
**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 06, 2026

APTEVO THERAPEUTICS INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-37746
(Commission File Number)

81-1567056
(IRS Employer
Identification No.)

**2401 4th Avenue
Suite 1050
Seattle, Washington**
(Address of Principal Executive Offices)

98121
(Zip Code)

Registrant's Telephone Number, Including Area Code: (206) 838-0500

(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, \$0.001 par value | APVO | 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 8.01 Other Events.

On May 6, 2026, Aptevo Therapeutics Inc. (the "Company") issued a press release announcing new clinical results from its RAINIER frontline acute myeloid leukemia (AML) trial. The Company is on track to complete the Phase 1b dose-optimization trial and select the recommended Phase 2 dose this year. As with the current study, the Phase 2 trial will dose mipletamig in combination with venetoclax and azacitidine.

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits**

The following exhibits are being filed herewith:

| Exhibit No. | Description |
|--------------------|--|
| 99.1 | Press release of Aptevo Therapeutics Inc. dated May 6, 2026. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

SIGNATURES

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.

APTEVO THERAPEUTICS INC.

Date: May 6, 2026

By: /s/ Daphne Taylor

Daphne Taylor

Senior Vice President and Chief Financial Officer

Exhibit 99.1

Aptevo Reports 87% Clinical Benefit and 81% Remission in 31 Evaluable Frontline AML Patients Through Cohort 5, Substantially Outperforming Benchmark; RAINIER on Track for 2026 Completion and Phase 2 Dose Selection

Program Enters Final Stage of Dose Optimization

Data Continue to Demonstrate Strong Clinical Activity and Favorable Safety Across an Expanding Frontline Dataset

SEATTLE, WA – May 6, 2026 – Aptevo Therapeutics Inc. (Nasdaq: APVO) today reported new clinical results from its RAINIER frontline acute myeloid leukemia (AML) trial. The Company is on track to complete the Phase 1b dose-optimization trial and select the recommended Phase 2 dose (RP2D) this year. As with the current study, the Phase 2 trial will dose mipletamig in combination with venetoclax and azacitidine.

Across 31 evaluable frontline AML patients treated to date (includes data through RAINIER Cohort 5, plus 4 patients from the previously completed dose expansion trial), mipletamig in combination with venetoclax and azacitidine has demonstrated an 87% clinical benefit rate (CR/CRi/PR) and an 81% remission rate (CR/CRi), with results continuing to reflect a consistent profile of clinical activity and favorable safety as the dataset expands.

With Cohort 5 complete, dosing has progressed through all previously evaluated mipletamig dose levels. The trial has now entered its final stage, which includes:

- Two final dose-level cohorts—Cohorts 6 and 7—representing the highest dose levels of mipletamig evaluated. Enrollment in Cohort 6 is nearing completion
- Two groups of six additional patients will be enrolled at select dose levels, with the first enrolling concurrently with Cohort 6

These activities will complete the dataset required for RP2D selection and the planned Phase 2 regulatory interaction, with the trial on track for completion this year.

“With the completion of Cohort 5, we have evaluated mipletamig across all previously studied dose levels and have entered the final stage of the RAINIER trial,” said Jeff Lamothe, President and Chief Executive Officer of Aptevo Therapeutics. *“The data is compelling, the remaining work is clearly defined, and the study is on track for completion this year, with the dataset enabling selection of the Phase 2 dose and our advancement into Phase 2. The strength and consistency of the data as it expands gives us confidence in the path forward.”*

Among the evaluable frontline patient population treated to date (N=31), including 27 patients from the RAINIER trial through Cohort 5 and 4 patients from the completed dose-expansion trial, mipletamig in combination with venetoclax and azacitidine has demonstrated:

- 87% clinical benefit rate,* demonstrating broad anti-leukemia activity and blast reduction across response categories

- 81% achieved CR or CRi (remission), comparing favorably to the historical benchmark**.
- 65% achieved CR (complete remission), comparing favorably to the historical benchmark**
- 52% of patients who achieved CR/CRi had blast reductions that reached the important measurable residual disease-negative level, a result that is typically associated with stronger, more durable responses
- 36% of patients with remissions had the TP53 genetic mutation, a high-risk biomarker typically associated with poor prognosis in AML and for which most treatment options frequently fail
- 6 patients treated to date have proceeded to allogeneic stem cell transplant, which represents the best possible outcome in AML treatment and is rarely achieved in the older or unfit frontline patient population
- No cytokine release syndrome reported

*Clinical benefit rate, including complete remission (**CR**), complete remission with incomplete hematologic recovery (**CRi**), and partial remission (**PR**)

**In the Phase 3 VIALE-A trial evaluating venetoclax plus azacitidine in frontline intent-to-treat AML patients who were ineligible for intensive induction chemotherapy, the reported composite CR/CRi rate was 66.4%, and the CR rate was 37% (DiNardo et al., New England Journal of Medicine, 2020).

Collectively, these data outperform the benchmark** and demonstrate mipletamig's potential to meaningfully enhance frontline AML treatment in older and/or unfit patients by improving efficacy outcomes without materially increasing toxicity.

