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 14, 2024

APTOSE BIOSCIENCES INC.

(Exact name of registrant as specified in its charter)

Canada	**001-32001**	**98-1136802**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

251 Consumers Road, Suite 1105
Toronto, Ontario M2J 4R3
Canada
(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 14, 2024, 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.

99.1	Press Release dated May 14, 2024
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 14, 2024

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

EXHIBIT 99.1

Aptose Reports Results for the First Quarter 2024

- *TUS+VEN+HMA Triplet Protocol in 1L Therapy for Newly Diagnosed AML was Submitted to the FDA During Q1 and is Now Being Activated at Clinical Sites*
- *TUS+VEN+HMA Triplet 1L Therapy for Newly Diagnosed AML is Supported by Extensive TUS and TUS+VEN Data from Completed Trials with R/R AML*
- *Conference Call and Webcast at 5:00 pm ET Today*

SAN DIEGO and TORONTO, May 14, 2024 (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 the first quarter ended March 31, 2024. The Company will provide a corporate update webcast at 5:00 pm ET today, which will include slides focused on the new triplet pilot study expected to deliver clinical data in the second half of this year.

"Tuspetinib (TUS) has now moved to triplet frontline (1L) treatment for newly diagnosed (ND) acute myeloid leukemia (AML) patients who need a superior 1L therapy. The introduction of venetoclax (VEN) to establish the venetoclax/hypomethylating agent (VEN+HMA) doublet was a major advancement in the frontline treatment of ND AML, but response rates still remain too low and survival too short in 1L therapy. Even more concerning, patients who fail a VEN-containing regimen respond poorly to subsequent salvage therapies in the relapsed or refractory (R/R) setting and have a dismal prognosis," said William G. Rice, Ph.D., Chairman, President and Chief Executive Officer of Aptose. "Our solution is the addition of TUS to VEN-HMA to increase response rates, prolong survival, safely improve quality of life, treat a broad spectrum of AML genetic subpopulations, and prevent ND AML patients from becoming resistant to VEN. We're delighted to have an active protocol to initiate this pilot clinical study and look forward to sharing initial TUS+VEN+HMA triplet data before year-end."

Key Corporate Highlights

- **Tuspetinib Advancement to TUS+VEN+HMA Triplet Therapy Supported by Extensive Dose Exploration as TUS Single Agent and TUS+VEN Doublet** – Tuspetinib, a convenient once daily oral agent that potently targets SYK, FLT3, mutated KIT, JAK1/2, and RSK2 kinases, is being developed for the treatment of patients with ND AML. Tuspetinib avoids many typical toxicities observed with other agents, showing no treatment related QTc prolongation or CPK elevations; no differentiation syndrome; and no drug-related myelosuppression during remission with no drug-related discontinuations or deaths. In the APTIVATE trial, Tuspetinib achieved broad activity across AML patients with a diversity of adverse genetics as a single agent (TUS) and in combination with venetoclax (TUS+VEN) in very ill relapsed/refractory (R/R) and heavily pre-treated AML populations. Blast reductions and responses were observed in patients with Prior-VEN, Prior-FLT3 inhibitor (FLT3i), and Prior-HSCT therapies, those with highly adverse genetics, including mutations in TP53 and RAS genes, and those with mutated or unmutated FLT3 genes. Patients naïve to VEN therapy achieved higher response rates.

- **Tuspetinib Protocol Now Ready for Triplet Therapy Pilot Study; Clinical Sites Being Activated** – Tuspetinib is the ideal third agent for a 1L triplet because of its distinctly favorable safety profile. Tuspetinib enhances antileukemic activity when combined with VEN or HMA in pre-clinical models, Tuspetinib has demonstrated a broad scope of activity across genetic subgroups of AML, and Tuspetinib mechanistically cooperates with VEN to thwart drug resistance. The protocol was submitted to the U.S. Food and Drug Administration (FDA) in Q1, more than 45 days ago, and is currently being activated at clinical sites to initiate the TUS+VEN+AZA triplet pilot study. The new study will enroll ND AML patients who are ineligible to receive intensive induction chemotherapy due to age or co-morbidity. By definition, study participants will be VEN-naïve, FLT3i-naïve, and HMA-naïve, a group that has been shown to be highly responsive to triplet regimens. However, current triplet therapies containing kinase inhibitors can be limited by toxicities often requiring dose reductions of all three agents and are not being pursued in the larger FLT3-unmutated AML population. Clinical sites are now preparing to open the TUS+VEN+HMA triplet study, which is expected to commence enrollment early next quarter. Initial data are expected in the fourth quarter of this year.

