

November 11, 2021



# Aptose Reports Results for the Third Quarter 2021

*- Conference call and webcast at 5:00 pm ET today -*

*- HM43239, myeloid kinase inhibitor with clinically validated activity added to pipeline -*

*- HM43239 phase 1/2 study in AML advances to 200 mg dose-*

*- Luxeptinib phase 1a/b studies in AML/MDS and B cell malignancies advance to 900 mg dose -*

SAN DIEGO and TORONTO, Nov. 11, 2021 (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 three months ended September 30, 2021 and provided a corporate update.

The net loss for the quarter ended September 30, 2021 was \$11.3 million (\$0.13 per share) compared with \$13.2 million (\$0.15 per share) for the quarter ended September 30, 2020. The net loss for the nine months ended September 30, 2021 was \$41.0 million (\$0.46 per share), compared with \$40.5 million (\$0.51 per share) for the nine months ended September 30, 2020. Total cash and cash equivalents and investments as of September 30, 2021 were \$95.1 million. Based on current operations, Aptose expects 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 2023.

"Our recent agreement with Hanmi Pharmaceutical has provided us with a clinical-stage asset in HM43239 (or 239) that already has clinically validated anti-leukemic activity in a diverse array of AML patients, delivering multiple complete responses early in a Phase 1/2 trial thus far," said William G. Rice, Ph.D., Chairman, President and Chief Executive Officer. "As a complement to luxeptinib (Lux), 239 strengthens Aptose's ability to treat a wider spectrum of AML cancer patients across genotypes; in addition, Lux has the potential to treat a range of patients with relapsed or refractory CLL and other B-cell lymphoid malignancies. Both 239 and Lux are exceptional assets that could propel us to the next level in the field of kinase inhibitors."

## Key Corporate Highlights

- **Exclusive Worldwide License with Hanmi Pharmaceutical for Clinical Candidate HM43239** – Aptose recently entered into an exclusive license agreement with Hanmi Pharmaceutical, a Korean pharmaceutical company, to develop and commercialize HM43239, an oral, highly potent, clinical-stage myeloid kinase inhibitor (MKI), designed to target a distinct constellation of kinases operative in myeloid malignancies,

including SYK, FLT3, and others. HM43239 has been well tolerated to date and demonstrated significant genotype-agnostic anti-leukemic activity in an ongoing Phase 1/2 clinical trial, including multiple complete responses (CRs) in patients with relapsed or refractory acute myeloid leukemia (AML). The CRs occurred in AML patients with both FLT3-ITD and FLT3-TKD mutations, including a prior gilteritinib failure patient, and in patients with the wild-type form of FLT3. The AML in these patients harbored additional mutations in TP53, NRAS, NPM1, IDH2, and other important driver genes. More information is available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT03850574).

- **Luxepitinib Phase 1 a/b Clinical Study in AML and MDS**– Luxepitinib, a dual lymphoid and myeloid kinome inhibitor (LKI/MKI), currently is being evaluated in a Phase 1 a/b dose escalation clinical study in patients with relapsed/refractory (R/R) acute myeloid leukemia (AML) and higher risk MDS. Aptose recently completed the 750 mg dose level, and has escalated to the 900 mg dose cohort. To date, Lux has delivered encouraging anti-leukemic activity in multiple patients, including a durable MRD-negative complete response in a FLT3-ITD AML patient who had relapsed after two allogeneic stem cell transplants, multiple lines of chemotherapy, and prior FLT3 inhibitor therapy. More information is available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT04477291).
- **Luxepitinib Phase 1 a/b Clinical Study in B-cell Malignancies**– Luxepitinib also is being evaluated in a Phase 1 a/b dose escalation clinical study in patients with B-cell malignancies, including chronic lymphocytic leukemia (CLL) and non-Hodgkin’s lymphomas (NHL), who have failed or are intolerant to two or more lines of established therapies, including drugs such as ibrutinib, rituximab and venetoclax or for whom no other treatment options are available. Thus far, Lux has been well-tolerated in patients treated up to 750 mg BID over multiple cycles and recently has advanced to the 900 mg dose level. Of the evaluable patients at these dose levels, two thirds experienced various reductions of lesion size compared to baseline, demonstrating measurable anti-tumor activity. More information is available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT03893682).
- **Development of New Formulation for Luxepitinib**– In parallel with the dose escalation of the current formulation of luxepitinib in patients with AML and B-cell malignancies, Aptose has made significant progress in the development of a “third generation” (G3) formulation that could deliver up to 30-fold greater exposures per mg of luxepitinib administered. The capsules have been GMP manufactured and passed stability tests; clinical studies are planned for 2022.
- **Accepted Abstracts for American Society of Hematology Annual Meeting** – Aptose has four abstracts, one for each of its ongoing clinical trials, accepted for presentation at the 63rd American Society of Hematology (ASH) Annual Meeting and Exposition, being held Saturday, December 11 – Tuesday, December 14, 2021 in Atlanta, GA and virtually. Clinical data for HM43239 has been selected for an oral presentation. In addition, clinical data for luxepitinib and APTO-253 have been accepted for poster presentations. The abstracts accepted for presentation can be viewed online at the [ASH conference website](http://www.asconline.org). Aptose also will be holding an investor event during the ASH timeframe. Details will be forthcoming.

