

**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 8, 2024

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.)

**66 Wellington Street West, Suite 5300
TD Bank Tower, Box 48
Toronto, Ontario M5K 1E6
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	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 (§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 August 8, 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 August 8, 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: August 8, 2024

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

Aptose Reports Results for the Second Quarter 2024

- *TUS+VEN+HMA Triplet Protocol in Frontline Therapy for Newly Diagnosed AML was Reviewed by the FDA and Allowed to Proceed*
- *Abstract Supporting Exploration of the TUS+VEN+AZA Triplet in Frontline Therapy for Newly Diagnosed AML has been Submitted to the 2025 Annual Meeting of the American Society of Hematology (ASH)*

SAN DIEGO and TORONTO, Aug. 08, 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 three months ended June 30, 2024, and provided a corporate update.

“We are pleased that our triplet protocol of tuspentinib with venetoclax and azacitidine (TUS+VEN+AZA) has been allowed to proceed at the 40 mg dose of tuspentinib, a dose that as a single agent and in doublet therapy has been shown to be safe and active,” said William G. Rice, Ph.D., Chairman, President and Chief Executive Officer of Aptose. “We – along with our board and outside scientific advisors – strongly believe tuspentinib is an ideal drug for frontline triplet therapy and we remain committed to securing financing to pursue its development for the newly diagnosed AML patient population in desperate need of an improved frontline therapy.”

Key Corporate Highlights

- **Tuspentinib Protocol Now Ready for Triplet Therapy Study** – Aptose’s company-sponsored phase 1/2 TUS+VEN+AZA triplet study is designed to test tuspentinib in combination with standard of care dosing of azacitidine and venetoclax as frontline therapy in newly diagnosed AML patients unfit for chemotherapy. The planned study will dose VEN-naïve, FLT3i-naïve, and HMA-naïve patients, a group expected to be highly responsive to the TUS+VEN+AZA triplet regimen. Current triplet therapies containing kinase inhibitors can be limited by toxicities often requiring dose reductions of all three agents and may not be effective in the larger FLT3-unmutated AML population. The U.S. Food and Drug Administration (FDA) has allowed TUS to be administered as part of the triplet at 40 mg daily, at an initial dose shown active as a single agent in relapsed or refractory AML patients.
- **ASH Abstract** – On July 31, 2024, Aptose submitted an abstract for presentation at the 2025 Annual Meeting of the American Society of Hematology (ASH) in December 2024. Lead author Navel Daver, MD, University of Texas MD Anderson Cancer Center, Houston, TX and research team explore the safety and efficacy results that support the upcoming combination study of TUS+VEN+AZA as a triplet drug combination frontline therapy in newly diagnosed AML patients ineligible for intensive chemotherapy, independent of FLT3 mutation status, which is an important differentiator for tuspentinib.
- **Nasdaq** – On July 19, 2024, Aptose announced that it had received a deficiency letter (the “Deficiency Letter”) from the Nasdaq Listing Qualifications Department of The Nasdaq Stock Market LLC (“Nasdaq”) notifying the Company that, for the last thirty (30) consecutive business days, the closing bid price for the Company's common shares had been below the minimum \$1.00 per share required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the “Minimum Bid Price Requirement”). The Deficiency Letter has no immediate effect on the listing of the Company's common shares, and its common shares will continue to trade on The Nasdaq Capital Market under the symbol “APTO” at this time. The Company's common shares continue to trade on the Toronto Stock Exchange (“TSX”) under the symbol “APS”. The Company's listing on the TSX is independent and will not be affected by the Nasdaq listing status.

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has been given one hundred and eighty (180) calendar days, or until January 10, 2025, to regain compliance with the Minimum Bid Price Requirement. If at any time before January 10, 2025, the bid price of the Company's common shares closes at \$1.00 per share or more for a minimum of ten (10) consecutive business days, the Staff will provide written confirmation that the Company has achieved compliance. If the Company does not regain compliance with the Minimum Bid Price Requirement by January 10, 2025, the Company may be afforded a second one hundred and eighty (180) calendar day period to regain compliance. The Company intends to monitor the closing bid price of its common shares and may, if appropriate, consider available options to regain compliance with the Minimum Bid Price Requirement. However, there can be no assurance that the Company will be able to regain compliance with the Minimum Bid Price Requirement or will otherwise be in compliance with other Nasdaq Listing Rules.

