

**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): May 8, 2023

APTOSE BIOSCIENCES INC.

(Exact name of registrant as specified in its charter)

Canada
(State or Other Jurisdiction of Incorporation)

001-32001
(Commission File Number)

98-1136802
(I.R.S. Employer Identification No.)

251 Consumers Road, Suite 1105
Toronto, Ontario 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	Nasdaq Capital Market

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

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 May 8, 2023, 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 May 8, 2023](#)

Exhibit 104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: May 8, 2023

By: /s/ William G. Rice, Ph.D.
William G. Rice, Ph.D.
Chairman, President, and Chief Executive Officer

Aptose Reports Results for the First Quarter 2023

— *Tuspetinib Dose Escalation and Dose Exploration Trial Completed and Delivered Clinical Responses as Monotherapy Over Four Dose Levels in Very Difficult to Treat AML Patient Populations* —

— *Doublet of Tuspetinib and Venetoclax Dosing Underway for Relapsed/Refractory AML Patients in APTIVATE Expansion Trial* —

— *Brisk Enrollment of Tuspetinib Monotherapy and Doublet Arms in APTIVATE Expansion Trial; Early Clinical Activity Already Noted* —

— *Tuspetinib Superior Safety Profile Continues* —

— *Luxepetinib G3 Formulation Continuous Dosing is Ongoing* —

— *Conference Call and Webcast at 5:00 pm ET Today* —

SAN DIEGO and TORONTO, May 08, 2023 (GLOBE NEWSWIRE) -- Aptose Biosciences Inc. (“Aptose” or the “Company”) (NASDAQ: APTO, TSX: APS), a clinical-stage precision oncology company developing highly differentiated oral targeted agents to treat hematologic malignancies, today announced financial results for first quarter ended March 31, 2023, and provided a corporate update.

“Tuspetinib’s significant response rates among patients with relapsed or refractory acute myeloid leukemia (R/R AML) harboring difficult-to-treat adverse mutations, along with its favorable safety record, have driven investigator enthusiasm for our APTIVATE trial of tuspetinib and the rate of accrual in both the monotherapy and combination treatment arms has been brisk,” said William G. Rice, Ph.D., Chairman, President and Chief Executive Officer. “While it is still too early to report confirmed responses in the APTIVATE trial, it is moving in the right direction. We look forward to providing more color as data evolve, including an update during the EHA timeframe next month, and reporting more complete data later in the year. Also, the favorable safety record of tuspetinib continues, confirmed by our most recent safety review. Tuspetinib’s safety profile, especially the absence of prolonged myelosuppression in responding patients, coupled with its breadth of activity on diverse mutational subgroups of AML, may elevate tuspetinib to become the ideal drug for combination therapy in multiple lines of therapy.”

