# 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 9, 2022

# **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):

□ 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))

Dere-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  $\Box$ 

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 9, 2022, Aptevo Therapeutics Inc. (the "Company") issued a press release announcing a \$10 million milestone payment earned related to 2021 sales of RUXIENCE under the terms of its royalty purchase agreement with HealthCare Royalty Management, LLC (HCR). The proceeds from the milestone payment will be used to pay down MidCap Financial term loan to \$5 million, further strengthening the Company's balance sheet. For the year ended December 31, 2021, the Company had a total of \$46.3 million of cash and cash equivalents.

The Company's multi-site, multi-cohort Phase 1b clinical trial evaluating APVO436 for the treatment of acute myeloid leukemia (AML) continues to progress. The patient who achieved complete remission in the Phase 1b Expansion trial in November remains in remission and is proceeding to transplant.

Additionally, the Company reported that MD Anderson Cancer Center joined the APVO436 trial as an additional clinical trial site. 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	<u>Press Release dated February 9, 2022.</u>
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.

Date: February 09, 2022

# APTEVO THERAPEUTICS INC.

By: /s/ Marvin L. White

Marvin L. White President and Chief Executive Officer



# Aptevo Therapeutics Earns \$10 Million Non-Dilutive Milestone Payment on Sales of RUXIENCE®, Provides Company Update

APVO436 Phase 1b Trial for Acute Myeloid Leukemia Adds New Site

# Complete Remission Patient to Advance to Transplant

SEATTLE, WA – February 9, 2022 – Aptevo Therapeutics Inc. ("Aptevo" or the "Company") (NASDAQ: APVO), a clinicalstage biotechnology company focused on developing novel immuno-oncology therapeutics based on its proprietary ADAPTIR<sup>TM</sup> and ADAPTIR-FLEX<sup>TM</sup> platform technologies, today announced that the Company has earned a \$10 million non-dilutive milestone payment related to 2021 sales of RUXIENCE. Additionally, based on RUXIENCE 2021 fourth quarter and full-year sales results, the Company is optimistic about the possibility of earning additional non-dilutive milestones totaling \$22.5 million over the next two years. The Company also announced that its Phase 1b trial evaluating lead drug candidate APVO436 for the treatment of acute myeloid leukemia (AML) continues to enroll new clinical trial sites and that the first complete remission patient, announced in 2021, is proceeding to transplant.

# **RUXIENCE Milestones**

Aptevo has earned a \$10 million milestone payment related to sales of RUXIENCE under the terms of its royalty purchase agreement with HealthCare Royalty Management, LLC (HCR). The milestone will be used to pay down MidCap Financial debt, reducing outstanding principal on the debt to \$5 million and strengthening the Company's balance sheet. This, in combination with \$46.3 million of cash-on-hand as of December 31, 2021, gives the Company cash runway through 1Q23, positioning Aptevo well to complete dosing in its ongoing APVO436 Phase 1b clinical trial and, in partnership with Alligator BioScience, to initiate a clinical trial for ALG.APV-527.

RUXIENCE, a Pfizer drug, is a biosimilar to RITUXAN®. Pfizer reported 2021 revenue of \$491 million from RUXIENCE, including \$148 million in 4Q21, exceeding the \$395 million threshold required for Aptevo to fully earn the 2021 \$10 million milestone. Annualizing the \$148 million Q4 revenue suggests 2022 full-year revenue could be approximately \$592 million. Aptevo will earn \$12.5 million of additional milestones in 2022 if revenue is at least \$525 million. Similarly, an additional \$10 million milestone can be earned in 2023 if revenue is at least \$570 million. Given the above, Aptevo is optimistic about fully earning these additional future non-dilutive milestones totaling \$22.5 million.

