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): December 12, 2022

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** **(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 December 12, 2022, Aptevo Therapeutics Inc. ("Aptevo" or the "Company") announced that APVO436, in combination with venetoclax and azacytidine, achieved a 100% clinical benefit rate in venetoclax treatment naïve AML patients. The data, which was presented in a poster session at the 64th American Society of Hematology Annual Meeting and Exposition in New Orleans, also showed that APVO436, when given in combination with this standard-of-care regimen, was observed to be generally safe and well tolerated.

Aptevo plans to initiate a Phase 2 trial in the second half of 2023 to further evaluate APVO436 in combination with venetoclax and azacitidine among frontline and relapsed/refractory AML patients who are venetoclax treatment naïve.

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 December 12, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: December 12, 2022

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

EXHIBIT 99.1

100% Clinical Benefit Rate Achieved in Phase 1b Trial Evaluating APVO436 in Combination with Venetoclax and Azacitidine for Venetoclax Treatment Naïve Patients with Acute Myeloid Leukemia (AML)

Aptevo Therapeutics Plans a Phase 2 Trial in 2H23 in Frontline and Relapsed/Refractory Patients who are Venetoclax Treatment Naïve

Data Demonstrating APVO436 to be Safe and Well-Tolerated and Clinically Active Among AML Patients in Both Combination and Monotherapy Regimens Presented at the 64th American Society of Hematology (ASH) Annual Meeting and Exposition

SEATTLE, WA – December 12, 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 that APVO436, in combination with venetoclax and azacitidine, achieved a 100% clinical benefit rate (CBR) in venetoclax treatment naïve AML patients. The data, which was presented in a poster session at the 64th American Society of Hematology (ASH) Annual Meeting and Exposition in New Orleans, also showed that APVO436, when given in combination with this standard-of-care regimen, was observed to be generally safe and well tolerated.

Aptevo plans to initiate a Phase 2 trial in the second half of 2023 to further evaluate APVO436 in combination with venetoclax and azacitidine among frontline and relapsed/refractory AML patients who are venetoclax treatment naïve.

"The results of this APVO436 study are encouraging. More specifically, the combination of APVO436 with venetoclax and azacitidine (triple therapy) shows exciting potential, particularly in the venetoclax-naïve patient population," said Justin M. Watts, MD, Associate Professor of Medicine, Chief, Leukemia Section at the University of Miami Sylvester Comprehensive Cancer Center and lead author of the poster. "A larger Phase 2 trial of APVO436 in combination with venetoclax and azacitidine will be important to further explore its potential to improve outcomes in this AML patient population with high unmet need."

In the Phase 1b trial cohort 2, a total of 16 response-evaluable patients received the combination therapy of venetoclax and azacitidine with APVO436 and 75% experienced clinical benefit. 100% of patients in this cohort who had not received venetoclax previously, experienced clinical benefit; a favorable outcome with respect to a variety of response categories including CR, CRi and MLFS.

The combination of venetoclax and azacitidine with APVO436 in venetoclax treatment naïve response-evaluable patients in cohort 2 outperformed a composite benchmark across all clinical benefit categories as shown below.

	APVO436 % of Patients Achieving Clinical Benefit	**Benchmark*** % of Patients Achieving Clinical Benefit
Composite CR	**90%**	**33-57%**
CR/CRi	**80%**	**21-46%**
CR	**50%**	**13-26%**

***Benchmark Composite References:**
Aldoss 2019, Maiti 2021, Morsia 2020, Garciaz 2022, Feld 2021

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 CR: Composite Clinical Remission (CR, CRi, MLFS)

"Based on these positive outcomes we will prepare for a Phase 2 trial initiation in the second half of 2023, focused on evaluating frontline and relapsed/refractory AML patients who are venetoclax treatment naïve and who will be treated with the combination of APVO436 plus standard-of-care venetoclax and azacitidine, where the clinical benefit in a subset of cohort 2 patients in the current trial is 100%," said Dirk Huebner, MD, Chief Medical Officer of Aptevo Therapeutics. "The results we observed in this study inform and support advancing APVO436 in the clinic, while also validating our platform technology. The data also show clinical activity, safety and tolerability in both combination and monotherapy settings."

Additional Results

Aptevo's ongoing Phase 1b expansion trial in both combination and monotherapy, will enroll adult patients (aged ≥18 years) with AML, at different disease stages, into five different cohorts of up to approximately 18 patients each. Current results are being reported for combination cohorts 1 and 2, and monotherapy cohorts 3 and 5. Trial enrollment for cohort 3 is ongoing while enrollment for cohorts 1 and 2 has finished. Additional data and observations include the following:

- Clinical activity was observed in both monotherapy and combination cohorts
  - Monotherapy activity observed in cohort 3
  - APVO436 Safety: APVO436 has been observed to be generally well tolerated in both combination therapy and monotherapy
    - CRS was observed in fewer than one-quarter of patients within the safety population and in most cases was mild or moderate (grade 1 or 2) and was manageable in the clinic
    - Side effects were generally manageable and resolved while patients remained on treatment

"We are very excited about the data reporting out today because it shows that our lead candidate, APVO436, has the potential to impact the AML treatment paradigm in a meaningful way that could truly benefit patients. The data also provide additional evidence for safety and tolerability in both

combination therapy and monotherapy. Further, we observed a 100% clinical benefit in a patient population that supports advancement of APVO436 into Phase 2 evaluation," said Marvin L. White, President and CEO of Aptevo Therapeutics. "From a business perspective, this represents a win because first, we have positive data to report from the trial and second, we will use the data to inform the Phase 2 protocol and implement a trial with the highest probability of success."

To view the abstract, click here.

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.

About APVO436
APVO436 is a bispecific CD3xCD123 ADAPTIR currently in Phase 1b development in a multi-center, multi-cohort trial designed to evaluate safety, tolerability and efficacy in combination therapy and monotherapy for patients with AML. The Company plans to initiate a Phase 2 trial, evaluating APVO436 in combination with venetoclax and azacitidine in patients with AML who are venetoclax treatment naïve, in 2H23.

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 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, whether the APVO436 data presented at the ASH conference and Phase 1b expansion trial results will be indicative of later stage clinical trials, statements related to Phase 2 trial initiation for APVO436, including whether our Phase 2 protocol will be successful, whether further study of APVO436 in a Phase 2 trial focusing on a targeted patient population will continue to show clinical benefit, let alone at a rate of 100%, whether Aptevo's strategy will translate into an improved overall survival in AML, whether Aptevo's final remission data or trial results will vary from its preliminary assessment, statements relating to the progress of Aptevo's clinical programs, including data, enrollment and the continued dosing of patients in the Company's Phase 1b expansion trial 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, 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, 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 rising inflation and interest 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, 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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