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 20, 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 November 20, 2024, Aptevo Therapeutics Inc. ("Aptevo" or the "Company") announced that the first patient dosed in Aptevo's ongoing RAINIER trial achieved a 90% reduction in leukemic blasts within the first 30 days of treatment, supporting the continued overall efficacy trend seen in prior mipletamig AML studies.

A copy of the press release is attached 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 November 20, 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: November 20, 2024

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

Exhibit 99.1

First Patient Dosed in Aptevo's Ongoing RAINIER Trial Achieves 90% Reduction in Leukemic Blasts within the First 30 Days of Treatment, Continues Overall Efficacy Trend Seen in Prior Mipletamig AML Studies

Potential to redefine frontline AML treatment being evaluated in clinic:
Mipletamig, CD3 x CD123 bispecific, in combination with standard of care, offers a multi-mechanism strategy for potential improved patient outcomes

Favorable early safety, efficacy, tolerability and durability of remission data informed Aptevo's ongoing RAINIER Phase 1b/2 trial

Seattle, Washington, November 20, 2024 - Aptevo Therapeutics ("Aptevo") (Nasdaq: APVO), a clinical-stage biotechnology company focused on developing novel immune-oncology therapeutics based on its proprietary ADAPTIR™ and ADAPTIR-FLEX™ platform technologies, today expanded on the potential of mipletamig, currently being evaluated as frontline therapy for the treatment of Acute Myeloid Leukemia (AML), in combination with standard of care venetoclax and azacitidine, noting the first patient dosed in the ongoing RAINIER trial achieved a 90% reduction in leukemic blasts within the first 30 days of treatment, continuing the overall efficacy trend seen in prior studies.

The Company's move to evaluate mipletamig as frontline combination therapy is informed by favorable data from earlier trials, which demonstrated strong safety, efficacy, and tolerability profiles, alongside evidence of durable remission. These early findings have fueled excitement around RAINIER among the group of investigators at premier cancer treatment institutions who have been working with the drug and members of the biotechnology industry who have been following its progress.

RAINIER seeks to further demonstrate the impact of mipletamig's unique, dual targeted mechanism of action by combining it with standard of care therapies venetoclax and azacitidine. The triplet combination targets AML from multiple angles and has the potential to improve patient outcomes, especially among the elderly who have few treatment options available.

"The FDA's decision to allow the RAINIER trial to proceed in a frontline setting allows us to explore mipletamig and the potential synergistic effect with standard of care in a well-defined patient population in need of improved therapy options. Safety data from our prior studies support our approach to conduct a study that is designed for a statistically defined quantitative efficacy analysis. RAINIER represents a clear development path that allows us to evaluate mipletamig in newly diagnosed patients and represents a pivotal opportunity to

make a difference right at the start of treatment, where outcomes can have the greatest impact," said Dirk Huebner, MD, Chief Medical Officer at Aptevo.

Dr. Huebner continued, "To date, mipletamig has demonstrated a strong safety profile with manageable incidence and severity of the most common therapeutic side effect, cytokine release syndrome (CRS), below levels seen with other treatment modalities of similar therapeutic mechanisms of action. Strong support for the development of a triplet combination that includes mipletamig is driven by efficacy data from prior mipletamig studies, showing compelling response and durability of remission compared to benchmarks from literature*." (*Aldoss 2019, Maiti 2021, Morsia 2020, Garciaz 2022, Feld 2021).

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 will be 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 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, 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. The Company 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, statements regarding advancement of Aptevo's therapeutic candidates in clinical trials, including the initiation of the Phase 1b/2 dose optimization trial to further evaluate mipletamig in combination with venetoclax and azacitidine , whether the Phase 1b/2 protocol will be successful, whether further study of mipletamig in Phase 1b/2 trial focusing on a targeted patient population will continue to show clinical benefit, whether Aptevo's strategy will translate into an improved overall survival rate in acute myeloid leukemia, statements related to the durability of mipletamig and whether its duration of remission results will be indicative of later stage clinical trials, whether the mipletamig data in combination therapy and monotherapy will be indicative of later stage clinical trials, statements related to mipletamig's mechanism of action and whether such mechanism of action will improve patient outcomes, the timing for its expected data readouts and whether this trial will establish a recommended Phase 2 dose, the potential use of any such candidate as therapeutics for treatment of disease, expectations about the safety, tolerability, efficacy and durability of its therapeutic candidate, statements regarding preclinical and clinical results and any suggestion that those results will be replicated in clinical development, the effectiveness of its ADAPTIR and ADAPTIR-FLEX platforms, and any other statements containing the words "may," "believes," "expects," "potential," "designed," "engineered," "innovative," "initiate," "allow," "promise," "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; adverse developments in the U.S. or global capital markets, credit markets or economies generally; 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 initiation, enrollment and maintenance of patients in clinical trials, uncertainties inherent in the results of preliminary or interim data and preclinical and clinical studies being predictive of the results of later-stage 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 the Company’s product candidates, business or economic disruptions due to catastrophes or other events, including natural disasters or public health crises such as the novel coronavirus (referred to as COVID-19), geopolitical risks, including the current war between Russia and Ukraine as well as the war between Israel and Hamas, and macroeconomic conditions such as rising inflation and interests rates, increased 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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