

**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): March 23, 2021

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 March 23, 2021, 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 March 23, 2021](#)

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: March 23, 2021

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

Aptose Reports Results for the Fourth Quarter and Full Year 2020

- Conference call and webcast at 5pm EDT today -

- Company announces resignation of CFO Gregory Chow -

- Luxeptinib (CG-806) continues dose escalation and evidence of clinical activity -

SAN DIEGO and TORONTO, March 23, 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 year and three months ended December 31, 2020 and a corporate update.

The net loss for the quarter ended December 31, 2020 was \$14.7 million (\$0.17 per share) compared with \$7.7 million (\$0.13 per share) for the quarter ended December 31, 2019. The net loss for the year ended December 31, 2020 was \$55.2 million (\$0.67 per share), compared with \$26.3 million (\$0.52 per share) for the year ended December 31, 2019. Total cash and cash equivalents and investments as of December 31, 2020 were \$122.4 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.

“During 2020, Aptose executed on our three clinical trials which are now all well under way: two studies with our cluster selective kinase inhibitor luxeptinib (CG-806) and one with our MYC repressor APTO-253,” said William G. Rice, Ph.D., Chairman, President and Chief Executive Officer. “Dose escalation continues in each of these trials, and we and our investigators are encouraged by indicators of luxeptinib’s anti-cancer activity and safety profile. With APTO-253, we are observing consistent MYC repression, an indicator of activity that suggests future potential for broad oncology application. We look forward to providing the next complete data update at the 2021 EHA Virtual Congress.”

Separately, Aptose today announced that Gregory Chow, Executive Vice President and Chief Financial Officer, is resigning to pursue an opportunity at a private biopharma company. Dr. Rice will serve as Chief Accounting Officer and Jotin Marango, M.D., Ph.D., Chief Business Officer will assume Chief Financial Officer duties until a permanent replacement is announced. In addition, Aptose and Mr. Chow intend to enter into a consulting agreement that would become effective upon his departure on March 26, 2021. “It has been an honor and a pleasure to work with Greg,” said Dr. Rice. “Greg has been a trusted business partner and an integral part of the development of Aptose, and Greg departs Aptose on the best of terms and we are certain he will be successful in this next adventure.”

Key Corporate Highlights

- **“Luxeptinib” adopted as generic name for CG-806** – The United States Adopted Name (USAN) Council recently adopted “luxeptinib” as the generic name for Aptose’s lead drug candidate CG-806, an oral cluster-selective kinase inhibitor. Aptose will use “luxeptinib” for all future references of the drug, including in scientific publications and corporate materials. After April 1, 2021, the USAN information on luxeptinib will be posted on the USAN Web site (www.ama-assn.org/go/usan).
- **Luxeptinib Phase 1 a/b Clinical Study in AML** – In October 2020, Aptose announced dosing of the first patient with R/R acute myeloid leukemia (AML) in a Phase 1 a/b clinical study with luxeptinib, the only known clinical agent that potently inhibits both FLT3 and BTK, in addition to other driver kinases, giving it broad therapeutic potential across the spectrum of lymphoid and myeloid hematologic malignancies. Encouraging anti-leukemic activity has been observed at the first dose level of 450mg bid, including a patient with a complete response who remains on study after multiple cycles with no apparent safety signals. Aptose completed the 450 mg bid dose cohort, and has escalated to the 600 mg bid dose. Complete updated data will be presented at EHA in June. Currently, 6 U.S. sites are open for screening and enrolling patients for the study, and more information is available at www.clinicaltrials.gov (NCT04477291).
- **Luxeptinib Phase 1 a/b Clinical Study in B-cell Malignancies** – Aptose is treating patients at the fifth dose level of 750 mg BID in its Phase 1 a/b dose escalation study with luxeptinib in patients with B-cell malignancies, including chronic lymphocytic leukemia (CLL) and non-Hodgkin’s lymphomas (NHL), who have failed or are intolerant to current therapies. To date, Aptose has observed on-target activity, including inhibition of multiple oncogenic driver kinases, lymphocytosis and tumor reductions. As previously reported at the 2020 ASH Annual Meeting, encouraging benefit has been observed in a patient with follicular lymphoma who has been on luxeptinib for more than one year and remains on drug at this time. At the 750 mg dose, steady state plasma levels exceed 2 micromolar and to date we have observed no safety trends that we believe would prevent further dose escalation. Updated data will be presented at EHA in June. Currently, 30 U.S. sites are open for screening and enrolling patients for the study, and more information is available at www.clinicaltrials.gov (NCT03893682).
- **APTO-253 Phase 1 a/b Clinical Study in AML and MDS** – 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 hematologic malignancies. In the ongoing Phase 1 a/b clinical study of APTO-253 in patients with relapsed or refractory AML or high-risk MDS, Aptose has escalated dosing to the fifth dose level of 150 mg/ m2. APTO-253 treatment has demonstrated MYC repression, an indicator of activity that suggests future potential for broad oncology application. The investigational drug continues to be well tolerated with no evidence of drug-related adverse events, including no observed myelosuppression. More information is available at www.clinicaltrials.gov (NCT02267863).
- **Aptose Expansion of Senior Leadership Team** – Earlier this month, Aptose announced the appointment of George Melko, Pharm.D., as Vice President, Regulatory Affairs; and Robert Killion Jr., Ph.D. as Vice President, CMC. Dr. Melko brings more than 20 years of senior regulatory experience to Aptose, with a strong focus on oncology. Most recently he served as Vice President of Regulatory Affairs for biotechnology companies Tmunity Therapeutics and Tessa Therapeutics, which included developing regulatory strategy operations, policy and procedure design, serving as an FDA liaison and document preparation/submission. Dr. Killion has been named to the newly established position of Vice President of Chemistry, Manufacture and Control (CMC). Dr. Killion’s more than 20 years of CMC experience span roles in Relypsa, Gilead, Genentech, Roche and Syntex. The full press release can be accessed [here](#).