## RESULTS OF OPERATIONS

A summary of the results of operations for the three- and nine-month periods ended September 30, 2021 and 2020 is presented below:

(in thousands)	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Revenues	\$ -	\$ -	\$ -	\$ -
Research and development expenses	7,718	7,519	25,777	20,319
General and administrative expenses	3,641	5,775	15,322	20,690
Net finance income	26	45	69	484
Net loss	(11,333)	(13,249)	(41,030)	(40,525)
Other comprehensive loss	-	(2)	-	(17)
Total comprehensive loss	\$ (11,333)	\$ (13,251)	\$ (41,030)	\$ (40,542)
Basic and diluted loss per common share	\$ (0.13)	\$ (0.15)	\$ (0.46)	\$ (0.51)

The net loss for the three-month period ended September 30, 2021 decreased by \$1.9 million to \$11.3 million as compared with \$13.2 million for the comparable period in 2020. The net loss for the nine-month period ended September 30, 2021 increased by \$505 thousand to \$41 million as compared with \$40.5 million for the comparable period in 2020. Components of the net loss are presented below:

### Research and Development

The research and development expenses for the three- and nine-month periods ended September 30, 2021 and 2020 were as follows:

(in thousands)	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Program costs – luxetpinib	\$ 4,412	\$ 4,300	\$ 14,111	\$ 11,000
Program costs – APTO-253	767	725	2,976	2,460
Personnel related expenses	1,929	1,440	5,702	4,060
Stock-based compensation	609	1,051	2,985	2,784
Depreciation of equipment	1	3	3	15
	\$ 7,718	\$ 7,519	\$ 25,777	\$ 20,319

Research and development expenses increased by \$199 thousand to \$7.7 million for the three-month period ended September 30, 2021 as compared with \$7.5 million for the comparative period in 2020. Changes to the components of our research and development expenses presented in the table above are primarily as a result of the following events:

- Program costs for luxetpinib increased by approximately \$112 thousand, mostly as a result of higher manufacturing costs, including costs to scale up manufacturing and research costs associated with optimizing the formulation.
- Program costs for APTO-253 increased by approximately \$42 thousand, mostly as a result of higher clinical trial costs related to the APTO-253 Phase 1b trial.
- Personnel-related expenses increased by \$489 thousand, mostly related to new positions hired to support our clinical trials and manufacturing activities.

- Stock-based compensation decreased by approximately \$442 thousand in the three months ended September 30, 2021, compared with the three months ended September 30, 2020, mostly related to lower grant date fair value of options in the current period.

Research and development expenses increased by \$5.5 million to \$25.8 million for the nine-month period ended September 30, 2021 as compared with \$20.3 million for the comparative period in 2020. Changes to the components of our research and development expenses presented in the table above are primarily as a result of the following events:

- Program costs for luxepitinib increased by approximately \$3.1 million, mostly as a result of higher manufacturing costs, including costs to scale up manufacturing and research costs associated with optimizing the formulation and higher costs related to the luxepitinib AML trial, for which we received an IND allowance in June 2020.
- Program costs for APTO-253 increased by approximately \$516 thousand, mostly as a result of higher manufacturing costs and higher clinical trial costs related to the APTO-253 Phase 1b trial.
- Personnel-related expenses increased by \$1.6 million, mostly related to new positions hired to support our clinical trials and manufacturing activities.
- Stock-based compensation increased by approximately \$201 thousand in the nine months ended September 30, 2021, compared with the nine months ended September 30, 2020, mostly related to higher total compensation expense in the current period on options issued in the first half of 2021.

### **General and Administrative**

The general and administrative expenses for the three-month periods and nine-month periods ended September 30, 2021 and 2020 were as follows:

(in thousands)	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
General and administrative, excluding items below	\$ 2,387	\$ 1,888	\$ 7,568	\$ 6,367
Stock-based compensation	1,219	3,854	7,650	14,223
Depreciation of equipment	35	33	104	100
	\$ 3,641	\$ 5,775	\$ 15,322	\$ 20,690

General and administrative expenses for the three-month period ended September 30, 2021 were \$3.6 million as compared with \$5.8 million for the comparative period in 2020, a decrease of approximately \$2.1 million. The decrease was primarily as a result of the following:

- General and administrative expenses, other than stock-based compensation and depreciation of equipment, increased by approximately \$499 thousand in the three months ended September 30, 2021, primarily as a result of higher insurance costs, higher professional costs and higher regulatory costs offset by lower personnel related costs.

