

August 3, 2021



# Aptose Reports Results for the Second Quarter 2021

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

*- Luxeptinib Phase 1a/b studies in AML and B cell malignancies fully enrolled at 750 mg dose -*

*- APTO-253 Phase 1a/b study in AML / MDS treating patients at sixth dose cohort of 210 mg/m<sup>2</sup> -*

SAN DIEGO and TORONTO, Aug. 03, 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 June 30, 2021 and provided a corporate update.

The net loss for the quarter ended June 30, 2021 was \$13.5 million (\$0.15 per share) compared with \$15.8 million (\$0.21 per share) for the quarter ended June 30, 2020. The net loss for the six months ended June 30, 2021 was \$29.7 million (\$0.33 per share), compared with \$27.3 million (\$0.36 per share) for the six months ended June 30, 2020. Total cash and cash equivalents and investments as of June 30, 2021 were \$103.3 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 the first half of 2023.

"The progress we are seeing in our Phase 1 a/b clinical trials with luxeptinib in very challenging patient populations with AML and B-cell malignancies is especially encouraging," said William G. Rice, Ph.D., Chairman, President and Chief Executive Officer. "As we have begun to observe dose-dependent anti-tumor activity, we plan to continue dose escalation for extended duration to treat as many patients as possible on these higher dose levels and tackle these increasingly refractory patient populations."

## Key Corporate Highlights

- **Luxeptinib Phase 1 a/b Clinical Study in AML**– Luxeptinib is currently being evaluated in a Phase 1 a/b dose escalation clinical study in patients with relapsed/refractory (R/R) acute myeloid leukemia (AML). In concurrence with participation at the EHA2021 Virtual Congress (EHA) in June, Aptose reported 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. Aptose has completed the 450 and 600 mg dose levels, with some patients remaining on treatment at those levels, and has fully enrolled the 750 mg dose

cohort. More information is available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT04477291).

- Luxepitinib Phase 1 a/b Clinical Study in B-cell Malignancies**– In parallel with the trial in AML patients, luxepitinib 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, luxepitinib has been well-tolerated in patients treated at 150mg, 300mg, 450mg and 600mg BID over multiple cycles. Of the evaluable patients at these dose levels, two-thirds of them experienced various reductions of lesion size or IgM measurements compared to baseline, demonstrating measurable anti-tumor activity. Patients now are being treated at the fifth dose level of 750mg BID, which is fully enrolled. More information is available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT03893682).
- APTO-253 Phase 1 a/b Clinical Study in AML and MDS**– As a direct inhibitor of MYC transcription, APTO-253 represents a novel approach for targeting MYC, an oncogene estimated to contribute to the majority of all human cancers, including hematologic malignancies. Given this mode of action, Aptose is expanding the target patient population to include those with relapsed or refractory B-cell malignancies characterized by chromosomal translocations involving the MYC locus. These include Burkitt’s lymphoma, double- or triple-hit diffuse large B-cell lymphomas, and other aggressive lymphomas with MYC translocations.

In the ongoing Phase 1a/b study in patients with relapsed or refractory AML and high-risk myelodysplastic syndrome (MDS), APTO-253 has been well-tolerated in five dose cohorts ranging from 20 – 150 mg/m<sup>2</sup> over multiple cycles. Thus far, there is no evidence of drug-related adverse events, including no myelosuppression. Aptose currently is treating patients in the sixth dose cohort at 210 mg/m<sup>2</sup> and several subsequent dose escalations are anticipated. More information is available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT02267863).

## RESULTS OF OPERATIONS

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

(in thousands)	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Revenues	\$ -	\$ -	\$ -	\$ -
Research and development expenses	9,831	6,866	18,059	12,800
General and administrative expenses	3,657	9,015	11,681	14,915
Net finance income	18	131	43	439
Net loss	(13,470)	(15,750)	(29,697)	(27,276)
Other comprehensive loss	-	(15)	-	(15)
Total comprehensive loss	\$(13,470)	\$(15,765)	\$(29,697)	\$(27,291)
Basic and diluted loss per common share	\$(0.15)	\$(0.21)	\$(0.33)	\$(0.36)

The net loss for the three-month period ended June 30, 2021 decreased by \$2.3 million to

\$13.5 million as compared with \$15.8 million for the comparable period in 2020. The net loss for the six-month period ended June 30, 2021 increased by \$2.4 million to \$29.7 million as compared with \$27.3 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-month and six-month periods ended June 30, 2021 and 2020 were as follows:

(in thousands)	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Program costs – luxetpinib	\$5,728	\$3,755	\$9,699	\$6,700
Program costs – APTO-253	1,119	856	2,209	1,735
Personnel related expenses	1,985	1,317	3,773	2,620
Stock-based compensation	998	933	2,376	1,733
Depreciation of equipment	1	5	2	12
	\$9,831	\$6,866	\$18,059	\$12,800

Research and development expenses increased by \$3.0 million to \$9.8 million for the three-month period ended June 30, 2021, as compared with \$6.9 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 \$1.97 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 luxetpinib AML trial, for which we received an IND allowance in June 2020.
- Program costs for APTO-253 increased by approximately \$263 thousand, mostly as a result of higher manufacturing costs.
- Personnel-related expenses increased by \$668 thousand, mostly related to new positions hired to support our clinical trials and manufacturing activities.
- Stock-based compensation increased by approximately \$65 thousand in the three months ended June 30, 2021, compared with the three months ended June 30, 2020, mostly related to higher total compensation expense in the current period on options issued in the first half of 2021.

Research and development expenses increased by \$5.3 million to \$18.1 million for the six-month period ended June 30, 2021, as compared with \$12.8 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 \$3.0 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 luxetpinib AML trial, for which we received an IND allowance in June 2020.
- Program costs for APTO-253 increased by approximately \$474 thousand, mostly as a

result of higher manufacturing costs.

- Personnel-related expenses increased by \$1.2 million, mostly related to new positions hired to support our clinical trials and manufacturing activities.
- Stock-based compensation increased by approximately \$643 thousand in the six months ended June 30, 2021, compared with the six months ended June 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 and six-month periods ended June 30, 2021 and 2020 were as follows:

(in thousands)	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
General and administrative, excluding items below	\$2,456	\$2,214	\$5,181	\$4,479
Stock-based compensation	1,166	6,768	6,431	10,369
Depreciation of equipment	35	33	69	67
	\$3,657	\$9,015	\$11,681	\$14,915

General and administrative expenses for the three-month period ended June 30, 2021 were \$3.7 million, as compared with \$9.0 million for the comparative period in 2020, a decrease of approximately \$5.4 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 \$242 thousand in the three months ended June 30, 2021, primarily as a result of higher insurance costs, professional costs and investor relations advisory costs offset by lower personnel related costs and lower office administrative costs.
- Stock-based compensation decreased by approximately \$5.6 million in the three months ended June 30, 2021 as compared with the three months ended June 30, 2020, mostly as a result of a lower number of options granted in the six month period ended June 30, 2021 as compared with the six month period ended June 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. No RSUs were granted in the current period.

General and administrative expenses for the six-month period ended June 30, 2021 were \$11.7 million as compared with \$14.9 million for the comparative period, a decrease of approximately \$3.2 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 \$702 thousand in the six months ended June 30, 2021, primarily as a result of higher insurance costs, higher professional costs, higher investor relations advisory costs offset by lower office

administrative costs and lower travel expenses.

- Stock-based compensation decreased by approximately \$3.9 million in the six months ended June 30, 2021, compared with the six months ended June 30, 2020. Stock-based compensation decreased by approximately \$5.6 million mostly as a result of a lower number of options granted in the six-month period ended June 30, 2021 as compared with the six month period ended June 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 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 current period related to these modifications for the vested and unvested options, respectively.

### **Conference Call and Webcast**

Aptose will host a conference call to discuss results for the quarter ended June 30, 2021 today, Tuesday, August 3, 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 # 7272387. 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 # 7272387.

The press release, the financial statements and the management's discussion and analysis for the quarter ended June 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 two clinical-stage investigational products for hematologic malignancies: luxetpinib, an oral, first-in-class mutation-agnostic FLT3/BTK kinase inhibitor, is in a Phase 1a/b 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, and is in a separate Phase 1a/b trial in patients with relapsed or refractory acute myeloid leukemia (AML); APTO-253, the only known clinical stage agent that directly targets the MYC oncogene and suppresses its expression, is in a Phase 1a/b clinical trial for the treatment of patients with relapsed or refractory AML or high risk myelodysplastic syndrome (MDS).

## **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, timelines and dose escalations; the clinical potential, anti-cancer activity, therapeutic potential and applications, favorable properties and safety profile of APTO-253 and luxetpinib; the APTO-253 Phase 1 a/b, the luxetpinib Phase 1 a/b B-cell malignancy and Phase 1 a/b AML clinical trials; 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", "encourage", "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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