

March 29, 2016



# Aptose Reports Fourth Quarter and Year End 2015 Results

SAN DIEGO and TORONTO, March 29, 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 financial results for the three months and fiscal year ended December 31, 2015 and reported on corporate developments. Unless specified otherwise, all amounts are in Canadian dollars.

Effective July 17, 2014, the Company changed its fiscal year end from May 31 to December 31. As a result, the current period being reported is for the year ended December 31, 2015, while the prior year comparative period is for the seven months ended December 31, 2014.

The net loss for the year ended December 31, 2015 was \$14.6 million (\$1.23 per share) compared with \$7.8 million (\$0.67 per share) in the seven months ended December 31, 2014. Total cash and cash equivalents and investments as of December 31, 2015 were \$19.7 million.

“From an operations, development and clinical perspectives, the first quarter of 2016 has been an extremely busy and dedicated time for our teams working on APTO-253,” said William G. Rice, Ph.D., Chairman, President and Chief Executive Officer. “We undertook a thorough and comprehensive approach to evaluating the manufacturing issue responsible for the previously announced clinical delay of APTO-253 and to optimizing a new methodology to formulate APTO-253 into a soluble and stable drug product. We continue to work diligently through this process and, ultimately, the FDA will need to review our analysis and approve our new formulation methodology for APTO-253 as a potential clinical drug product. In the meantime, we have made great progress towards bringing additional clinical sites on board, and expect to emerge from the clinical delay at an accelerated enrollment pace.”

## Corporate Highlights

- During the fourth quarter, Aptose engaged an independent third party to review the manufacturing batch records and to search for issues that might be responsible for the filter clogging event that led to the delay in the APTO-253 clinical trial.
- Aptose qualified a new contract manufacturing organization (CMO) that optimized the synthetic chemistry process to manufacture reliably the freebase and HCl salt forms of the API. The CMO now has manufactured new GMP batches of the API to provide material for formulation studies and to supply the clinical trials into the future.
- Aptose also qualified a separate CMO with expertise in liquid formulations to perform formulation development studies and to manufacture the final form of the drug product

for return to the clinic. The CMO has performed numerous formulation studies using a variety of methodologies and is now evaluating their solubility and stability over time to select the best methodology to manufacture the new batch of drug product to take to the FDA. Aptose will need to demonstrate to the FDA that the fresh batch of GMP clinical supply is unlikely to cause filter clogging in the future.

- Aptose’s clinical team has identified additional clinical sites to enroll patients as soon as the company resumes dosing for APTO-253. The advance preparation of these sites is intended to ensure an accelerated pace of patient accrual into the future.
- The Company has demonstrated that treatment of AML cells with APTO-253 can induce expression of KLF4 and p21 (as described in prior disclosures), but also inhibits expression of the c-Myc oncogene at the mRNA and protein level. APTO-253 can lead to the transcriptional regulation of these key genes and yet not cause myelosuppression of normal bone marrow.
- In the fourth quarter of 2015, Aptose and its partners presented several abstracts at the 57th American Society of Hematology Meeting (ASH).
  - Researchers from the Knight Cancer Institute at Oregon Health & Science University (OHSU) presented data demonstrating the ability of APTO-253 to kill acute myeloid leukemia (AML) cells in the majority of patient samples, with a trend toward correlation with baseline KLF4 expression level. Moreover, APTO-253 exhibited enhanced killing ability of AML cells in patient samples when combined with either the BET inhibitor JQ1 or with the FLT3 inhibitor quizartinib. These data also demonstrated APTO-253 activity against other hematologic malignancies, in particular CLL.
  - Researchers from Moffitt Cancer Center described the *in vitro* activity of dual-targeting bromodomain/kinase inhibitor, MA2-014, which is a representative candidate from a new family of small molecule, dual-targeting BRD/kinase inhibitors licensed to Aptose. The MA2-014 program was developed to inhibit both the bromodomain 4 (BRD4) protein and the Janus kinase 2 (JAK2) for the potential treatment of various hematologic and solid tumor cancers. MA2-014 demonstrated activity in myeloproliferative neoplasm, or MPN, cell lines, which include rare blood cancers such as polycythemia vera, essential thrombocythemia and myelofibrosis.
  - MA2-014 exhibits similar anti-JAK2 activity as TG101209, a known JAK2 inhibitor, with an approximate ten-fold improvement in anti-BRD activity. Data also demonstrated a ten-fold improvement in the ability of MA2-014 to inhibit JAK2-V617F signaling over TG101209 and comparable to ruxolitinib, the only FDA-approved JAK inhibitor for MPNs.

