

**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 23, 2021**

**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**

**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 (see General Instruction A.2. below):

- 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))

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).

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

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 23, 2021, Aptevo Therapeutics Inc. issued a press release providing a clinical update for its Phase 1b multi center, multi cohort expansion trial in the treatment of acute myeloid leukemia (“AML”), including one complete remission for a high-risk AML patient in cohort 1 receiving combination therapy. 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

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release dated November 23, 2021.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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.

APTEVO THERAPEUTICS INC.

Date: November 23, 2021

By: /s/ Marvin L. White

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Marvin L. White

President and Chief Executive Officer



## **Aptevo Therapeutics Reports First Complete Remission, Providing Clinical Update for its Phase 1b Multi Center, Multi Cohort Expansion Trial in the Treatment of Acute Myeloid Leukemia**

**SEATTLE, WA – November 23, 2021** – Aptevo Therapeutics Inc. (“Aptevo” or the “Company”) (NASDAQ: APVO), a clinical-stage biotechnology company focused on developing novel immuno-oncology therapeutics based on its proprietary ADAPTIR™ and ADAPTIR-FLEX™ platform technologies, today announced a clinical update for the Company’s Phase 1b Expansion trial evaluating APVO436 in the treatment of acute myeloid leukemia (AML). Preliminary data observed to date includes one complete remission.

A high-risk AML patient treated in Cohort 1 with a combination of chemotherapy plus APVO436 achieved a complete remission (CR) after one cycle of therapy. The chemotherapy regimen included the standard leukemia drugs Mitoxantrone, Etoposide, and Cytarabine. The patient tolerated treatment without evidence of overt toxicity.

The overarching goal of the Phase 1b expansion phase study is to determine if APVO436 treatments can improve the quality of remission in high-risk AML patients by reducing the residual chemotherapy-resistant measurable residual disease (MRD) burden. The quality of remission will be assessed using state-of-the art multiparameter flow cytometry methods for quantitative MRD assessment in a centralized laboratory.

MRD, previously known as minimal residual disease, in AML refers to leukemia cells that are present at very low numbers but can be detected using highly sensitive flow cytometric or genomic methods. A recent systematic review of the clinical significance of MRD in over 10,000 AML patients has demonstrated that achievement of MRD negativity is associated with superior leukemia-free survival and overall survival. Therefore, MRD status has emerged as an attractive and clinically meaningful end point that may allow for accelerated evaluation of novel therapies in AML (reference: Short et al., Association of Measurable Residual Disease with Survival Outcomes in Patients with Acute Myeloid Leukemia: A Systematic Review and Meta-analysis. JAMA Oncol. 2020 Dec 1;6(12):1890-1899. Click here to view the publication: <https://jamanetwork.com/journals/jamaoncology/fullarticle/2771199>).

Aptevo believes that APVO436 has the potential to help AML patients achieve complete remissions without MRD and thereby reduce their risk of leukemic relapses. Aptevo also believes that the use of APVO436 for targeting MRD in AML may be associated with a very low risk of cytokine release syndrome (CRS) as well as an increased likelihood of responses as both CRS as well as responses are inversely correlated with the leukemia burden of the patients. If successful, deepening the remission to an MRD-negative remission using this strategy could translate into an improved overall survival in AML.

The Company recently published information about the compound's favorable safety profile, characterized by a low incidence of CRS, and promising single agent activity of APVO436 in two back-to-back peer-reviewed publications in the prestigious oncology journal *Cancers* (Basel):

1. Uckun, F.M.; Lin, T.L.; Mims, A.; Patel, P.; Lee, C.; Shahidzadeh, A.; Shami, P.; Cull, E.; Cogle, C.R.; Watts, J. A Clinical Phase 1B Study of the CD3xCD123 Bispecific Antibody APVO436 in Patients with Relapsed/Refractory Acute Myeloid Leukemia or Myelodysplasia. *Cancers (Basel)* **2021**, *13*, Aug 15;13(16):4113. Click here to view the publication: <https://doi.org/10.3390/cancers>.

2. Uckun FM, Watts J, Mims AS, Patel P, Wang E, Shami PJ, Cull E, Lee C, Cogle CR, Lin TL. Risk, Characteristics and Biomarkers of Cytokine Release Syndrome in Patients with Relapsed/Refractory AML or MDS Treated with CD3xCD123 Bispecific Antibody APVO436. *Cancers (Basel)* **2021**; *13*(21):5287. Click here to view the publication: <https://doi.org/10.3390/cancers13215287>

#### **About APVO436**

Overexpression of CD123 is the hallmark of many forms of leukemia. Aptevo's lead proprietary drug candidate, APVO436 is a bispecific CD3xCD123 ADAPTIR that is designed to redirect the immune system of the patient to destroy leukemia cells expressing the target CD123 molecule on their surface. This antibody-like recombinant protein therapeutic is designed to engage both leukemia cells and T-cells of the immune system and bring them closely together to trigger the destruction of leukemia cells. APVO436 has been engineered using Aptevo's proprietary and enabling bioengineering methods and is designed to reduce the likelihood and severity of CRS. APVO436 has received orphan drug designation ("orphan status") for AML according to the Orphan Drug Act.

#### **About Aptevo Therapeutics**

Aptevo Therapeutics Inc. is a clinical-stage biotechnology company focused on developing novel immunotherapies for the treatment of cancer. Aptevo is seeking to improve treatment outcomes of cancer patients. For more information, please visit [www.aptevotherapeutics.com](http://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 and safety of its therapeutic candidates and potential use of any such candidates as therapeutics for treatment of disease, advancement of its clinical trials and its expectations regarding the effectiveness of its ADAPTIR and ADAPTIR-FLEX platforms, whether APVO436 treatments can improve the quality of remission in high-risk AML patients, whether APVO436 helps AML patients achieve complete remissions without MRD, whether the use of APVO436 for targeting MRD in AML will be associated with a very low risk of CRS as well as an increased likelihood of responses, whether Aptevo's strategy will translate into an improved overall survival in AML, and any other statements containing the words "may," "believes," "expects," "anticipates," "hopes," "intends," "optimism," "potential," "designed," "engineered," "breakthrough," "innovative," "innovation," "promising," "plans," "forecasts," "estimates," "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; 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, 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, and completion of clinical trials, 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 APVO436, expectations for the timing and steps required in the regulatory review process, including our ability to obtain regulatory clearance to commence clinical trials, expectations for regulatory approvals, the impact of competitive products, actions of activist stockholders, our ability to enter into agreements with strategic partners 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). 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, 2020, 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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