

Aptose Reports Results for the First Quarter 2020

CG-806 Phase 1 a/b Study in B Cell Malignancies Now Dosing in Fourth Cohort

CG-806 Proposed Starting Dose for Upcoming Phase 1 Study in AML Identified

Conference Call and Webcast at 5pm EDT Today

SAN DIEGO and TORONTO, May 05, 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 and corporate update for the three months ended March 31, 2020.

The net loss for the quarter ended March 31, 2020 was \$11.5 million (\$0.15 per share) compared with \$5.5 million (\$0.14 per share) for the quarter ended March 31, 2019. Total cash and cash equivalents and investments as of March 31, 2020 were \$90.0 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 2022.

"I'm pleased to report that Aptose has made significant progress thus far in 2020. Despite external turmoil caused by the COVID-19 pandemic, we've continued to advance our two clinical programs, CG-806 and APTO-253, and continued dose escalation," said William G. Rice, Ph.D., Chairman, President and Chief Executive Officer. "Both drug candidates continue to demonstrate favorable safety profiles to date, and have generated proof of pharmacologic activity and early indications of clinical activity. CG-806 has, thus far, materialized as resilient to the COVID-19 disruptions because of its profile as a safe, orally administered agent directed at critically ill patients with hematologic malignancies and because of the sites chosen for our clinical studies. We look forward to reporting our progress on both clinical fronts at major hematology conferences throughout the remainder of the year."

Key Corporate Highlights

 Aptose COVID-19 Update — Because treatment of critically ill patients with hematologic cancers is not elective, Aptose's Phase 1 clinical trials for CG-806 and APTO-253 have continued to enroll and treat patients, despite recent events. The Company is continually adapting to COVID-19-driven disruptions at clinical sites, but thus far has experienced no material delays. Although headwinds may be felt in the coming days, Aptose has introduced adaptive and precautionary measures and safeguards such as virtual monitoring, for the safety of the patients and clinical teams as a top priority.

- CG-806 Phase 1 a/b B-cell Malignancy Clinical Study— During the quarter, Aptose successfully completed dose level three (450 mg dose cohort) of the CG-806 trial. The safety review monitoring committee then reviewed all data and unanimously agreed to advance to the 600 mg dose level. Currently, patient treatment is ongoing in this fourth dose cohort. To date, CG-806 continues to be well-tolerated, and initial indications of desired pharmacologic activity have been observed starting at the second dose level, including strong inhibition of several oncogenic driver kinases and a robust increase in peripheral blood lymphocytes or lymphocytosis classically ascribed as a response to the inhibition of BTK. Currently, 21 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.
- CG-806 Proposed AML Study CG-806 is the only BTK inhibitor that also possesses strong FLT3 inhibitory activity, giving it broad therapeutic potential across hematology in both lymphoid and myeloid malignancies. Based on safety, pharmacokinetic and pharmacodynamic data from patients in the ongoing Phase 1 a/b study in B cell malignancies, we now have identified what we believe may be a therapeutic starting dose for the treatment of AML patients, and are finalizing our efforts to submit the IND application to proceed into a parallel study in this new indication. In due course, this initiative will be designed to treat AML and MDS patients with CG-806 as a stand alone treatment and in combination with other agents.
- APTO-253 Phase 1b Clinical Study APTO-253 is the only known clinical-stage molecule that can directly target and inhibit expression of the MYC oncogene, shown to reprogram survival signaling pathways and contribute to drug resistance in many malignancies, including AML and B cell malignancies. In the ongoing Phase 1b trial, Aptose has observed MYC suppression at all dose levels to date, and plans to continue dose escalation to higher dose levels that may deliver responses for AML and MDS patients and will inform decisions on how to move forward with development of the molecule. Other therapies directed at MYC suppression are limited by severe toxicities, drug resistance and myelosuppression of the healthy bone marrow, which has not been observed in extensive preclinical testing of APTO-253 and is being borne out in clinical testing to date. More information is available at www.clinicaltrials.gov.

