# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
# Washington, D.C. 20549

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# FORM 8-K

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## 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 20, 2025**

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## APTOSE BIOSCIENCES INC.

(Exact name of registrant as specified in its charter)

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| **Canada** | **001-32001** | **98-1136802** |
|---|---|---|
| (State or Other Jurisdiction of Incorporation) | (Commission File Number) | (I.R.S. Employer Identification No.) |

**66 Wellington Street West, Suite 5300**
**TD Bank Tower, Box 48**
**Toronto, Ontario M5K 1E6**
**Canada**
(Address of Principal Executive Offices) (Zip Code)

**(310) 849-8060**
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

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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 Shares, no par value | APTO | The Nasdaq Stock Market |

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 February 20, 2025, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in the press release attached as Exhibit 99.1 hereto shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

| **Exhibit Number** | **Description** |
|---|---|
| 99.1 | Press Release dated February 20, 2025 |
| 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.

**Aptose Biosciences Inc.**

Date: February 20, 2025

By: /s/ William G. Rice, Ph.D.
William G. Rice, Ph.D.
President and Chief Executive Officer

**EXHIBIT 99.1**

# Aptose Announces Positive Clinical Safety Review Committee (CSRC) Approval to Dose Escalate in Phase 1/2 Tuscany Trial of Frontline Triple Drug Therapy with Tuspetinib Amid Complete Responses and Favorable Safety in First Cohort

- *TUS+VEN+AZA triplet achieves complete responses (CRs) in difficult-to-treat TP53-mutated/CK AML and FLT3-wildtype AML patients, including a measurable residual disease (MRD) negative remission*
- *Dosing of initial 40 mg cohort complete; no prolonged myelosuppression or dose-limiting toxicities*
- *No dose reductions to the standard-of-care components of the regimen (AZA/VEN) in first cohort*
- *CSRC endorses escalation to 80 mg dosing, enrollment is open*

SAN DIEGO and TORONTO, Feb. 20, 2025 (GLOBE NEWSWIRE) -- Aptose Biosciences Inc. ("Aptose" or the "Company") (NASDAQ: APTO, TSX: APS), a clinical-stage precision oncology company developing the tuspetinib (TUS)-based triple drug frontline therapy to treat patients with newly diagnosed AML, today announced that the Cohort Safety Review Committee (CSRC) monitoring Aptose's Phase 1/2 TUSCANY trial of tuspetinib in combination with standard of care dosing of venetoclax and azacitidine (TUS+VEN+AZA triplet) has unanimously approved escalating from 40 mg TUS to 80 mg TUS based on its favorable review of data from the first four patients in the trial. The TUS+VEN+AZA triplet is being developed as a frontline therapy to treat large, mutationally diverse populations of newly diagnosed AML patients who are ineligible to receive induction chemotherapy.

No significant safety concerns or dose limiting toxicities (DLTs) have been reported, including no prolonged myelosuppression of subjects in remission. All four subjects treated in the 40 mg cohort remain on study while enrollment is open for the 80 mg cohort.

"With a high level of enthusiasm, our CSRC - comprised of study investigators that include key leaders in the development of therapeutic agents for AML - recommended we escalate dosing in our TUSCANY trial with tuspetinib," said Rafael Bejar, M.D., Ph.D., Chief Medical Officer of Aptose. "The lack of prolonged myelosuppression with no DLT's and several complete responses, including an MRD-negative CRh noted early in treatment, is truly encouraging. As one our chief investigators remarked, if the TUS+VEN+AZA triplet shows efficacy and tolerability in difficult-to-treat AML populations with little myelosuppression, tuspetinib could be a game changer for frontline AML treatment."

**TUSCANY: TUS+VEN+AZA Triplet Phase 1/2 Study**

Tuspetinib based TUS+VEN+AZA triplet therapy is being advanced in the TUSCANY Phase 1/2 trial with the goal of creating an improved frontline therapy for newly diagnosed AML patients that is active across diverse AML populations, durable, and well tolerated. Earlier APTIVATE trials of TUS as a single agent and in combination as TUS+VEN demonstrated favorable safety and broad activity in diverse relapsed or refractory (R/R) AML populations that went beyond the more prognostically favorable NPM1 and IDH mutant subgroups. Responses to TUS were also observed in those with prior-VEN and prior-FLT3 inhibitor (FLT3i) therapies, those with highly adverse TP53 and RAS mutations, and those with mutated or unmutated (wildtype) FLT3 genes.

