

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event Reported): August 4, 2020

Aptose Biosciences Inc.

(Exact Name of Registrant as Specified in Charter)

Canada
(State or Other Jurisdiction of Incorporation)

001-32001
(Commission File Number)

98-1136802
(I.R.S. Employer Identification Number)

251 Consumers Road, Suite 1105, Toronto, Ontario, Canada M2J 4R3
(Address of Principal Executive Offices) (Zip Code)

647-479-9828
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Shares, no par value	APTO	The Nasdaq Stock Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On August 4, 2020, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in the press release attached as Exhibit 99.1 hereto shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

[Exhibit 99.1. Press release dated August 4, 2020](#)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Aptose Biosciences Inc.

Date: August 5, 2020

By: /s/ Gregory K. Chow
Gregory K. Chow
Senior Vice President and Chief Financial Officer

Aptose Reports Results for the Second Quarter 2020

CG-806 Phase 1 a/b Study in B Cell Malignancies Advances to Fifth (750mg) Dose Cohort

FDA Allows IND for Phase 1 a/b Study of CG-806 in AML to Initiate at 450mg Dose Level

APTO-253 Phase 1b Study in AML / MDS Advances to Fifth (150mg/m²) Dose Cohort

Conference Call and Webcast at 5pm EDT Today

SAN DIEGO and TORONTO, Aug. 04, 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 June 30, 2020.

The net loss for the quarter ended June 30, 2020 was \$15.8 million (\$0.21 per share) compared with \$6.2 million (\$0.13 per share) for the quarter ended June 30, 2019. Total cash and cash equivalents and investments as of June 30, 2020 were \$82.7 million. Based on current operations, we expect that cash on hand and proceeds from the recent public offering provide the Company with sufficient resources to fund all planned operations including research and development into 2023.

“Aptose’s two distinctive clinical assets, CG-806 and APTO-253, are advancing well through dose escalation in their respective clinical trials, both with signs of pharmacologic activity and favorable safety and tolerability to date,” said William G. Rice, Ph.D., Chairman, President and Chief Executive Officer. “For CG-806 in particular, we believe these higher doses provide momentum toward the goal of delivering responses in R/R-CLL patients. Plus, with the FDA’s recent allowance of our IND for CG-806 in AML patients at a potentially therapeutic starting dose of 450 mg BID, we continue to execute on our broad strategic plan and are hopeful that CG-806 will deliver benefit to yet another fragile patient population in great need of new therapies.”

Key Corporate Highlights

- **CG-806 Phase 1 a/b B-cell Malignancy Clinical Study** – Aptose has completed dose level four (600 mg BID dose cohort) of the CG-806 trial in patients with CLL and other B-cell malignancies. The safety review committee then advanced CG-806 to the fifth dose level of 750 mg BID, and potential patients are being screened for enrollment into this cohort. To date, CG-806 continues to be well-tolerated, and initial indications of desired pharmacologic activity continue to be observed, including strong inhibition of multiple oncogenic driver kinases and a robust increase in peripheral blood lymphocytes - or lymphocytosis - classically ascribed as a response to the inhibition of BTK. Currently, 23 U.S. sites are open for screening and enrolling patients for the study, and more information is available at www.clinicaltrials.gov.
- **FDA Allowance of IND for CG-806 in AML** – In June, Aptose announced that the U.S. Food and Drug Administration (FDA) allowed the company’s Investigational New Drug (IND) application for the initiation of a Phase 1a/b clinical study of CG-806, the company’s highly potent, oral FLT3/BTK inhibitor, in patients with acute myeloid leukemia (AML). Importantly, the desired starting dose of 450mg BID was allowed, as this dose is expected to be pharmacologically active in patients with FLT3 mutated AML. Aptose is working with key AML sites to start enrollment for this study (NCT04477291) in late Q3. Despite recent advances in the treatment of AML, many patients continue to have a poor overall prognosis. CG-806 is the only BTK inhibitor that also possesses strong FLT3 inhibitory activity and is applicable therefore to both lymphoid and myeloid malignancies.
- **APTO-253 Phase 1b Clinical Study** – Aptose recently completed dose level four (100 mg/m²) of the APTO-253 study in patients with AML and MDS and the safety review committee then escalated dosing to 150 mg/m². Approval of the current protocol amendment with accelerated dosing will allow enrollment at 8 sites. 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 in the peripheral blood mononuclear cells (PBMCs) from treated patients with AML and MDS. More information is available at www.clinicaltrials.gov.
- **Public Offering of Common Shares** – In July, Aptose completed an underwritten public offering of 10,500,000 common shares (the “Offering”) at the public offering price of US\$5.25 per share. Piper Sandler & Co. acted as the sole active book-running manager for the Offering and has been granted a 30-day option to purchase up to an additional 1,575,000 common shares in the Offering, under the same terms and conditions. Gross proceeds from the Offering, before deducting underwriting discounts and commissions and estimated offering expenses payable by Aptose, are approximately US\$55.125 million.

