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): November 20, 2024

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)

(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 November 20, 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 November 20, 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: November 20, 2024

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

EXHIBIT 99.1

Aptose Initiates TUSCANY Phase 1/2 Study for Newly Diagnosed AML Patients to Receive Tuspetinib-based Triplet Therapy

- *TUSCANY study is open to enroll patients to receive TUS+VEN+AZA triplet at select US sites*
- *Favorable safety and broad clinical activity make tuspetinib an ideal agent to combine with venetoclax and azacitidine to potentially address larger AML populations*
- *Study execution update is expected during ASH 2024*

SAN DIEGO and TORONTO, Nov. 20, 2024 (GLOBE NEWSWIRE) -- Aptose Biosciences Inc. (“Aptose” or the “Company”) (NASDAQ: APTO, TSX: APS), a clinical-stage precision oncology company developing highly differentiated oral targeted agents to treat hematologic malignancies, today announced initiation of the TUSCANY study, tuspetinib (TUS) in combination therapy with azacitidine (AZA) and venetoclax (VEN) as a frontline triplet combination therapy for patients newly diagnosed with acute myeloid leukemia, or AML. The trial is being conducted at multiple U.S. clinical sites.

Tuspetinib is being developed for frontline AML therapy as part of the TUS+VEN+AZA triplet for newly diagnosed AML patients ineligible to receive intensive chemotherapy. Tuspetinib, a convenient once daily oral agent that potently targets SYK, FLT3, mutated KIT, JAK1/2, and RSK2 kinases, avoids many typical toxicity concerns observed with other agents and has the potential to treat the larger AML populations, not just narrow subpopulations. In the recently conducted Phase 1/2 APTIVATE trial in a very ill and heavily pre-treated relapsed or refractory (R/R) AML population, tuspetinib as a single agent (TUS) and in combination with venetoclax (TUS+VEN) safely achieved broad activity across various difficult-to-treat AML subpopulations. This included patients with prior-VEN, prior-FLT3 inhibitor (FLT3i) and prior-hematopoietic stem cell transplantation (HSCT) therapies, those with highly adverse genetics - including mutations in TP53 and RAS genes, and those with mutated or unmutated (wildtype) FLT3 genes.

“Initiation of the trial is a key milestone for Aptose. AML treatment has rapidly shifted to combination therapies, and we are pleased to include tuspetinib as part of TUS+VEN+AZA triplet combination therapy in patients with newly-diagnosed AML – representing a new patient population for TUS,” said William G. Rice, Chairman, President and Chief Executive Officer. “We thank our investigators for their enthusiasm and our clinical team for activating the TUSCANY triplet study. As one of our investigators noted, if TUS brings added efficacy to frontline treatment of a broad array of AML patients without the added toxicities that are plaguing some other agents, we may have a game changer in TUS.”

TUSCANY: TUS+VEN+AZA Triplet Phase 1/2 Study
The triplet Phase 1/2 study is designed to test various doses and schedules of TUS in combination with standard of care dosing of azacitidine and venetoclax. TUS will be administered in 28-day cycles, beginning with 40mg, with dose escalations planned after safety review of each dose level. A planned 12 sites in the US will enroll in the TUSCANY trial with anticipated enrollment of 18-24 patients by mid-late 2025.

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 small molecule cancer therapeutics pipeline includes products designed to provide single agent efficacy and to enhance the efficacy of other anti-cancer therapies and regimens without overlapping toxicities. The Company has two clinical-stage oral kinase inhibitors under development for hematologic malignancies: tuspetinib (TUS), 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; and luxeptinib (CG-806), an oral, dual lymphoid and myeloid kinase inhibitor in Phase 1 a/b stage development for the treatment of patients with relapsed or refractory hematologic malignancies. 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 and its clinical development, expected study updates and milestones 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”, “potential”, 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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