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): August 17, 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 8.01 Other Events.

On August 17, 2021, Aptevo Therapeutics Inc. issued a press release announcing the publication of a peer-reviewed research article reporting the results of a multi-institutional Phase 1 clinical study of Aptevo's lead leukemia drug candidate APVO436. 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 August 17, 2021.
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: August 17, 2021

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

Aptevo Therapeutics Announces APVO436 Monotherapy is Active in Patients Who Have Relapsed Acute Myeloid Leukemia or Myelodysplastic Syndrome

Phase 1 study showed some patients with relapsed acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS) achieved a remission with APVO436 after failing 1-8 lines of prior therapies

Data was published in the prestigious oncology journal Cancers

SEATTLE, WA / ACCESSWIRE / August 17, 2021 / 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 the publication of a peer-reviewed research article in the prestigious oncology journal **Cancers**. The research article reports the results of a multi-institutional Phase 1 clinical study of Aptevo's lead leukemia drug candidate APVO436 in 46 adult patients with relapsed or refractory AML or MDS.

"*AML and MDS are common forms of blood cancer in adults. Patients with AML or MDS who relapse following available standard of care treatments have a dismal prognosis and they are in urgent need for new treatment options,*" explained Dr. Fatih Uckun, a leukemia expert and Chief Clinical Advisor at Aptevo, who is the lead author of the new article. He added: "*This study was undertaken to evaluate if AML or MDS patients who have failed the available standard treatment options could tolerate and potentially benefit from a new form of therapy which activates patient's own immune system against AML cells. Specifically, APVO436 is a recombinant protein engineered to redirect host immune system to leukemic cells from patients with hematologic malignancies that express on their surface a protein known as the interleukin 3 receptor or CD123.*"

A total of 46 relapsed AML/MDS patients received APVO436 as weekly intravenous (IV) infusions at 10 different dose levels. APVO436 exhibited a favorable safety profile with acceptable tolerability and generally manageable drug-related adverse events (AEs), and its maximum tolerated dose (MTD) was not reached at a weekly dose of 60 mcg. The most common APVO436-related AEs were infusion-related reactions (IRR) occurring in 13 (28.3%) patients and cytokine release syndrome (CRS) occurring in 10 (21.7%) patients. The incidence of severe CRS was 8.7%.

Promising clinical activity was observed in 11 of 40 patients (27.5%) evaluable for efficacy: Eight of 34 (23.5%) evaluable relapsed AML patients showed favorable responses including prolonged stable disease (SD), >50% reduction of leukemic cell count in the bone marrow with

clearance of leukemic cells from the blood, partial remissions (PR), and complete remissions (CR). Seven of these 8 with favorable responses had failed 2-4 prior lines of anti-AML therapy and one 76 years old patient had relapsed after achieving a remission on frontline venetoclax plus decitabine therapy. Furthermore, 3 of 6 (50%) evaluable relapsed MDS patients had a marrow CR.

The median survival was >300 days for the 8 relapsed AML patients with a favorable response. By contrast, the median survival for the remaining 31 AML patients was 100 days. Five of the 8 AML patients with favorable responses remained alive at 110, 124, 323, 352, and 395 days, respectively.

A clinically active, so-called “recommended phase 2 dose (RP2D) level” was identified for further clinical development of APVO436. Of 9 patients treated at the RP2D level, 4 (44.4%) showed evidence of clinical activity: 2 AML patients achieved a CR, one MDS patient achieved a marrow CR, and the disease was stabilized in an AML patient with a time to progression of more than 7 months.

“*The safety profile and preliminary evidence of efficacy of APVO436 in relapsed AML and MDS patients warrant further investigation of its clinical potential.”* stated Dr. Uckun. “*We are excited about the potential clinical impact of our lead leukemia drug candidate, and we are hopeful that the continued development of APVO436 may provide the foundation for a potentially more effective combination therapy as a new standard of care regimen that is less likely to fail*.” added Marvin White, CEO of Aptevo.

The article "A Clinical Phase 1B Study of the CD3xCD123 Bispecific Antibody APVO436 in Patients with Relapsed/Refractory Acute Myeloid Leukemia or Myelodysplastic Syndrome” has been published in Cancers as part of the Special Issue “Acute Myeloid Leukemia (AML)” and is available online:
Abstract: https://www.mdpi.com/2072-6694/13/16/4113
PDF Version: https://www.mdpi.com/2072-6694/13/16/4113/pdf
Special Issue:
https://www.mdpi.com/journal/cancers/special_issues/Acute_Myeloid_Leukemia_AML

Citation Reference: Uckun, F.M.; Lin, T.L.; Mims, A.S.; Patel, P.; Lee, C.; Shahidzadeh, A.; Shami, P.J.; Cull, E.; Cogle, C.R.; Watts, J. A Clinical Phase 1B Study of the CD3xCD123 Bispecific Anti-body APVO436 in Patients with Relapsed/Refractory Acute Myeloid Leukemia or Myelodysplastic Syndrome. *Cancers* **2021**, 13, 4113. https://doi.org/10.3390/cancers 13164113

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 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 can generate 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**.

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 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; 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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