Key Corporate Highlights

- **Tuspetinib APTIVATE Expansion Trial** – In the APTIVATE Phase 1/2 clinical trial of tuspetinib, a once daily oral agent with a unique kinase targeting pattern being developed for the treatment of patients with R/R AML, the doublet combination treatment arm of tuspetinib with venetoclax (TUS/VEN) recently initiated dosing, has been well tolerated in patients during the early weeks of dosing, and early blast reductions have been observed. In parallel, patients were accrued rapidly to the APTIVATE monotherapy arm, which was designed to confirm tuspetinib activity in specific mutationally defined AML populations, including TP53-mutant patients and FLT3-mutant patients who have been failed by a prior FLT3 inhibitor. Aptose has a growing network of U.S. and international clinical sites up and running, and the APTIVATE trial expects to enroll up to 100 patients, inclusive of a large spectrum of the R/R AML population.
- **Tuspetinib Safety Review** – In a recent safety cut of more than 70 patients treated with tuspetinib to date, it continued to show a favorable safety record with no drug induced myelosuppression upon prolonged dosing in responding patients with only mild adverse events (AEs), no drug discontinuations from drug related toxicities, and no dose-limiting toxicities (DLTs) up to the dosage of 160 mg per day. The unique kinase targeting pattern of tuspetinib avoids many of the typical toxicities observed with other kinase inhibitors and has no drug related serious adverse events, drug-related deaths, no differentiation syndrome, no drug related QT prolongation and no observed muscle destruction. Aptose has identified a safe therapeutic range with a broad therapeutic window, spanning the dose levels of 40, 80, 120 and 160 milligrams.
- **Tuspetinib Dose Escalation and Exploration Arms of the Phase 1/2 Trial** – The Phase 1/2 clinical trial of tuspetinib dose escalation and exploration arms are complete, with more than 70 R/R AML patients having received once daily oral tuspetinib over a dosage range of 20 mg to 200 mg. Formal clinical responses spanning from complete remissions (CR) to CRs with partial hematologic recovery (CRh), incomplete platelet recovery (CRp), incomplete hematologic recovery (CRI), or partial remission (PR) were observed among R/R AML patients with adverse mutations and co-mutations in the RAS, TP53, FLT3, MLL, IDH, NPM1, DNMT3A, RUNX1 and various splicing factors, among other genes. Extensive dose exploration allowed identification of 40 mg, 80 mg, 120 mg, and 160 mg as safe and effective doses for the treatment of R/R AML patients and the selection of 80 mg as the planned recommended phase 2 dose (RP2D).
- **Luxepetinib “G3” Continuous Dosing** – Dosing of the G3 formulation of luxepetinib, an oral, lymphoid and myeloid kinase inhibitor, in the ongoing Phase 1 a/b clinical trial in patients with R/R AML continues. Pharmacokinetic (PK) data show the 50 mg dose of luxepetinib G3 enables greater absorption relative to the original G1 formulation and delivers roughly equivalent exposures to 900 mg of the G1 formulation. If findings continue as anticipated, Aptose plans to escalate the dose of G3 and seek a dose with robust safety and higher exposure levels.

Expected Milestones

- End of Phase 1 (EOP1) meeting with U.S. Food and Drug Administration (FDA) – Scheduled to ensure agreement on tuspetinib clinical study parameters and next steps (2Q 2023)
- European Hematology Association (EHA) 2023 Congress – Plan to present clinical findings circa EHA to include tuspetinib dose escalation/exploration findings in R/R AML patients and early/preliminary findings in patients dosed with monotherapy (TUS) and doublet (TUS/VEN) in the APTIVATE Trial (June 2023)
- European School of Haematology (ESH) Meeting – Plan to present more mature tuspetinib clinical data set (October 2023)

- 65th American Society of Hematology (ASH) Annual Meeting & Exposition – Plan to present more robust clinical data set with tuspetinib at the (December 2023)
- Year-end 2023 – Plan to discuss strategies for potential future monotherapy accelerated development, doublet phase 2 development, and triplet pilot development (4Q 2023)

FINANCIAL RESULTS OF OPERATIONS

Aptose Biosciences, Inc.
Statements of Operations Data
(unaudited)
(\$ in thousands, except per share data)

	Three months ended	
	March 31, 2023	March 31, 2022
Expenses:		
Research and development	\$ 8,811	\$ 7,393
General and administrative	5,285	4,107
Operating expenses	14,096	11,500
Other income, net	420	19
Net loss	\$ (13,676)	\$ (11,481)
Net Loss per share, Basic and diluted	\$ (0.15)	\$ (0.12)
Weighted average number of common shares outstanding used in computing net loss per share, basic and diluted (in thousands)	92,562	92,226

The net loss for the three months ended March 31, 2023, was \$13.7 million (\$0.15 per share) compared with \$11.5 million (\$0.12 per share) for the three months ended March 31, 2022.

The increase in net loss for the three months ended March 31, 2023, compared with the three months ended March 31, 2022, was primarily a result of an increase in research and development costs of \$1.4 million and an increase in general and administrative costs of \$1.2 million, offset in part by an increase in interest income of \$0.4 million.

