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 22, 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 22, 2024, Aptevo Therapeutics Inc. ("Aptevo" or the "Company") issued a press release highlighting the potential of the Company's robust portfolio in cancer immunotherapy, the success of bispecifics as a category, and their growing importance in the oncology treatment paradigm.

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 November 22, 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 22, 2024

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

Exhibit 99.1

Aptevo Highlights the Potential of the Company's Robust Portfolio in Cancer Immunotherapy, the Success of Bispecifics as a Category, and Their Growing Importance in the Oncology Treatment Paradigm

Developing innovative bispecific antibodies for monotherapy and combination with the potential to expand the frontiers of cancer treatment

SEATTLE, WA—November 22, 2024—Aptevo Therapeutics (NASDAQ: APVO), a leader in the development of novel bispecific antibodies for cancer treatment, provided additional details about its robust oncology pipeline which is poised to potentially address some of the most challenging and aggressive forms of cancer in both blood and solid tumors. As bispecific antibodies gain prominence for their revolutionary therapeutic potential and expanding market opportunities, Aptevo's differentiated platforms (ADAPTIR and ADAPTIR-FLEX) and promising clinical results across two clinical programs (mipletamig and ALG.APV-527), together with preclinical assets (APVO711, APVO603 and APVO442) are demonstrating how bispecifics rationally differentiated for safety and targeted efficacy may impact the future of cancer care. The company plans to add another targeted asset to the pipeline in the near-term and looks forward to providing more detail about the new compound at that time.

"Bispecifics are increasing in importance across the cancer therapeutic landscape and the market is expected to grow by as much as 44% through 2030*. Fueled by their ability to engage multiple targets, bispecifics provide a technology that utilizes various mechanisms of action with an enhanced safety profile. Aptevo's focused yet diversified pipeline aligns with these industry trends, offering a compelling investment opportunity that may address critical therapeutic gaps," said Marvin White, President and CEO of Aptevo. (*Grand View Research)

The Potential of the Pipeline

Aptevo's commitment to transforming cancer therapeutics is exemplified by its development pipeline, which features five bispecific antibodies, two clinical and three preclinical, targeting hematological malignancies and solid tumors. The company's focus on developing highly potent, safe, and versatile therapeutics positions it as a significant player in the expanding field of bispecific antibody based therapies.

Lead Candidate Mipletamig for Acute Myeloid Leukemia (AML): Mipletamig, Aptevo's lead bispecific antibody, is currently in a frontline Phase 1b/2 combination trial, RAINIER, following positive results from earlier studies. The Company announced an initial efficacy response earlier this week where the first patient dosed experienced a 90% reduction in leukemic blasts within 30 days of treatment initiation, continuing the efficacy trend seen in prior mipletamig clinical studies.

Mipletamig is designed to engage the immune system and directly target AML cells, offering new hope for a patient population with historically poor outcomes. Mipletamig's encouraging clinical performance underscores the potential to transform AML treatment standards, reinforcing Aptevo's innovative approach to tackling blood cancers.

Clinical Candidate: ALG.APV-527: ALG.APV-527 is being evaluated in a Phase 1 trial for solid tumors likely to express the tumor antigen 5T4. Tumor types treated to date include breast, colon, pancreatic and non-small cell lung cancer. Positive preliminary data from the study were presented at the European Society of Medical Oncology Congress in September and at the Society for Immunotherapy of Cancer conference earlier in November. These results showed that ALG.APV-527 demonstrated positive safety and tolerability across all cohorts, nine of 16 evaluable patients (56%) achieved stable disease (SD), and biomarker analysis confirmed immune activation in the tumor microenvironment.

This drug has the potential to advance treatment in hard-to-treat solid tumors, demonstrating the versatility of Aptevo's technology across a wide range of cancer types.

"As competitors face challenges in bispecific development, Aptevo continues to demonstrate resilience and success, particularly in safety—a crucial factor in the oncology space. With a focused strategic direction, proprietary technology, and a strong clinical foundation, Aptevo is well-positioned to lead the growing momentum in the bispecific antibody market," said Marvin White, President and CEO of Aptevo. "Our work is rooted in delivering groundbreaking therapies that harness the precision of bispecific antibodies to bring hope to patients facing some of the most devastating cancers. As we advance our pipeline, we remain steadfast in our commitment to innovation, collaboration, and, most importantly, improving patient outcomes."

Preclinical Potential

The Company's preclinical candidates represent diverse but complementary approaches to cancer treatment and were designed, like the clinical candidates, with safety, targeted efficacy and combinability in mind.

- **APVO711 (PD-L1 x CD40**): Dual immune mechanisms that act as an immune checkpoint blockade plus immune activator where CD40 only functions when both binding domains are engaged
- **APVO603 (4-1BB x OX40**): Broad solid tumor targeting that simultaneously engages two co-stimulatory molecules in the tumor and only functions when both binding domains are engaged
- **APVO442 (PSMA x CD3)**: Precision targeting of prostate cancer antigens with immune engagement driven by CD3 engagement on (cancer fighting) T cells which are intended to directly kill PSMA-expressing prostate tumor cells

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, 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 Aptevo's technology utilizing various mechanisms of action and whether such mechanisms of action will improve patient outcomes, statements related to the progress of Aptevo's clinical programs, including initial results from the Phase 1b/2 dose optimization trial to further evaluate mipletamig in combination with venetoclax and azacitidine , 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, whether the mipletamig data in combination therapy and monotherapy will be indicative of later stage clinical trials, whether further study of ALG.APV-527 across multiple tumor types will continue to show clinical benefit, whether biomarker analyses will continue to confirm biological activity of ALG.APV-527, the possibility and timing of future preliminary or interim data readouts for mipletamig and ALG.APV-527, whether Aptevo's final trial results will vary from its preliminary or interim assessments, statements related to the progress of and enthusiasm for Aptevo's preclinical and clinical programs, statement related to Aptevo's expectation to add another targeted preclinical asset to the pipeline, 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," "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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