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 26, 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 26, 2021, Aptevo Therapeutics Inc. (the "Company") issued a press release announcing results from the Company's Phase 1 dose escalation trial evaluating lead ADAPTIR candidate, APVO436, for the treatment of acute myeloid leukemia and myelodysplastic syndromes (AML/MDS). 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 26, 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 26, 2021

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

For Immediate Release

APTEVO THERAPEUTICS REPORTS POSITIVE PHASE 1 CLINICAL DATA FOR ITS LEAD LEUKEMIA DRUG CANDIDATE APVO436 IN ADULTS WITH RELAPSED ACUTE MYELOID LEUKEMIA

Dose Escalation Study of APVO436 Shows Favorable Safety Profile and No Severe Neutropenia, a Potentially Life-threatening Side Effect, Reported in a Significant Number of Patients Receiving CD123-Targeting Drugs

Dosing Level Established For Advanced Clinical Trials

SEATTLE, WA / May 26, 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 positive results from the Company's Phase 1 dose escalation trial evaluating lead ADAPTIR candidate, APVO436, for the treatment of acute myeloid leukemia and myelodysplastic syndromes (AML/MDS). APVO436 was generally well tolerated and demonstrated a favorable side effect profile, including the absence of severe or prolonged neutropenia, an often serious condition associated with CD123-targeting therapies. Further, APVO436 showed encouraging single agent activity and a promising benefit to risk profile in patients with relapsed, advanced stage AML.

The Phase 1 dose escalation study, conducted at leading cancer centers across the United States (US), as listed in www.clinicaltrials.gov as NCT03647800, enrolled 46 patients with AML or myelodysplastic syndromes, each of whom received escalated intravenous infusions of APVO436 ranging in dose from 0.3 micrograms to 60 micrograms. The long half-life of APVO436 enabled its administration over short infusion times. The study met its primary endpoint – identification of an active dose level for advanced studies. The Company plans to submit the data for publication later this year.

AML is the most common form of adult acute leukemia with >20,000 estimated new cases and >10,000 deaths in the United States (US) for 2021 (SEER Program, www.seer.cancer.gov).

The therapeutic landscape for leukemias is rapidly evolving in the era of personalized medicine but development of new drugs capable of killing chemotherapy resistant leukemia cells that can be used to improve the efficacy of standard of care induction and consolidation regimens remains an unmet medical need.

Unlike the potency of chemotherapy drugs, the clinical activity of bispecific antibodies in leukemia patients is often not "dose-linear," so a higher dose may potentially be less effective than a much lower dose. Likewise, the most effective concentrations are frequently not concentrations that are achieved at the highest tolerated dose levels. This is because these antibodies can be captured by normal cells, including T-cells that bind to the CD3 directed portion of the bispecific antibody. In order to avoid such a "sink effect", a dose level needs to be carefully identified at which the likelihood of excessive binding to normal

cells in blood and bone marrow is very low. That is to say, an optimal dose needs to be identified at which leukemia cells are selectively killed without causing severe neutropenia, a complication reported for CD123-targeting drugs that can lead to life-threatening infections and sepsis. Therefore, the contemporary strategy in clinical development of bispecific antibodies is to identify a biologically optimal dose level, ideally a dose level much lower than the maximum tolerated dose level. Importantly, the APTEVO study 5001 has met the primary endpoint of its Part 1, identifying Cohort 6 dose as an active dose level for advanced studies of APVO436, also known as the recommended Phase 2 dose (RP2D).

“We observed, as preliminary signs of clinical activity both stabilization of leukemia as well as complete remissions,” reported Dr. Fatih Uckun, leukemia expert and Chief Clinical Advisor, who is coordinating the APVO436 clinical development program. Of seven evaluable relapsed AML patients treated in Cohort 6, four showed stabilization of their leukemias. Of those four patients with disease stabilization, three patients lived 246^{+} days, 261^{+} days, and 281^{+} days, respectively and one progressed after a month. Two relapsed AML patients, who experienced stabilization of their leukemia, achieved a partial remission (PR) and subsequently a complete remission (CR). No partial or complete remissions have been observed at APVO436 dose levels either lower or higher than the Cohort 6 dose level. Therefore, APVO436 will be used at the Cohort 6 dose level in Part 2 of the study.

“We are very pleased to see lead ADAPTIR platform candidate, APVO436, progress in the clinic. APVO436 has demonstrated the potential to address a significant unmet need for patients with AML and provide the foundation for new and more effective multi-modality standard of care regimens that offer renewed hope for leukemia patients,” said Jane Gross, PhD, the Chief Scientific Officer for Aptevo.

One of the most significant and frequent side effects associated with the use of bispecific, T-cell engaging antibodies are neurologic toxicities. Neurological toxicities may be severe, life-threatening, or fatal. Serious neurologic toxicity has not been a frequent complication associated with APVO436 treatments in this study. Another potential complication associated with treatment using bispecific, T-cell engaging antibodies is a systemic inflammatory syndrome known as Cytokine Release Syndrome (CRS). CRS has occurred in some patients and has been managed using the generally recommended standard CRS treatments. In Cohort 6, of 9 AML/MDS patients evaluable for toxicity, 2 patients developed a Grade 1 CRS and one patient developed a transient Grade 3 CRS related to APVO436 which resolved with routine clinical management.

CD123, although highly expressed on AML blasts, is also expressed on normal bone marrow hematopoietic stem cells and myeloid progenitor cells that give rise to the infection-fighting white blood cells. Therefore, treatment platforms targeting CD123 have been associated with a prolonged and profound decrease of white blood cell counts, known as severe neutropenia, and infections, especially pneumonias. This side effect caused by CD123 targeting overlaps with the blood count lowering side effects of standard chemotherapy drugs is among the main hurdles impeding the desired incorporation of CD123 targeting drugs into contemporary frontline as well as second-line standard of care treatment regimens. Notably, Aptevo researchers discovered that APVO436 does not cause severe or prolonged neutropenia at doses that resulted in complete remissions. None of the 46 patients treated with APVO436 developed severe or prolonged neutropenia as a side effect of the drug.

“This finding will inform the clinical development path for APVO436, as a novel drug candidate for blood cancers,” stated Dr. Uckun. “AML patients are in urgent need of active new drugs capable of destroying

leukemia cells without causing profound neutropenia. We will diligently advance the clinical development of APVO436 and evaluate its potential clinical impact for leukemia patients." Dr. Uckun added.

"We are pleased to report progress in the clinical development of our ADAPTIR platform candidate, APVO436," said Marvin White, President and CEO of Aptevo. "We remain confident about the breakthrough potential of APVO436 and look forward to sharing interim data from Part 2 of our study later this year. The scientific data from multiple studies so far suggest tremendous therapeutic potential for the APVO436 ADAPTIR platform and provides the foundation for our optimism regarding the potential commercialization of APVO436."

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, and is an inventor on numerous patents.

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.

Contacts

Investors
Email: **IR@apvo.com**
Phone: 206-859-6629

Media
Paul Caminiti/Delia Cannan/Nicholas Leasure
Reevemark
Email: **aptevo@reevemark.com**
Phone: 212-433-4600
SOURCE: Aptevo Therapeutics