## 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): November 9, 2020

### APTEVO THERAPEUTICS INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware (State or Other Jurisdiction of Incorporation) 001-37746 (Commission File Number) 81-1567056 (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):

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o 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 7.01 Regulation FD Disclosure.

On November 9, 2020, Aptevo Therapeutics Inc. issued a press release announcing preliminary data in its ongoing APVO436 Phase 1 clinical trial. The full text of the press release is furnished herewith as Exhibit 99.1.

The information in this Current Report on Form 8-K is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

#### Item 9.01 Financial Statements and Exhibits

(d) Exhibit

#### Exhibit No. Description

99.1 <u>Press Release dated November 9, 2020</u>

#### **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.

Date: November 9, 2020

APTEVO THERAPEUTICS INC.

By: /s/ Marvin L. White

Marvin L. White

President and Chief Executive Officer



# APTEVO THERAPEUTICS ANNOUNCES SECOND COMPLETE REMISSION IN ONGOING APVO436 PHASE 1 CLINICAL TRIAL Second Complete Remission Observed in a Patient in Cohort 6 Enrollment in Cohort 8 Has Started

**Seattle, WA** – **November 9, 2020** – Aptevo Therapeutics Inc. ("Aptevo") (NASDAQ: APVO), a clinical-stage biotechnology company focused on developing novel immuno-oncology therapeutics based on its proprietary ADAPTIR™ platform, today provided an update on its ongoing APVO436 Phase 1 clinical trial.

APVO436 is a novel anti-CD123 x anti-CD3 targeted investigational bispecific antibody therapy being evaluated for the treatment of acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS), in a Phase 1/1b open-label, dose-escalation study evaluating the safety and pharmacokinetic profile.

On Friday, November 6, Aptevo received preliminary data regarding cohort 6, which indicated complete remission in a second patient, in addition to the one previously announced. In total, there are now two patients with clinical remission in cohort 6. The data received also showed one patient exhibiting stable disease status, and six patients where the disease had progressed. A total of nine patients were listed in cohort 6 of the clinical trial.

Details related to the second patient with complete remission are as follows:

- Patient bone marrow blasts were 33% at screen, exhibited a rise in blasts to 46% after the first cycle of treatment. Subsequently, the bone marrow blasts dropped to 8% after the second cycle, and to 4% after the fourth cycle of treatment.
- · The patient's platelet count and absolute neutrophil count (ANC) met complete remission criteria (CR).

"It is very encouraging that two complete remissions have been observed in Cohort 6, as we are now enrolling in cohort 8," said Marvin White, President and CEO of Aptevo Therapeutics. "We are now in a critical phase of the study, as pharmacokinetic modelling suggests that dosing in cohorts 5 through 8 is in a therapeutic range, which could result in potential clinical activity of the drug. We look forward to continuing the dose escalation and monitoring potential clinical responses as we advance through the upcoming dose cohorts," concluded Mr. White.

APVO436 was built on Aptevo's next generation proprietary ADAPTIR<sup>TM</sup> protein therapeutic platform. Focused on generating novel, targeted bispecific antibody-based immunotherapies for cancer the ADAPTIR<sup>TM</sup> platform offers key advantages over other bispecific formats, derived in part from the flexible and modular nature of the ADAPTIR<sup>TM</sup> structure.

Aptevo believes that its differentiated ADAPTIR<sup>TM</sup> bispecific technology platform has the potential to offer a more convenient and cost-effective solution compared to other immunotherapies such as CAR-T therapies. While CAR-T therapies have proven effective in generating robust and durable treatment responses, they remain challenging and expensive to manufacture and administer to patients. In contrast, bispecific technologies may represent a simpler, more competitive 'off-the-shelf' solution in the rapidly advancing field of cancer immunotherapy.

Aptevo will be presenting a poster at the 62<sup>nd</sup> Annual American Society of Hematology (ASH) this year, to be held virtually December 5-8, 2020.

The ASH conference has already posted an abstract on APVO436 titled: "Preliminary Results from a Phase 1 Study of APVO436, a Novel Anti-CD123 x Anti-CD3 Bispecific Molecule, in Relapsed/Refractory Acute Myeloid Leukemia and Myelodysplastic Syndrome" publicly available on the conference site, which provides details on the clinical trial: https://ash.confex.com/ash/2020/webprogram/Paper141619.html

Aptevo will continue to provide updates on its ongoing APVO436 Phase 1 Clinical Trial as and when appropriate.

Aptevo defines complete remission (CR), stable disease, and progressive disease in a manner consistent with the European LeukemiaNet (ELN) 2017 criteria, reference: Döhner H, Estey E, Grimwade D, et al. Diagnosis and management of AML in adults: 2017 ELN recommendations from an international expert panel. Blood. 2017; 129(4): 424-447.

#### **About Aptevo Therapeutics Inc.**

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 technology platform. The ADAPTIR™ platform is capable of generating highly differentiated bispecific antibodies with unique mechanisms of action for the treatment of different types 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. Any statements, other than statements of historical fact, including, without limitation, Aptevo's expectations about the advancement of its clinical trials and its expectations regarding the effectiveness of its ADAPTIR platform, and any other statements containing the words "believes," "expects," "anticipates," "intends," "plans," "forecasts," "estimates," "will" and similar expressions are 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. Any forward-looking statement speaks only as of the date of this press release, and, except as required by law, Aptevo does not undertake to update any forward-looking statement to reflect new information, events or circumstances.

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 research and development; 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, 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). Additional risks and factors that may affect results are set forth in Aptevo's filings with the Securities and Exchange Commission, including its most recent Annual Report on Form 10-K, as filed on March 25, 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.

#### **Contact Information:**

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