# **APVO436 Clinical Trial**

The Company's multi-site, multi-cohort Phase 1b clinical trial evaluating APVO436 for the treatment of acute myeloid leukemia (AML) continues to progress:

- MD Anderson Cancer Center joins numerous other sites already enrolling and Aptevo plans to add additional sites this year
- A patient with complete remission, announced in November 2021, is progressing to transplant
- Initial data is expected mid-year 2022

"We are very pleased to announce meaningful progress in our clinical work and to reinforce the strength of our financial position, especially during such a challenging time in the market. From our inception, Aptevo has remained committed to a focused business strategy designed to deliver results that will ultimately benefit patients," said Marvin White, CEO. "On the clinical side, we are pleased to expand the number of trial sites as this increases the pool of patients potentially eligible to participate in the study. Further, we are happy to report that the patient we reported on in November, who achieved complete remission in the expansion trial, remains in remission and is proceeding to transplant. We wish them well."

"Adding to Marvin's comments about a previously reported complete remission patient, it's encouraging that they are proceeding to transplant after receiving a combination of chemotherapy plus APVO436. Complete remission and transplant in patients who have failed prior frontline therapy such as this one, are indicators that the patient is making positive clinical progress in fighting this difficult-to-treat disease." said Dirk Huebner, MD, Senior Medical Advisor.

# **About Aptevo Therapeutics**

Aptevo Therapeutics Inc. is a clinical-stage biotechnology company focused on developing novel immunotherapies for the treatment of cancer. Aptevo is seeking to improve treatment outcomes of cancer patients. For more information, please visit <u>www.aptevotherapeutics.com</u>.

# **About RUXIENCE Milestones**

On March 30, 2021, the Company entered into and closed a royalty purchase agreement (the "Royalty Purchase Agreement") with an entity managed by HealthCare Royalty Management, LLC ("HCR") pursuant to which the Company sold to HCR the right to receive all royalty payments made by Pfizer Inc. ("Pfizer") in respect of net sales of RUXIENCE. Under the terms of the Royalty Purchase Agreement, the Company received \$35 million (the "Investment Amount") at closing and the Company is eligible to receive additional payments in aggregate of up to an additional \$32.5 million based on the achievement of sales milestones in 2021, 2022, and 2023 (collectively, the "Milestone Amounts"). The Royalty Purchase Agreement further provides that, once HCR reaches aggregate royalty payments totaling 190% of the Investment Amount plus the Milestone Amounts to the extent paid by HCR to the Company, Aptevo will be entitled to receive 50% of any additional royalty payments by Pfizer thereafter.

# About APVO436

Overexpression of CD123 is the hallmark of many forms of leukemia. Aptevo's lead proprietary drug candidate, APVO436, is a bispecific CD3xCD123 ADAPTIR that 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 the 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 CRS. APVO436 has received orphan drug designation ("orphan status") for AML according to the Orphan Drug Act.

# **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, its expectations regarding the effectiveness of its ADAPTIR and ADAPTIR-FLEX platforms, whether APVO436 treatments can improve the quality of remission in high-risk AML patients, whether APVO436 helps AML patients achieve complete remissions without transplant, whether Aptevo's strategy will translate into an improved overall survival in AML, whether Pfizer can continue to generate RUXIENCE revenue for Aptevo to fully earn 2022 and 2023 milestones, statements relating to Aptevo's cash position, 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.

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 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 results of pre-clinical studies being predictive of the results of later-stage clinical trials, the availability and timing of data from ongoing clinical trials, the trial design includes combination therapies that may make it difficult to accurately ascertain the benefits of APVO436, expectations for the timing and steps required in the 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 Aptevo'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.

# **Use of Estimates**

This press release contains estimates relating to Aptevo's cash position and such amounts are unaudited and preliminary estimates that (i) represent the most current information available to management as of the date of this release, (ii) are subject to completion of financial closing and auditing procedures that could result in significant changes to the estimated amounts and (iii) do not present all information necessary for an understanding of our financial condition as of, and our results of operations for the year ended, December 31, 2021. Accordingly, you should not place undue reliance on these preliminary estimates.

**Contacts** Aptevo Therapeutics Investors Miriam Weber Miller Aptevo Therapeutics Phone: +1 206-859-6629 Email: IR@apvo.com / Millerm@apvo.com

Media Jules Abraham JQA Partners Phone: +1 917-884-7378 Email: jabraham@jqapartners.com