**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 19, 2026**

# PASSAGE BIO, INC.

**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-39231** | **82-2729751** |
|---|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(Commission File Number)** | **(I.R.S. Employer Identification No.)** |
| **Address Not Applicable[1]** | | **ZIP Code Not Applicable** |
| **(Address of principal executive offices)** | | **(Zip Code)** |

**(267) 866-0311**
**(Registrant's telephone number, including area code)**

**N/A**
**(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, $0.0001 par value per share | PASG | The Nasdaq Stock Market LLC (Nasdaq Capital Market) |

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. ☐

[1] We are a remote-only company. Accordingly, we do not maintain a headquarters. For purposes of compliance with applicable requirements of the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended, any stockholder communication required to be sent to our principal executive offices may be directed to P.O. Box 7, Hopewell, New Jersey 08525.

**Item 7.01 Regulation FD Disclosure**

On November 19, 2026, Remix Therapeutics, Inc. ("***Remix***") issued a press release announcing updated Phase 1 data from its ongoing ARIA Phase 1/2 clinical trial of REM-422, an oral MYB mRNA degrader, in patients with adenoid cystic carcinoma ("***ACC***"), in a late-breaking oral presentation at the 2026 EORTC-NCI-AACR (ENA) Symposium on Molecular Targets and Cancer Therapeutics. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01, including Exhibit 99.1 to this Current Report on Form 8-K, shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act. The information contained in this Item 7.01 and in the accompanying Exhibit 99.1 shall not be incorporated by reference into any other filing under the Exchange Act or under the Securities Act, except as shall be expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| **Exhibit No.** | **Description** |
|---|---|
| 99.1 | Remix Therapeutics, Inc. press release, dated November 19, 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.

**PASSAGE BIO, INC.**

Date: November 19, 2026

By: /s/ Kathleen Borthwick
Kathleen Borthwick
Chief Financial Officer

**Exhibit 99.1**

**Remix Therapeutics Announces Updated Positive REM-422 Phase 1 Data in Adenoid Cystic Carcinoma at 2026 EORTC-NCI-AACR Symposium**

*Late-breaking presentation highlights durable clinical activity, including 57% overall response rate at recommended Phase 2 dose in biomarker-positive patients*

*Time on REM-422 treatment reached up to two years and remains ongoing, supporting potential for long term dosing*

**Watertown, Mass., November 19, 2026** – Remix Therapeutics, Inc., a clinical-stage biotechnology company developing small molecule therapies to modulate RNA processing and address the underlying drivers of disease, today announced updated Phase 1 data from its ongoing ARIA Phase 1/2 study of REM-422, an oral MYB mRNA degrader, in a late-breaking oral presentation at the 2026 EORTC-NCI-AACR (ENA) Symposium on Molecular Targets and Cancer Therapeutics. Durable responses, prolonged progression-free survival and continued favorable tolerability were observed in patients with biomarker-positive recurrent or metastatic adenoid cystic carcinoma (ACC).

"There are currently no FDA-approved therapies for patients with ACC, despite the urgent need for an effective treatment," said Peter Smith, Ph.D., Co-Founder and Chief Executive Officer of Remix Therapeutics. "The updated REM-422 data continue to reinforce the promise of our RNA-processing platform and highlight the potential of targeted MYB degradation to address the underlying biology of this disease. We are particularly encouraged by the 57% overall response rate observed at the recommended Phase 2 dose in biomarker-positive patients, the durability of responses extending beyond one year, and median progression-free survival that has not yet been reached. Together, these compelling findings support our confidence that REM-422 has the potential to become a meaningful long-term treatment option for ACC patients."

“The relationship between MYB biomarker status and clinical outcomes observed in this study is compelling,” said Alan Ho, M.D., Ph.D., Chief of the Head and Neck Oncology Service at Memorial Sloan Kettering Cancer Center. “The ability to identify patients most likely to benefit, combined with the durability of activity seen to date, highlights the potential of this precision medicine approach in ACC and supports further evaluation of REM-422.”

The ongoing Phase 1/2 ARIA study is evaluating REM-422 in patients with recurrent, metastatic or unresectable ACC. REM-422 is a first-in-class oral small molecule designed to bind a poison exon within MYB mRNA, inducing degradation of the transcript and reducing MYB protein expression. MYB dysregulation is a defining feature of ACC and represents a promising therapeutic target.
As of August 24, 2026, 69 patients had been enrolled in the Phase 1 study, including 60 efficacy-evaluable patients. REM-422 was generally well tolerated across all dose levels evaluated, with no dose-limiting toxicities observed. The potentially registrational Phase 2 study enrolling biomarker positive patients treated at dose of 24 mg is expected to complete enrollment by year end.

