

**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): July 16, 2019

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))

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

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.

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	Nasdaq Capital Market

Item 8.01. Other Events.

On July 16, 2019, 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 July 16, 2019](#)

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: July 16, 2019

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

Aptose Doses First CLL Patient in Phase 1 Study of CG-806 and Doses Third Cohort in Phase 1 Study of APTO-253

– *CG-806 oral non-covalent pan-FLT3/pan-BTK inhibitor being developed for the treatment of CLL and other B-cell malignancies and for AML* –

– *APTO-253 MYC inhibitor being developed for the treatment of AML and MDS* –

SAN DIEGO and TORONTO, July 16, 2019 (GLOBE NEWSWIRE) -- Aptose Biosciences Inc. (NASDAQ: APTO, TSX: APS), a clinical-stage company developing highly differentiated therapeutics targeting the underlying mechanisms of cancer, today announced that dosing of CG-806, the company's highly potent, first-in-class pan-FLT3/pan-BTK inhibitor, has commenced its Phase 1a/b dose-escalation study in patients with chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL) or non-Hodgkin lymphomas (NHL) who have failed or are intolerant to standard therapies. In parallel, the company has successfully completed the first two dose levels of the Phase 1b clinical trial of MYC inhibitor APTO-253, and is now dosing the third dose cohort. Initial data from the first two cohorts demonstrate MYC inhibition in patients with acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS).

“We are pleased to announce that the much anticipated first-in-human dosing with CG-806 has occurred, and that we have successfully initiated oral dosing of CG-806 in a patient with CLL,” said William G. Rice, Ph.D., Chairman, President and Chief Executive Officer. “CG-806 is a highly potent non-covalent inhibitor of all forms of BTK and FLT3 driver kinases that simultaneously suppresses multiple oncogenic signaling pathways upon which cancer cells rely for survival, yet with a precision that avoids targets typically associated with toxicity. Separately,” continued Dr. Rice, “we completed dosing of the first two cohorts in a Phase 1b trial with our APTO-253 MYC inhibitor, with only one patient required in each cohort. Both patients completed the 28-day cycle and experienced reductions of MYC gene expression in their peripheral blood cells, an important finding as MYC plays a central role in the oncogenic process. In addition, the third dose cohort at 66mg/m² is enrolling efficiently for a total of three planned patients. We are hopeful that both CG-806 and APTO-253 will provide benefit to those patients with devastating hematologic malignancies who have failed standard therapies. We are eager to treat additional patients in the coming months and look forward to reporting results later this year.”

About the CG-806 Clinical Trial

The Phase 1a/b multicenter, open-label, dose-escalation clinical trial of CG-806 is designed to assess the safety, tolerability, pharmacokinetics and pharmacodynamic responses, and preliminary efficacy of CG-806, and establish the recommended Phase 2 dose. Aptose is conducting the Phase 1 trial with orally administered CG-806 in ascending doses to patients with relapsed or refractory B cell malignancies, including CLL/SLL and NHL, until the maximum tolerated dose or recommended dose that is most efficacious and safe is reached. Seven U.S. sites are currently open for screening and enrolling patients for the study. More clinical sites are planned to open for enrollment in the near future. More information is available at [www.clinicaltrials.gov_\(here\)](http://www.clinicaltrials.gov_(here)). Pending collection and careful review of the initial safety data and predictive pharmacokinetic data in humans from the Phase 1 dose escalation trial in patients with B-cell cancers, Aptose plans to seek allowance from the FDA to move into patient populations that include relapsed or refractory AML and MDS in a separate Phase 1 trial.

About CG-806

CG-806 is an oral, first-in-class pan-FLT3/pan-BTK multi-cluster kinase inhibitor and is in a Phase 1 clinical trial for the treatment of hematologic malignancies. This small molecule, in-licensed from CrystalGenomics Inc. in Seoul, South Korea, 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 xenograft models, and represents a potential best-in-class therapeutic for patients with AML and other hematologic 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 APTO-253 and the APTO-253 Clinical Trial

The Phase 1b, multicenter, open-label dose-escalation clinical trial of APTO-253 is designed to assess the safety, tolerability, pharmacokinetics and pharmacodynamic responses and establish the recommended Phase 2 dose and efficacy of APTO-253 as a single agent. APTO-253 is being administered once weekly, over a 28-day cycle. The study is expected to enroll up to 20 patients with relapsed or refractory acute myeloid leukemia (AML) and high-risk MDS patients. The study is designed to then transition, as appropriate, to single-agent expansion cohorts in AML and MDS, followed by combination studies. More information can be found at [www.clinicaltrials.gov_\(here\)](http://www.clinicaltrials.gov_(here)). APTO-253 is a small molecule, targeted therapeutic agent that inhibits expression of the MYC oncogene, leading to cell cycle arrest and programmed cell death (apoptosis) in human-derived solid tumor and hematologic cancer cells. The MYC oncogene is overexpressed in hematologic cancers, including AML. Aptose researchers have reported the ability of APTO-253 to induce cell death, or apoptosis, in multiple blood cancer cell lines including AML, as well as *in vitro* synergy with various classes of conventional approved and investigational therapies for AML or MDS, but without causing toxicity to the normal bone marrow functions.

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 for hematologic malignancies: CG-806, an oral, first-in-class pan-FLT3/pan-BTK multi-cluster kinase inhibitor, is in a Phase 1a/b 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; APTO-253, the only clinical stage agent that directly targets the MYC oncogene and inhibits 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.aptose.com.

About CrystalGenomics

CrystalGenomics, Inc. is a commercial stage biopharmaceutical company focused in the structure-based drug discovery and development of novel therapeutics in unmet medical need areas of inflammation, oncology, and infectious disease. In addition to several drug programs in the R&D pipeline, the Company has an osteoarthritis drug on the market and, has recently added commercial manufacturing capabilities through acquisitions. For more information, please visit: www.cgxinc.com or www.crystalgenomics.com. CrystalGenomics, Inc. is listed on KOSDAQ (083790).

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 plan, the clinical potential, and favorable properties of CG-806 and APTO-253, the CG-806 Phase 1 clinical trial, the APTO-253 Phase 1b clinical trial, and presentation of new data 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.

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