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): December 12, 2024

APTEVO THERAPEUTICS INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-37746**	**81-1567056**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
2401 4th Avenue Suite 1050 Seattle, Washington		**98121**
(Address of Principal Executive Offices)		**(Zip Code)**

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

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, $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 December 12, 2024, Aptevo Therapeutics Inc. ("Aptevo" or the "Company") issued a press release announcing 100% of patients achieved remission within 30 days, in Cohort 1 of the RAINIER frontline acute myeloid leukemia (AML) Phase 1b trial, including two patients who experienced complete remission with minimal residual disease negative status (100% elimination of cancer cells).

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

Exhibit No.	Description
99.1	Press Release dated December 12, 2024.
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: December 12, 2024

By: /s/ Marvin L. White
President and Chief Executive Officer

Exhibit 99.1

100% of Patients Achieve Remission within 30 Days in Cohort 1 of Bispecific Mipletamig Frontline AML Trial

Two of three patients achieved both complete remission and MRD-negative status

High response rates observed in earlier studies continue in ongoing mipletamig trial

Cohort 2 enrollment commencing

Seattle, Washington, December 12, 2024 - Aptevo Therapeutics ("Aptevo") (Nasdaq: APVO), a clinical-stage biotechnology company focused on developing novel bispecific immune-oncology therapeutics based on its proprietary ADAPTIR and ADAPTIR-FLEX platform technologies, today announced 100% of patients achieved remission* within 30 days, in Cohort 1 of the RAINIER frontline acute myeloid leukemia (AML) Phase 1b trial, including two patients who experienced complete remission with minimal residual disease (MRD)-negative status (100% elimination of cancer cells). The results build on data from the prior trial, in which 100% of frontline patients *also* achieved remission. *(Remission = complete remission (CR) and, complete remission with blood markers that have not yet recovered (CRi).

"*We are very excited by these Cohort 1 results as they add to an already compelling story that highlights mipletamig's potential to elevate the frontline AML treatment paradigm. We now have a 100% rate of remission in Cohort 1 of RAINIER. We saw a 100% rate of remission in frontline patients treated with the combination in our completed dose expansion trial. Remarkably, 86% of patients across both trials went into remission within 30 days of receiving their first treatment,"* said Marvin White, President and CEO of Aptevo. *"It's also important to note that mipletamig continues to demonstrate a favorable safety and tolerability profile, reinforcing its potential as a transformative addition to the standard of care combination. Cohort 2 enrollment is commencing, marking the next step in the study. We look forward to sharing new results as they become available*."

Mipletamig, a CD3 x CD123 bispecific antibody, is being investigated as frontline therapy in combination with venetoclax and azacitidine, a current standard of care for AML. These latest results further reinforce mipletamig's potential as a transformative treatment, supported by impressive efficacy, safety, and tolerability data from two prior clinical trials involving 90 patients.

"*Achieving remission in all three Cohort 1 patients is highly encouraging, particularly when viewed alongside prior trial results. Notably, two of these three patients achieved MRD-negative status, a critical outcome indicating that even the most sensitive diagnostic methods detect no remaining cancer cells. This result is strongly associated with longer-lasting remissions and improved survival rates,*" said Dirk Huebner, MD, Chief Medical Officer at Aptevo. "*What makes these outcomes even more compelling is that one of the MRD-negative patients had a TP53 mutation, a subgroup known for its poor prognosis due to chemotherapy resistance, genetic instability, and overall treatment challenges. This growing body of data*

underscores mipletamig's potential to address some of the most difficult hurdles in AML treatment, delivering deep and durable responses for patients with the greatest need."

About RAINIER

RAINIER, a frontline AML study, is a Phase 1b/2 dose optimization, multi-center, multi-cohort, open label study of up to 39 patients who are being treated across five dose levels ranging from 9 mcg – 140 mcg in combination with venetoclax and azacitidine (ven/aza). Subjects will be adults aged 18 or older, newly diagnosed with AML who are not eligible for intensive induction chemotherapy. Phase 1b consists of 28-day cycles of treatment in five sequential cohorts. Aptevo has partnered with Prometrika (https://www.prometrika.com/), a premier contract research organization for the trial. RAINIER will be conducted in two parts. First, a Phase 1b dose optimization study in frontline AML patients followed by a Phase 2 study.

About Mipletamig

Aptevo's wholly owned lead proprietary drug candidate, mipletamig, targeting AML, MDS and other leukemias, 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 a unique CD3 derived from CRIS-7 vs. the CD3 used by other competitors. Mipletamig has received orphan drug designation ("orphan status") for AML according to the Orphan Drug Act. Mipletamig has been evaluated in 90 patients over two trials to date. RAINIER, Aptevo's Phase 1b/2 frontline AML program, was initiated in 3Q24.

About Aptevo Therapeutics

Aptevo Therapeutics Inc. (Nasdaq: APVO) is a clinical-stage biotechnology company focused on developing novel bispecific immunotherapies for the treatment of cancer. The company has two clinical candidates. Mipletamig is currently being evaluated in RAINIER, a Phase 1b/2 trial for the treatment of frontline acute myeloid leukemia in combination with standard of care venetoclax + azacitidine. Mipletamig has orphan status for AML according to the Orphan Drug Act. ALG.APV-527, a bispecific conditional 4-1BB agonist that is only active upon simultaneous binding to 4-1BB and 5T4, is being co-developed with Alligator Bioscience and is being evaluated in a Phase 1 clinical trial for the treatment of multiple solid tumor types likely to express 5T4. Aptevo has three pre-clinical 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 . The Aptevo 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 + azacitidine on a targeted patient population will continue to show remissions, let alone at a

rate of 100%, whether Aptevo's final remission data or 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 future preliminary or interim data readouts for ALG.APV-527, statements related to the progress of and enthusiasm for Aptevo's clinical programs, 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, and 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 such as the coronavirus (referred to as COVID-19), geopolitical risks, including the current war between Russia and Ukraine, war between Israel and Hamas, and macroeconomic conditions such as economic uncertainty, 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, 2023, 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.

Aptevo Therapeutics
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