

March 10, 2020



# Aptose Reports Results for the Fourth Quarter and Full Year 2019

## Conference Call and Webcast at 5pm EDT Today

SAN DIEGO and TORONTO, March 10, 2020 (GLOBE NEWSWIRE) -- Aptose Biosciences Inc. ("Aptose" or the "Company") (NASDAQ: APTO, TSX: APS), a clinical-stage company developing highly differentiated agents that target the underlying mechanisms of cancer, today announced financial results for the year and three months ended December 31, 2019 and reported on corporate developments.

The net loss for the quarter ended December 31, 2019 was \$7.7 million (\$0.13 per share) compared with \$6.3 million (\$0.17 per share) for the quarter ended December 31, 2018. The net loss for the year ended December 31, 2019 was \$26.3 million (\$0.52 per share) compared with \$28.9 million (\$0.86 per share) for the year ended December 31, 2018. Total cash and cash equivalents and investments as of December 31, 2019 were \$97.6 million. Based on current operations, we expect that cash on hand and available capital provide the Company with sufficient resources to fund all planned Company operations including research and development into early 2022.

"2019 was a transformative year for Aptose as we became a true clinical-stage company, treating patients in two distinct clinical programs – with our first in class FLT3 / BTK inhibitor CG-806 and our MYC inhibitor APTO-253," said William G. Rice, Ph.D., Chairman, President and Chief Executive Officer. "We have been treating patients with ascending doses in each trial and have reported early clinical data that illustrate initial pharmacologic activity for both compounds, in addition to clean safety profiles to date.

"We expect 2020 to be a year of continued execution. We believe we are approaching a therapeutic dose with CG-806 in our current trial in B-cell cancers and plan to initiate a clinical trial for patients with AML who are resistant or refractory to current standard-of-care therapies. Indeed, we look forward to bringing a new treatment option to these patients, while bringing a long-term value proposition to Aptose shareholders."

## Key Corporate Highlights

- **CG-806 Phase 1 a/b B-cell Malignancy Clinical Trial**— During the year, Aptose initiated dosing of CG-806 in the Phase 1 a/b clinical trial: a multicenter, open-label, dose-escalation study in patients with relapsed or refractory B-cell malignancies (BCM), including chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL) or non-Hodgkin lymphomas (NHL). After dosing one patient each at the 150 mg BID and 300 mg BID dose levels, and after review from the Cohort Safety Review Committee (CSRC), the Company proceeded to the 3rd dose cohort of 450 mg BID which requires a minimum of three patients. The 450 mg BID dosing cohort is expected

to be completed imminently, and the resulting data will be reviewed by the CSRC.

Upon satisfactory review of the data, we plan screening and dosing patients for the 4<sup>th</sup> dose cohort of 600 mg BID followed by planned ascending dose cohorts with three patients each at 750 and 900 mg BID, with the intent to select the recommended phase 2 dose for patients with B-cell cancers, including relapsed or refractory CLL/SLI or NHL. Upon selection of a phase 2 dose, we plan to enroll up to 100 patients in an expansion phase of the trial. Currently, 18 U.S. sites are open for screening and enrolling patients for the study, with additional sites scheduled to come on board. More information is available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) ([here](#)).