Multiple Planned Value-creating Milestones Ahead

- Frontline therapy triplet pilot dose initiation planned in newly diagnosed (ND) AML: 2H 2024
- Triplet pilot dose escalation planned with early 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 June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Expenses:				
Research and development	\$ 4,413	\$ 10,582	\$ 10,858	\$ 19,393
General and administrative	2,932	3,870	6,247	9,155
Operating expenses	7,345	14,452	17,105	28,548
Other income, net	93	323	213	743
Net loss	\$ (7,252)	\$ (14,129)	\$ (16,892)	\$ (27,805)
Net Loss per share, Basic and diluted	\$ (0.43)	\$ (2.27)	\$ (1.13)	\$ (4.47)
Weighted average number of common shares outstanding used in computing net loss per share, basic and diluted (in thousands)	16,755	6,234	14,944	6,219

Net loss for the three-month period ended June 30, 2024 decreased by \$6.9 million to \$7.3 million, as compared to \$14.1 million for the comparable period in 2023. Net loss for the six-month period ended June 30, 2024 decreased by \$10.9 million to \$16.9 million, as compared to \$27.8 million for the comparable period in 2023. Components of net loss are presented below:

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

	June 30, 2024	December 31, 2023
Cash, cash equivalents and short-term investments	\$ 8,330	\$ 9,252
Working capital	(2,552)	(3,375)
Total assets	10,949	12,989
Long-term liabilities	414	621
Accumulated deficit	(532,429)	(515,537)
Stockholders' equity	(2,176)	(2,901)

- Total cash and cash equivalents and investments as of June 30, 2024, were \$8.3 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.
- As of August 8, 2024, we had 18,109,393 Common Shares issued and outstanding. In addition, there were 1,347,002 Common Shares issuable upon the exercise of outstanding stock options and there were 18,341,491 Common Shares issuable upon the exercise of the outstanding warrants.

RESEARCH AND DEVELOPMENT EXPENSES

The research and development expenses for the three months and six months ended June 30, 2024, and 2023 were as follows:

(in thousands)	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Program costs – Tuspentinib	\$ 2,666	\$ 8,070	\$ 6,589	\$ 12,845
Program costs – Luxeptinib	304	706	512	1,995
Program costs – APTO-253	(9)	19	13	26

Personnel related expenses	1,379	1,506	3,333	3,584
Stock-based compensation	70	271	398	924
Depreciation of equipment	3	10	13	19
Total	\$ 4,413	\$ 10,582	\$ 10,858	\$ 19,393

Research and development expenses decreased by \$6.2 million to \$4.4 million for the three-month period ended June 30, 2024, as compared to \$10.6 million for the comparative period in 2023. 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 tuspetinib were \$2.7 million for the three-month period ended June 30, 2024, compared with \$8.1 million for the comparative period in 2023. The lower program costs for tuspetinib in the current period represent the reduction of activity in our APTIVATE clinical trial, reduced manufacturing costs, and related expenses. In the comparative period in 2023, tuspetinib program costs included the healthy volunteer study, which was completed in 2023.
- Program costs for luxepitinib decreased by approximately \$402 thousand, primarily due to lower clinical trial and manufacturing activities.
- Program costs for APTO-253 decreased by approximately \$28 thousand. The Company discontinued further clinical development of APTO-253.
- Personnel-related expenses decreased by \$127 thousand, related to fewer employees in the current three-month period, partially offset by salary increases.
- Stock-based compensation decreased by approximately \$201 thousand in the three months ended June 30, 2024, compared to the three months ended June 30, 2023, primarily due to stock options granted with lower grant date fair values in the current period.

Research and development expenses decreased by \$8.5 million to \$10.9 million for the six-month period ended June 30, 2024, as compared to \$19.4 million for the comparative period in 2023. 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 tuspetinib were \$6.6 million for the six-month period ended June 30, 2024, a decrease of \$6.3 million compared with \$12.8 million for the comparative period in 2023. The lower program costs for tuspetinib in the current period represent the reduction of activity in our APTIVATE clinical trial, reduced manufacturing costs, and related expenses. In the comparative period in 2023, tuspetinib program costs included the healthy volunteer study, which was completed in 2023.
- Program costs for luxepitinib decreased by approximately \$1.5 million to \$512 thousand for the six months ended June 30, 2024, as compared to \$2.0 million in the comparative period, primarily due to lower clinical trial and manufacturing activities.
- Program costs for APTO-253 decreased by approximately \$13 thousand, due to the Company's decision on December 20, 2021 to discontinue further clinical development of APTO-253.
- Personnel-related expenses decreased by \$251 thousand, related to fewer employees in the current six-month period and partially offset by salary increases.
- Stock-based compensation decreased by approximately \$526 thousand in the six months ended June 30, 2024, compared to the six months ended June 30, 2023, primarily due to stock options granted with lower grant date fair values, in the current period.

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's lead clinical-stage compound tuspetinib (TUS), is 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. 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, the submission of a compliance plan to Nasdaq and available options to regain compliance, upcoming milestones, financing activities, expectations regarding capital available to the Company to fund planned Company operations, maintenance of the Nasdaq and TSX listings 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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