- **Tuspetinib Abstract Accepted for Poster Presentation at EHA** – Aptose will deliver a clinical poster presentation at the European Hematology Association (EHA) 2024 Hybrid Congress in Madrid, Spain (Poster ID # P557) that describes the safety and efficacy of tuspetinib (TUS) monotherapy and the TUS+VEN doublet in the APTIVATE Phase 1/2 trial with R/R AML patients. The data illustrate the safety and breadth of activity of TUS and TUS+VEN and support our launch of the TUS+VEN+HMA triplet frontline therapy in newly diagnosed AML. A separate preclinical abstract, which has been accepted for e-poster publication, demonstrates that TUS retains nanomolar potency against AML cells engineered to express the NRAS-G12D mutation or selected for resistance to venetoclax (Poster ID # P1756).

- **Tuspetinib Preclinical Studies Elucidate Mechanistic Cooperativity Among TUS and VEN** – Aptose continues to investigate the mechanisms underlying the complementary activity between TUS and VEN. In addition to targeting certain VEN resistance mechanisms, TUS retains activity against VEN-resistant AML cell lines. Likewise, resistance to TUS creates a synthetic lethality for VEN with a 2000-fold increase in sensitivity to VEN. Other studies demonstrate TUS retains potent antitumor activity in preclinical models of human AML resistant to the gilteritinib FLT3 inhibitor (FLT3i), a finding that is clinically validated by response rates to TUS in R/R AML study participants with prior FLT3i treatment.

- **Nasdaq** – On February 29, 2024, Aptose received a deficiency letter from the Listings Qualifications Department of The Nasdaq Stock

Market LLC ("**Nasdaq**") regarding the previously announced private placement with Hanmi Pharmaceutical, Inc. ("**Hanmi**") which closed in January 2024. In response to the deficiency letter, Aptose submitted a plan to Nasdaq to regain compliance. On April 25, 2024, the Company received confirmation from Nasdaq that the Company had regained compliance with Nasdaq Listing Rule 5635(d) and determined that the matter is now closed. Pursuant to the Company's plan to regain compliance, on April 26, 2024, the Company announced that it had amended the terms of the warrant agreement with Hanmi to prohibit the exercise of the warrants if such exercise would result in Hanmi owning more than 19.99% of the issued and outstanding shares of Aptose, unless shareholder approval is first obtained.

- On April 2, 2024, Aptose received a second Notification Letter from Nasdaq stating that the Company was not in compliance with Nasdaq's listing rules because the stockholders' equity as of December 31, 2023, was below the minimum requirement of $2.5 million. The shareholder's equity as of December 31, 2023 was negative $2.9 million. As of March 31, 2024, the shareholder's equity is $137,000, positive. Aptose intends to submit a compliance plan on or before May 17, 2024, to monitor stockholders' equity and, if appropriate, consider further available options to evidence compliance with the requirement.

Multiple Planned Value-creating Milestones Ahead

- TUS and TUS+VEN data in R/R AML to support TUS+VEN+HMA in ND AML: EHA 2024
- Triplet pilot dose initiation planned in ND AML: Summer 2024
- Triplet pilot dose escalation planned with early CR/MRD/safety data in ND AML: ASH 2024
- Triplet pilot completed with CR/MRD data and dose selection: EHA 2025
- Triplet Ph2/Ph3 pivotal program planned initiation: 2H 2025

FINANCIAL RESULTS OF OPERATIONS

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

	Three months ended	
	March 31, 2024	March 31, 2023
Expenses:		
Research and development	$ 6,445	$ 8,811
General and administrative	3,315	5,285
Operating expenses	9,760	14,096
Other income, net	120	420
Net loss	$ (9,640)	$ (13,676)
Net Loss per share, Basic and diluted	$ (0.73)	$ (2.22)
Weighted average number of common shares outstanding used in computing net loss per share, basic and diluted (in thousands)	13,133	6,171

The net loss for the three months ended March 31, 2024, was $9.6 million ($0.73 per share) compared with $13.7 million ($2.22 per share) for the three months ended March 31, 2023.