"Our results demonstrate a consistent pattern of clinical activity and favorable safety across patients treated to date," said Dirk Huebner, M.D., Chief Medical Officer of Aptevo Therapeutics. *"As dose selection progresses, the focus is on identifying a Phase 2 dose that is supported by a complete and well-characterized dataset."*

About the RAINIER Trial

RAINIER, a frontline AML study, is a Phase 1b/2 dose-optimization, multi-center, multi-cohort, open-label study. Subjects are adults aged 18 or older, newly diagnosed with AML, who are not eligible for intensive induction chemotherapy. RAINIER will be conducted in two parts: first, a Phase 1b dose-optimization study in frontline AML patients, followed by a Phase 2 study. The Phase 1b trial consists of 28-day cycles of treatment across multiple sequential cohorts.

About Mipletamig

Aptevo's wholly owned lead proprietary drug candidate, mipletamig, being evaluated for the treatment of AML, is differentiated by design™ to redirect the immune system of the patient to destroy leukemic cells and leukemic stem cells expressing the target antigen CD123, which is a compelling target for AML due to its overexpression on leukemic stem cells and AML blasts. This antibody-like recombinant protein therapeutic is designed to engage both leukemic cells and T cells of the immune system and bring them closely together to trigger the destruction of leukemic cells.

Mipletamig is purposefully designed to reduce the likelihood and severity of CRS by use of the CRIS-7-derived CD3 binding pathway, an approach that differentiates Aptevo from competitors. Mipletamig has received orphan drug designation (“orphan status”) for AML under the Orphan Drug Act. Orphan drug designation provides key advantages—including the opportunity to seek U.S. market exclusivity for a specific period of time upon approval, FDA fee reductions, and access to development and tax credits. Mipletamig has been evaluated in more than 120 patients over three trials to date.

About Aptevo Therapeutics

Aptevo Therapeutics Inc. (Nasdaq: APVO) is a clinical-stage biotechnology company focused on developing novel bispecific and trispecific immunotherapies for the treatment of cancer. The Company has two clinical candidates and six preclinical candidates with different mechanisms of action designed to target a range of solid tumors. All pipeline candidates were created from two proprietary platforms, ADAPTIR and ADAPTIR-FLEX. Aptevo’s mission is to improve treatment outcomes and transform the lives of cancer patients. For more information, please visit www.aptevotherapeutics.com.

Safe Harbor Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact, including, without limitation, Aptevo’s expectations about the activity, efficacy, safety, tolerability, and durability of its therapeutic candidates and potential use of any such candidates, including in combination with other drugs, as therapeutics for treatment of disease; its expectations regarding the effectiveness of its ADAPTIR and ADAPTIR-FLEX platforms; statements related to the progress of Aptevo’s clinical programs, including statements related to anticipated clinical and regulatory milestones; whether further study of mipletamig in a Phase 1b dose optimization trial focusing on multiple doses of mipletamig in combination with venetoclax and azacitidine on a targeted patient population will continue to show clinical benefit; whether further study of mipletamig in a Phase 1b dose-optimization trial will continue to report a favorable safety profile, let alone no instances of cytokine release syndrome, whether Aptevo’s final trial results will vary from its earlier assessment; whether Aptevo’s strategy will translate into an improved overall survival in AML, especially among patient subgroups with poor prognosis; whether further study of ALG.APV-527 across multiple tumor types will continue to show clinical benefit; the possibility and timing of interim data readouts for ALG.APV-527; statements related to Aptevo’s ability to generate stockholder value; whether Aptevo will continue to have momentum in its business in the future; and any other statements containing the words “may,” “continue to,” “believes,” “knows,” “expects,” “optimism,” “potential,” “designed,” “promising,” “plans,” “will” and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based on Aptevo’s current intentions, beliefs, and expectations regarding future events. Aptevo cannot guarantee that any forward-looking statement will be accurate. Investors should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from Aptevo’s expectations. Investors are, therefore, cautioned not to place undue reliance on any forward-looking statement.

There are several important factors that could cause Aptevo's actual results to differ materially from those indicated by such forward-looking statements, including a deterioration in Aptevo's business or prospects; further assessment of preliminary or interim data or different results from later clinical trials; adverse events and unanticipated problems; adverse developments in clinical development, including unexpected safety issues observed during a clinical trial; and changes in regulatory, social, macroeconomic, and political conditions. For instance, actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including the uncertainties inherent in the results of preliminary or interim data and preclinical studies being predictive of the results of later-stage clinical trials; initiation, enrollment, and maintenance of patients; the completion of clinical trials; the availability and timing of data from ongoing clinical trials; the trial design includes combination therapies that may make it difficult to accurately ascertain the benefits of mipletamig; expectations for the timing and steps required in the regulatory review process; expectations for regulatory approvals; the impact of competitive products; our ability to enter into agreements with strategic partners or raise funds on acceptable terms or at all; and other matters that could affect the availability or commercial potential of Aptevo's product candidates, business, or economic disruptions due to catastrophes or other events, including natural disasters or public health crises; geopolitical risks, including the current war between Russia and Ukraine, the United States and Iran, and any other military event that could evolve out of any of the current conflicts; and macroeconomic conditions such as economic uncertainty, imposition of tariffs, rising inflation and interest rates, continued market volatility, and decreased consumer confidence. These risks are not exhaustive; Aptevo faces known and unknown risks. Additional risks and factors that may affect results are set forth in Aptevo's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the fiscal year ended December 31, 2025, and its subsequent reports on Form 10-Q and current reports on Form 8-K. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Aptevo's expectations in any forward-looking statement. Any forward-looking statement speaks only as of the date of this press release, and, except as required by law, Aptevo does not assume any obligation to update any forward-looking statement to reflect new information, events, or circumstances.

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