A summary of the results of operations for the three-month periods ended March 31, 2020 and 2019 is presented below:

	Three months ended March 31,				
(in thousands)	2020		2019		
Revenues	\$	_	\$	_	
Research and development expenses		5,934		3,340	
General and administrative expenses		5,900		2,260	
Total other income		308		94	
Net loss		(11,526)	<u> </u>	(5,506)	
Other comprehensive gain/(loss)		-		9	
Total comprehensive loss		(11,526)		(5,497)	
Basic and diluted loss per common share	\$	(0.15)	\$	(0.14)	

The net loss for the three-month period ended March 31, 2020 increased by \$6.0 million to \$11.5 million as compared with \$5.5 million for the comparable period in 2019, primarily as a result of an increase of \$3.7 million in stock-based compensation in the current period, a combined increased in program costs and related labor costs of approximately \$1.9 million on our CG-806 and APTO-253 development programs, and higher cash-based general and administrative expenses of \$569 thousand. These expenses were partially offset by higher net finance income of \$308 thousand in the current period, which increased by \$214 thousand compared to the comparative period, mostly as a result of higher interest earned on larger balances of cash equivalents and investments held during the three-month period ended March 31, 2020.

Research and Development

The research and development expenses for the three-month periods ended March 31, 2020 and 2019 were as follows:

	Three months ended March 31,			
(in thousands)	2020		2019	
Program costs – CG-806	\$	2,945	\$	1,386
Program costs – APTO-253		879		1,128
Personnel expenses		1,303		699
Stock-based compensation		800		118
Depreciation of equipment		7		9
		5,934		3,340

Research and development expenses for the three-month period ended March 31, 2020 were \$5.9 million as compared with \$3.3 million for the comparative period in 2019, an increase of approximately \$2.6 million. Changes to the components of our research and development expenses presented in the table above were primarily as a result of the following events:

- In the three-month period ended March 31, 2020, program costs for our CG-806 program consisted mostly of manufacturing costs, including costs to scale up manufacturing and research costs associated with optimizing the formulation, and clinical trial costs. In the three-month period ended March 31, 2019, program costs for our CG-806 program consisted mostly of costs to complete the preclinical studies and prepare regulatory filings in support of an IND filing and the manufacturing of drug product for the Phase 1 clinical trial.
- In the three-month period ended March 31, 2020, program costs for our APTO-253 program consisted mostly of costs related to the Phase 1b clinical trial, and manufacturing costs for a second GMP. In the comparative period in 2019, the Company completed production of a GMP batch of drug product, and initiated necessary studies to present to the FDA in support of removing the clinical hold.
- An increase in personnel expenses mostly related to seven new positions, including a Chief Medical Officer, hired since the second quarter of 2019 to support two Phase 1 clinical trials.

• Stock-based compensation increased by approximately \$682 thousand in the three months ended March 31, 2020, compared with the three months ended March 31, 2019 mostly related to an increase in the number of options granted in the current period and a higher grant date fair value of options. In the current period, 1,322,500 stock options were granted to employees working in research and development with an average grant date fair value of \$4.40. In the comparative period, 390,050 stock options were granted to employees in research and development with a grant date fair value of \$1.29.

General and Administrative

The general and administrative expenses for the three-month periods ending March 31, 2020 and 2019 were as follows:

	Three months ended March 31,			
(in thousands)	2020		2019	
General and administrative, excluding items below	\$	2,265	\$	1,696
Stock-based compensation		3,601		544
Depreciation of equipment		34		20
	\$	5,900	\$	2,260

General and administrative expenses for the three-month period ended March 31, 2020 were \$5.9 million as compared with \$2.3 million for the comparative period, an increase of approximately \$3.6 million. The increase was primarily as a result of the following:

- General and administrative expenses, other than stock-based compensation and depreciation of equipment, increased by approximately \$569 thousand in the three months ended March 31, 2020, primarily as a result of higher personnel related costs mostly related to two additional hires, including a Chief Business Officer, in the second quarter of 2019, higher insurance and professional and regulatory costs, and higher office administrative costs.
- Stock-based compensation increased by approximately \$3.1 million in the three months ended March 31, 2020 compared with the three months ended March 31, 2019, mostly related to an increase in the number of options granted in the current period, and a higher grant date fair value of options. In the current period, 4,786,334 stock options were granted to directors, executive offices and general and administrative employees with an average grant date fair value of \$4.66 and we issued 645,000 restricted stock units (RSUs) with an average grant date fair value of \$7.32. In the comparative period, 1,024,000 stock options were granted to directors, executive officers and general and administrative employees with a grant date fair value of \$1.29.

Conference Call and Webcast

Aptose will host a conference call to discuss results for the quarter ended March 31, 2020 today, Tuesday, May 5, 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 # 6470926. The conference call can be

accessed <u>here</u> 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 # 6470926.

The press release, the financial statements and the management's discussion and analysis for the quarter ended March 31, 2020 will be available on SEDAR at www.sedar.com and EDGAR at www.sec.gov/edgar.shtml.

Note

The information contained in this news release is unaudited.

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; 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.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 maligancy 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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