
**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 29, 2020

Aptose Biosciences Inc.

(Exact Name of Registrant as Specified in Charter)

Canada

(State or Other Jurisdiction of Incorporation)

001-32001

(Commission File Number)

98-1136802

(I.R.S. Employer Identification Number)

251 Consumers Road, Suite 1105, Toronto, 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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company ☒ [X]

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. ☒ [X]

Item 7.01. Regulation FD Disclosure.

On June 29, 2020, 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.

[Exhibit 99.1. Press release dated June 29, 2020](#)

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 29, 2020

By: /s/ Gregory K. Chow
Gregory K. Chow
Senior Vice President and Chief Financial Officer

Aptose Announces FDA Allowance of IND for Phase 1a/b Study of CG-806 in Acute Myeloid Leukemia

Oral FLT3/BTK inhibitor CG-806 expands development beyond B-cell malignancies to the treatment of AML

Phase 1a/b study in B-cell malignancies continues through dose escalation

SAN DIEGO and TORONTO, June 29, 2020 (GLOBE NEWSWIRE) -- Aptose Biosciences Inc. (Nasdaq: APTO; TSX: APS), a clinical-stage company developing highly differentiated therapeutics that target the underlying mechanisms of cancer, today announced that the U.S. Food and Drug Administration (FDA) completed its review of the company's Investigational New Drug (IND) application and has granted IND allowance for the initiation of a Phase 1a/b clinical study of CG-806, the company's highly potent, oral FLT3/BTK inhibitor, in patients with acute myeloid leukemia (AML). CG-806 is currently in a Phase 1 dose escalation study in patients with B-cell malignancies, including chronic lymphocytic leukemia (CLL) and non-Hodgkin's lymphomas (NHL), who have failed or are intolerant to current therapies.

"Our strategy was to identify a starting dose of CG-806 that we believe could be therapeutically active in critically ill patients with relapsed or refractory AML. We are pleased that the FDA has allowed us to initiate a clinical trial in these patients at a starting dose of 450mg BID. Despite recent advances in the treatment of AML, many patients relapse or remain refractory to current therapies leading to a poor overall prognosis," said Rafael Bejar, M.D., Ph.D., Senior Vice President and Chief Medical Officer. "Based on strong preclinical evidence of CG-806's activity against AML – including demonstration of mutation-agnostic and genotype-agnostic potency, particularly compared against other FLT3 inhibitors, and its ability to safely cure AML in murine leukemia models – we believe CG-806 offers hope to the fragile and difficult-to-treat AML patient population. We continue to dose escalate in an ongoing study in patients with CLL and other B cell cancers, and are eager to advance this separate AML protocol through Institutional Review Boards at key clinical sites, recruit appropriate AML patients, and initiate dosing as soon as possible."

Aptose intends to initiate the Phase 1 a/b study in the second half of 2020 in AML patients who have relapsed, are resistant or refractory to current treatment.

About CG-806

CG-806 is an oral, first-in-class FLT3/BTK cluster selective kinase inhibitor and is in Phase 1 clinical studies for the treatment of hematologic malignancies. This small molecule demonstrates potent inhibition of wild type and all mutant forms of FLT3 (including internal tandem duplication, or ITD, and mutations of the receptor tyrosine kinase domain and gatekeeper region), cures animals of AML in the absence of toxicity in murine leukemia models, and represents a potential best-in-class therapeutic for patients with AML and other myeloid malignancies. Likewise, CG-806 demonstrates potent, non-covalent inhibition of the wild type and Cys481Ser (C481S) mutant forms of the BTK enzyme, as well as other oncogenic kinase pathways operative in B cell malignancies, suggesting CG-806 may be developed for various B cell malignancy patients (including CLL/SLL, FL, MCL, DLBCL and others) that are resistant/refractory/intolerant to covalent or other non-covalent BTK inhibitors. Because CG-806 targets key kinases/pathways operative in malignancies derived from the bone marrow, it is in development for B-cell cancers and AML.

About Aptose Biosciences

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 for hematologic malignancies: CG-806, an oral, first-in-class mutation-agnostic FLT3/BTK kinase inhibitor, is in a Phase 1 trial in patients with relapsed or refractory B cell malignancies, including chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL) and non-Hodgkin lymphoma (NHL), who have failed or are intolerant to standard therapies, and is expected to start a separate Phase 1 trial in patients with relapsed or refractory acute myeloid leukemia (AML); APTO-253, the only clinical stage agent that directly targets the MYC oncogene and suppresses its expression, is in a Phase 1b clinical trial for the treatment of patients with relapsed or refractory acute myeloid leukemia (AML) or high risk myelodysplastic syndrome (MDS). For further information, please visit www.apptose.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 development plans for CG-806, the clinical potential and favorable properties of CG-806, the CG-806 Phase 1 a/b B-cell malignancy clinical trial, the planned CG-806 Phase 1 AML clinical trial, and statements relating to the Company's 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; 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:

Aptose Biosciences Inc.

Greg Chow
Executive Vice President, CFO
650-718-5028
gchow@aptose.com

LifeSci Advisors, LLC

Dan Ferry, Managing Director
617-535-7746
Daniel@LifeSciAdvisors.com

SMP Communications

Susan Pietropaolo
201-923-2049
susan@smpcommunications.com