

Aptose Biosciences Reports Financial Results for the Third Quarter Ended September 30, 2016

SAN DIEGO and TORONTO, Nov. 14, 2016 (GLOBE NEWSWIRE) -- Aptose Biosciences Inc. (NASDAQ:APTO) (TSX:APS), a clinical-stage company developing new therapeutics and molecular diagnostics that target the underlying mechanisms of cancer, today announced unaudited financial results for the three months ended September 30, 2016 and reported on corporate developments. Unless specified otherwise, all amounts are in Canadian dollars.

Net loss for the three months ended September 30, 2016 was \$4.0 million (\$0.31 per share) compared with \$3.3 million (\$0.27 per share) during the three months ended September 30, 2015. Total cash and cash equivalents at September 30, 2016 were \$10.3 million.

"During the third quarter of this year we focused on collecting and delivering to the U.S. Food and Drug Administration (FDA) the manufacturing information required to get our clinical trial of APTO-253 for acute myeloid leukemia (AML) back on track, as returning APTO-253 to the clinic is a major event for the company and for patients with AML," said William G. Rice, Ph.D., Chairman, President and Chief Executive Officer. "Simultaneously, we advanced the development of CG'806, which we believe can be a transformational drug for patients with FLT3-driven AML and for patients with B cell malignancies driven by the Cys481Ser mutant of the BTK enzyme."

Corporate Highlights

- During the quarter, Aptose submitted a formal response and data package to the FDA, providing responses to all of the questions cited in the clinical hold letter issued by the FDA. The response to the FDA was based on a prototype drug product that was developed and manufactured to demonstrate the root cause and the corrective actions taken by Aptose to deliver ultimately a drug product that meets FDA standards for the return to the clinic.
- As announced in October, the FDA requested that Aptose provide the FDA with the Chemistry, Manufacturing and Control (CMC) package for the actual GMP drug substance and drug product intended to serve as the clinical supply for the trial.
- Aptose has now manufactured a batch of APTO-253 drug product that is intended to serve as the clinical supply for the trial, and vials of this new drug product batch have been placed on an accelerated and long-term stability-testing program. Data generated from this drug product batch will comprise much of the CMC package that Aptose will provide to the FDA.

- In parallel, Aptose's clinical team has identified and prepared multiple new clinical sites
 for the Phase 1b trial of APTO-253. The clinical sites, at major cancer research and
 treatment centers in the U.S., will be prepared to start the study as soon as the
 company resumes trial activities and re-initiates dosing and enrollment after the
 approval by FDA to do so.
- Aptose recently announced that new preclinical data for APTO-253 will be presented at the American Society of Hematology (ASH) Meeting, being held December 3-6, 2016 in San Diego, CA. The poster presentation, *Inhibition of c-Myc By Apto-253 As* an Innovative Therapeutic Approach to Induce Cell Cycle Arrest and Apoptosis in Acute Myeloid Leukemia, abstract # 1716, can be viewed at the ASH conference website.
- Aptose continued to profile the mechanistic properties and range of action of CG'806.
 This once daily, oral, first-in-class FLT3/BTK inhibitor demonstrates potent inhibition of mutant forms of FLT3 (including internal tandem duplication, or ITD, and mutations of the receptor tyrosine kinase domain), and the molecule is being positioned as a potential best-in-class therapeutic for patients with FLT3-driven AML. Likewise, CG'806 demonstrates potent, non-covalent inhibition of the Cys481Ser mutant of the BTK enzyme, suggesting the agent may be developed for CLL and MCL patients that are resistant/refractory/intolerant to covalent BTK inhibitors.

Financial Results

Net loss for the three months ended September 30, 2016 was \$4.0 million (\$0.31 per share) compared with \$3.3 million (\$0.27 per share) in the same period in the prior year. Net loss for the nine months ended September 30, 2016 was \$14.7 million (\$1.19 per share) compared with \$10.2 million (\$0.86 per share) during the nine months ended September 30, 2015.

Aptose utilized cash of \$3.3 million in operating activities in the three months ended September 30, 2016 compared with \$2.6 million during the three months ended September 30, 2015. For the nine months ended September 30, 2016 Aptose utilized cash of \$12.4 million compared with \$9.0 million in the nine months ended September 30, 2015. The cash utilized in the three months ended September 30, 2016 is higher than the three months ended September 30, 2015 due to a higher net loss as well as cash used to reduce accounts payable and accrual balances in the prior year period. The cash utilized in the nine months ended September 30, 2016 increased compared to the prior year period predominantly due to an increased net loss in the current year period.

