

**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): May 4, 2022

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.)

251 Consumers Road, Suite 1105
Toronto, Ontario, Ontario Canada M2J 4R3
(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
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 May 4, 2022, 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.

[99.1](#) [Press Release dated May 4, 2022](#)

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: May 4, 2022

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

Aptose Receives Fast Track Designation for HM43239 in Relapsed/Refractory AML Patients and FLT3 Mutation

SAN DIEGO and TORONTO, May 04, 2022 (GLOBE NEWSWIRE) -- Aptose Biosciences Inc. ("Aptose" or the "Company") (NASDAQ: APTO, TSX: APS), a clinical-stage precision oncology company developing highly differentiated oral kinase inhibitors to treat hematologic malignancies, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to HM43239, an oral, myeloid kinase inhibitor, for the treatment of patients with relapsed or refractory (R/R) acute myeloid leukemia (AML) with FLT3 mutation. Currently, an international Phase 1/2 clinical trial is ongoing for HM43239 in the R/R AML patient population. HM43239 received orphan drug designation from the FDA for treatment of acute myeloid leukemia in 2018.

"Fast Track status acknowledges HM43239's potential to fill an unmet need for AML patient populations and supports our efforts as we advance it towards a potential registration study," said William G. Rice, Ph.D., Chairman, President and Chief Executive Officer. "HM43239, which potently inhibits all tested forms of FLT3 and the SYK and JAK driven pathways, already has delivered complete remissions in a broad diversity of relapsed or refractory AML patients in an ongoing Phase 1/2 clinical trial, including patients with prior failure of other FLT3 inhibitor agents. Fast Track designation will help facilitate the drug's development."

About Fast Track Designation

Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. Once a drug receives Fast Track designation, early and frequent communication between the FDA and the sponsor is encouraged throughout the entire drug development and review process. The frequency of communication assures that questions and issues are resolved quickly, often leading to earlier drug approval and access by patients. Visit the FDA website for more information.

About HM43239

HM43239 is a potent oral genotype-agnostic small molecule inhibitor of a constellation of kinases operative in myeloid malignancies and known to be involved in tumor proliferation, resistance to therapy, and differentiation. Currently being developed for the treatment of patients with acute myeloid leukemia (AML), HM43239 is a potent inhibitor of FLT3, SYK, mutant forms of cKIT, JAK1/2, and other kinases. Regarding FLT3, HM43239 is highly active *in vivo* against FLT3 internal tandem duplication (ITD), as well as resistance-conferring D835 and gatekeeper (F691) tyrosine kinase domain (TKD) mutations. *In vivo* murine xenograft models suggest superior antitumor activity and favorable tolerability relative to established kinase inhibitor in AML, including gilteritinib (FLT3 inhibitor) and entospletinib (SYK inhibitor). Additionally, *in vivo* xenograft models suggest synergy with inhibitors of DNMT, BCL-2, and other key therapeutic targets, highlighting the combinatorial optionality of HM43239 in AML. In an ongoing international Phase 1/2 clinical trial, HM43239 has delivered complete remissions in a diversity of relapsed or refractory AML patients and continues to be a well-tolerated oral agent.

About Aptose

Aptose Biosciences is a clinical-stage biotechnology company committed to developing personalized therapies 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 investigational products under development for hematologic malignancies: HM43239, an oral, myeloid kinase inhibitor in an international Phase 1/2 trial in patients with relapsed or refractory acute myeloid leukemia (AML); and luxetininib, an oral, dual lymphoid and myeloid kinase inhibitor in a Phase 1 a/b trial in patients with relapsed or refractory B-cell malignancies who have failed or are intolerant to standard therapies, and in a separate Phase 1 a/b trial in patients with relapsed or refractory AML or high risk myelodysplastic syndrome (MDS). For more information, please visit www.apdose.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of Canadian and U.S. securities laws, including, but not limited to, statements regarding the clinical potential and development of HM43239 and statements relating to the Company's growth, plans, objectives, expectations and intentions and other statements including words such as "continue", "expect", "intend", "will", "hope", "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; 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 and economic conditions; inability of new manufacturers to produce acceptable batches of GMP in sufficient quantities; unexpected manufacturing defects; the potential impact of the COVID-19 pandemic and other risks detailed from time-to-time in our ongoing current reports, 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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