

**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): June 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 8.01. Other Events.

On June 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 June 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: June 10, 2023

By: /s/ William G. Rice, Ph.D. _____

William G. Rice, Ph.D.

Chairman, President, and Chief Executive Officer

Aptose Presents Highlights from Clinical Update

Finalized Dose Escalation/Dose Exploration Trial in 77 R/R AML Patients

Favorable safety with monotherapy responses across four dose levels with no DLT in mutationally diverse and difficult to treat R/R AML

Populations

$TP53^{MUT} \text{ CR/CRh} = 20\% \mid RAS^{MUT} \text{ CR/CRh} = 22\%$

Completed Successful Type B EOP1 Meeting with US FDA

Monotherapy RP2D selected as 80mg daily and single arm accelerated path remains open

Initiated APTIVATE Expansion Trial with R/R AML

*Tuspetinib monotherapy and Tuspetinib + Venetoclax (TUS/VEN) doublet show brisk enrollment
TUS/VEN doublet well tolerated, all patients remain on study, preliminary CR activity reported among
first patients treated*

SAN DIEGO and TORONTO, June 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 kinase inhibitors to treat hematologic malignancies, today released highlights from a clinical update event held today, June 10, 2023, in conjunction with EHA 2023 International Congress of the European Hematology Association in Frankfurt, Germany. The event included an up-to-date review of clinical data for Aptose's two investigational products under development for hematologic malignancies: tuspetinib, an oral, myeloid kinase inhibitor in the Phase 1/2 APTIVATE trial in patients with relapsed or refractory acute myeloid leukemia (AML); and luxetpinib, 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. The webcast of the presentation is available on Aptose's website here.

Aptose provided updated clinical findings with tuspetinib, a potent suppressor of FLT3, SYK, JAK 1/2, mutant forms of cKIT, and the RSK1/2 kinases operative in AML:

- Completed tuspetinib dose escalation and dose exploration Phase 1/2 trial in 77 R/R AML patients.
 - Tuspetinib demonstrated a favorable safety profile.
 - Tuspetinib delivered monotherapy responses across four dose levels with no DLT in mutationally diverse and difficult to treat R/R AML populations, including TP53-mutated patients with a CR/CRh = 20% and RAS-mutated patients with a CR/CRh = 22%.
- Completed successful End of Phase 1 (EOP1) Meeting with US FDA for tuspetinib, and a monotherapy RP2D was selected as 80mg daily, and all development paths remain open, including the single arm accelerated path.
- Initiated tuspetinib APTIVATE expansion trial with R/R AML patients.
 - Tuspetinib is being administered as a monotherapy and as a combination doublet with tuspetinib + venetoclax (TUS/VEN), and enrollment has been brisk.
 - TUS/VEN doublet has been well tolerated, all patients remain on study, and preliminary CR activity has already been reported in patients previously treated with VEN.

Aptose also reviewed clinical findings with the new G3 formulation of luxetpinib (Lux):

- 50mg G3 formulation with continuous dosing achieves roughly equivalent PK profile as 900mg original G1 formulation.
- Expect to dose escalate G3 formulation with continuous dosing in patients soon.

"We are delighted to have finalized our dose escalation and dose exploration Phase 1/2 trial with tuspetinib (TUS), to have demonstrated single agent responses across four dose levels that had no DLTs and across a range of R/R AML populations with a diversity of adverse mutations," said William G. Rice, Ph.D., Chairman, President and Chief Executive Officer. "As part of our EOP1 meeting with the FDA, we designated 80mg daily as our monotherapy recommended phase 2 dose (RP2D), and now we focus all attention on our APTIVATE expansion trial to place monotherapy TUS in more patients with highly adverse mutations and to evaluate TUS in combination with venetoclax (VEN) as a doublet in R/R AML patients. Notably, to date, the doublet appears to be well tolerated, with all patients remaining on study, including a preliminary CR in a R/R AML patient who previously failed venetoclax. We look forward to accelerating testing of the doublet, adding MDS patients to our APTIVATE trial, and with the aim of moving into triplet therapy (TUS/VEN/HMA) in 1L AML patients."

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.apptose.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 therapeutic potential of tuspentinib, its clinical development and safety profile, as well as statements relating to the Company's plans, objectives, expectations and intentions and other statements including words such as "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 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.

For further information, please contact:

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