- Stock-based compensation decreased by approximately \$2.6 million in the three months ended September 30, 2021 as compared with the three months ended September 30, 2020, mostly as a result of a lower number of options granted in the nine month period ended September 30, 2021 as compared with the nine month period ended September 30, 2020, that those options granted in the current period had a lower grant date fair value, and that in the three months ended March 31, 2020, the Company had issued restricted share units (RSUs) that had fully vested by the end of the comparative period. No RSUs were granted in the current period.

General and administrative expenses for the nine-month period ended September 30, 2021 were \$15.3 million as compared with \$20.7 million for the comparative period, a decrease of approximately \$5.4 million. The decrease was primarily a result of the following:

- General and administrative expenses, other than share-based compensation and depreciation of equipment, increased by approximately \$1.2 million in the nine months ended September 30, 2021, primarily as a result of higher insurance costs, higher professional costs, and higher investor relations advisory costs offset by lower personnel related costs, lower office administrative costs and lower travel expenses.
- Stock-based compensation decreased by approximately \$6.6 million in the nine months ended September 30, 2021, compared with the nine months ended September 30, 2020. Stock-based compensation decreased by approximately \$8.3 million, mostly as a result of a lower number of options granted in the nine-month period ended September 30, 2021 as compared with the options granted in the nine-month period ended September 30, 2020, that those options granted in the current period had a lower grant date fair value, and that in the comparative period the Company had issued restricted share units (RSUs) that had fully vested by the end of the comparative period. This decrease was offset by increased compensation of approximately \$1.7 million, mostly related to the modification of option agreements of one officer as part of a separation and release agreement. Vested options of 1,679,169 with exercise prices ranging from \$1.03 to \$7.44 were allowed to continue to be exercisable for an additional twelve-month period, and also 504,833 options that would have expired unvested were allowed to continue to vest for a twelve-month period. As there was no service requirement, the Company recorded \$945 thousand and \$663 thousand additional compensation in the nine-month period related to these modifications for the vested and unvested options, respectively.

COVID-19 did not have a significant impact on our results of operations for the nine-month period ended September 30, 2021. We have not experienced and do not foresee material delays to the enrollment of patients or timelines for the luxepatinib and HM43239 trials due to the variety of clinical sites that are actively recruiting for these trial. APTO-253, which is administered intravenously, requires the need for hospital / clinical site resources to assist and monitor patients during each infusion and based on the current conditions caused by COVID-19, future enrollment of patients on this trial is likely to be negatively impacted. As of the date of this report, we have not experienced material delays in the manufacturing of luxepatinib, HM43239, or APTO-253 directly related to COVID-19. Should our manufacturers be required to shut down their facilities due to COVID-19 for an extended period of time, our trials may be negatively impacted.

## **Conference Call and Webcast**

Aptose will host a conference call to discuss results for the quarter ended September 30, 2021 today, Thursday, November 11, 2021 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 # 5675957. 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.

The press release, the financial statements and the management's discussion and analysis for the quarter ended September 30, 2021 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 three clinical-stage investigational products for hematologic malignancies: HM43239, an oral, myeloid kinase inhibitor in a Phase 1/2 trial in patients with relapsed or refractory acute myeloid leukemia (AML); luxepitinib, an oral, lymphoid and myeloid kinase inhibitor in a Phase 1 a/b trial in patients with relapsed or refractory B cell malignancies who have failed or are intolerant to standard therapies, and in a separate Phase 1 a/b trial in patients with relapsed or refractory AML or high risk myelodysplastic syndrome (MDS); and APTO-253, the only known clinical stage agent that directly targets the MYC oncogene and suppresses its expression, in a Phase 1 a/b clinical trial in patients with relapsed or refractory AML or high risk MDS. For more 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 and dose escalations, the clinical potential, anti-cancer activity, therapeutic potential and applications and safety profile of HM43239, luxepitinib and APTO-253, the HM43239 Phase 1/2 AML clinical trial, the luxepitinib Phase 1 a/b B-cell malignancy and Phase 1 a/b AML clinical trials and their timeline, the APTO-253 Phase 1 a/b clinical trial the development of a G3 formulation for luxepitinib and the impact of COVID-19 on the Company and its operations; upcoming updates regarding the clinical trials, and operations 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; the potential impact of the COVID-19 pandemic 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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Source: Aptose Biosciences, Inc.