

**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): November 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 November 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 November 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: November 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 Third Quarter 2024

Aptose and Hanmi Pharmaceutical Co-developing Triplet Therapy of Tuspentinib with Azacitidine and Venetoclax for Newly Diagnosed AML

SAN DIEGO and TORONTO, Nov. 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 September 30, 2024, and provided a corporate update.

"Triple drug therapies (triplets) that build on the standard of care in AML have yielded higher response rates yet are limited to specific subpopulations and often cause myelosuppression and other toxicities," said William G. Rice, Ph.D., Chairman, President and Chief Executive Officer of Aptose. "Tuspentinib, with its breadth of activity and unique safety profile, is a potential game-changer as part of a triplet therapy regimen and we continue to advance its development."

Key Corporate Highlights

- **Aptose Facility Agreement with Hanmi** – During the quarter, Aptose announced that it received a \$10 million loan through a Facility Agreement with Hanmi Pharmaceutical Co. ("Hanmi"), and that the companies are actively negotiating a new tuspentinib co-development collaboration agreement intended to provide additional support to accelerate the clinical development of tuspentinib. The loan is convertible as prepayment of milestone obligations under the future collaboration agreement or repayable after the expected completion of a triple drug combination trial with tuspentinib in newly diagnosed AML patients. Aptose plans to use the proceeds from such loan for the development of tuspentinib.
- **Tuspentinib Data Drives Interest as Treatment Paradigm for AML Shifts to Triplet Therapy** – During our APTIVATE trial, tuspentinib (TUS) as a monotherapy and in combination treatment with venetoclax in a very ill AML patient population safely demonstrated broad clinical activity in AML patients with diverse mutation profiles, including those with adverse genetics. As presented at the European Hematology Association (EHA) 2024 Congress in June, tuspentinib potently targets SYK, FLT3, mutated KIT, JAK1/2, and RSK2 kinases, yet avoids many typical toxicities, drug-related discontinuations, and deaths observed with other agents. In the APTIVATE trial, TUS achieved broad activity across AML patients with a diverse array of mutations, both 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. 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 (wildtype) FLT3 genes. Patients naïve to VEN therapy achieved higher response rates. TUS appears to be an ideal third agent to add to a venetoclax and hypomethylating agent regimen. These data support the launch of the triplet therapy trial in newly diagnosed AML patients who are ineligible to receive induction chemotherapy, irrespective of their FLT3 mutation status. Other triplet therapies in development can achieve high response rates but are limited by toxicities and inability to treat certain AML populations, leaving an unmet need that may be addressed with the addition of tuspentinib. With Hanmi's support, Aptose plans to initiate its planned triplet combination study during the quarter and to treat patients with and without FLT3 mutations. In addition, the company is evaluating other co-development opportunities to further expand the role of tuspentinib in other settings.
- **Nasdaq** – Aptose has a scheduled meeting with the Nasdaq Listing Qualifications during the current quarter to address compliance with the minimum requirement of \$2.5 million in stockholders' equity (the "Stockholders' Equity Requirement") and Aptose continues to work on its compliance with minimum \$1.00 per share closing bid price for thirty (30) consecutive business days, needed for continued listing on Nasdaq (the "Minimum Bid Price Requirement").

On April 2, 2024, the Company received a deficiency letter from Nasdaq stating that the Company was not in compliance with the Stockholders' Equity Requirement. The Company submitted a Compliance Plan to Nasdaq on this issue on May 17, 2024 and received an extension to meet this Nasdaq requirement by September 30, 2024. On October 1, 2024, the Company received a letter from Nasdaq stating that the Company did not meet the terms of the extension because it did not complete its proposed financing initiatives to regain compliance. On October 8, 2024, the Company requested an appeal and hearing; such hearing is scheduled for November 21, 2024.

On July 16, 2024, Aptose announced that it had received a deficiency letter notifying the Company that was not in compliance with the Minimum Bid Price Requirement. This 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 13, 2025, to regain compliance with the Minimum Bid Price Requirement. If the Company does not regain compliance with the Minimum Bid Price Requirement by January 13, 2025, the Company may, at Nasdaq's discretion, be afforded a second one hundred and eighty (180) calendar day period to regain compliance, but if Nasdaq does not grant such extension, the Company's common shares could be delisted from Nasdaq.

