

**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): February 09, 2023

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:

- 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))

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 8.01 Other Events.

On February 13, 2023, Alligator Bioscience AB (“Alligator”) and Aptevo Therapeutics Inc. (“Aptevo”) issued a press release to announce the dosing of the first patient in the companies' Phase 1 trial evaluating ALG.APV-527 for the treatment of solid tumors expressing the tumor-associated antigen 5T4.

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.

Exhibit No.	Description
99.1	Press Release dated February 13, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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: February 13, 2023

By: /s/ Marvin L. White

Marvin L. White

President and Chief Executive Officer



Alligator Bioscience & Aptevo Therapeutics Announce Dosing of First Patient with ALG.APV-527 in Phase 1 Clinical Trial

Trial to Evaluate Safety, Tolerability and Clinical Activity in Solid Tumors Expressing 5T4

Lund, Sweden, and Seattle, Washington, February 13, 2023 - Alligator Bioscience AB ("Alligator") (Nasdaq Stockholm: ATORX) and Aptevo Therapeutics ("Aptevo") (Nasdaq: APVO) today announced the dosing of the first patient in the companies' Phase 1 trial evaluating ALG.APV-527 for the treatment of solid tumors expressing the tumor-associated antigen 5T4. ALG.APV-527 is a bispecific antibody with a tumor-directed 4-1BB agonistic effect and the ability to specifically stimulate antitumor-specific T cells and NK cells involved in tumor control.

*"We are very pleased to announce the initiation of a clinical trial to evaluate ALG.APV-527 in patients with solid tumors with high prevalence of 5T4. For Aptevo, the initiation of a second clinical program means we are now developing therapeutics to treat both solid tumors and hematological malignancies - a strategic win for our company," said **Marvin White, President, and CEO of Aptevo.** "ALG.APV-527 is a compelling candidate, as preclinical studies showed it has the potential to activate key immune cell populations within the tumor microenvironment while demonstrating a favorable safety profile. We look forward to sharing preliminary results, which we anticipate will be available in 2023."*

*"The start of this Phase 1 first in human study is an important milestone in the development of ALG.APV-527 and demonstrates the growing strength and effectiveness of our partnership with Aptevo," said **Søren Bregenholt, PhD, CEO of Alligator Bioscience.** "It also marks Alligator's third asset currently in clinical development and we are particularly excited to evaluate its tumor-directed 4-1BB function with its promise of a broad therapeutic window and, alike ATOR-1017, highly differentiated safety and efficacy profile compared to the first generation 4-1BB agonists."*

The ALG.APV-527 Phase 1 trial is a multi-center, multi-cohort, open-label trial that will include six cohorts in a 3+3 design. The trial will be conducted at up to 10 sites in the U.S. among adult patients with multiple solid tumor types/histologies likely to express the 5T4 antigen, including (but not limited to) non-small cell lung cancer (NSCLC), gastric/gastro-esophageal cancer and head and neck cancer. ALG.APV-527 will be given intravenously once every two weeks. The trial will assess the safety and tolerability, pharmacokinetic, pharmacodynamic and preliminary anti-tumor activity of ALG.APV-527.

About ALG.APV-527

ALG.APV-527 is a bispecific conditional 4-1BB agonist, only active upon simultaneous binding to 4-1BB and 5T4. This has the potential to be clinically important because 4-1BB has the ability to stimulate the immune cells (antitumor-specific T cells and NK cells) involved in tumor control, making 4-1BB a particularly compelling target for cancer immunotherapy. 5T4 is an oncofetal tumor associated antigen overexpressed on numerous solid tumors including non-small-cell lung carcinoma (NSCLC), breast, head and neck, cervical, renal, gastric, and colorectal cancer.

Preclinical studies, highlighting the differentiated design of the molecule that minimizes systemic immune activation, allowing for highly efficacious tumor-specific responses as demonstrated by potent activity in preclinical models, were recently published in the peer-reviewed publication, *Molecular Cancer Therapeutics*, a journal of the American Association for Cancer Research (AACR). The full article is available via this link: [ALG.APV-527 MCT 2022 manuscript](#).

About Alligator Bioscience

Alligator Bioscience AB is a clinical-stage biotechnology company developing tumor-directed immuno-oncology antibody drugs. Alligator's portfolio includes several promising drug candidates, with the CD40 agonist mitazalimab as its key asset. Furthermore, Alligator is co-developing ALG.APV-527 with Aptevo Therapeutics Inc., several undisclosed molecules based on its proprietary technology platform, Neo-X-Prime™, and novel drug candidates based on the RUBY™ bispecific platform with Orion Corporation. Out-licensed programs include AC101/HLX22, in Phase 2 development, by Shanghai Henlius Biotech Inc. and an undisclosed target to Biotheus Inc.

Alligator Bioscience's shares are listed on Nasdaq Stockholm (ATORX) and is headquartered in Lund, Sweden.

For more information, please visit alligatorbioscience.com.

About Aptevo Therapeutics

Aptevo Therapeutics Inc. is a clinical-stage biotechnology company focused on developing novel bispecific immunotherapies for the treatment of cancer. Aptevo is seeking to improve treatment outcomes and transform the lives of cancer patients. 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, statements regarding advancement of Aptevo's therapeutic candidate into clinical trials, including the entry of ALG.APV-527 for multiple indications, and the possibility of meaningful data readouts, the potential use of any such candidate as therapeutics for treatment of disease, expectations about the safety, clinical activity and efficacy of its therapeutic candidate, statements regarding preclinical results and any suggestion that those results will be replicated in clinical development, the effectiveness of its ADAPTIR and ADAPTIR-FLEX platforms, and any other statements containing the words "may," "believes," "expects," "potential," "designed," "engineered,"

“innovative,” “initiate,” “allow,” “promise,” “plans,” “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; adverse developments in the U.S. or global capital markets, credit markets or economies generally; and changes in regulatory, social, macroeconomic, 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, enrollment and maintenance of patients in clinical trials, preclinical studies being predictive of the results of early-stage 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 or raise funds on acceptable terms or at all 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), geopolitical risks, including the current war between Russia and Ukraine, and macroeconomic conditions such as rising inflation and interests rates, increased market volatility and decreased consumer confidence. 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, 2021, 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.

For further information, please contact:

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