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 10, 2026

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** (Address of principal executive offices)	**27713** (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**

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 November 10, 2026, Humacyte, Inc. issued a press release regarding its financial results for its fiscal third quarter ended September 30, 2026. 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 10, 2026.
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 10, 2026

By: /s/ Dale A. Sander

Name: Dale A. Sander

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

Exhibit 99.1

Humacyte Reports Third Quarter 2026 Results, Highlighted by More Than Doubling Symvess Revenue and Expanding Commercial Adoption

– Commercial adoption of Symvess® accelerated during the third quarter with sales totaling $1.0 million, a 151% increase over the 2nd quarter.

– Symvess commercial momentum continued into the fourth quarter, with October 2026 sales totaling $0.8 million.

– Supplemental Biologics License Application (sBLA) for the ATEV in dialysis access on track for filing with the Food and Drug Administration (FDA) in November 2026.

– Company initiates first-in-human clinical Phase 2a study of CTEV for CABG.

– Conference call today at 8:00 am ET.

DURHAM, N.C., November 10, 2026 – Humacyte, Inc. (Nasdaq: HUMA), a commercial-stage biotechnology platform company developing universally implantable, bioengineered human tissues at commercial scale, today announced financial results for the third quarter ended September 30, 2026, and provided a business update.

"During our third quarter, we continued the transformation of our Symvess commercial program in vascular injury repair, doubling revenue over our second quarter and significantly increasing the number of hospitals ordering Symvess," said Laura Niklason, M.D., Ph.D., Founder and Chief Executive Officer of Humacyte. "In our future targeted market in dialysis access, our plan is to file a supplemental BLA for the ATEV in November 2026, supported by results from three Phase 3 studies. Publication of our V007 Phase 3 results in *The Lancet Digital Health* and presentation of our V012 Phase 3 results in a late-breaking session at ASN Kidney Week gave the vascular surgery and nephrology communities an overview of the data that will form the basis of our sBLA filing. These results also support our belief that the ATEV has the potential to address significant unmet needs for dialysis patients seeking improved hemodialysis access options. Elsewhere in our pipeline, we have initiated our Phase 2a study in coronary artery bypass grafting (CABG) and look forward to enrollment of the first patients."

"Execution of our revamped commercial program for Symvess generated significant momentum during the third quarter," said Jim Mercadante, Chief Commercial Officer of Humacyte. "Symvess sales revenue for the third quarter was $1.0 million, more than double our results for the second quarter, and achieved the goal we set for the period. Momentum has continued into the fourth quarter and based on expanded hospital adoptions and physician engagement, we anticipate at least doubling our third quarter sales revenue in Q4 2026. We believe the strategy we've established is working and that we have positioned Symvess for sustainable growth throughout the remainder of 2026 and beyond."

Third Quarter 2026 and Recent Corporate Highlights

Symvess Commercialization

- **Third Quarter Commercial Highlights*:*** Hospital adoption expanded significantly during the third quarter, with the number of hospitals that ordered Symvess increasing by 44%, from 34 hospitals at the end of the second quarter to 49 hospitals as of September 30, 2026.

    - Commercial sales reached $1.0 million in Q3, more than doubling the prior quarter, with new hospital orders increasing sequentially each month throughout the third quarter.
    - Symvess commercial growth accelerated entering the fourth quarter, with October 2026 sales reaching $0.8 million and Q4 2026 sales expected to at least double compared with Q3 sales.
    - Humacyte anticipates adding at least 20 new hospitals during the second half of 2026.

Breakthrough Phase 3 Results of ATEV in Dialysis Support Planned BLA Filing

- **Phase 3 V012 Trial Results for ATEV in Women Requiring Hemodialysis Access Presented in Late-Breaking Session at ASN Kidney Week 2026:** Interim results from the V012 Phase 3 clinical trial were presented in a prestigious late-breaking oral presentation at the *American Society of Nephrology (ASN) Kidney Week 2026* conference in October 2026. The Phase 3 results were presented by Prabir Roy-Chaudhury, M.D., Ph.D., FASN, of the University of North Carolina at Chapel Hill School of Medicine. In the V012 Phase 3 trial, women implanted with the ATEV were observed to achieve functional access more than three months sooner and spent significantly more time free of dialysis catheters over the first year than women who received an AV fistula, which is the current standard of care for hemodialysis access.

- **Planned BLA Filing**: The above V012 results, combined with results from the V007 Phase 3 trial reported previously, suggest that the ATEV could represent the first major advance in dialysis access in decades, offering surgeons an alternative option for patients where AV fistula maturation is difficult. Based on these results, Humacyte plans to submit a supplemental Biologics License Application to the FDA in November 2026 to add dialysis access as a second approved indication.