## Financial Results

### THREE MONTHS ENDED DECEMBER 31, 2015 AND 2014 (UNAUDITED)

<i>(Amounts in 000's except for per common share data)</i>	Dec 31, 2015	Dec 31, 2014
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Revenue	\$ —	\$ —
Research and development expense	2,340	1,093
General and administrative expense	2,364	2,554
<b>Operating expenses</b>	<b>4,704</b>	<b>3,647</b>
Finance expense	—	55
Finance income	(273 )	(118 )
Net financing income	(273 )	(63 )
<b>Net loss</b>	<b>(4,431 )</b>	<b>(3,584 )</b>
<b>Basic and diluted net loss per share</b>	<b>\$ (0.38 )</b>	<b>\$ (0.31 )</b>

Our net loss and comprehensive loss for the three months ended December 31, 2015 increased to \$4.4 million compared with \$3.6 million in the three months ended December 31, 2014. The increase in net loss is primarily due to costs associated with increased research and development activities of \$1.2 million offset by reduced general and administrative costs of \$190 thousand in the three months ended December 31, 2015, compared with the three months ended December 31, 2014. There was also an increase in net financing income of \$210 thousand in the three months ended December 31, 2015 which reduced the net loss in comparison to the prior year period.

The increased research and development expense in the three months ended December 31, 2015, compared with the three months ended December 31, 2014, results from the APTO-253 Phase Ib clinical trial for which the first patient was enrolled in January 2015 and related personnel and consulting costs.

General and administrative expenses decreased to \$2.4 million in the three months ended December 31, 2015 compared with \$2.6 million in the three months ended December 31, 2014. This decrease, despite the increased cost of our US dollar expenditures due to the devaluation of the Canadian dollar, is related to a reduction in bonus expense for executives. In addition, costs related to the termination of our Toronto lease were recognized in the final quarter of 2014, for which no comparable costs exist in the current year.

## FULL YEAR RESULTS

### *Consolidated Statements of Loss and Comprehensive Loss*

	Year ended December 31,		7 months ended December 31,	
	2015		2014	
<i>(amounts in Canadian thousands except for per common share data)</i>				
<b>REVENUE</b>	\$	—	\$	—
<b>EXPENSES</b>				
Research and development		6,254		2,404
General and administrative		9,845		5,542
<b>Operating expenses</b>		<b>16,099</b>		<b>7,946</b>
Finance expense		43		104
Finance income		(1,516 )		(279 )
<b>Net finance (income)</b>		<b>(1,473 )</b>		<b>(175 )</b>
<b>Net loss and total comprehensive loss for the period</b>		<b>14,626</b>		<b>7,771</b>
<b>Basic and diluted loss per common share</b>	\$	<b>1.23</b>	\$	<b>0.67</b>
<b>Weighted average number of common shares outstanding used in the calculation of:</b>				
<b>Basic and diluted loss per share</b>		<b>11,906</b>		<b>11,605</b>

## Research and Development

Research and development expenses totaled \$6.3 million in the year ended December 31, 2015 compared with \$2.4 million in the seven months ended December 31, 2014. Research and development expenses consist of the following:

(in thousands)	Year ended December 31, 2015	7 months ended December 31, 2014
Research and development costs	\$ 6,015	\$ 2,371
Stock-based compensation	210	29
Depreciation of equipment	29	4
	<b>\$ 6,254</b>	<b>\$ 2,404</b>

