

**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): September 6, 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 7.01. Regulation FD Disclosure.

On September 6, 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 September 6, 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: September 6, 2023

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

Aptose Announces Closing of \$3 Million Investment by Hanmi Pharmaceutical

— TUS/VEN doublet continues safe and effective in AML patients who failed prior venetoclax —

SAN DIEGO and TORONTO, Sept. 06, 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 closing of a \$3 million investment in common shares of the Company (the “Shares”) as the first tranche of a private equity investment for up to a maximum of \$7 million or 19.99 percent ownership interest by Hanmi Pharmaceutical, Inc. (“Hanmi”), Seoul, South Korea. Under the terms of the strategic investment, Hanmi purchased each Share at a price of \$4.488, representing a premium over Aptose’s common stock price.

The investment will provide additional financing for Aptose’s lead hematology drug, tuspetinib, formerly HM43239, which was licensed from Hanmi in November 2021 (press release here) and is currently in the APTIVATE international Phase 1/2 expansion trial in which patients with relapsed or refractory acute myeloid leukemia (R/R AML) receive tuspetinib monotherapy or in combination with venetoclax.

Aptose has granted Hanmi certain rights pursuant to an investor rights agreement, including registration rights, pre-emptive rights, information rights and the right to appoint non-executive consultants.

The closing of the second tranche for up to \$4 million or a maximum of 19.99 percent ownership interest will be triggered upon Aptose achieving, prior to July 1, 2024, certain manufacturing and data milestones related to tuspetinib. The Company currently anticipates achieving the milestones by year-end. Under the second tranche of the investment, Hanmi may not acquire more than 19.99% of the Shares issued and outstanding calculated as of the closing date (on a partially-diluted basis), and, if necessary, the proceeds from the second tranche will be reduced to the extent exceeding this limit irrespective of the Company achieving the milestones.

“We are grateful to our valued partner Hanmi Pharmaceutical for this investment and their confidence in our strategic direction,” said William G. Rice, Ph.D., Chairman, President and Chief Executive Officer. “Tuspetinib (TUS) has demonstrated single agent activity in critically ill AML patients across a diversity of genetically-defined AML populations. Importantly, TUS in combination with the venetoclax BCL-2 inhibitor (the “TUS/VEN” doublet) has been well tolerated and delivered responses in R/R AML patients who failed prior-VEN therapy, even among patients with wild-type FLT3 (FLT3-WT) and a TP53 mutation. Prior-VEN failure patients represent a rapidly emerging unmet need in AML, and the continued favorable safety profile, convenience and efficacy position this TUS/VEN doublet as a potential therapy of choice in R/R AML and position TUS to serve in future triplet combination therapies for newly diagnosed 1L AML. Our momentum for vigorous enrollment of patients onto the TUS/VEN doublet in the Phase 1b/2 APTIVATE clinical trial is driven by investigator enthusiasm for the mechanism, safety and efficacy of this unique drug combination, and we look forward to additional data release throughout the remainder of 2023.”

“Tuspetinib appears to have a clear development and commercial path forward with the potential to address large patient populations in AML,” said Ms. Juhyun Lim, President of Hanmi Pharmaceutical. “We are pleased to support our collaboration with Aptose with this investment, with the hope that this novel agent will help address the unmet needs of AML patients.”

The price of each Share to be issued as part of the second tranche of the investment will be determined based on the greater of, (i) the closing price of the Shares on Nasdaq on September 5, 2023, being the day immediately preceding the execution of the subscription agreement governing the strategic investment, (ii) the 5-day average closing price of the Shares on Nasdaq on September 5, 2023, being the day immediately preceding the execution of the subscription agreement governing the strategic investment, and (iii) the median of the 10-day volume weighted average trading price of the Shares on Nasdaq and the 30-day volume weighted average trading price of the Shares on Nasdaq plus a 10% premium on the closing date of the second investment.

