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): June 12, 2025

APTOSE BIOSCIENCES INC.

(Exact name of registrant as specified in its charter)

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)

(647) 479-9828
(Registrant's telephone number, including area code)

(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
None	N/A	N/A

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 June 12, 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 June 12, 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: June 12, 2025

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

Aptose Presents Safety, Response, and MRD Clinical Data from TUSCANY Phase 1/2 Clinical Trial of Tuspetinib Triplet Therapy in Newly Diagnosed AML at the 2025 EHA Congress

- *Addition of TUS to standard of care VEN+AZA creates a well-tolerated and mutation agnostic frontline triple drug therapy for newly diagnosed AML*
- *AML patients with diverse mutations, including TP53-mutated/CK and FLT3-wildtype, safely achieved complete remissions and MRD negativity*
- *Ten AML patients dosed across 40 mg, 80 mg, and 120 mg TUS with TUS+VEN+AZA triplet*

SAN DIEGO and TORONTO, June 12, 2025 (GLOBE NEWSWIRE) -- Aptose Biosciences Inc. ("Aptose" or the "Company") (TSX: APS; OTC: APTOF), a clinical-stage precision oncology company, today announced data from its Phase 1/2 TUSCANY trial in newly diagnosed AML patients treated with tuspetinib (TUS) in combination with standard of care dosing venetoclax and azacitidine (TUS+VEN+AZA triplet) in an oral presentation at the European Hematology Association Congress (EHA 2025), being held June 12-15, 2025, in Milan, Italy.

The TUS+VEN+AZA triplet is being developed as a mutation agnostic frontline therapy to treat large, mutationally diverse populations of newly diagnosed AML patients who are ineligible to receive induction chemotherapy. Dr. Gabriel Mannis, Associate Professor of Medicine, Stanford University School of Medicine, and an investigator in the TUSCANY study, reported safety and efficacy data from the first two dose cohorts at 40 mg of TUS or 80 mg of TUS in the TUS+VEN+AZA triplet. Dr. Mannis also noted three patients were rapidly enrolled on the third dose cohort of 120 mg TUS in the TUS+VEN+AZA triplet, and that no DLTs have been observed to date.

The oral presentation at EHA included updated safety, complete remission, minimal residual disease (MRD) assessments, and longer duration of follow-up:
Title: TUSCANY Study of Safety and Efficacy of Tuspetinib Plus Standard of Care Venetoclax and Azacitidine in Study Participants with Newly Diagnosed AML Ineligible for Induction Chemotherapy
Presenter: Dr. Gabriel Mannis, Associate Professor of Medicine, Stanford University School of Medicine
Abstract #: S139

Key findings:

- To date, ten newly diagnosed AML patients have received the TUS+VEN+AZA combination:
  - Four received the 40 mg dose of TUS, three received the 80 mg dose of TUS, and three received the 120 mg dose of TUS
- At the initial dose of 40 mg TUS (n=4), with patients on longest duration of drug:
  - Three subjects achieved CRs and were MRD-negative, including
    - Patient with FLT3-ITD
    - Patient with FLT3-WT
    - Patient with TP53/CK
- At the 80 mg TUS dose level (n=3):
  - All three patients (100%) already achieved composite complete remissions (CR and CRi)
  - A TP53-mutated/CK AML patient achieved an early CRi
  - Too early in treatment for final MRD assessment
- At the 120 mg TUS dose level (n=3):
  - All three patients at the 120 mg TUS dose level remain on therapy
  - Too early in treatment for formal response and MRD assessments
- Regardless of mutation status, TUS is active in newly diagnosed AML patients
  - MRD-negative responses achieved across diverse genetic populations, including adverse*TP53* mutations and CK
  - Responses continue to evolve, and the triplet continues to be well tolerated with no DLTs
- TUS can be administered safely with standard-of-care dosing of VEN/AZA
  - TUS PK properties not altered by VEN, AZA, antifungals or food
  - No prolonged myelosuppression in Cycle 1 in the absence of AML
  - No treatment-related deaths; all 10 subjects treated to date remain alive
  - No treatment related QT_c prolongation, CPK elevations, differentiation syndrome or non-hematologic SAEs

"The TUSCANY triplet trial is well under way, and we are observing exciting activity with the addition of TUS to the VEN+AZA standard treatment," said William G. Rice, Ph.D., Chairman, President and Chief Executive Officer of Aptose. "The data presented today reveal complete responses across patients with diverse mutations, including TP53-mutated/CK AML and FLT3-wildtype AML patients. TUS appears to have tremendous opportunity in the largest markets and the most challenging of AML cases."

Abstracts are available on the EHA2025 website here. The presentation is available on the Aptose website here.

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

The tuspetinib-based TUS+VEN+AZA triplet therapy is being advanced in the TUSCANY Phase 1/2 clinical study 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. Indeed, responses were also in R/R AML patients with highly adverse TP53 and RAS mutations, and those with mutated or unmutated (wildtype) FLT3 genes.

The TUSCANY Phase 1/2 study, being conducted at 10 leading U.S. clinical sites by elite clinical investigators, 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, is being administered in 28-day cycles. 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.

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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