

**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 10, 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
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 August 10, 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.

[99.1](#) [Press Release dated August 10, 2023](#)

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 10, 2023

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 2023

— CRc Response Rate 50% with Tuspentinib/Venetoclax Doublet in Evaluable Patients —

— CRc 44% in Patients Who Failed Prior Venetoclax —

— CRc 43% in Patients with Wildtype FLT3 —

— CRc 67% in Patients with Mutated FLT3 —

— Data Guide to Accelerated Approval Path for TUS/VEN Doublet in Patients Who Failed Prior Venetoclax, Including FLT3 Mutated and Wildtype —

— Hanmi Pharmaceutical Commits Investment in Aptose Up to 19.99% Ownership or \$7 Million —

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

SAN DIEGO and TORONTO, Aug. 10, 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 the three months ended June 30, 2023, and provided a corporate update.

“While still early in our APTIVATE dose expansion trial with tuspentinib in combination with venetoclax (TUS/VEN), we are encouraged by what we’re seeing in very difficult to treat AML populations,” said William G. Rice, Ph.D., Chairman, President and Chief Executive Officer. “Of particular importance are the tolerability of the TUS/VEN doublet and the breadth of responses in deep relapsed or refractory (R/R) AML patients who failed prior therapy with venetoclax (4 of 9 evaluable with Prior-VEN), among which responses were achieved in patients with wildtype FLT3 (2 of 3 evaluable with FLT3-WT) and one of whom harbored a TP53 mutation. Given the paucity of treatment options in this subpopulation that failed prior venetoclax therapy, we’re excited to build off of these positive results at future medical meetings later this year and leverage the TUS/VEN doublet data as a springboard to future triplet therapy in the front line setting.”

“We are delighted to strengthen our relationship with Hanmi Pharmaceutical, which we believe reflects their recognition of the growing value of tuspentinib as a unique treatment for AML and possibly MDS, of the significant progress that Aptose has made with tuspentinib’s clinical development, and of the experienced and thoughtful nature of our team,” said Dr. Rice. “We thank the Hanmi team, and in particular, Ms. Juhyun Lim, President of Hanmi Pharmaceutical, for her leadership and commitment to Aptose.”

Key Corporate Highlights

- **Tuspentinib APTIVATE Expansion Trial** – In the APTIVATE Phase 1/2 clinical trial of tuspentinib, a once daily oral agent with a unique kinase targeting pattern being developed for the treatment of patients with R/R AML, the tuspentinib and venetoclax (TUS/VEN) doublet combination treatment arm has demonstrated early responses (composite Complete Response rate (CRc) includes any CR, CRh, CRi and CRp to date) among efficacy evaluable R/R patients who previously failed venetoclax treatment. Among fifteen (15) patients dosed with TUS/VEN as of August 1, 2023, ten (10) patients have reached an efficacy evaluable stage. Among the ten evaluable patients, five (5) patients have achieved responses (50% CRc). Nine (9) of the ten (10) evaluable patients had failed prior venetoclax treatment, with four (4) of the nine (9) achieving responses (44% CRc). Three (3) responses emerged among seven (7) patients with wildtype FLT3 (43% CRc), which accounts for approximately 70% of the AML population, yet there are few treatment options and little in development for the wildtype patient population. The TUS/VEN combination continues to be well tolerated.

Aptose has a growing network of U.S. and international clinical sites recruiting a large spectrum of the R/R AML population, and the APTIVATE trial is focused on the rapid enrollment of patients to the TUS/VEN doublet.