**Key findings from the Phase 1 analysis, as of August 24, 2026 include:**

- Across all dose levels tested, 10 patients achieved a partial response (PR) among 32 efficacy-evaluable biomarker-positive (BM+) patients while no objective responses were observed among biomarker-negative patients.
- At the recommended Phase 2 dose (RP2D) of 24 mg, the overall response rate was 57% (4 of 7 efficacy-evaluable BM+ patients) with three confirmed partial responses (1 of 3 was confirmed subsequent to data-cut) and one unconfirmed partial response.
- Among BM+ patients median duration of response had not been reached, with responses ongoing up to 19 months.
- Time on treatment in BM+ patients reached up to 27 months and remains ongoing.
- Median progression-free survival was not reached in biomarker-positive patients, compared with 9 months in biomarker-negative patients at dose levels ≥ 24 mg.
- MYB biomarker status emerged as the key predictor of both clinical and pharmacodynamic response, with responses observed across patient subgroups regardless of mutation status, prior therapies, histologic subtype, or primary tumor location.

**About REM-422**
REM-422 is a potent, selective, and oral small molecule mRNA degrader that induces the reduction of MYB mRNA and subsequent protein expression. REM-422 functions by facilitating the incorporation of a poison exon in the MYB mRNA transcript, leading to nonsense-mediated decay of the transcript. REM-422 is currently in Phase 1/2 clinical studies in both Adenoid Cystic Carcinoma (ACC) and Acute Myeloid Leukemia (AML) or high-risk myelodysplastic syndrome (HR-MDS). The U.S. Food and Drug Administration granted REM-422 Orphan Drug Designation for ACC and AML and Fast Track designation for ACC.

**About the ARIA (A study of REM-422 In Adenoid cystic carcinoma) Clinical Trial**
This Phase 1/2, open-label, non-randomized, multicenter study (NCT06118086) is investigating REM-422 in patients with recurrent, metastatic or unresectable Adenoid Cystic Carcinoma (ACC). The study includes a Dose Escalation Phase and a Dose Expansion Phase. The purpose of the Dose Escalation Phase is to determine the maximum tolerated dose and/or recommended Phase 2 dose (RP2D) of REM-422 in patients with recurrent, metastatic, or unresectable ACC. The purpose of dose expansion is to further evaluate the safety and anti-tumor activity of the REM-422 RP2D in biomarker positive patients.

**About Adenoid Cystic Carcinoma**
Adenoid cystic carcinoma (ACC) is solid tumor that that most commonly arises in the salivary glands, though it can also occur in the breast, trachea, skin, and other exocrine tissues, with the majority of cases involving the head and neck. The disease is characterized by frequent perineural invasion and, in the majority of cases dysregulation of the MYB oncogene. Depending on tumor location, symptoms may include facial numbness, difficulty swallowing, vision changes, or difficulty breathing. No systemic therapy is currently FDA-approved for recurrent or metastatic ACC. Surgery, often combined with radiation, remains the standard of care for localized disease, while chemotherapy, kinase inhibitors, and immunotherapy have all been studied in advanced disease with modest or disappointing results overall.

**About Remix Therapeutics**
Remix Therapeutics is a clinical stage biotechnology company developing novel small molecule therapies designed to reprogram RNA processing and address disease drivers at their origin. Remix's REMaster™ technology platform leverages data science, biomolecular sciences and chemistry approaches to identify orally administered compounds that modulate gene expression. Remix's therapeutic approach led to the discovery of REM-422, an investigational small molecule designed to modulate RNA processing in oncology, currently being evaluated in two clinical programs: the ARIA clinical study, a Phase 1/2 clinical study in adenoid cystic carcinoma (ACC) and a Phase 1 clinical study in acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (HR-MDS).

**Cautionary Statement Regarding Forward-Looking Statements**

This communication contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, including statements regarding Remix's expectations, hopes, beliefs, intentions or strategies regarding the future of its pipeline and business including, without limitation, the expectations surrounding the potential, safety, efficacy, and regulatory and clinical progress of Remix's product candidates, including REM-422, anticipated milestones and timing. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "expect," "anticipate," "plan," "likely," "believe," "estimate," "project," "intend," and other similar expressions among others. Statements that are not historical facts are forward-looking statements. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation, the early stage of Remix's development efforts; potential unforeseen events during clinical trials could cause delays or other adverse consequences; risks relating to the regulatory approval process; interim, topline and preliminary data may change as more patient data become available, and are subject to audit and verification procedures that could result in material changes in the final data; Remix's product candidates may cause serious adverse side effects; failure to obtain U.S. or international marketing approval; ongoing regulatory obligations; effects of significant competition; and the other risks related to those uncertainties and factors more fully described in Passage's most recent filings with the Securities and Exchange Commission (including its registration statement on Form S-4, most recently amended on October 8, 2026 and declared effective by the Securities and Exchange Commission on October 9, 2026). Except as required by applicable law, Remix undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

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