparation for the anticipated U.S. commercial launch of the HAV, including increased personnel costs, professional fees and insurance costs. The decrease for the quarter ended June 30, 2022 compared to the prior-year quarter resulted primarily from non-cash stock compensation expense incurred in 2021 related to restructuring of the management team to accommodate the transition to being a public company.

- Other net income was $55.4 million for the second quarter of 2022, compared to $2.1 million for the second quarter of 2021, and was $57.3 million for the six months ended June 30, 2022, compared to $1.5 million for the six months ended June 30, 2021. The current-period increases in other net income resulted primarily from non-cash gains related to the remeasurement of the contingent earnout liability associated with the August 2021 merger with Alpha Healthcare Acquisition Corp.

- Net income was $36.9 million for the second quarter of 2022, compared to a net loss of $17.2 million for the second quarter of 2021, and net income was $17.0 million for the six months ended June 30, 2022, compared to a net loss of $37.5 million for the six months ended June 30, 2021. The current-period increases in net income resulted from the increases in other net income described above, partially offset by expense increases also described above.

Conference Call and Webcast Details

Date:	Friday, August 12, 2022
Time:	8:00 a.m. ET
Conference Call Details:	Toll-Free: 1-877-704-4453 International: 1-201-389-0920 Conference ID: 13731541
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 and complex tissue 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 human acellular vessels (HAVs), is currently in late-stage clinical trials targeting multiple vascular applications, including vascular trauma repair, arteriovenous 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 arteriovenous (AV) access for performing 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. 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; our rights and obligations under our partnership with Fresenius Medical Care; the scope of protection we are able to establish and maintain for intellectual property rights covering our HAVs and related technology; the timing or likelihood of regulatory filings and approvals; 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, the impact of COVID-19 on Humacyte's business, 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, 2021, 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 Income (Loss)

(unaudited)

(in thousands except for share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Grant Revenue	$ 1,301	$ 690	$ 1,534	$ 845
Operating expenses:				
Research and development	14,652	14,568	30,966	29,705
General and administrative	5,180	5,391	10,862	10,178
Total operating expenses	19,832	19,959	41,828	39,883
Loss from operations	**(18,531)**	**(19,269)**	**(40,294)**	**(39,038)**
Other income (expenses), net				
Change in fair value of contingent earnout liability	56,353	—	59,611	—
Other (expenses) income (net)	(954)	2,071	(2,281)	1,539
Total other income, net	55,399	2,071	57,330	1,539
Net income (loss) and comprehensive income (loss)	**$ 36,868**	**$ (17,198)**	**$ 17,036**	**$ (37,499)**
Net income (loss) per share, basic	$ 0.36	$ (2.89)	$ 0.17	$ (6.35)
Weighted-average shares outstanding, basic	103,005,651	5,941,675	103,004,874	5,908,372
Net income (loss) per share, diluted	$ 0.35	$ (2.89)	$ 0.16	$ (6.35)
Weighted-average shares outstanding, diluted	103,908,440	5,941,675	103,923,138	5,908,372

Humacyte, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 181,035	$ 217,502
Short-term investments	8,000	8,000
Prepaid expenses and other current assets	3,995	3,838
Total current assets	193,030	229,340
Property, plant and equipment, net	32,227	35,034
Lease right-of-use assets, net	21,108	22,159
Total assets	**$ 246,365**	**$ 286,533**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,537	$ 2,094
Accrued expenses	6,186	6,757
Other current liabilities	2,335	2,199
Total current liabilities	11,058	11,050
Contingent earnout liability	44,049	103,660
SVB loan payable	28,132	27,361
Finance lease obligation, net of current portion	20,018	21,109
Other long-term liabilities	848	1,179
Total liabilities	**104,105**	**164,359**
Stockholders' equity		
Common stock and additional paid-in capital	539,797	536,747
Accumulated deficit	(397,537)	(414,573)
Total stockholders' equity	142,260	122,174
Total liabilities and stockholders' equity	**$ 246,365**	**$ 286,533**