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): May 27, 2021

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 (*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 7.01 Regulation FD Disclosure.

On May 27, 2021, Aptevo Therapeutics Inc. (the "Company") issued a press release announcing that the company has initiated the expansion phase of lead anti-leukemia drug candidate, APVO436, in adult patients with acute myeloid leukemia (AML) with a multi-center, multi-arm trial using the active recommended dose identified in the dose escalation phase of the study. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in this Item 7.01 (including Exhibit 99.1) is being furnished, not filed, pursuant to Regulation FD. Accordingly, the information in this Item 7.01 will not be incorporated by reference into any registration statement filed by the Company under the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated therein by reference. The furnishing of the information in this Item 7.01 is not intended to, and does not, constitute a determination or admission by the Company that this information is material or complete, or that investors should consider this information before making an investment decision with respect to any security of the Company.

Item 9.01 Financial Statements and Exhibits.

The Exhibit Index set forth below is incorporated by reference in response to this Item:

EXHIBIT INDEX

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated May 27, 2021.

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: May 27, 2021

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

APTEVO THERAPEUTICS ANNOUNCES EXPANSION PHASE OF LEAD ANTI-LEUKEMIA DRUG APVO436 IN ADULT PATIENTS WITH ACUTE MYELOID LEUKEMIA

Initiates Multi-Center, Multi-Arm Trial Using Active Dose Identified in the Dose Escalation Phase of the Trial

SEATTLE, WA /May 27, 2021 / Aptevo Therapeutics Inc. ("Aptevo") (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 the company has initiated the expansion phase of lead anti-leukemia drug candidate, APVO436, in adult patients with acute myeloid leukemia (AML) with a multi-center, multi-arm trial using the active recommended dose identified in the dose escalation phase (Part 1) of the study. During Part 1, APVO436 exhibited a manageable side effect profile, encouraging single agent activity and a promising benefit to risk profile in relapsed AML patients. The Company has plans to submit data from the dose escalation phase for publication later this year.

The dose expansion phase (Part 2), has been rationally designed to further evaluate the tolerability and clinical impact potential of APVO436 for indications of unmet and urgent medical need. During Part 2, the dose expansion phase of the study, a total of 90 AML patients will be enrolled into 5 cohorts of 18 patients each, as explained in the detailed and publicly available study information provided at CinicalTrials.gov (NCT03647800) The study will be conducted under an FDA-approved IND and has been Central IRB-approved. Patient enrollment is anticipated to commence in June. The goal of the expansion phase is to evaluate the safety and tolerability of APVO436 at the recommended Phase 2 dose level, when it is used as an adjunct to the standard of care and to obtain a preliminary assessment of the anti-leukemia activity of APVO436 containing experimental monotherapy and combination therapy modalities.

Protocol-specific training has started for the participating academic cancer centers in the US. Aptevo is planning to conduct Part 2 of the study at up to 20 clinical trial sites.

“The greatest challenge in AML is relapsed or refractory disease. For relapsed or refractory AML, there is no consensus on a single re-induction regimen” explained Dr. Fatih Uckun, leukemia expert and Chief Clinical Advisor. “By combining APVO436 with the standard of care, Aptevo hopes to develop an innovative approach that improves outcomes for patients with relapsed AML, who generally have a dismal prognosis,” he stated.

Dr. Uckun explained further: “In addition, newly diagnosed AML patients with inherent drug resistance who have documented residual leukemia after standard frontline chemotherapy regimens, have a very poor prognosis and are in urgent need of therapeutic innovations. Part 2 of the Aptevo study will therefore seek proof of concept in the use of APVO436 as part of frontline

multimodality regimens would enable the eradication of residual leukemia cells that have escaped standard chemotherapy. To this end we will carefully study the tolerability and clinical activity of APVO436 when used as rationally designed in each of the 5 cohorts of Part 2 of our Phase 1B study."

Overview of Cohorts

In Cohort 1, AML patients in relapse will be treated with the standard chemotherapy drug cytarabine or the standard chemotherapy triple drug combination MEC (mitoxantrone, etoposide, cytarabine) plus APVO436. Also treated in this cohort will be patients with primary refractory AML whose leukemia failed to respond to frontline standard induction chemotherapy.