The TUSCANY triplet Phase 1/2 study is designed to test various doses and schedules of TUS in combination with standard dosing of AZA and VEN for patients with AML who are ineligible to receive induction chemotherapy. A convenient, once daily oral agent, TUS will be administered in 28-day cycles, beginning at 40 mg once daily, with dose escalations planned after a safety review of each dose level. Multiple U.S. sites are enrolling in the TUSCANY trial with anticipated enrollment of 18-24 patients by mid-late 2025. Data will be released as it becomes available.

In January 2025, Aptose announced the initiation of the TUSCANY trial and dosing in the first cohort of newly diagnosed AML patients with the lowest starting dose (40 mg) of TUS as part of the TUS+VEN+AZA triplet, and the early data reveal promising clinical safety and antileukemic activity:

- To date, four newly diagnosed AML patients have received the lowest dose of TUS (40 mg) as part of the (TUS+VEN+AZA) combination.
- Three patients with unmutated (wildtype) FLT3 (FLT3-WT) completed Cycle 1 of treatment with no dose-limiting toxicities (DLTs) and no TUS dose adjustments.
    - Two FLT3-WT patients achieved complete remissions (CR and CRh) by the end of Cycle 1.
    - Notably, a patient with biallelic TP53 mutations and a complex karyotype obtained CR.
    - The third FLT3-WT patient experienced significant reductions in bone marrow leukemic blasts during Cycle 1 and remains on therapy in Cycle 2.
- The fourth patient, harboring FLT3-ITD and NPM1 mutations, is currently dosing in Cycle 1 and is not yet eligible for response evaluation.
- Pharmacokinetic (PK) analyses for TUS show plasma levels unaffected by the addition of AZA, providing predictability and avoiding the need for dose alterations due to PK interactions.
- Similarly, VEN plasma levels in Cycle 1 are consistent with published results and the prior TUS/VEN APTIVATE study in R/R AML, indicating no clinically significant interactions with TUS.

More information on the TUSCANY Phase 1/2 study can be found on www.clinicaltrials.gov (here).

**About Aptose**

Aptose Biosciences is a clinical-stage biotechnology company committed to developing precision medicines addressing unmet medical needs in oncology, with an initial focus on hematology. The Company's lead clinical-stage, oral kinase inhibitor tuspetinib (TUS) has demonstrated activity as a monotherapy and in combination therapy in patients with relapsed or refractory acute myeloid leukemia (AML) and is being developed as a frontline triplet therapy in newly diagnosed AML. For more information, please visit www.aptose.com.

**Forward Looking Statements**

This press release may contain forward-looking statements within the meaning of Canadian and U.S. securities laws, including, but not limited to, statements relating to the therapeutic potential and safety profile of tuspetinib (including the triplet therapy) and its clinical development, the anticipated enrollment rate in the TUSCANY trial and the timing thereof, as well as statements relating to the Company's plans, objectives, expectations and intentions and other statements including words such as "continue", "expect", "intend", "will", "should", "would", "may", and other similar expressions. Such statements reflect our current views with respect to future events and are subject to risks and uncertainties and are necessarily based upon a number of estimates and assumptions that, while considered reasonable by us are inherently subject to significant business, economic, competitive, political and social uncertainties and contingencies. Many factors could cause our actual results, performance or achievements to be materially different from any future results, performance or achievements described in this press release. Such factors could include, among others: our ability to obtain the capital required for research and operations and to continue as a going concern; the inherent risks in early stage drug development including demonstrating efficacy; development time/cost and the regulatory approval process; the progress of our clinical trials; our ability to find and enter into agreements with potential partners; our ability to attract and retain key personnel; changing market conditions; inability of new manufacturers to produce acceptable batches of GMP in sufficient quantities; unexpected manufacturing defects; and other risks detailed from time-to-time in our ongoing quarterly filings, annual information forms, annual reports and annual filings with Canadian securities regulators and the United States Securities and Exchange Commission.

Should one or more of these risks or uncertainties materialize, or should the assumptions set out in the section entitled "Risk Factors" in our filings with Canadian securities regulators and the United States Securities and Exchange Commission underlying those forward-looking statements prove incorrect, actual results may vary materially from those described herein. These forward-looking statements are made as of the date of this press release and we do not intend, and do not assume any obligation, to update these forward-looking statements, except as required by law. We cannot assure you that such statements will prove to be accurate as actual results and future events could differ materially from those anticipated in such statements. Investors are cautioned that forward-looking statements are not guarantees of future performance and accordingly investors are cautioned not to put undue reliance on forward-looking statements due to the inherent uncertainty therein.

For further information, please contact:

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