# 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): April 21, 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**<br>**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:

☐ 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** |
| **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 ☐

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 1.01. Entry into a Material Definitive Agreement.**

On April 21, 2026, Humacyte, Inc. (the "Company") entered into the Third Amendment to Distribution Agreement (the "Amendment") with Fresenius Medical Care Holdings, Inc. ("Fresenius"), to amend the Distribution Agreement, dated as of June 25, 2018, as amended, between the Company and Fresenius (the "Agreement"). Under the Agreement, Humacyte granted to Fresenius rights to develop and commercialize the Company's 6 millimeter acellular tissue engineered vessel-tyod (the "Distribution Product") outside of the U.S. As a result of the Amendment, the Company has the sole right to develop and commercialize, and conduct all regulatory matters relating to, the Distribution Product on a worldwide basis. Additionally, the Company will pay to Fresenius low-single-digit royalties on net sales of the Distribution Product in connection with this reversion of ex-U.S. rights to the Company under the Amendment subject to a two-year royalty free period following launch of the Distribution Product in each applicable country, The Company will continue to pay royalties on net sales of the Distribution Product in the U.S. at rates ranging from mid-single digits to low double digits and Fresenius remains obligated to adopt the Distribution Product as a standard of care in hemodialysis patients for which such use is supported by clinical results and health economic analyses..

The description of the Amendment set forth above is only a summary of its material terms and does not purport to be complete, and is qualified in its entirety by reference to the full and complete terms contained in the Amendment, which is filed as Exhibit 10.1 to this Form 8-K and is incorporated into this Item 1.01 by reference. The Amendment is not intended to be a source of factual, business or operational information about the Company or its subsidiaries. The representations, warranties and covenants contained in the Amendment were made only for purposes of the Amendment and as of specific dates, were solely for the benefit of the parties to the Amendment, and may be subject to limitations agreed upon by the parties, including being qualified by disclosures for the purpose of allocating contractual risk between the parties instead of establishing matters as facts; and may be subject to standards of materiality applicable to the contracting parties that differ from those applicable to investors or security holders. Accordingly, investors should not rely on the representations, warranties and covenants or any descriptions thereof as characterizations of the actual state of facts or condition of the parties.

**Item 7.01. Regulation FD Disclosure**

On April 24, 2026, the Company issued a press release announcing the entry into the Amendment. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 7.01 is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Item 7.01 shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit Number | Description |
|---|---|
| 10.1* | Third Amendment to Distribution Agreement, dated as of April 21, 2026, between Humacyte, Inc. and Fresenius Medical Care Holdings, Inc. |
| 99.1 | Press release, dated April 24, 2026. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). |

* Certain confidential information contained in this exhibit, market by brackets, has been omitted because the information (i) is not material and (ii) is the type of information the company both customarily and actually treats as private or confidential.

**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: April 24, 2026

By: /s/ Dale A. Sander

Name: Dale A. Sander

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

**Exhibit 10.1**

**Certain identified information has been excluded from this exhibit because such information both (i) is not material and (ii) is the type that the registrant both customarily and actually treats as private or confidential. Excluded information is indicated with brackets and asterisks.**

**THIRD AMENDMENT TO DISTRIBUTION AGREEMENT**

This THIRD AMENDMENT TO DISTRIBUTION AGREEMENT (this "**Third Amendment**"), entered into as of April 21, 2026 (the "**Third Amendment Date**"), and effective as of the Third Amendment Date, is made and entered into by and between Fresenius Medical Care Holdings, Inc., a corporation organized and existing under the Laws of the State of New York ("**Fresenius**"), and Humacyte, Inc., a corporation organized and existing under the Laws of the State of Delaware ("**Humacyte**").

WHEREAS, Fresenius and Humacyte entered into that certain Distribution Agreement, effective as of June 25, 2018 (the "**Original Agreement**"), as amended by that certain First Amendment, dated as of October 2, 2019 (the "**First Amendment**"), and as amended by that certain Second Amendment, dated as of February 16, 2021 (the "**Second Amendment**");

WHEREAS, the term "Agreement" where used in the Original Agreement and this Third Amendment, is deemed inclusive of the Original Agreement as amended by the First Amendment, the Second Amendment, and this Third Amendment; and

WHEREAS, Fresenius and Humacyte each wish to amend and update certain aspects of the Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and obligations set forth out in this Third Amendment and other good and valuable consideration, the sufficiency of which are acknowledged, the parties to this Third Amendment agree as follows:

1. Definitions; Cross References.

1.1 All terms not expressly defined or modified in this Third Amendment shall have the meaning ascribed therefor in the Agreement.

1.2 Unless otherwise indicated, all references to Sections and Articles herein are references to the corresponding Section or Article of the Agreement.