- **Equity Investments in Aptose** – Today, Aptose announced that it has entered into a binding term sheet with Hanmi Pharmaceutical, Inc. (“Hanmi Pharmaceutical”) of Seoul, South Korea, for an investment of up to \$7 million or 19.99 percent ownership interest in Aptose, in two tranches. The investment will provide additional financing for Aptose’s lead hematology drug, tuspentinib, formerly HM43239, which was licensed from Hanmi Pharmaceutical in November 2021 and is currently in the APTIVATE international phase 1/2 expansion trial in which patients with relapsed or refractory (R/R) acute myeloid leukemia (AML) receive tuspentinib monotherapy or in combination with venetoclax. The Company anticipates that the first tranche for \$3 million will close by the end of August, subject to the satisfaction of customary closing conditions. The second tranche for up to \$4 million or a maximum of 19.99 percent ownership interest will be triggered upon Aptose achieving certain manufacturing and data milestones related to tuspentinib, to be described in greater detail in definitive documentation and anticipated to be achieved by year-end.

The investment is conditional upon the Company receiving the conditional approval of the Toronto Stock Exchange (the “TSX”) to list the Common Shares on the TSX. Listing will be subject to satisfying all of the requirements of the TSX. The investment is also subject to the requirements of the Nasdaq Capital Market.

During the quarter, Aptose also entered into a \$25 million committed equity facility with Keystone Capital that provides Aptose the right to issue and sell up to \$25 million of its common shares over the course of 24 months to the investor, subject to certain conditions being met, and subject to certain limitations and conditions imposed by Nasdaq, SEC and other regulators.

- **Completed Successful Type B EOP1 Meeting with US FDA** – In June, Aptose held an End of Phase 1 (EOP1) Meeting with the FDA,

where all tuspetinib data was reviewed. A monotherapy recommended Phase 2 dose of 80 mg daily was selected and all tuspetinib development paths remain open, including the single arm accelerated path.

Expected Milestones

- European School of Haematology (ESH) Meeting – Plan to present expanded tuspetinib clinical data set (October 2023)
- 65th American Society of Hematology (ASH) Annual Meeting & Exposition – Plan to present more mature clinical data set with tuspetinib (December 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 June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Expenses:				
Research and development	\$ 10,582	\$ 7,341	\$ 19,393	\$ 14,734
General and administrative	3,870	3,332	9,155	7,439
Operating expenses	14,452	10,673	28,548	22,173
Other income, net	323	108	743	127
Net loss	\$ (14,129)	\$ (10,565)	\$ (27,805)	\$ (22,046)
Net Loss per share, Basic and diluted	\$ (2.27)	\$ (1.72)	\$ (4.47)	\$ (3.59)
Weighted average number of common shares outstanding used in computing net loss per share, basic and diluted (in thousands)	6,234	6,150	6,219	6,149

Net loss for the three-month period ended June 30, 2023 increased by \$3.6 million to \$14.1 million, as compared to \$10.6 million for the comparable period in 2022. Net loss for the six-month period ended June 30, 2023 increased by \$5.7 million to \$27.8 million, as compared to \$22 million for the comparable period in 2022.

Aptose Biosciences, Inc.

Balance Sheet Data

(unaudited)

(\$ in thousands)

	June 30, 2023	December 31, 2022
Cash, cash equivalents and short-term investments	\$ 23,306	\$ 46,959
Working capital	13,287	37,235
Total assets	26,575	51,027
Long-term liabilities	817	1,002
Accumulated deficit	(492,135)	(464,330)
Stockholders' equity	13,786	37,741

- Total cash and cash equivalents and investments as of June 30, 2023, were \$23.3 million, a decrease of \$12.4 million as compared to March 31, 2023, and a decrease of \$23.7 million as compared to December 31, 2022. 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 August 10, 2023, were 6,519,201.