In Cohort 2, AML patients in first relapse will receive a combination of APVO436 + venetoclax + azacitidine. Also included in this cohort will be newly diagnosed AML patients with a poor prognosis who will receive this novel combination as their frontline induction regimen.

In Cohort 3, AML patients with poor prognosis who are newly diagnosed will receive their frontline chemotherapy to induce a remission and APVO436 will be added if there is evidence of residual leukemia remaining. Also included in this cohort will be AML patients who experienced an early first relapse within 1 year of receiving their frontline chemotherapy. Such patients are generally known to have a dismal outcome.

In Cohort 4, AML patients in 1st remission who have evidence of residual leukemia, also known as minimal residual disease (MRD), will receive the standard drug oral azacytidine in combination with APVO436.

In Cohort 5, AML patients in 2nd remission who are MRD+ will be treated with APVO436 monotherapy.

"New treatments are urgently needed for frontline adverse risk and relapsed AML populations and I look forward to working with Dr. Uckun and other investigators for a step-wise evaluation of the clinical potential of APVO436", says Dr. Justin Watts, Associate Professor of Medicine at the University of Miami Sylvester Comprehensive Cancer Center.

"This week has been exciting for Aptevo, as we announced both positive results from the dose escalation part of our Phase 1 trial and the initiation of the expansion phase. We are particularly excited about the fact that APVO436 did not cause severe neutropenia in any of the AML patients treated so far. This is a potentially paradigm-shifting discovery as it provides the unique opportunity to integrate APVO436 into standard treatment regimens that inherently cause severe neutropenia," said Mr. Marvin White, President and CEO of Aptevo. "The initiation of Part 2 in our APVO436 study emphasizes our commitment to advance our ADAPTIR and ADAPTIR-FLEX platforms as integral parts of a novel standard of care for the most difficult-to-treat forms of cancer. We look forward to sharing interim data from Part 2 of the trial, later this year."

About Aptevo Therapeutics

Aptevo Therapeutics Inc. is a clinical-stage biotechnology company focused on developing novel immunotherapies for the treatment of cancer. The Company's lead clinical candidate, APVO436,

and preclinical candidates, ALG.APV-527 and APVO603, were developed based on the Company's versatile and robust ADAPTIR™ modular protein platform technology. APVO442 was developed based on the new ADAPTIR-FLEX™ platform technology. The ADAPTIR and ADAPTIR-FLEX platforms are capable of generating highly differentiated bispecific and multi-specific antibodies with potentially unique mechanisms of action for the treatment of different types of cancer. Aptevo is seeking to leverage its deep expertise in oncology drug development to improve treatment outcomes and survival of cancer patients with a special emphasis on difficult to treat forms of cancer. For more information, please visit 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 ADAPTIR that targets CD123 x CD3 and 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 a rapid and complete 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 an unintended and potentially harmful activation of the immune system. APVO436 has been engineered to stay in the blood circulation long enough to locate, bind with and destroy target leukemia cells. APVO436 has received orphan drug designation ("orphan status") for AML according to the Orphan Drug Act.

About Dr. Uckun

Dr Fatih Uckun MD, PhD, is an internationally renowned hematologist-oncologist and key opinion leader in leukemia research and treatment. Dr. Uckun is an elected Member of the American Society for Clinical Investigation (ASCI), an honor society for physician-scientists, and an active member of several professional organizations, including ASCO and AACR. He received numerous awards for his work in the field of leukemia, including the Stohlman Memorial Award of the Leukemia Lymphoma Society (previously known as the Leukemia Society of America), the highest honor given to a Leukemia Lymphoma Society Scholar. Dr. Uckun has more than thirty years of professional experience in developmental therapeutics with a special emphasis on targeted therapeutics/precision medicines and biopharmaceuticals. He has published more than 500 peer-reviewed papers, authored numerous review articles and book chapters.

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, 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 a number of 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 and enrollment of future clinical trials, availability and timing of data from ongoing clinical trials, expectations for the timing and steps required in the regulatory review process, 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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