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 12, 2022

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 Canada M2J 4R3

(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 | АРТО | 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 \Box

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 12, 2022, 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.

 Exhibit 99.1
 Press Release dated September 12, 2022

 Exhibit 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 12, 2022

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

Aptose's New "G3" Formulation of Luxeptinib Boosts Bioavailability

- Initial modeling predicts up to 18-fold improvement in plasma steady-state exposure -

- Supports exploration of continuous dosing of G3 formulation -

- Lead clinical compound HM43239 continues to progress on schedule -

SAN DIEGO and TORONTO, Sept. 12, 2022 (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 announced the G3 formulation of luxeptinib, designed for rapid and efficient absorption, demonstrates approximately an 18-fold improvement in oral bioavailability relative to the original G1 formulation, and that Aptose plans to move forward with the development of the G3 formulation of luxeptinib to determine if it can achieve desired exposures and deliver clinical responses while continuing to demonstrate a favorable safety profile.

The original G1 formulation was found to deliver suboptimal absorption, limiting the effectiveness of luxeptinib when administered to patients with relapsed/refractory (R/R) acute myeloid leukemia (AML) and R/R B-cell malignancies during two Phase 1 a/b clinical trials.

The new G3 formulation, designed for more efficient absorption that could lead to greater accumulation and higher steady-state exposure levels, now has been tested as a single dose in 15 patients in the ongoing clinical trials. Initial computational modeling of the pharmacokinetic (PK) properties of G3 predicts that plasma steady-state exposure achieved with continuous dosing of 50 mg of G3 (every 12 hours, Q12h) is equivalent to that of 900 mg of G1 Q12h, representing up to an 18-fold improvement in bioavailability with G3.

Aptose plans to amend the protocol of its existing Phase 1 a/b clinical trial in relapsed/refractory AML patients for submission to the FDA to incorporate continuous dosing and dose escalation of G3 into the trial. Enrollment in the Phase 1 a/b study in B-cell malignancies is paused pending favorable results from continuous dosing in the AML study.

"The G3 formulation of luxeptinib has shown a significant improvement in bioavailability and the potential for greater absorption, and we are eager to move forward with continuous dosing in our AML trial," said William G. Rice, Ph.D., Chairman, President, and Chief Executive Officer of Aptose. "The original G1 formulation of luxeptinib delivered a complete remission (CR) in one AML patient that safely achieved a particularly high plasma steady-state exposure, and we are hopeful the new G3 formulation will enable patients to receive greater exposures and benefit from treatment with Lux."

"AML is a heterogeneous disease characterized by a multitude of gene mutations, making the treatment of AML quite diverse and challenging. Our lead clinical compound, HM43239, has demonstrated clinical responses in multiple genetically defined target populations of AML. We are pleased to have two well-tolerated hematology drugs with the potential to help patients in their fight against AML," continued Dr. Rice.

About Aptose

Aptose Biosciences is a clinical-stage biotechnology company committed to developing personalized therapies 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 investigational products under development for hematologic malignancies: HM43239, an oral myeloid kinase inhibitor in an international Phase 1/2 trial in patients with relapsed or refractory acute myeloid leukemia (AML); and luxeptinib, an oral, dual lymphoid and myeloid kinome inhibitor in a Phase 1 a/b trial in patients with relapsed or refractory B-cell malignancies who have failed or are intolerant to standard therapies, and in a separate Phase 1 a/b trial in patients with relapsed or refractory AML or high-risk myelodysplastic syndrome (MDS). 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, the clinical potential and development of Luxeptinib, its "G3" formulation and safety profile and the clinical potential, development and progress of HM43239 statements regarding the potential to regain compliance with the Nasdaq minimum bid price requirement, and statements relating to the Company's growth, 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.

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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