RESULTS OF OPERATIONS

A summary of the results of operations for the years ended December 31, 2020 and 2019 is presented below:

	Year ended December 31,	
(in thousands except per Common Share data)	2020	2019

Revenues	\$	—	\$	—
Research and development expenses		29,288		16,835
General and administrative expenses		26,480		10,022
Net finance income		530		580
Net loss	\$	(55,238)	\$	(26,277)
Unrealized gain/(loss) on securities available-for-sale		(18)		18
Total comprehensive loss	\$	(55,256)	\$	(26,259)
Basic and diluted loss per Common Share	\$	(0.67)	\$	(0.52)

Net loss of \$55.2 million for the year ended December 31, 2020 increased by approximately \$28.9 million as compared with \$26.3 million for the year ended December 31, 2019, primarily as a result of an increase of \$19.1 million in stock-based compensation in the current period, a combined increase in program costs and related labor costs of approximately \$9.8 million on our luxepitinib development program and higher cash-based general and administrative expenses of approximately \$549 thousand. These expenses were partially offset by lower costs of \$545 thousand on our APTO-253 development programs.

Research and Development Expenses

The research and development (“R&D”) expenses for the years ended December 31, 2020 and 2019 were as follows:

(in thousands)	Year ended December 31,	
	2020	2019
Program costs – luxepitinib	16,329	8,475
Program costs – APTO-253	3,632	4,177
Personnel expenses	5,590	3,679
Stock-based compensation	3,720	474
Depreciation of equipment	17	30
	\$ 29,288	\$ 16,835

R&D expenses increased by \$12.5 million to \$29.3 million for the year ended December 31, 2020 as compared with \$16.8 million for the comparative period in 2019. Changes to the components of our R&D expenses presented in the table above are primarily as a result of the following activities:

- Program costs for luxepitinib increased by approximately \$7.9 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 luxepitinib Phase 1a/b trial and the costs associated with the luxepitinib AML trial.
- Program costs for APTO-253 decreased by approximately \$545 thousand, mostly as a result of lower manufacturing costs and lower clinical trial costs related to the APTO-253 Phase 1a/b trial.
- Personnel-related expenses increased by \$1.9 million, mostly related to new positions hired since the second quarter of 2019 to support the luxepitinib Phase 1a/b and APTO-253 Phase 1a/b clinical trials and the luxepitinib AML Phase 1a/b clinical trial.
- Stock-based compensation increased by approximately \$3.2 million in the year ended December 31, 2020, compared with the year ended December 31, 2019, mostly related to an increase in the number of options granted during the year ended December 31, 2020 and a higher grant date fair value of options as compared with the year ended December 31, 2019, and a higher rate of forfeitures in the comparative period in 2019.

General and Administrative Expenses

The general and administrative expenses for the years ended December 31, 2020 and 2019 are as follows:

(in thousands)	Year ended December 31,	
	2020	2019
General and administrative, excluding items below:	\$ 8,627	\$ 8,078
Stock-based compensation	17,718	1,822
Depreciation of equipment	135	122
	\$ 26,480	\$ 10,022

General and administrative expenses for the year ended December 31, 2020 were approximately \$26.5 million as compared with \$10.0 million for the comparative period in 2019, an increase of approximately \$16.5 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 \$549 thousand in the year ended December 31, 2020 primarily as a result of higher personnel related costs, higher insurance costs and higher office administrative costs offset by lower financing costs and lower travel expenses.
- Stock-based compensation increased by approximately \$15.9 million in the year ended December 31, 2020, compared with the year ended December 31, 2019 mostly related to an increase in the number of restricted share units and options granted during the year ended December 31, 2020, and a higher grant date fair value of options as compared with December 30, 2019.

COVID-19 did not have a significant impact on our results of operations for the year ended December 31, 2020. We have not experienced and do not foresee material delays to the enrollment of patients or timelines for the luxepitinib Phase 1a/b trial due to the variety of clinical sites that we have actively recruited for this trial. Similarly, we do not expect our enrollment of the luxepitinib AML trial to be negatively impacted by COVID-19 as we plan to use a variety of clinical

sites for this trial as well. 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 luxetpinib 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 year and quarter ended December 31, 2020 today, Tuesday, March 23, 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 # 9179487. 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 # 9179487.

The press release, the financial statements and the management's discussion and analysis for the year and quarter ended December 31, 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: 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 and dose escalations, the clinical potential, anti-cancer activity, therapeutic potential and applications and safety profile of APTO-253 and luxetpinib, the APTO-253 Phase 1b, the luxetpinib Phase 1 a/b B-cell malignancy, and Phase 1 a/b AML clinical trials, upcoming updates regarding the clinical trials, the transition at the Chief Financial Officer level, the impact of COVID-19 on the Company and its activities 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.

For further information, please contact:

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