A summary of the results of operations for the three-month and six-month periods ended June 30, 2020 and 2019 is presented below:

	Three months ended		Six months ended	
	June 30,		June 30,	
(in thousands)	2020	2019	2020	2019

Revenues	\$	-	\$	-	\$	-	\$	-
Research and development expenses		6,866		3,491		12,800		6,831
General and administrative expenses		9,015		2,855		14,915		5,115
Net finance income		131		128		439		222
Net loss	\$	(15,750)	\$	(6,218)	\$	(27,276)	\$	(11,724)
Other comprehensive gain/(loss)		(15)		9		(15)		18
Total comprehensive loss	\$	(15,765)	\$	(6,209)	\$	(27,291)	\$	(11,706)
Basic and diluted loss per common share	\$	(0.21)	\$	(0.13)	\$	(0.36)	\$	(0.27)

The net loss for the three-month period ended June 30, 2020 increased by \$9.5 million to \$15.8 million as compared with \$6.2 million for the comparable period in 2019, primarily as a result of an increase of \$7.1 million in stock-based compensation in the current period, a combined increase in program costs and related labor costs of approximately \$2.6 million on our CG-806 and APTO-253 development programs, and offset by lower general and administrative expenses, after adjusting for stock option compensation, of \$185 thousand.

The net loss for the six-month period ended June 30, 2020 increased by \$15.6 million to \$27.3 million as compared with \$11.7 million for the comparable period, primarily as a result of an increase of \$10.9 million in stock-based compensation in the current period, a combined increase in program costs and related labor costs of approximately \$4.5 million on our CG-806 and APTO-253 development programs, and higher cash-based general and administrative expenses of \$384 thousand. These expenses were partially offset by an increase in net finance income of \$217 thousand in the current period compared to the comparative period, mostly as a result of higher interest earned on larger balances of cash equivalents and investments held during the six-month period ended June 30, 2020.

Research and Development

The research and development expenses for the three-month and six-month periods ended June 30, 2020 and 2019 were as follows:

(in thousands)	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Program costs – CG-806	\$ 3,755	\$ 1,678	\$ 6,700	\$ 3,064
Program costs – APTO-253	856	722	1,735	1,850
Personnel related expenses	1,317	925	2,620	1,624
Stock-based compensation	933	157	1,733	275
Depreciation of equipment	5	9	12	18
	\$ 6,866	\$ 3,491	\$ 12,800	\$ 6,831

Research and development expenses increased by \$3.4 million to \$6.9 million for the three-month period ended June 30, 2020 as compared with \$3.5 million for the comparative period. 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 CG-806 increased by approximately \$2.1 million, mostly as a result of higher manufacturing costs, including costs to scale up manufacturing and research costs associated with optimizing the formulation, higher costs associated with the CG-806 Phase 1a/b trial, and the costs associated with start-up for the CG-806 AML trial.
- Personnel-related expenses increased by \$392 thousand, mostly related to new positions hired since the second quarter of 2019 to support the conduct of the CC-806 Phase 1a/b and APTO-253 Phase 1b clinical trials, and start-up of the CG-806 AML Phase 1 a/b clinical trial.
- Stock-based compensation increased by approximately \$776 thousand in the three months ended June 30, 2020, compared with the three months ended June 30, 2019, mostly related to an increase in the number of options granted during the six months ended June 30, 2020 and a higher grant date fair value of options as compared with the six months ended June 30, 2019.

Research and development expenses increased by \$6.0 million to \$12.8 million for the six-month period ended June 30, 2020 as compared with \$6.8 million for the comparative period for the same reasons as described above for the three-month period ended June 30, 2020.

General and Administrative

The general and administrative expenses for the three-month and six-month periods ending June 30, 2020 and 2019 were as follows:

(in thousands)	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
General and administrative, excluding items below	\$ 2,214	\$ 2,399	\$ 4,479	\$ 4,095
Stock-based compensation	6,768	411	10,369	955

Depreciation of equipment	33	45	67	65
	\$ 9,015	\$ 2,855	\$ 14,915	\$ 5,115

General and administrative expenses for the three-month period ended June 30, 2020 were \$9.0 million as compared with \$2.9 million for the comparative period, an increase of approximately \$6.2 million. The increase was primarily as a result of the following:

- General and administrative expenses, other than stock-based compensation and depreciation of equipment, decreased by approximately \$185 thousand in the three months ended June 30, 2020, primarily as a result of lower financing costs in the current period, offset by 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 \$6.4 million in the three months ended June 30, 2020, compared with the three months ended June 30, 2019 mostly related to an increase in the number of restricted share units (RSUs) and options granted during the six-month period ended June 30, 2020, and a higher grant date fair value of options as compared with June 30, 2019.

General and administrative expenses for the six-month period ended June 30, 2020 were \$14.9 million as compared with \$5.1 million for the comparative period, an increase of approximately \$9.8 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 \$384 thousand in the six months ended June 30, 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 \$9.4 million in the six months ended June 30, 2020, compared with the six months ended June 30, 2019 for the same reasons as described above for the three-month period ended June 30, 2020.

COVID-19 did not have a significant impact on our results of operations for the quarter ended June 30, 2020; although the pandemic did necessitate reconfiguration of office space and the introduction of numerous policies and processes to ensure safety of employees and guests. We have not experienced and do not foresee material delays to the enrollment of patients or timelines for the CG-806 Phase 1a/b trial due to the variety of clinical sites that we have actively recruited for this trial. APTO-253 is administered intravenously, which 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. Monitoring across all ongoing and planned studies will be impacted by COVID-19, necessitating more remote visits versus on-site; risk-based monitoring plans will minimize the impact on deliverables. As of the date of this report, we have not experienced material delays in the manufacturing of CG-806 or APTO-253 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 June 30, 2020 today, Tuesday, August 4, 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 # 8367033. 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 # 8367033.

The press release, the financial statements and the management's discussion and analysis for the quarter ended June 30, 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

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, and has received an IND allowance to conduct a separate Phase 1 trial in patients with relapsed or refractory acute myeloid leukemia (AML); 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).

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, the CG-806 Phase 1 a/b B-cell malignancy, and Phase 1 a/b AML clinical trials, 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.

For further information, please contact:

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