2. Certain Agreements and Amendments of the Agreement.

2.1 Section 2 is hereby deleted in its entirety and replaced with "Reserved.".

2.2 Sections 3.2-3.3 (inclusive) are hereby deleted in their entirety and replaced with “Reserved.”.

2.3 Sections 4.2-4.6 (inclusive) are hereby deleted in their entirety and replaced with “Reserved.”.

2.4 Section 5 is hereby deleted in its entirety and replaced with “Reserved.”.

2.5 Section 6 is hereby deleted in its entirety and replaced with “Reserved.”.

2.6 Section 7 is hereby deleted in its entirety and replaced with “Reserved.”.

2.7 Section 8 is hereby deleted in its entirety and replaced with “Reserved.”.

2.8 Section 9 is hereby deleted in its entirety and replaced with “Reserved.”.

2.9 Section 10.1.1 is hereby deleted in its entirety and replaced with the following:

10.1.1 Royalties to Fresenius. Humacyte will make royalty payments to Fresenius based on (a) aggregate Net Sales of the Distribution Product in the United States in the Field [***], and (b) aggregate Net Sales of the Distribution Product in the EU and ROW in the Field [***]with the rates, set forth in the table below.

| Time Period | Royalty Rate of Net Sales | Territory |
|---|---|---|
| Until such time that Humacyte has paid to Fresenius a total of [***] in royalty payments pursuant to this Section 10.1.1 | [***] | US |
| Beginning on the Third Amendment Effective Date | [***] | EU and ROW |
| After Humacyte has paid to Fresenius a total of [***] in royalty payments pursuant to this Section 10.1.1 | [***] | US |

Humacyte’s obligation to make royalty payments to Fresenius pursuant to the first paragraph of this Section 10.1.1 in the EU and ROW for sales in a particular country shall only begin on the third Product Year for such country (for each such country, the “**Holiday Period**”). During the Holiday Period, Net Sales in a country shall exclude [***].

The Parties acknowledge that for purposes of this Section 10.1.1, the definition of Net Sales shall apply to Humacyte, mutatis mutandis, where, for clarity, (a) the "Selling Parties" for calculating Net Sales are Humacyte or any of Humacyte's Related Parties and (b) in the case of any sale or other disposal of a Distribution Product, in each case, between or among Humacyte and any other Selling Party for resale, Net Sales will be calculated only on the value charged or invoiced on the first arm's-length sale thereafter to the first Third Party other than a Related Party by a Selling Party.

All such royalty payments to Fresenius are, in part, consideration for Fresenius' activities under the Agreement prior to the Third Amendment Date and are in lieu of any other consideration with respect to the Commercialization of the Distribution Product and any Additional Products in the US, EU or ROW.

2.10 Section 10.1.2 is hereby deleted in its entirety and replaced with "Reserved.".

2.11 Section 10.1.3 is hereby deleted in its entirety and replaced with "Reserved.".

2.12 Section 10.1.5 is hereby deleted in its entirety and replaced with "Reserved.".

2.13 Section 10.2.2 is hereby deleted in its entirety and replaced with "Reserved.".

2.14 Section 11 is hereby deleted in its entirety and replaced with "Reserved.".

2.15 Section 12 is hereby deleted in its entirety and replaced with the following:

12.1 License Grants to Humacyte. Subject to the terms and conditions of this Agreement, Fresenius hereby grants Humacyte a non-exclusive, non-transferable (except as provided in Section 18.1), sublicensable (through multiple tiers) license (including a right of reference) under the Fresenius Technology to Exploit the Distribution Product in the Field anywhere in the world, solely (a) to the extent used in and necessary for the Exploitation of the Distribution Product on the Third Amendment Date and (b) as the Distribution Product exists on the Third Amendment Date (it being understood that with respect to any such Fresenius Technology that is in-licensed by Fresenius or any of its Affiliates, Humacyte will be responsible for any payments due to a Third Party with respect thereto and Humacyte's rights thereunder will be subject to the terms and conditions of the applicable Third Party agreement and Humacyte agreeing to be bound thereby).

2.16 Section 14.2 is hereby deleted in its entirety and replaced with "Reserved.".

2.17 Section 14.3 is hereby deleted in its entirety and replaced with "Reserved.".

2.18 Section 14.4 is hereby deleted in its entirety and replaced with “Reserved.”.

2.19 Section 14.6 is hereby deleted in its entirety and replaced with “Reserved.”.

2.20 Sections 16.4-16.10 (inclusive) are hereby deleted in their entirety and replaced with “Reserved.”.

2.21 The section references in the second sentence of Section 17.8 following the phrase “shall survive expiration or termination of this Agreement for any reason:” are hereby deleted in their entirety and replaced with the following:

Sections 1, 10.1.1, 10.2.4, 12.1, 13, 15, 16.2.3, 16.3.1, 17.8 and 18.