RESEARCH AND DEVELOPMENT EXPENSES

The research and development expenses for the three-month and six-month periods ended June 30, 2023, and 2022 were as follows:

(in thousands)	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Program costs – Tuspetinib	\$ 8,070	\$ 2,343	\$ 12,845	\$ 3,521
Program costs – Luxeptinib	706	2,404	1,995	5,234
Program costs – APTO-253	19	188	26	279
Personnel related expenses	1,506	1,860	3,584	4,194
Stock-based compensation	271	537	924	1,483
Depreciation of equipment	10	9	19	23
Total	\$ 10,582	\$ 7,341	\$ 19,393	\$ 14,734

Research and development expenses increased by \$3.2 million to \$10.6 million for the three-month period ended June 30, 2023, as compared to \$7.3 million for the comparative period in 2022. 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 \$8.1 million for the three-month period ended June 30, 2023. The higher program costs for Tuspetinib in the current period represent the enrollment of patients in our APTIVATE clinical trial, our healthy volunteer trial, manufacturing activities to support clinical development, and related expenses.
- Program costs for luxeptinib decreased by approximately \$1.7 million, primarily due to lower clinical trial costs and lower manufacturing costs as a result of the current formulation requiring less API than the prior formulation.
- Program costs for APTO-253 decreased by approximately \$169 thousand, due to the Company's decision on December 20, 2021 to discontinue further clinical development of APTO-253.
- Personnel-related expenses decreased by \$354 thousand, related to fewer employees in the current three-month period, partially offset by salary increases.
- Stock-based compensation decreased by approximately \$266 thousand in the three months ended June 30, 2023, compared to the three months ended June 30, 2022, primarily due to stock options granted with lower grant date fair values, in the current period.

Research and development expenses increased by \$4.7 million to \$19.4 million for the six-month period ended June 30, 2023, as compared to \$14.7 million for the comparative period in 2022. 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 \$12.8 million for the six-month period ended June 30, 2023, an increase of \$9.3 million compared with \$3.5 million in the corresponding period in 2022. The higher program costs for Tuspetinib in the current period represent the enrollment of patients in our APTIVATE clinical trial, our healthy volunteer trial, clinical study supplies, and related expenses.
- Program costs for luxeptinib decreased by approximately \$3.2 million from \$5.2 million in the six months ended June 30, 2022 to \$2.0 million in the current period, primarily due to lower clinical trial costs and lower manufacturing costs as a result of the current formulation requiring less API than the prior formulation.
- Program costs for APTO-253 decreased by approximately \$253 thousand, due to the Company's decision on December 20, 2021 to discontinue further clinical development of APTO-253.
- Personnel-related expenses decreased by \$610 thousand, related to fewer employees in the current six-month period and partially offset by salary increases.
- Stock-based compensation decreased by approximately \$559 thousand in the six months ended June 30, 2023, compared to the three months ended June 30, 2022, primarily due to stock options granted with lower grant date fair values, in the current period.

Conference Call & Webcast:

Date: Thursday, August 10, 2023
Time: 5:00 PM ET

Audio Webcast Only: [link](#)
Q&A Participant Registration Link*: [link \(https://register.vevent.com/register/B129f5f8f4655b45cf8b92fd8f79f69f8f\)](https://register.vevent.com/register/B129f5f8f4655b45cf8b92fd8f79f69f8f)

*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 June 30, 2023 will be available on SEDAR+ at www.sedarplus.ca 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 (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 luxepitinib (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 investment of Hanmi into the Company, including the anticipated closing date, the structure of such investment, the ability to receive the full \$7 million investment and the proposed use of proceeds, the Company's clinical development plans, the clinical potential, anti-cancer activity, therapeutic potential and applications and safety profile of tuspetinib and luxepitinib, the APTIVATE clinical trial, patient enrollment, the luxepitinib Phase 1 a/b clinical trials and the upcoming milestones of such trials, the development and clinical potential of the G3 formulation of luxepitinib, 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 requisite approvals, including approval of the TSX and Nasdaq for Hanmi's investment; our ability to complete the Hanmi investment on the terms and structure described herein or at all; our ability to meet certain milestones related to tuspetinib in order to complete the second tranche of the investment; our ability to structure the second tranche of Hanmi's Investment to receive the full \$7 million; 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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