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): July 18, 2023

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 July 18, 2023, Aptevo Therapeutics Inc. (the "Company") issued a press release announcing that its bispecific AML drug candidate APVO436, in combination with emerging standard of care venetoclax and azacitidine, achieved positive duration of remission results in its Phase 1b dose escalation trial. The Company also provided an update of its APVO436 Phase 2 program design that will include both frontline and relapsed/refractory trials beginning later in the second half of 2023. 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 July 18, 2023.
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: July 18, 2023

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

Aptevo Announces Positive Duration of Remission Data from Phase 1b Expansion Trial Evaluating the Bispecific APVO436 for AML

Phase 2 Trials in Relapsed/Refractory and Frontline Settings Planned, APVO436 to be administered in Combination with Emerging Standard of Care

New Data Adds to Growing Body of Clinical Evidence in Support of APVO436 Clinical Potential

SEATTLE, WA – July 18, 2023 – 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 that its bispecific AML drug candidate APVO436, in combination with emerging standard of care venetoclax and azacitidine, achieved positive duration of remission results in its Phase 1b dose escalation trial. The Company is also providing an update of its APVO436 Phase 2 program design that will include both frontline and relapsed/refractory trials beginning later in the second half of 2023.

Duration of Remission (DOR)
Positive and clinically meaningful DOR results was observed from the company's bispecific AML drug candidate APVO436 in combination with the emerging standard of care (venetoclax + azacitidine) in venetoclax treatment naïve patients, as follows:

- **High response rate observed** – 82% (9/11) of patients had a favorable response and were eligible for inclusion in the DOR analysis
- **Multiple patients moved to transplant -** 3/11 patients responded sufficiently to move to stem cell transplant – receiving stem cell transplant is the treatment option with the ***best probability for survival and highest benefit to patients***
- **Sustained complete response** – Of the patients with responses, one patient remained on study with sustained complete response for 8 cycles (the maximum allowed per protocol) which translated into at least 8 months of response duration
- **Median DOR not reached** – The median DOR was not reached, which is clinically meaningful because ***a substantial number of patients*** **either stayed on treatment or moved to transplant** and did not experience a relapse event

This DOR data adds to a growing body of clinical evidence (safety, tolerability, efficacy and now durability), that provides strong support for the further development of APVO436 in combination therapy for patients with AML.

Phase 2 Program Update
The Company's APVO436 Phase 2 program will further evaluate the triplet combination of APVO436 + venetoclax + azacitidine among frontline and relapsed/refractory AML patients who are venetoclax treatment naïve. The Company intends to conduct two trials. The first, among relapsed/refractory patients, will initiate in 2H23. The second, among frontline patients, will initiate in 1H24. Aptevo anticipates that approximately 100 patients will participate between the two trials and that interim results will be available in late 2H24.

APVO436 Dose Escalation Trial Results: Safety and Efficacy Data (previously reported)

- **Efficacy:** APVO436 demonstrated a 91% clinical benefit* in combination with venetoclax + azacitidine in venetoclax treatment naïve patients, more than doubling the response rate in a composite benchmark** across all benefit categories
- **Safety:** APVO436, when given in combination with this regimen, has been shown to be generally safe and well tolerated. Cytokine Release Syndrome (CRS), a common side effect in other trials, was observed in fewer than one quarter of patients within the patient population and in most cases was mild or moderate (grade 1 or 2) and was manageable in the clinic

For more information about previously reported data click **HERE.**

About Aptevo Therapeutics Inc.
Aptevo Therapeutics Inc. is a clinical-stage biotechnology company focused on developing novel immuno-oncology therapies for the treatment of cancer. Aptevo is seeking to improve treatment outcomes for cancer patients. For more information, please visit www.aptevotherapeutics.com.

About APVO436
APVO436 is a bispecific CD3xCD123 ADAPTIR drug candidate. The Company previously reported positive Phase 1b expansion trial results in AML and is planning to initiate Phase 2 trials in relapsed/refractory and frontline patients in 2H23 and 1H24 respectively. The Phase 2 trial will evaluate APVO436 in combination with venetoclax and azacitidine in patients with AML who are venetoclax treatment naïve.

Overexpression of CD123 is the hallmark of many forms of leukemia. Aptevo's lead proprietary drug candidate, APVO436 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.

* CR: Composite Clinical Remission (CR, CRi, MLFS), CR: Complete remission, CRi: Complete remission with incomplete hematologic recovery, MLFS: Bone marrow complete remission, SD; Stable disease, CBR: Clinical benefit rate (CR, CRi, MLFS, SD), Composite
**Benchmark Composite References: Aldoss 2019, Maiti 2021, Morsia 2020, Garciaz 2022, Feld 2021.

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 safety, tolerability, efficacy and durability of its therapeutic candidates as monotherapies or combination therapies 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, statements related to the durability of APVO436 and whether its duration of remission results will be indicative of later stage clinical trials, statements related to Phase 2 trial initiations for APVO436, including whether our Phase 2 protocols will be successful, whether further study of APVO436 in Phase 2 trials focusing on a targeted patient population will continue to show clinical benefit, whether Aptevo's strategy will translate into an improved overall survival in AML, whether Aptevo's final duration of remission data or trial results will vary from its preliminary assessment, statements relating to the progress of Aptevo's clinical programs, including statements related to the anticipated Phase 2 trial initiations among relapsed/refractory as well as frontline patients, the timing for their expected interim results and any other statements containing the words "may," "continue to," "believes," "expects," "potential," "designed," "engineered," "ongoing," "plans," "probability," "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, among others, a deterioration in Aptevo's business or prospects, further assessment of preliminary data or different results from later clinical trials, adverse events and unanticipated problems, adverse developments in clinical development, 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 data and pre-clinical 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 APVO436, expectations for the timing and steps required in the regulatory review process, including our ability to obtain regulatory clearance, 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, and macroeconomic conditions such as economic uncertainty, rising inflation and interest rates, conditions in the banking system and financial markets, including the failure of banks and financial institutions, 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, 2022, 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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