- **CG-806 Proposed AML Study** — In 2019, preclinical data presented at a number of respected medical conferences supported Aptose's plans to develop CG-806 for patients with acute myeloid leukemia (AML). Tested against AML primary patient samples and cell lines, CG-806 was more potent than other FLT3 inhibitors including midostaurin, sorafenib, sunitinib, dovitinib, quizartinib, crenolanib and gilteritinib. Now in 2020, Aptose is well under way with the clinical protocol for an AML trial and, upon identification of a potential therapeutic dose for AML patients in the ongoing Phase 1 a/b trial in patients with CLL and NHL, we plan to seek allowance from the FDA to initiate clinical testing in patients with AML.
- **APTO-253 Phase 1b Clinical Study** — Throughout the year, Aptose successfully completed three dose cohorts in the Phase 1b trial of MYC inhibitor APTO-253 in patients with AML and myelodysplastic syndromes (MDS). We have completed dosing of one patient at the fourth dose cohort of 100 mg/m<sup>2</sup> and now are screening for the second and third patients for the 100 mg/kg dose cohort and expect to complete this dose cohort in Q2. No drug-related toxicities have been observed, including no myelosuppression, and dosing will continue to ascend until a maximum tolerated dose is reached. MYC biomarker data from patients at all dose levels thus far continue to demonstrate reductions of MYC gene expression in their peripheral blood cells. The dose escalation portion of the study is designed to 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](http://www.clinicaltrials.gov) ([here](#)).
- **2019 Financial Equity Offerings** — During 2019, Aptose closed two public offerings of common shares, raising gross proceeds of \$74.2 million in December and \$21.3 million in June. Aptose is using the net proceeds of the offerings to accelerate and expand its clinical trial programs, and for working capital and general corporate purposes.

## RESULTS OF OPERATIONS

A summary of the results of operations for the years ended December 31, 2019 and 2018 is presented below:

(in thousands except per common share data)	Year ended December 31,	
	2019	2018
Revenues	\$ —	\$ —
Research and development expenses	16,835	18,733
General and administrative expenses	10,022	10,374

Net finance income	580	239
Net loss	\$ (26,277 )	\$ (28,868 )
Unrealized gain on securities available-for-sale	18	—
Total comprehensive loss	\$ (26,259 )	\$ (28,868 )
Basic and diluted loss per common share	\$ (0.52 )	\$ (0.86 )

Net loss of \$26.3 million for the year ended December 31, 2019 decreased by approximately \$2.6 million as compared with \$28.9 million for the year ended December 31, 2018, primarily as a result of a decline in research and development expenses of \$5.0 million in license fees paid to CG for development and commercial rights of CG-806 in fiscal 2018 and a decrease in stock option compensation expense of approximately \$2.0 million, offset by increased expenditures of approximately \$3.7 million on our CG-806 and 253 development programs, reflecting program costs and related labor and higher cash-based general and administrative expenses of \$1 million in the year ended December 31, 2019. The net loss was also lower in 2019 due to higher net finance income, which increased by \$341 thousand compared to 2018, mostly as a result of higher interest earned on larger balances of cash equivalents and investments held during the year ended December 31, 2019.

### ***Research and Development Expenses***

The research and development expenses for the years ended December 31, 2019 and 2018 were as follows:

(in thousands)	Year ended December 31,	
	2019	2018
License fees – CG-806	\$ —	\$ 5,000
Program costs – CG-806	8,475	6,119
Program costs – APTO-253	4,177	4,490
Personnel expenses	3,679	2,063
Stock-based compensation	474	1,026
Depreciation of equipment	30	35
	<u>\$ 16,835</u>	<u>\$ 18,733</u>

Research and development expenses of \$16.8 million for the year ended December 31, 2019, decreased by approximately \$1.9 million compared with \$18.7 million for the prior year, primarily as a result of the following events:

- License fees paid in the year ended December 31, 2018 to CG of \$2.0 million for development and commercial rights of CG-806 in all territories outside of Korea and China, and a further \$3.0 million paid for development and commercial rights of CG-806 in China. CG is eligible for development, regulatory and commercial-based milestones, as well as royalties on future product sales. There were no license fees paid to CG or other collaborators in the year ended December 31, 2019.
- An increase in research and development activities related to our CG-806 development program of approximately \$2.4 million, mostly as a result of increases to our clinical trial operating costs for our CG-806 BCM phase 1a/b clinical trial and planned CG-806 AML phase 1 clinical trial. For the year ended December 31, 2019, program costs consisted mostly of manufacturing costs to supply our clinical trials,

operating costs to conduct our CG-806 BCM phase 1a/b clinical trial, which was approved by the FDA in March 2019, as well as preparation costs for our planned CG-806 AML clinical trial. For the year ended December 31, 2018, program costs consisted mostly of manufacturing costs to supply our clinical trials, for preclinical studies to support the IND application we filed in February of 2019 to test CG-806 in patients with BCM, and for consultant and CRO costs to prepare for the CG-806 BCM trial.