- **Lancet Digital Health Publication of V007 Phase 3 Hemodialysis Access Trial Results:** One-year results from the V007 Phase 3 clinical trial of the acellular tissue engineered vessel (ATEV) in arteriovenous (AV) access for hemodialysis patients were published in *The Lancet Digital Health*, a leading peer-reviewed journal in the Lancet family. The publication, entitled "Bioengineered Acellular Tissue Engineered Vessels Versus Autogenous Fistulae for Haemodialysis Access: a Multicentre, Randomised, Controlled, Phase 3 Trial," reports the positive findings from Humacyte's V007 trial, previously presented at major medical conferences. During this trial the superiority of the ATEV over autogenous arteriovenous fistula (AVF) for hemodialysis vascular access was observed after one year of follow up, particularly for female patients and male patients having obesity and diabetes, patient populations that often experience higher rates of AVF failure.

- **Appointed Key Nephrologists as Advisors to Prepare for Planned Dialysis Commercialization:** Robert J. (Rob) Kossmann, MD, FACP, FASN, and Prabir Roy-Chaudhury, MD, PhD, FASN, have been appointed as advisors to Humacyte. These leading nephrologists will help prepare for the planned commercialization of the ATEV in dialysis access, if approved by the FDA. They will also contribute to the development of health economic, reimbursement and market access strategies as well as provide peer-to-peer scientific support and medical education.

First Human Study in CABG

- **First Human Study in Coronary Tissue Engineered Vessel (CTEV) Initiated**: The FDA has accepted the IND application for a first-in-human clinical study of the CTEV in coronary artery bypass grafting, and Humacyte initiated a Phase 2a study of the CTEV in CABG patients in November 2026 with activation of the first clinical site. To support this study, Humacyte has completed the first large-scale manufacturing lot of CTEV in its commercial-scale production facilities.

- **CTEV Presentations at American Heart Association Scientific Sessions:** Three presentations related to the CTEV were made at the American Heart Association Scientific Sessions meeting November 7-8, 2026. Humacyte collaborators presented an overview of the clinical trial protocol for the Phase 2a study of the CTEV in CABG. Humacyte researchers also presented preclinical results supporting the progression of the CTEV into the first human study and the potential of regenerative medicine products to treat pediatric patients with congenital heart disease.

Corporate Update

- **Expanded Board Expertise with Appointments of Scott Coward and Paul Kuznik:** In September 2026, the Company announced the addition of life science industry veterans Scott Coward and Paul Kuznik to the Company's Board of Directors, both of whom bring substantial experience in the areas of commercialization, enterprise leadership, and global operations.

For uses other than the FDA approval in the extremity vascular trauma indication, the ATEV is an investigational product and has not been approved for sale by the FDA or any other regulatory agency. The CTEV is an investigational product and has not been approved for sale by the FDA or any other regulatory agency.

Third Quarter 2026 Financial Highlights

- Commercial sales of Symvess increased to $1.0 million in the third quarter of 2026, compared to $0.4 million in the second quarter of 2026 and $0.7 million in the third quarter of 2025. Sequential quarter sales growth, and growth compared to the prior-year quarter, resulted from commercialization initiatives implemented during the first half of 2026 and an increase in the number of hospitals ordering Symvess during the third quarter. For the nine months ended September 30, 2026, commercial sales of Symvess were $1.9 million compared to $1.0 million for the nine months ended September 30, 2025. Contract revenue was minimal during the third quarters of 2026 and 2025 and for the nine months ended September 30, 2026, due to the completion of a research project, and was $0.6 million for the nine months ended September 30, 2025.

- Cost of goods sold was $1.4 million for the third quarter of 2026 compared to $0.3 million for the third quarter of 2025. In the third quarter of 2026, $0.6 million of cost of goods sold related to the cost of units recorded as sales revenue during the period, and $0.8 million was primarily comprised of overhead related to unused production capacity and royalties. Cost of goods sold was $4.7 million for the nine months ended September 30, 2026, compared to $0.6 million for the nine months ended September 30, 2025. In the nine months ended September 30, 2026, $1.2 million of cost of goods sold related to the cost of units recorded as sales revenue during the period, $2.3 million related to inventory reserves, and $1.2 million was primarily comprised of overhead related to unused production capacity and royalties.