2.22 Section 18.18 is hereby deleted in its entirety and replaced with “Reserved.”.

2.23 Schedule 10.1 is hereby deleted in its entirety.

3. Other Provisions.

3.1 Both Parties hereby confirm that the Agreement is in full force and effect, including as modified hereby.

3.2 As amended hereby, the Agreement shall remain in full force and effect.

3.3 This Third Amendment will be construed and the respective rights of the Parties determined in accordance with the substantive Laws of the State of Delaware, notwithstanding any Laws governing conflicts of Laws to the contrary.

3.4 As stated in its Code of Ethics and Business Conduct, Fresenius upholds the values of quality, honesty and integrity, innovation and improvement, respect and dignity, as well as lawful conduct, especially with regard to anti-bribery and anti-corruption. Fresenius upholds these values in its own operations, as well as in its relationships with business partners. Fresenius’ continued success and reputation depends on a common commitment to act accordingly. This Third Amendment has been reviewed by Humacyte and its advisors and Fresenius and its advisors. The parties agree that this Third Amendment is the product of all their efforts, and that it should not be interpreted in favor of any one party merely because of its efforts in preparing it, and that both parties are entering into this Third Amendment in good faith.

3.5 The Parties acknowledge and agree that the effect of this Third Amendment is that Humacyte will have the sole right to Develop, conduct all regulatory matters relating to, and Commercialize the Distribution Product on a worldwide basis, and that Fresenius will have no obligations to Develop, conduct any regulatory matters relating to, or Commercialize the Distribution Product. For clarity, the foregoing does not limit Fresenius's obligations under Section 3.1 of the Agreement.

3.6 Except as expressly set forth in this Third Amendment or the Agreement, no Person other than the Parties and their respective Affiliates and permitted assignees hereunder will be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Third Amendment or the Agreement.

3.7 This Third Amendment may be executed in two or more counterparts, including by facsimile of PDF signature pages, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

(Signature page follows)

IN WITNESS WHEREOF, the Parties have caused this Third Amendment to Distribution Agreement to be executed by their duly authorized representatives as of the Third Amendment Date.

FRESENIUS MEDICAL CARE HOLDINGS, INC.

By: /s/ Patricia Rich
Name: Patricia Rich
Title: Sr. Vice President and Secretary
Date: April 9, 2026

HUMACYTE, INC.

By: /s/ Dale Sander
Name: Dale Sander
Title: Chief Financial Officer
Date: April 21, 2026

**Exhibit 99.1**

**Humacyte Expands Commercial and Business Development Opportunities Through Realignment of Ex-U.S. Rights to Symvess®**

*- Ex-U.S. rights realigned under amendment to distribution agreement with Fresenius Medical Care -*

*- Positions Humacyte to advance discussions with corporate partners regarding international and indication-specific rights to Symvess –*

*- Existing terms related to U.S. distribution of Symvess remain unchanged*

DURHAM, N.C., April 24, 2026 – Humacyte, Inc. (Nasdaq: HUMA), a commercial-stage biotechnology platform company developing universally implantable, bioengineered human tissues at commercial scale, today announced that it has realigned the ex-U.S. rights to Symvess (acellular tissue engineered vessel) through an amendment to its distribution agreement with Fresenius Medical Care (FME).

““We are pleased to have worked successfully with our long-time partner and largest shareholder Fresenius Medical Care, to realign the global rights to Symvess in a manner that benefits both companies and best enables Humacyte’s planned international expansion,” said Dr. Laura Niklason, CEO of Humacyte. “The restructuring of ex-U.S. commercial rights enables us to fully advance the commercial initiatives that we previously announced in the Kingdom of Saudi Arabia and Israel in vascular injury repair and other indications. In addition, we are now positioned to advance discussions with prospective corporate partners regarding international and indication-specific rights to Symvess. As amended, the distribution agreement now provides that Humacyte will have the exclusive rights to distribute Symvess outside the U.S., and FME will be entitled to low-single-digit royalties on our net sales of Symvess outside the U.S. Existing terms related to the U.S. remain unchanged.”

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

**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 (including commercial initiatives in the Kingdom of Saudi Arabia and Israel) and, if approved by regulatory authorities, our product candidates, successfully and on our anticipated timelines; 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 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; 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; and the timing or likelihood of regulatory filings, 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 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.

**Humacyte Investor Contact:**
Joyce Allaire
LifeSci Advisors LLC
+1-617-435-6602
jallaire@lifesciadvisors.com
investors@humacyte.com

**Humacyte Media Contact:**
Rich Luchette
Precision Strategies
+1-202-845-3924
rich@precisionstrategies.com
media@humacyte.com