The decrease in net loss for the three months ended March 31, 2024, compared with the three months ended March 31, 2023, was primarily a result of a decrease in research and development costs of $2.4 million, a decrease in general and administrative costs of $2.0 million, and a decrease in interest income of $0.3 million.

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

	March 31, 2024	December 31, 2023
Cash, cash equivalents and short-term investments	$ 9,328	$ 9,252
Working capital	(318)	(3,375)

Total assets	12,796	12,989
Long-term liabilities	520	621
Accumulated deficit	(525,177)	(515,537)
Stockholders' equity	137	(2,901)

- Total cash and cash equivalents and investments as of March 31, 2024, were $9.3 million. Based on current operations, the Company expects that cash on hand and available capital provides the Company with sufficient resources to fund planned Company operations including research and development through August of 2024.

- Common shares outstanding on May 14, 2024, were 16,309,393.

RESEARCH AND DEVELOPMENT EXPENSES

The research and development expenses for the three months ended March 31, 2024, and 2023 were as follows:

	Three months ended March 31,	
(in thousands)	2024	2023
Program costs – Tuspetinib	$ 3,923	$ 4,774
Program costs – Luxeptinib	208	1,289
Program costs – APTO-253	22	8
Personnel related expenses	1,954	2,078
Stock-based compensation	328	652
Depreciation of equipment	10	10
Total	$ 6,445	$ 8,811

Research and development ("R&D") expenses decreased by $2.4 million to $6.4 million for the three months ended March 31, 2024, as compared with $8.8 million for the comparative period in 2023. Changes to the components of our R&D expenses are primarily as a result of the following activities:

- Program costs for tuspetinib were $3.9 million for the three-month period ended March 31, 2024, compared with $4.7 million in the comparative period in 2023. The lower program costs for tuspetinib in the current period represent the near completion of our APTIVATE clinical trials, and reduced manufacturing costs. In the comparative period in 2023, tuspetinib program costs included the healthy volunteer study, which was completed in 2023.

- Luxeptinib program costs were $208,000 and decreased by approximately $1.1 million, primarily due to lower clinical trial and manufacturing costs associated with the conclusion of certain luxeptinib clinical trial activities.

- Program costs for APTO-253 were $22,000. The Company decided on December 20, 2021 to discontinue further development of APTO-253.

- Stock-based compensation decreased by approximately $324,000 in the three months ended March 31, 2024, compared to the three months ended March 31, 2023, primarily due to stock options granted with lower grant date fair values, in the current period.

Conference Call & Webcast:

Date:	Tuesday, May 14, 2024
Time:	5:00 PM ET
Webcast Only (will include slides):	**link** (https://edge.media-server.com/mmc/p/bm3d3k5a/)
Q&A Participant Registration Link*:	**link** (https://register.vevent.com/register/BIebf7d306b67a4388b6a8d9cc63464f80)

*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 live 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 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, 2024 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: tuspetinib (TUS), an oral, kinase inhibitor that has demonstrated activity as a monotherapy and in combination therapy in patients with relapsed or refractory acute myeloid leukemia (AML) and is being developed as a frontline triplet therapy in newly diagnosed 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 Company's clinical development plans, the clinical potential, anti-cancer activity, therapeutic potential and applications and safety profile of tuspetinib, clinical trials, the enrollment in clinical trials and the data therefrom, timing of submitting a compliance plan to Nasdaq, upcoming milestones, expectations regarding capital available to the Company to fund planned Company 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; unexpected manufacturing defects 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.

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