- Research and development expenses were $14.1 million and $51.7 million for the three and nine months ended September 30, 2026, respectively, compared to $17.3 million and $54.7 million for the same periods in 2025. The decrease in research and development expenses during the third quarter of 2026 and the nine months ended September 30, 2026, compared to the prior-year periods, was primarily due to a reduction in non-commercial manufacturing runs and the wind-down of certain programs. Research and development expenses have declined sequentially each quarter in 2026, and the $14.1 million incurred in the third quarter of 2026 was $4.0 million less than the $18.1 million incurred in the second quarter of 2026.

- General and administrative expenses were $9.0 million and $25.0 million for the three and nine months ended September 30, 2026, respectively, compared to $7.6 million and $23.6 million for the same periods in 2025. The current-year increase in general and administrative expenses was primarily related to $0.6 million in net expense related to a reserve for the settlement of shareholder litigation and legal costs related to the litigation.

- Other net income was $8.0 million and $9.5 million for the three and nine months ended September 30, 2026, respectively, compared to other net income of $6.9 million and $61.3 million for the same periods in 2025. Other net income for all periods resulted primarily from the non-cash remeasurement of the contingent earnout liability and other derivative liabilities.

- Net loss was $15.5 million and $70.0 million for the three and nine months ended September 30, 2026, respectively, compared to net loss of $17.5 million and $16.0 million for the same periods in 2025. The decrease in net loss for the 3rd quarter of 2026 was primarily related to the decrease in research and developments expenses. The increase in net loss for the nine months ended September 30, 2026 was primarily due to the non-cash remeasurement of the contingent earnout liability described above.

- The Company had cash, cash equivalents and restricted cash of $64.9 million as of September 30, 2026. Total net cash used in operating activities was $15.0 million and $62.1 million for the three and nine months ended September 30, 2026, respectively, compared to $23.9 million and $78.9 million for the same periods in 2025. Cash used in operations decreased in 2026 compared to the prior-year periods primarily due to lower inventory production costs.

Conference Call and Webcast Details

Title:	Humacyte Third Quarter 2026 Financial Results and Corporate Update
Date:	November 10, 2026
Time:	8:00 AM Eastern Time
Conference Call Details:	1-877-704-4453 (U.S. Investors Dial) 1-201-389-0920 (International Investors Dial) 13763173 (Conference ID)
Call me™ Feature:	Click Here
Webcast:	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.

INDICATION

Symvess is an acellular tissue engineered vessel indicated for use in adults as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and autologous vein graft is not feasible.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: GRAFT FAILURE

Loss of Symvess integrity due to mid-graft rupture or anastomotic failure can result in life threatening hemorrhage.

CONTRAINDICATIONS

DO NOT use Symvess in patients who have a medical condition that would preclude long-term antiplatelet therapy (such as aspirin or clopidogrel) after resolution of acute injuries.

WARNINGS AND PRECAUTIONS

- **Graft Rupture**

Vascular graft rupture has occurred in patients treated with Symvess. Advise patients that arterial bleeding can be life-threatening and to seek emergent medical evaluation for any signs or symptoms of graft rupture such as bleeding, pain and swelling in the extremity, or signs of extremity ischemia.

- **Anastomotic Failure**

Anastomotic failure has occurred in patients treated with Symvess. In clinical studies of Symvess, anastomotic failure occurred within the first 36 days post-implantation. Monitor patients for signs of anastomotic failure such as pain and swelling at the surgical site, decreasing hemoglobin or other signs and symptoms of bleeding. Advise patients to seek urgent medical evaluation if they have any signs or symptoms that may be indicative of anastomotic failure such as bleeding, swelling or worsening pain at the surgical site or changes in color of overlying skin.

- **Thrombosis**

Thrombosis has occurred in patients treated with Symvess. In clinical trials of Symvess, patients received antiplatelet therapy following implantation of Symvess to reduce the risk of thrombosis. The risk of thrombosis may increase in patients who discontinue antiplatelet therapy. Anti-platelet therapy is recommended following treatment with Symvess.

- **Transmission of Infectious Diseases**

Symvess is manufactured using cells and reagents that may transmit infectious diseases or infectious agents. The cells used in the manufacture of Symvess are derived from a donor who met the donor eligibility requirements for transmissible infectious diseases which includes screening and testing of risks associated with human immunodeficiency virus 1 (HIV-1), human immunodeficiency virus 2 (HIV-2), hepatitis B virus (HBV), hepatitis C virus (HCV), and syphilis (Treponema pallidum). The cell banks are tested negative for human and animal viruses, retroviruses, bacteria, fungi, yeast, and mycoplasma. While all animal-derived reagents are tested for animal viruses, bacteria, fungi, and mycoplasma before use, these measures do not eliminate the risk of transmitting these or other transmissible infectious diseases and disease agents. Fetal bovine serum is sourced to minimize the risk of transmitting a prion protein that causes bovine spongiform encephalopathy and the cause of a rare fatal condition in humans called variant Creutzfeldt-Jakob disease. No transmissible agent infections have been reported during clinical testing.

