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): September 19, 2022

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** **(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):

☐ 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 September 19, 2022, Alligator Bioscience AB ("Alligator") and Aptevo Therapeutics Inc. ("Aptevo") issued a press release to announce that the US Food and Drug Administration ("FDA") has issued a "may proceed" notification for the ALG.APV-527 IND, allowing the companies to initiate clinical trials evaluating the compound for the treatment of 5T4-expressing tumor antigens in multiple solid tumor types. The companies are moving rapidly to initiate a multi-center Phase 1 trial in the US.

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 September 19, 2022.
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: September 19, 2022

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

Alligator Bioscience and Aptevo Therapeutics Announce that FDA has Issued a "May Proceed" Notification for the ALG.APV-527 IND

Drug Candidate progressing to the clinic for evaluation in the treatment of 5T4-expressing tumor antigens in multiple solid tumor types

Lund, Sweden, and Seattle Washington, September 19, 2022 – Alligator Bioscience AB ("**Alligator**") and **Aptevo Therapeutics ("Aptevo")** today announced that the US Food and Drug Administration (FDA) has issued a "may proceed" notification for the ALG.APV-527 investigational new drug application (IND), allowing the companies to initiate clinical trials evaluating the compound for the treatment of 5T4-expressing tumor antigens in multiple solid tumor types. The companies are moving rapidly to initiate a multi-center Phase 1 trial in the US.

"We are very happy to see ALG.APV-527 make significant progress towards the clinic this year, an important milestone achievement for the Alligator and Aptevo teams. It's exciting to know that this compound will soon join APVO436, currently in a Phase 1b clinical trial for the treatment of AML, in clinical studies here in the US. I would like to thank our partners at Alligator for their close collaboration and expertise. Advancing ALG.APV-527 has been a true team effort and we value our partnership," said Marvin White, President, and CEO of Aptevo.
"ALG.APV-527 is specifically designed to trigger 4-1BB-mediated antitumor activity in 5T4-expressing tumor indications, meaning it has potential across a range of solid tumors with high unmet medical need. The addition of a new clinical candidate in active development serves as further validation of Aptevo's proprietary ADAPTIRÒ platform."

"This IND clearance marks an important step in the development of ALG.APV-527 and is a testament to the strength of our partnership with Aptevo. This new IND also demonstrates our ability to bring innovative antibodies to the clinic" said Søren Bregenholt, PhD, CEO of Alligator Bioscience. "This compound will now become Alligator's third asset in clinical development. We are looking forward to initiating this Phase 1 first in human study in multiple solid tumors and further investigating the indications where it is most effective."

ALG.APV-527 is an antibody with dual function: tumor-binding and 4-1BB immunomodulatory agonist effects. This has the potential to be clinically important because 4-1BB has the ability to stimulate the immune cells (antitumor-specific T cells) involved in tumor control, making immune cell stimulation through 4-1BB a particularly compelling target for cancer immunotherapy. Preclinical results, presented at the Society of Immunotherapy Cancer's 2021 Annual Meeting, highlighted the differentiated design of the molecule that minimizes systemic immune activation, allowing for highly efficacious tumor-specific responses as demonstrated by potent activity in *in vitro* models.

The tumor-binding function of ALG.APV-527 targets the 5T4 tumor-associated antigen. 5T4 is a protein expression in multiple solid tumor types and limited expression in normal tissues, making 5T4 a compelling target molecule for cancer therapy.

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 mitazalimab, a CD40 agonist, and ATOR-1017, a 4-1BB agonist. Furthermore, Alligator is co-developing ALG.APV-527 with Aptevo Therapeutics Inc., several undisclosed molecules based on its proprietary technology platform, Neo-X-Prime™, with MacroGenics Inc. and novel drug candidates based on the RUBY™ bispecific platform with Orion Corporation. Out licensed programs include AC101, in phase II 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 http://www.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, the potential use of any such candidate as therapeutics for treatment of disease, 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," "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, 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, 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, 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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