Multiple Planned Value-creating Milestones Ahead

2024: Q4

- Initiate dosing of TUS+VEN+AZA triplet in newly diagnosed AML
- Completion of Hanmi/Aptose Collaboration ~ Year-end 2024

2024: ASH

- Report CR/Safety data from APTIVATE TUS+VEN doublet study
- Report dosing accrual from TUS+VEN+AZA triplet study

2025: 1H

- Enroll two dose cohorts in TUS+VEN+AZA triplet study
- Report CR/MRD/Safety data from TUS+VEN+AZA triplet study

2025: EHA

- Report maturing data readout from TUS+VEN+AZA triplet study

2025: ASH

- Select TUS dose for TUS+VEN+HMA triplet Ph 2/3 PIVOTAL trials
- Prepare for Ph 2 portion of Ph 2 / Ph 3 pivotal program

FINANCIAL RESULTS OF OPERATIONS

Aptose Biosciences Inc.
Statements of Operations Data
(unaudited)

(\$ in thousands, except per share data)

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2024	2023	2024	2023
Expenses:				
Research and development	\$ 4,702	\$ 8,256	\$ 15,560	\$ 27,649
General and administrative	2,263	3,425	8,510	12,580
Operating expenses	6,965	11,681	24,070	40,229
Other income, net	12	234	225	977
Net loss	\$ (6,953)	\$ (11,447)	\$ (23,845)	\$ (39,252)
Net Loss per share, Basic and diluted	\$ (0.37)	\$ (1.76)	\$ (1.48)	\$ (6.14)
Weighted average number of common shares outstanding used in computing net loss per share, basic and diluted (in thousands)	18,560	6,495	16,107	6,391

Net loss for the three-month period ended September 30, 2024 decreased by \$4.5 million to \$7.0 million, as compared to \$11.4 million for the comparable period in 2023. Net loss for the nine-month period ended September 30, 2024 decreased by \$15.5 million to \$23.8 million, as compared to \$39.3 million for the comparable period in 2023.

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

	September 30,	December 31,
	2024	2023
Cash, cash equivalents and short-term investments	\$ 7,962	\$ 9,252
Working capital	477	(3,375)
Total assets	10,929	12,989
Long-term liabilities	10,305	621
Accumulated deficit	(539,382)	(515,537)
Stockholders' equity	(9,134)	(2,901)

- Total cash and cash equivalents and investments as of September 30, 2024, were \$8 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 to January 2025.

- As of November 8, 2024, we had 19,521,183 Common Shares issued and outstanding. In addition, there were 1,212,355 Common Shares issuable upon the exercise of outstanding stock options and there were 16,946,491 Common Shares issuable upon the exercise of the outstanding warrants.

RESEARCH AND DEVELOPMENT EXPENSES

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

(in thousands)	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Program costs – Tuspentinib	\$ 4,067	\$ 5,814	\$ 10,656	\$ 18,659
Program costs – Luxeptinib	(225)	648	287	2,643
Program costs – APTO-253	-	2	13	28
Personnel related expenses	941	1,523	4,274	5,108
Stock-based compensation	(81)	259	317	1,182
Depreciation of equipment	-	10	13	29
Total	\$ 4,702	\$ 8,256	\$ 15,560	\$ 27,649

Research and development expenses decreased by \$3.6 million to \$4.7 million for the three-month period ended September 30, 2024, as compared to \$8.3 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 tuspentinib were \$4.1 million for the three-month period ended September 30, 2024, compared with \$5.8 million for the comparative period in 2023. The lower program costs for tuspentinib 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, tuspentinib program costs included the healthy volunteer study, which was completed in 2023.
- Program costs for luxeptinib decreased by approximately \$873 thousand, primarily due to lower clinical trial and manufacturing activities.
- Program costs for APTO-253 decreased by approximately \$2 thousand. The Company discontinued further clinical development of APTO-253.
- Personnel-related expenses decreased by \$582 thousand, related to fewer employees in the current three-month period.
- Stock-based compensation decreased by approximately \$340 thousand in the three months ended September 30, 2024, compared to the three months ended September 30, 2023, primarily due to stock options granted with lower grant date fair values in the current period and option forfeitures recorded in the current period.

Research and development expenses decreased by \$12.0 million to \$15.6 million for the nine-month period ended September 30, 2024, as compared to \$27.6 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 tuspentinib were \$10.7 million for the nine-month period ended September 30, 2024, a decrease of \$8 million compared with \$18.7 million for the comparative period in 2023. The lower program costs for tuspentinib 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, tuspentinib program costs included the healthy volunteer study, which was completed in 2023.
- Program costs for luxeptinib decreased by approximately \$2.4 million to \$287 thousand for the nine months ended September 30, 2024, as compared to \$2.6 million in the comparative period, primarily due to lower clinical trial and manufacturing activities.
- Program costs for APTO-253 decreased by approximately \$15 thousand, due to the Company's decision on December 20, 2021 to discontinue further clinical development of APTO-253.
- Personnel-related expenses decreased by \$834 thousand, related to fewer employees in the current six-month period and partially offset by salary increases.
- Stock-based compensation decreased by approximately \$865 thousand in the nine months ended September 30, 2024, compared to the nine months ended September 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 tuspentinib (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 tuspentinib, 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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