ADVERSE REACTIONS

The most common adverse reactions (occurring at ≥ 10%), were vascular graft thrombosis, pyrexia (fever) and pain.

Please see full Prescribing Information at www.symvess.com, including Boxed Warning, for Symvess.

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 Biologics License Application for the acellular tissue engineered vessel (ATEV) in the vascular trauma indication was approved by the FDA in December 2024. ATEVs are also currently in late-stage clinical trials targeting other vascular applications, including arteriovenous (AV) access for hemodialysis and peripheral artery disease (PAD). 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 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.

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, our plans and ability to commercialize Symvess and, if approved by regulatory authorities, our product candidates, successfully and on our anticipated timelines; our expectations regarding future sales and sales growth of Symvess; the degree of market acceptance of and the availability of third-party coverage and reimbursement for Symvess and, if approved by regulatory authorities, our product candidates; our ability to manufacture Symvess and, if approved by

regulatory authorities, our product candidates in sufficient quantities to satisfy our clinical trial and commercial needs; the anticipated benefits of our ATEVs and CTEVs relative to existing alternatives; our plans and ability to execute product development, process development and preclinical development efforts successfully and on our anticipated timelines; our ability to design, initiate and successfully complete clinical trials and other studies for our product candidates and our plans and expectations regarding our ongoing or planned clinical trials; the anticipated characteristics and performance of our ATEVs or CTEVs; our plans and expectations regarding the potential commercialization of the ATEV for dialysis access, if approved, including our expectations regarding market access, reimbursement and commercialization preparations; the implementation of our business model and strategic plans for our business; our ability to execute and achieve the expected benefits of our cost-saving measures and whether our efforts will result in further actions or additional asset impairment charges that adversely affect our business; our ability to realize the benefits of the DoD's funding in the DoD Appropriations Act; and the timing or likelihood of regulatory filings and submissions, 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, competitive and/or reputational 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, 2025 and Form 10-Q for the quarter ended June 30, 2026, 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,	
	2026	2025	2026	2025
Revenue:				
Product revenue, net	$ 1,023	$ 703	$ 1,922	$ 950
Contract revenue	5	50	7	621
Total revenue	1,028	753	1,929	1,571
Operating expenses:				
Cost of goods sold	1,429	260	4,698	620
Research and development	14,104	17,273	51,710	54,697
General and administrative	9,014	7,610	24,971	23,555
Total operating expenses	24,547	25,143	81,379	78,872
Loss from operations	**(23,519)**	**(24,390)**	**(79,450)**	**(77,301)**
Other income, net:				
Change in fair value of contingent earnout liability	3,387	4,893	5,401	49,154
Other income, net	4,594	1,987	4,090	12,118
Total other income, net	7,981	6,880	9,491	61,272
Net loss and comprehensive loss	**$ (15,538)**	**$ (17,510)**	**$ (69,959)**	**$ (16,029)**
Net loss per share, basic and diluted	$ (0.06)	$ (0.11)	$ (0.30)	$ (0.11)
Weighted-average shares outstanding, basic and diluted	277,798,105	158,313,290	236,901,920	148,514,044

Humacyte, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands)

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 64,523	$ 50,497
Inventory, net	5,611	13,589
Insurance recovery asset	9,119	-
Prepaid expenses and other current assets	3,426	3,709
Total current assets	82,679	67,795
Restricted cash	209	209
Property and equipment, net	14,883	18,544
Finance lease right-of-use assets, net	27,801	29,146
Other long-term assets	-	672
Total assets	**$ 125,572**	**$ 116,366**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,820	$ 5,404
Accrued expenses	11,582	10,540
Litigation settlement liability	9,750	-
Other current liabilities	609	2,428
Total current liabilities	24,761	18,372
Long-term debt	36,803	35,444
Contingent Earnout Liability	6,091	11,492
Common stock warrant liabilities	9,115	19,392
Finance lease obligation, net of current portion	29,070	26,974
Other long-term liabilities	1,668	1,583
Total liabilities	**107,508**	**113,257**
Stockholders' equity:		
Common stock and additional paid-in capital	814,871	729,957
Accumulated deficit	(796,807)	(726,848)
Total stockholders' equity	**18,064**	**3,109**
Total liabilities and stockholders' equity	**$ 125,572**	**$ 116,366**