Aptose Biosciences, Inc.
Balance Sheet Data
(unaudited)
(\$ in thousands)

	March 31, 2023	December 31, 2022
Cash, cash equivalents and short-term investments	\$ 35,720	\$ 46,959
Working capital	25,510	37,235
Total assets	39,330	51,027
Long-term liabilities	918	1,002
Accumulated deficit	(478,006)	(464,330)
Stockholders' equity	25,993	37,741

- Total cash and cash equivalents and investments as of March 31, 2023, were \$35.7 million. Based on current operations, the Company expects that cash on hand and available capital provide the Company with sufficient resources to fund planned Company operations including research and development through March of 2024.
- Common shares outstanding on May 8, 2023, were 93,653,662.

RESEARCH AND DEVELOPMENT EXPENSES

The research and development expenses for the three months ended March 31, 2023, and 2022 were as follows:

(in thousands)	Three months ended March 31,	
	2023	2022
Program costs – Tuspetinib	\$ 4,774	\$ 1,178
Program costs – Luxeptinib	1,289	2,830
Program costs – APTO-253	8	91
Personnel related expenses	2,078	2,334
Stock-based compensation	652	946
Depreciation of equipment	10	14
Total	\$ 8,811	\$ 7,393

Research and development (“R&D”) expenses increased by \$1.4 million to \$8.8 million for the three months ended March 31, 2023, as compared with \$7.4 million for the comparative period in 2022. Changes to the components of our R&D expenses are primarily as a result of the following activities:

- Program costs for tuspentinib were \$4.8 million for the three-month period ended March 31, 2023. The Company in-licensed the development rights of tuspentinib in the fourth quarter of 2021 and assumed sponsorship, and the related costs, of the study effective January 1, 2022. The higher program costs for tuspentinib in the current period represent the enrollment of patients in our APTIVATE clinical trial, our healthy volunteer trial, and related expenses.
- Luxeptinib program costs decreased by approximately \$1.5 million, primarily due to lower manufacturing costs as a result of the current G3 formulation requiring less API than the prior formulation, partially offset by higher clinical trial costs, mostly related to higher contractor costs to support the trials.
- Program costs for APTO-253 decreased by approximately \$83 thousand due to the Company's decision on December 20, 2021 to discontinue further development of APTO-253.
- Stock-based compensation decreased by approximately \$294 thousand in the three months ended March 31, 2023, compared to the three months ended March 31, 2022, primarily due to stock options granted with lower grant date fair values, in the current period.

Conference Call & Webcast:

Date: Monday, May 8, 2023

Time: 5:00 PM ET

Audio Webcast Only: [link](#)

Q&A Participant Registration Link*: [here](#)

<https://register.vevent.com/register/B10c4e6d84e0b848f79be80dfa78e465bd>

*Analysts interested in participating in the question-and-answer session will pre-register for the event from the participant registration link above to receive the dial-in numbers and a unique PIN, which are required to access the conference call. They also will have the option to take advantage of a Call Me button and the system will automatically dial out to connect to the Q&A session.

The audio webcast also can be accessed through a link on the Investor Relations section of Aptose’s website [here](#). A replay of the webcast 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 March 31, 2023 will be available on SEDAR at www.sedar.com and EDGAR at www.sec.gov/edgar.shtml.

About Aptose

Aptose Biosciences is a clinical-stage biotechnology company committed to developing precision medicines 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 oral kinase inhibitors under development for hematologic malignancies: tuspentinib (HM43239), an oral, myeloid kinase inhibitor being studied as monotherapy and in combination therapy in the APTIVATE international Phase 1/2 expansion trial in patients with relapsed or refractory acute myeloid leukemia (AML); and luxeptinib (CG-806), an oral, dual lymphoid and myeloid kinase inhibitor in Phase 1 a/b stage development for the treatment of patients with relapsed or refractory hematologic malignancies. For more information, please visit 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, the clinical potential, anti-cancer activity, therapeutic potential and applications and safety profile of tuspentinib and luxeptinib, the APTIVATE clinical trial, patient enrollment, the luxeptinib Phase 1 a/b clinical trials and the upcoming milestones of such trials, the development and clinical potential of a new formulation (G3) for luxeptinib, upcoming updates regarding the 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 current reports, 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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