Expenditures for the year ended December 31, 2015 increased significantly over the seven months ended December 31, 2014 (on an annualized basis) due to the following:

- Costs associated with the Phase 1b clinical trial of APTO-253 in patients with relapsed or refractory hematologic malignancies including clinical site costs, patient costs, contract research organization and consulting charges. The first patient in the trial was enrolled in January 2015;
- Development costs related to the Moffitt/LALS programs that were initiated in the fourth quarter of 2015;
- Formulation, manufacturing and compliance costs related to the development of APTO-253 including costs related to the clinical hold described above;
- Additional payroll related costs in the clinical department due to restructuring to support ongoing activities; and
- The increased cost of US dollar denominated expenditures due to the devaluation of the Canadian dollar.

Stock-based compensation expense increased in the year ended December 31, 2015 compared with the seven months ended December 31, 2014 primarily due to option grants to new employees and advisors during the year.

## General and Administrative

General and administrative expenses totaled \$9.8 million for the year ended December 31, 2015 compared with \$5.5 million in the seven months ended December 31, 2014. General and administrative expenses consisted of the following:

(in thousands)	12 months ended December 31, 2015	7 months ended December 31, 2014
General and administrative excluding salaries	\$ 4,327	\$ 2,421

Salaries	2,849	1,505
Stock-based compensation	2,602	1,598
Depreciation and amortisation	67	18
	\$ 9,845	\$ 5,542

On an annualized basis, general and administrative costs excluding salaries have increased slightly in the year ended December 31, 2015 compared with the seven months ended December 31, 2014. The increase is attributable to increased costs associated with our NASDAQ listing (initiated late 2014) including listing fees and insurance charges, internal control documentation work completed during the year as well as the devaluation of the Canadian dollar which has increased the cost of our US dollar denominated expenditures including, board fees, legal and other corporate costs. These increases have been offset by the charges related to the termination of the Toronto lease in December 2014 as well as costs incurred in 2014 related to our rebranding for which no comparable costs were incurred in the current year.

Salary costs on an annualized basis, a majority of which are incurred in US dollars, increased slightly in the year ended December 31, 2015 compared with the seven months ended December 31, 2014. This increase, however, has been offset by a reduction in bonus payments made to executives in the year ended December 31, 2015.

Stock-based compensation on an annualized basis in the year ended December 31, 2015 is consistent compared with the seven months ended December 31, 2014.

## Finance Income

Finance income totaled \$1.5 million in the year ended December 31, 2015 compared with \$279 thousand in the seven months ended December 31, 2014. The components of finance income are as follows:

	Year ended December 31, 2015	7 months ended December 31, 2014
Interest income	\$ 286	\$ 279
Foreign exchange gain on cash and cash equivalents	1,230	-
	\$ 1,516	\$ 279

Interest income represents interest earned on our cash and cash equivalent and investment balances.

The foreign exchange gain realized in the year ended December 31, 2015 is due to the depreciation of the Canadian dollar and the subsequent increase in value of our US dollar currency balances.

The reported financial results were prepared in accordance with the International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB).

## Conference Call and Webcast

Aptose will host a conference call to discuss results for the three months and year ended December 31, 2015 today, Tuesday, March 29, 2016 at 5:00 p.m. EDT. Participants can access the conference call by dialing toll-free 855-546-9557 (North America toll free number) or +1 412-455-6106 (international toll free number), using the conference call passcode 62005139. The conference call will be available via a live webcast through a link on the Investor Relations section of Aptose's website at [ir.apptose.com](http://ir.apptose.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 1-855-859-2056, using the passcode 62005139.

## **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.apptose.com](http://www.apptose.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 will return to the clinic, that we will be able to manufacture APTO-253 in a soluble and stable formulation, that it will be possible to accelerate enrolment if or when we return to the clinic 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 lift 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.

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