## **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 16, 2020

# **APTEVO THERAPEUTICS INC.**

(Exact Name of Registrant as Specified in its Charter)

81-1567056 (IRS Employer Identification No.)

2401 4th Avenue, Suite 1050 Seattle, Washington

Delaware

(State or Other Juris-diction of Incorporation)

98121

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):

П 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))

001-37746

(Commission File Number)

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 I

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. 🗵

(Address of Principal Executive Offices)

(Zip Code)

Registrant's telephone number, including area code: (206) 838-0500

#### Item. 7.01 Regulation FD Disclosure.

On November 16, 2020, Aptevo Therapeutics Inc. (the "Company") issued a press release announcing an update on ALG.APV-527, a novel immunotherapeutic bispecific candidate intended for the treatment of multiple solid tumors expressing 5T4, a tumor-restricted antigen. A copy of the press release is furnished herewith as Exhibit 99.1.

The information in this report, including the exhibit hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before, on or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

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### 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: November 16, 2020

By:

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



## APTEVO THERAPEUTICS and ALLIGATOR BIOSCIENCE ADVANCING THE BISPECIFIC 4-1BBx5T4 ANTIBODY ALG.APV-527 INTO PHASE 1 CLINICAL DEVELOPMENT

SEATTLE, WA – November 16, 2020 – Aptevo Therapeutics Inc. ("Aptevo") (NASDAQ:APVO), a biotechnology company focused on developing novel immuno-oncology therapeutics based on its proprietary ADAPTIR<sup>TM</sup> bispecific technology platform, and Alligator Bioscience ("Alligator") (Nasdaq Stockholm: ATORX), a biotechnology company developing antibody-based pharmaceuticals for tumor-directed immunotherapy, today provided an update on ALG.APV-527, a novel immunotherapeutic bispecific candidate intended for the treatment of multiple solid tumors expressing 5T4, a tumor-restricted antigen.

Aptevo and Alligator are advancing ALG.APV-527 into Phase 1 clinical development in a co-development 50/50 partnership. The companies anticipate filing a Clinical Trial Authorization during the first half of 2021 to initiate Phase 1 clinical development in multiple sites in the European Union. Aptevo and Alligator will continue to explore licensing opportunities as ALG.APV-527 moves into clinical development.

"We are very excited about taking ALG.APV-527 into the clinic now, as recent APVO436 complete remission data in two patients in cohort 6 of that Phase 1 clinical trial speaks to the potential of our ADAPTIR platform. As a potential first-in-class molecule, ALG.APV-527 showcases the versatility of our ADAPTIR platform in generating bispecific antibodies with unique mechanisms of action and a therapeutic profile that is more consistent with traditional antibodies, including an extended half-life, desirable antibody-like manufacturing characteristics and optimized for potency and stability," said Mr. Marvin White, President and CEO of Aptevo.

"Our collaboration with Alligator Bioscience continues to yield encouraging data supporting the potential advantages of this novel pathway for targeted immunotherapy of cancer. For these reasons, and given recent improvements in our financial position, we are excited to advance this asset into the clinic with the desire to enable potential additional value creation for shareholders as we develop the asset," concluded Mr. White.

"Aptevo's clinical candidate APVO436 is based on the same ADAPTIR platform as ALG.APV-527. It is my belief that the response data observed in the APVO436 Phase 1 trial validates the bispecific format of ALG.APV-527, and strengthens our view that it has the potential to become a successful cancer therapy," said Per Norlén, CEO of Alligator Bioscience.

ALG.APV-527 is designed to simultaneously target 5T4 and the co-stimulatory receptor 4-1BB (CD137) to promote potent, tumor-directed immune T-cell activation. 5T4 is a well-defined tumor antigen expressed on many different types of malignancies including, non-small cell lung, renal, pancreatic, prostate, breast,

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colorectal, gastric, ovarian and cervical cancers and mesothelioma. Conversely, 5T4 has limited expression on adult normal tissues, making it an attractive target for cancer immunotherapy.

#### Presentation at the SITC 35th Annual Meeting

As announced on Monday, November 9, Aptevo is presenting two new posters at the Society for Immunotherapy of Cancer's (SITC) 35th Virtual Annual Meeting, including one on ALG.APV-527. The poster will present preclinical data demonstrating that ALG.APV-527 has a potentially favorable safety profile with no indication of systemic immune activation or liver toxicity in NHP or murine models. ALG.APV-527 induces robust *in vitro* killing of tumors that is dependent on 5T4 engagement. *In vivo*, ALG.APV-527 augmented anti-tumor responses and promoted tumor-specific memory.

#### **Details of the Poster Presentation are as follows:**

#### ALG.APV-527: Potent tumor-directed T cell activation and in vivo tumor inhibition induced by a 4-1BB x 5T4 ADAPTIR bispecific antibody

The abstracts and the accompanying posters will be available in the Virtual Poster Hall to registered attendees from 8:00 am EST on Monday, November 9, until the Virtual Poster Hall closes on December 31, 2020 on the SITC abstract website

### About ALG.APV-527

ALG.APV-527 is a novel immunotherapeutic bispecific candidate intended for the treatment of multiple solid tumors expressing 5T4, a tumor-restricted antigen. 5T4 is an antigen that is highly expressed in a large percentage of solid tumors, including, non-small cell lung cancer (NSCLC), head and neck cancer and mesothelioma. ALG.APV-527 is designed to activate anti-tumor responses by inducing signaling through the co-stimulatory receptor 4-1BB (CD137), which is an immune receptor that is upregulated on activated T cells and natural killer (NK) cells.

#### 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<sup>TM</sup> modular protein technology platform. The ADAPTIR<sup>TM</sup> 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 <u>www.aptevotherapeutics.com</u>

#### About Alligator Bioscience

Alligator Bioscience AB is a clinical-stage biotechnology company developing tumor-directed immuno-oncology antibody drugs. Alligator's pipeline includes the two key assets ATOR-1017 and mitazalimab. Furthermore, there are two partnered assets: ALG.APV-527 in co-development with Aptevo Therapeutics Inc. and AC101 in clinical development by Shanghai Henlius Biotech Inc.). In addition, the company has developed a novel concept for more patient-specific immunotherapy: Neo-X-Prime. Alligator's shares are listed on Nasdaq Stockholm (ATORX). The Company is headquartered in Lund, Sweden. For more information, please visit <u>www.alligatorbioscience.com</u>.

#### For Further Information:

Aptevo Therapeutics Elif McDonald

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#### **Alligator Bioscience**

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The information was submitted for publication, through the agency of the contact person set out above, at 8:00 a.m. EST on November 16, 2020.

#### 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, statements regarding our expectations about the timing of the filing of a Clinical Trial Authorization for ALG.APV-527, our intention to continue to explore licensing opportunities for ALG.APV-527, our intention to advance ALG.APV-527 into Phase 1 clinic development 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

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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.