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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event Reported): March 25, 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 [ 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 ]

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**Item 8.01. Other Events.**

On March 25, 2019, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

[Exhibit 99.1. Press release dated March 25, 2019](#)

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**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: March 25, 2019

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

## **Aptose Announces FDA Allowance of Investigational New Drug Application for CG-806**

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

*– Phase 1 trial in relapsed or refractory CLL and B cell malignancies planned to initiate in Q2/2019 –*

SAN DIEGO and TORONTO, March 25, 2019 (GLOBE NEWSWIRE) -- Aptose Biosciences Inc. (“Aptose” or the “Company”) (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 their review of the Company’s Investigational New Drug (IND) submission for CG-806. Aptose has been granted IND allowance to initiate its Phase 1 clinical trial, which is a Phase 1, multicenter, open label, dose-escalation study with expansions to assess the safety, tolerability, PK, and preliminary efficacy of CG-806 in patients with chronic lymphocytic leukemia (CLL/SLL) or non-Hodgkin lymphomas (NHL).

Aptose will conduct a Phase 1 trial with orally administered CG-806 in patients with relapsed or refractory B cell malignancies, including CLL/SLL and NHL who have failed or are intolerant to standard therapies. The Phase 1 trial is expected to initiate in the 2<sup>nd</sup> quarter of 2019. Pending collection and careful review of the initial safety data and predictive pharmacokinetic data in humans from this trial, Aptose plans to seek allowance from the FDA to move into patient populations that include relapsed or refractory acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS) in a separate Phase 1 trial.

“We are pleased that the FDA has allowed Aptose to perform clinical trials with CG-806, our first-in-class pan-FLT3/pan-BTK inhibitor,” said William Rice, Ph.D., Chairman, President & CEO. “CG-806 has demonstrated a favorable safety profile and compelling durable tumor elimination in animal models of cancer, and we look forward to advancing it into human clinical testing.”

### **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 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 acute myeloid leukemia (AML) tumors in the absence of toxicity in murine xenograft models, and represents a potential best-in-class therapeutic for patients with AML. 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 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. APTO-253, the only known 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 MDS. CG-806 is an oral, first-in-class pan-FLT3/pan-BTK multi-cluster kinase inhibitor being developed to treat AML and certain B cell malignancies, is in a Phase 1 clinical trial for hematologic malignancies. For further information, please visit [www.apdose.com](http://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 our development plans and timelines of CG-806, potential regulatory actions, the clinical potential and favorable properties of CG-806, the clinical trials results for CG-806 and their expected timing, and 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; 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:

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