- A decrease in research and development activities related to our APTO-253 development program of approximately \$313 thousand related to lower manufacturing costs to supply the trial, and offset by an increase in costs associated with conducting the phase 1b clinical trial for APTO-253. For both the fiscal years ended December 31, 2018 and 2019, program costs consisted of costs for manufacturing APTO-253 to supply the trial, and for operating costs to conduct the ongoing phase 1b clinical trial. The APTO-253 clinical trial, which had been on a clinical hold since November 2015 was taken off clinical hold in June 2018.
- An increase in personnel expenses of \$1.6 million in the year ended December 31, 2019, as compared with prior year mostly related to additional clinical research staff to support two Phase 1 clinical trials. At December 31, 2019, we had 23 employees in research and development, including clinical operations as compared to 16 employees as at December 31, 2018.
- A decrease in stock option compensation of approximately \$552 in the year ended December 31, 2019, related mostly to higher forfeitures in the year ended December 31, 2019, as well as faster vesting of certain stock options granted in the period ended December 31, 2018. In the three-month period ended March 31, 2018, 100,000 stock options with a grant date fair value of \$2.03 vested immediately, contributing to higher expenses in that period.

### **General and Administrative Expenses**

The general and administrative expenses for the years ended December 31, 2019 and 2018 are as follows:

(in thousands)	Year ended December 31,	
	2019	2018
General and administrative, excluding items below:	\$ 8,078	\$ 7,071
Stock-based compensation	1,822	3,250
Depreciation of equipment	122	53
	<u>\$ 10,022</u>	<u>\$ 10,374</u>

General and administrative expenses of \$10.0 million for the year ended December 31, 2019, decreased by approximately \$352 thousand as compared with \$10.4 million for the prior year. Changes to the components of our general and administrative expenses presented in the table above are primarily as a result of the following:

- General and administrative expenses, other than stock-based compensation and depreciation of equipment increased by approximately \$1.0 million to \$8.1 million for

the year ended December 31, 2019, primarily as a result of higher compensation costs, increased travel, rent, consulting and office administrative costs associated with additional employees to support increased operations of the Company, and offset by lower professional and regulatory costs.

Stock-based compensation decreased for the year ended December 31, 2019, by approximately \$1.4 million compared with the year ended December 31, 2018, mostly related to faster vesting of certain stock options granted in 2018 when 850,000 of the approximately 1.7 million stock options granted had immediate vesting.

### **Conference Call and Webcast**

Aptose will host a conference call to discuss results for the year and quarter ended December 31, 2019 today, Tuesday, March 10, 2020 at 5:00 PM ET. Participants can access the conference call by dialing 1-844-882-7834 (North American toll free number) and 1-574-990-9707 (international/toll number) and using conference ID # 1097606. The conference call can be accessed [here](#) and will also be available through a link on the Investor Relations section of Aptose's website at <https://ir.aptose.com/>. An archived version of the webcast along with a transcript will be available on the Company's website for 30 days. An audio replay of the webcast will be available approximately two hours after the conclusion of the call for seven days by dialing 1-855-859-2056 (toll free number) and 1-404-537-3406 (international/toll number), using the conference ID # 1097606.

The press release, the financial statements and the management's discussion and analysis for the year and quarter ended December 31, 2019 will be available on SEDAR at [www.sedar.com](http://www.sedar.com) and EDGAR at [www.sec.gov/edgar.shtml](http://www.sec.gov/edgar.shtml).

### **Note**

The information contained in this news release is unaudited.

### **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 FLT3/BTK cluster-selective 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; 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](http://www.aptose.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 expected cash runway of the Company, the clinical development plans, the clinical potential and favorable properties of APTO-253 and CG-806, the APTO-253 Phase 1b clinical trial and 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.

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