

**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): December 9, 2024

APTOSE BIOSCIENCES INC.

(Exact name of registrant as specified in its charter)

Canada
(State or Other Jurisdiction of Incorporation)

001-32001
(Commission File Number)

98-1136802
(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)

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 December 9, 2024, 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 December 9, 2024
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: December 9, 2024

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

Aptose Clinical Data Featured in Poster Presentation at the 2024 ASH Annual Meeting Support Tuspentinib Triple Drug Therapy for Newly Diagnosed AML

- TUS+VEN+AZA Triplet Frontline Therapy in Newly Diagnosed AML Patients Now Enrolling at U.S. Sites
- TUS and TUS+VEN Broadly Active Across AML Populations, with Favorable Safety
- TUS-based therapies are active in FLT3 wildtype, representing ~70% of AML patients
- TUS Targets VEN Resistance Mechanisms, Enabling TUS+VEN to Achieve Responses in Difficult-to-treat Prior-VEN Failure AML

SAN DIEGO and TORONTO, Dec. 09, 2024 (GLOBE NEWSWIRE) -- Aptose Biosciences Inc. (“Aptose” or the “Company”) (NASDAQ: APTO, TSX: APS), a clinical-stage precision oncology company developing highly differentiated targeted agents to treat hematologic malignancies, today featured a wealth of clinical data for Aptose’s lead compound tuspentinib (TUS) in a poster presentation at the 66th American Society of Hematology (ASH) Annual Meeting in San Diego.

Poster title: “Phase 1 Safety and Efficacy of Tuspentinib Plus Venetoclax Combination Therapy in Study Participants with Relapsed or Refractory Acute Myeloid Leukemia (AML) Support Exploration of Triplet Combination Therapy of Tuspentinib Plus Venetoclax and Azacitidine for Newly Diagnosed AML”

Key Findings and Messages:

- TUS+VEN+AZA triplet trial is proceeding in newly diagnosed AML patients
- TUS+VEN retains activity in the difficult-to-treat prior-VEN AML population
- TUS+VEN is active in FLT3 wildtype, representing ~70% of AML patients
- TUS+VEN is well tolerated and can be safely co-administered
- TUS+VEN is active across broad populations of R/R AML
- Combination of TUS with VEN may avoid VEN resistance
- TUS+VEN+AZA triplet may establish a more effective, mutation agnostic standard of care for chemotherapy ineligible AML patients

Tuspentinib (TUS), being developed by Aptose and originally created by Hanmi Pharmaceutical Co., is being advanced as the TUS+VEN+AZA triplet (tuspentinib+venetoclax+azacitidine) for frontline therapy of newly diagnosed AML patients ineligible for intensive chemotherapy. TUS is a once daily, oral, multi-kinase inhibitor selectively targeting kinases that drive AML cell proliferation. In the Phase 1/2 APTIVATE trial of relapsed/refractory (R/R) AML patients (NCT03850574), TUS single agent and the TUS+VEN doublet demonstrated excellent safety and broad efficacy across AML genetic subgroups – including those with adverse mutations in TP53 and RAS genes, and those with mutated or unmutated (wildtype) FLT3 genes.

“Our extensive dataset with TUS and TUS+VEN support advancement of the TUS+VEN+AZA triplet frontline therapy and we are pleased to now have the TUSCANY triplet clinical trial up and running,” said Rafael Bejar, MD, PhD, Chief Medical Officer at Aptose. “TUS targets known VEN resistance mechanisms, and in combination with VEN, could prevent emergence of resistance to both agents. Moreover, with its breadth of activity and unique safety profile, TUS, as part of a triplet therapy regimen, may target AML’s greatest unmet needs and largest markets.”

Highlights of the ASH poster presentation:

TUS as Single Agent (n= 93 Patients)

- 60% and 42% CR/CRh with 80 mg TUS in FLT3 mutated and all-comer VEN-naïve AML
- 33% CRc & 42% ORR (CR, CRp, CRh, CRi or PR) in FLT3 mutated and VEN-naïve patients
 - Includes 40, 80, 120, and 160 mg TUS dose as a single agent
 - Includes those who failed prior therapy with venetoclax
 - Includes those with mutated or unmutated FLT3, those who failed prior-HSCT, priorFLT3i, prior-chemotherapy, prior-HMA
 - TUS once daily orally as a single agent achieved CR/CRh responses at four different dose levels (40, 80, 120, and 160 mg) with no dose limiting toxicities (no DLTs)
 - TUS showed a favorable safety profile with no DLTs through 160 mg per day, and no drug related discontinuations, no QTc, no differentiation syndrome, and no deaths

TUS/VEN Combination Therapy (n= 79 Patients)

- 40% ORR with 80 mg TUS + 400 mg VEN in FLT3 mutated patients. Among these 83% (5/6) had failed prior-VEN treatment and 50% (3/6) had failed both prior-VEN and FLT3i treatment.
- TUS+VEN achieved responses among diverse R/R AML with adverse mutations in VEN-naïve, prior-VEN, FLT3WT, FLT3MUT, prior-FLT3
- TUS+VEN showed favorable safety and tolerability with no new or unexpected safety signals, no drug related CPK elevations, no differentiation syndrome, and no deaths

The ASH poster presentation is available on Aptose’s website [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 compound tuspetinib (TUS) is an oral kinase inhibitor that 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 of tuspetinib, its clinical development and safety profile and potential for accelerated approval, the value creating milestones planned for tuspetinib as part of a triplet study, including that TUS+VEN+AZA may establish a broader and safer standard of care and may target AML's greatest unmet needs and largest markets, 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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