Research and Development

Research and development expenses totaled \$2.2 million in the three months ended September 30, 2016 compared to \$1.7 million during the three months ended September 30, 2015 and totaled \$7.8 million for the nine month period ended September 30, 2016 compared with \$3.9 million in the same period in the prior year. Research and development costs consist of the following:

Components of research and development expenses:

	September 30,				September 30,					
(in thousands)		2016		2015		2016		2015		
Program costs	\$		\$		\$		\$			
r rogram coole	•	2,081	Ψ	1,633	•	6,207	Ψ	3,750		
CrystalGenomics Option Fee		-		-		1,294		-		
Stock-based compensation		71		79		236		145		
Depreciation of equipment		12		10		35		19		
	\$		\$		\$	7,772	\$			
		2,164		1,722				3,914		

The increase in program costs in the three and nine months ended September 30, 2016 compared with the three and nine months ended September 30, 2015 is due to the following reasons:

- Costs associated with the LALS/Moffitt collaboration developing epigenetic single molecule inhibitors of multiple targets, including the BET proteins, and other kinases for which no comparable expenses existed in the prior year periods;
- Increased research and clinical operations headcount and related costs;
- Formulation and manufacturing costs associated with APTO-253 and the root cause analysis of the filter clogging identified in November 2015; and
- Increased Contract Research Organization costs related to consultants and advisors as Aptose works towards returning APTO-253 to the clinic.

As of November 2016, Aptose and Laxai Avanti Life Sciences (LALS) have, as part of their drug discovery partnership, generated novel compounds that inhibit both the bromodomain proteins and oncogenic kinases, while improving pharmaceutical properties that could serve as a basis for further optimization towards a lead preclinical candidate. However, due to a prioritization of development efforts, Aptose and LALS have suspended work on the program, and the collaboration with LALS has been terminated. During the hiatus of this program, Aptose and LALS may choose to resume the collaboration in the future.

During the nine months ended September 30, 2016, the Company paid US\$1.0 million (CA\$1.294 million) for an option fee related to the CG'806 technology. No comparable expense existed in the same period in the prior year.

Stock-based compensation was consistent in the three months ended September 30, 2016 compared with the three months ended September 30, 2015. While the number of option grants in the current year was higher than the prior year, the fair value of those grants was lower in the current year due to a lower stock price.

Stock-based compensation costs allocated to research and development increased in the nine months ended September 30, 2016 to reflect option grants to new employees hired in the second half of 2015 as the expense related to those grants was amortized 50% in the first 12 months.

General and Administrative

General and administrative expenses totaled \$1.9 million in the three-month period ended September 30, 2016 compared to \$2.2 million in the three months ended September 30, 2015. For the nine month period ended September 30, 2016, general and administrative expenses totaled \$6.9 million compared with \$7.5 million in the same period in the prior year. General and administrative expenses consist of the following:

Components of general and administrative expenses:

	Three months ended					Nine months ended				
	September 30,					Septe	30,			
(in thousands)		2016	2015			2016		2015		
G&A expenses excluding salaries	\$	733	\$	819	\$		\$			
						2,688		2,997		
Salaries		858		838		2,656		2,348		
Stock-based compensation		320		572		1,476		2,091		
Depreciation of equipment		21		19		63		45		
	\$		\$		\$		\$			
		1,932		2,248		6,883		7,481		

General and administrative expenses excluding salaries, decreased in the three months ended September 30, 2016 compared with the three months ended September 30, 2015. The decrease is primarily attributable to lower travel, legal and consulting costs associated with projects completed in the prior year offset by higher patent costs in the current year due to new programs acquired in late 2015 and 2016.

General and administrative expenses excluding salaries, decreased in the nine months ended September 30, 2016 compared with the nine months ended September 30, 2015. The decrease is the result of lower travel, consulting and legal costs in the current year related to transactions completed in the prior year as well as lower press release and filing costs associated with a lower cost service provider in the current year periods.

Salary charges in the three months ended September 30, 2016 were consistent with the prior year period as headcount was consistent year over year in the three month period.

Salary charges in the nine months ended September 30, 2016 increased in comparison with the nine months ended September 30, 2015 due to additional headcount in the first half of 2016 compared with the first half of 2015 as well as a higher average CA/US exchange rate which increased the cost of our US denominated salaries in the first six months of 2016 in comparison with the prior year.

Stock-based compensation decreased in the three months ended September 30, 2016 compared with the three months ended September 30, 2015 due to options granted in the current year having a lower valuation and therefore expense compared with options granted in the prior year.

Stock-based compensation decreased in the nine months ended September 30, 2016 compared with the nine months ended September 30, 2015 due to large option grants in April, June and July 2014 which vested 50% during the first year and therefore contribute to higher stock-based compensation expense during the first twelve month period captured in the prior year period.