The completion of the investment has been conditionally approved by the Toronto Stock Exchange (the “TSX”). For the purposes of TSX approval, the Company is relying on the exemption set forth in Section 602.1 of the TSX Company Manual, which provides that the TSX will not apply its standards to certain transactions involving eligible interlisted issuers on a recognized exchange, such as Nasdaq, provided that the transaction is being completed in compliance with the requirements of such recognized exchange.

About Tuspetinib

Tuspetinib is a clinically de-risked, once daily, small molecule oral tyrosine kinase inhibitor to treat near-term and long-term unmet needs of patients with acute myeloid leukemia (AML). It suppresses a handful of targets critical to tumor proliferation and AML survival and in a Phase 1 study has delivered responses in AML patients resistant to competitor FLT3 inhibitors by simultaneously suppressing multiple “rescue pathways” that otherwise can lead to drug resistance to other FLT3 inhibitors. The dose escalation portion of this study thus far has delivered multiple complete responses in a diverse set of mutationally-defined populations, including those with AML harboring wild-type FLT3, ITD or TKD mutated FLT3, or mutated forms of NPM1, MLL, TP53, NRAS, KRAS, DNMT3A, RUNX1, various slicing factors, and other genes, with no toxicity trends to date. Tuspetinib’s favorable safety profile - especially when compared to competitive AML agents (no drug-related SAE, QTc prolongations, differentiation syndromes, or discontinuations to date) – and sensitivity across AML populations with unmet needs position tuspetinib as a potential drug of choice for doublet and triplet combination in later and earlier lines of therapy, which offer the biggest promise for real cures in AML.

With single agent activity observed, tuspetinib also has multiple paths for potential Phase 2 accelerated approval Aptose recently opened the Phase 1/2 APTIVATE study, which includes a monotherapy arm and combination treatment of tuspetinib with venetoclax, with multiple data readouts expected during 2023. Tuspetinib was granted Orphan Drug Designation (ODD) in AML in the US in October 2018. For more

information, please visit clinicaltrials.gov (NCT03850574).

About Hanmi Pharmaceutical Co., Ltd.

Hanmi Pharmaceutical, founded in 1973, is an R&D-oriented biopharmaceutical company representing Korea. After the establishment by Pharmacist Lim Sung-ki, it was converted into a holding company system in 2010 and incorporated into a subsidiary of Hanmi Science. Hanmi Pharmaceutical invests more than 15% of its sales in R&D every year, and is developing 26 drug candidates for innovative new drugs in three major fields; 1) Biologics: LAPSCOVERY platform applied long-acting pipeline; 2) NCE: Primarily oncology and auto-immune disease targeted pipelines; and 3) Fixed-dose combination programs. In addition, Hanmi Pharmaceutical operates production facilities ranging from raw materials to chemicals and biopharmaceuticals and has more than 5,000 employees in Korea, and China.

About Aptose

Aptose Biosciences is a clinical-stage biotechnology company 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 luxetpinib (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 may contain forward-looking statements within the meaning of Canadian and U.S. securities laws, including, but not limited to, statements relating to the investment of Hanmi into the Company, including the ability to achieve the milestones, the ability to receive the full \$4 million second tranche investment upon achieving the milestones and the proposed use of proceeds, the therapeutic and commercial potential of tuspetinib and its clinical development and safety profile and Aptose's strategic direction as well as statements relating to the Company's plans, objectives, expectations and intentions and other statements including words such as "anticipate", "continue", "expect", "intend", "will", "should", "would", "may", 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 meet certain milestones related to tuspetinib in order to complete the second tranche of the investment by Hanmi; our ability to find alternative financing if the full \$4 million is not received; our ability to obtain the capital required for research and operations and to continue as a going concern; 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 conditions; inability of new manufacturers to produce acceptable batches of GMP in sufficient quantities; unexpected manufacturing defects; and other risks detailed from time-to-time in our ongoing 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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