

**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): **June 9, 2022**

**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 June 9, 2022, Aptevo Therapeutics Inc. (the “Company”) issued a press release providing a clinical update on four additional patients enrolled in its ongoing APVO436 dose expansion Phase 1b trial for the treatment of acute myeloid leukemia (“AML”) and announcing 36% remission rate in cohort 1 among response-evaluable patients treated to date. The new data includes one patient who achieved a complete remission (CR), one patient who achieved a complete remission with incomplete hematologic recovery (CRi) and two patients who achieved bone marrow complete remissions, or morphological leukemia-free state (MLFS).

The Company also reported that a patient with high-risk myelodysplastic syndrome (MDS) enrolled in the dose escalation trial remains stable and continues treatment with APVO436 exceeding 18 months of treatment. 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 June 9, 2022.</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: June 9, 2022

By: /s/ Marvin L. White

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Marvin L. White

President and Chief Executive Officer



## **Aptevo Therapeutics Announces New Preliminary Remission Data on Four Additional Patients Enrolled in On-going APVO436 Dose Expansion Phase 1b Trial for the Treatment of Acute Myeloid Leukemia**

### **Cohort 1 Combination Therapy Arm Shows 36% Remission Rate Among Response-evaluable Patients Treated to Date**

#### **Cohort 3 Monotherapy Patient Achieved Bone Marrow Complete Remission**

#### **Company Also Reports Myelodysplastic Syndrome Patient Enrolled in Dose Escalation Trial Remains Stable and on APVO436 After 18 Months of Treatment**

**SEATTLE, WA – June 9, 2022** – 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 new remission data on four additional patients. The new data includes one patient who achieved a complete remission (CR), one patient who achieved a complete remission with incomplete hematologic recovery (CRi) and two patients who achieved bone marrow complete remissions, or morphological leukemia-free state (MLFS), in the Company’s on-going multi-cohort, multi-center Phase 1b expansion trial evaluating APVO436 for the treatment of acute myeloid leukemia (AML). The Company also provided an update on a myelodysplastic syndrome (MDS) patient from the dose escalation part of the trial.

Cohort 1 currently has the highest enrollment rate in the trial and preliminary data show that a total of four out of 11 response-evaluable patients (36%) reported on to date, have experienced remission while on therapy. Of the three new cohort 1 patients announced today, one is a CR, one is a CRi, and one is a bone marrow complete remission (MLFS). Cohort 1 is a combination arm of the trial that includes relapsed patients and those with primary refractory AML that failed to respond to frontline standard induction chemotherapy. Cohort 1 patients receive standard chemotherapy drug cytarabine or the standard chemotherapy triple drug combination MEC (mitoxantrone, etoposide, cytarabine) plus APVO436.

The fourth new patient reported on today participated in cohort 3, a monotherapy arm of the trial, and achieved a bone marrow complete remission (MLFS).

The table below summarizes the positive outcomes we have previously reported and those we are reporting today:

Summary of Reported Data (As of June 9, 2022)	Cohort 1	Cohort 3	Total
<b>Previously Reported</b>			
•Complete Remission (CR)	1		1
•Clinical Benefit Supporting Transplant		1	1
<b>Newly Reported – June 9, 2022</b>			
•Complete Remission (CR)	1		1
•Complete Remission with Incomplete Hematologic Response (CRi)	1		1
•Bone Marrow Complete Remission (MLFS)	1	1	2
<b>Total</b>	4	2	6

“We are enthusiastic about sharing this remission data for four new patients, including three cohort 1 participants who are receiving APVO436 in combination with standard of care, after experiencing relapsed/refractory disease, meaning they did not respond or stopped responding to prior therapy, narrowing their options for further treatment,” said Dirk Huebner, Chief Medical Officer at Aptevo Therapeutics. “The observed data are very encouraging and show a positive trend in the trial, potentially establishing a path for APVO436 in combination therapy.”

The Company also announced today that a patient with high-risk myelodysplastic syndrome (MDS) enrolled in the dose escalation trial remains stable and continues treatment with APVO436 now exceeding 18 months. Prior to joining the trial, this patient received and failed treatment with a hypomethylating agent, a situation that is commonly expected to be a poor prognostic event associated with short survival probability of approximately four to six months.

In this study, a “complete remission (CR)” is defined as a patient with no evidence of leukemia after treatment. This means the bone marrow contains < 5% leukemic blasts and hematologic (blood) recovery that includes normal white blood cell and platelet counts and other markers of healthy blood.

A “CRi” is defined as a complete remission except for residual thrombocytopenia or neutropenia. A “bone marrow complete remission (MLFS)” is defined as bone marrow blasts consistent with complete remission, <5%, but where peripheral blood recovery has not yet been observed.

#### **About Aptevo Therapeutics Inc.**

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).

## **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 cytokine release syndrome (CRS). APVO436 has received orphan drug designation ("orphan status") for AML according to the Orphan Drug Act.

## **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, its expectations regarding the effectiveness of its ADAPTIR and ADAPTIR-FLEX platforms, whether APVO436 treatments can improve the probability and quality of remission in AML or MDS patients, whether Aptevo's strategy will translate into an improved overall survival in AML or MDS, whether Aptevo's final remission data or trial results will vary from its preliminary assessment, statements relating to Aptevo's clinical programs, and any other statements containing the words "may," "continue to," "believes," "expects," "optimism," "potential," "designed," "engineered," "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 data 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 results of preliminary data and pre-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 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, our ability to enter into agreements with strategic partners 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), and geopolitical risks, including the current war between Russia and Ukraine. 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, 2021, 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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