Finance Expense

Finance expense for the three months ended September 30, 2016 totaled \$nil compared with \$8 thousand for the three months ended September 30, 2015. For the nine months ended September 30, 2016, finance expense totaled \$138 thousand compared with \$43 thousand for the same period in the prior year. Finance expense includes the following items:

	Three m	onth	s ended	Nine months ended					
	September 30,				September 30,				
(in thousands)	2016		2015		2016	:	2015		
Interest expense	\$ -	\$	8	\$	-	\$	43		
Foreign exchange loss	-		-		138		-		
	\$ -	\$	8	\$	138	\$	43		

Interest expense for the three and nine months ended September 30, 2015 relates to interest accrued at a rate of 10% on the remaining balance of convertible promissory notes issued in September 2013 as well as accretion expense related to the conversion feature of the notes. As the promissory notes were converted before September 2015, no interest expense was incurred in 2016.

Foreign exchange loss is the result of the fluctuation of exchange rates between US and Canadian dollars and the impact on our US dollar denominated cash balances.

Finance Income

Finance income totaled \$79 thousand in the three months ended September 30, 2016 compared to \$717 thousand in the three months ended September 30, 2015. For the nine months ended September 30, 2016, finance income totaled \$92 thousand compared with \$1.2 million in the same period in the prior year. Finance income includes the following items:

	Three months ended					Nine months ended					
	September 30,					September 30,					
(in thousands)	2016			2015	:	2016		2015			
Interest income	\$	12	\$	56	\$	92	\$	232			
Foreign exchange gain		67		661		-		1,011			
	\$	79	\$	717	\$	92	\$				
								1,243			

Interest income represents interest earned on our cash and cash equivalent and investment balances. Foreign exchange gains are the result of an increase in the value of US dollar denominated cash and cash equivalents balances during such periods due to a depreciation of the Canadian dollar compared to the US dollar.

Aptose Biosciences Inc. Condensed Consolidated Interim Statements of Loss and Comprehensive Loss (unaudited)

		Three		Three		Nine		Nine months ended
(amounts in 000's of Canadian Dollars except for per common share data)		months ended Sept. 30, 2016		months ended		months ended	-	
				Sept. 30, 2015		Sept. 30, 2016		Sept. 30, 2015
REVENUE	\$	-	\$	-	\$	-	\$	-
EXPENSES								
Research and development		2,164		1,722		7,772		3,914
General and administrative		1,932		2,248		6,883		7,481
Operating expenses		4,096		3,970		14,655		11,395
Finance expense		-		8		138		43
Finance income		(79)		(717)		(92)		(1,243)
Net financing (income) expense		(79)		(709)		46		(1,200)
Net loss and comprehensive loss for the period		4,017		3,261		14,701		10,195
Basic and diluted loss per common share	\$	0.31	\$	0.27	\$	1.19	\$	0.86

Weighted average number of common shares

The press release, the financial statements and the management's discussion and analysis for the quarter ended September 30, 2016 will be available on SEDAR at www.sec.gov/edgar.shtml

Conference Call and Webcast

Aptose will host a conference call to discuss results for the three months ended September 30, 2016 tomorrow, Tuesday, November 15, 2016 at 8:30 a.m. ET. Participants can access the conference call by dialing toll-free (844) 882-7834 (North America toll free number) or (574) 990-9707 (international toll free number), using the conference call passcode 17568049. The conference call can also be accessed at http://edge.mediaserver.com/m/p/nndfkz6o and will be available through a link on the Investor Relations section of Aptose's website at ir.aptose.com. Please log onto the webcast at least 10 minutes prior to the start of the call to ensure time for any software downloads that may be required. 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 7 days by dialing (855) 859-2056, using the passcode 17568049.

Note

The information contained in this news release is unaudited.

About Aptose

Aptose Biosciences is a clinical-stage biotechnology company committed to discovering and developing personalized therapies addressing unmet medical needs in oncology. Aptose is advancing new therapeutics focused on novel cellular targets on the leading edge of cancer research coupled with companion diagnostics to identify the optimal patient population for our products. 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. 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. Such statements include, but are not limited to, statements that APTO-253 could return to the clinic and relating to the process to respond to the continued clinical hold that could possibly result in the clinical trial being re-initiated upon approval by the FDA, the potential of CG'806 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 conditions; uncertainty in the length of the clinical hold and the conditions the FDA may impose to remove it; potential loss of API; 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.

Aptose Biosciences Greg Chow, CFO 647-479-9828 gchow@aptose.com

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



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