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 1, 2022

APTOSE BIOSCIENCES INC.

(Exact name of registrant as specified in its charter)

Canada	**001-32001**	**98-1136802**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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	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 November 1, 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 November 1, 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: November 1, 2022

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

EXHIBIT 99.1

Aptose Reports Results for the Third Quarter 2022

— Tuspetinib (HM43239) Dose Escalation and Exploration Phase 1/2 Trial in r/r AML Complete; Continued Superior Safety Profile and Clinical Responses Including Complete Remissions as Single Agent Across Three Dose Levels —

— Recruitment Open for Tuspetinib Dose Expansion Trial with Enriched Populations —

— Continuous Dosing of G3 Formulation of Luxeptinib to Begin Soon —

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

SAN DIEGO and TORONTO, Nov. 01, 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 financial results for the three and nine-month periods ended September 30, 2022 and provided a corporate update.

The net loss for the quarter ended September 30, 2022 was $9.8 million ($0.11 per share) compared with $11.3 million ($0.13 per share) for the quarter ended September 30, 2021. The net loss for the nine months ended September 30, 2022 was $31.8 million compared with $41.0 million for the nine months ended September 30, 2021. Total cash and cash equivalents and investments as of September 30, 2022 were $55.4 million. Based on current operations, Aptose expects that cash on hand and available capital provide the Company with sufficient resources to fund planned Company operations including research and development into the first quarter of 2024.

"Aptose assumed responsibility for clinical development of HM43239, Aptose's well differentiated lead agent now known as tuspetinib, just over 10 months ago, and the execution by our clinical team in that period has been exceptional. We completed the dose escalation and exploration stages of our Phase 1/2 trial having demonstrated not only a superior safety package, but also potent antileukemic activity in multiple mutationally defined populations of extremely challenging relapsed or refractory AML patients that had failed prior treatments," said William G. Rice, Ph.D., Chairman, President and Chief Executive Officer. "We continue to see meaningful responses across dose levels and look forward to providing the full scope of blast reduction and response rate data from the Phase 1/2 trial in the ASH timeframe next month."

Key Corporate Highlights

- **"Tuspetinib" adopted as generic name for HM43239** – The United States Adopted Name (USAN) Council recently adopted "tuspetinib" as the generic name for Aptose's lead drug candidate HM43239, an oral, myeloid kinase inhibitor. Aptose will use "tuspetinib" for all future references of the drug, including in scientific publications and corporate materials. The USAN information on tuspetinib will be posted on the USAN Web site (www.ama-assn.org/go/usan).

- **Tuspetinib Successfully Completes Dose Escalation and Dose Exploration in Phase 1/2 Trial; To Begin Recruitment of Enriched Patient Populations for Expansion Trial** – Aptose has completed Phase 1/2 dose escalation and dose exploration of tuspetinib (formerly HM43239), an oral, myeloid kinase inhibitor in an international Phase 1/2 trial in patients with relapsed or refractory (r/r) acute myeloid leukemia (AML) and will begin recruitment for the expansion trial. The company has identified a safe therapeutic range with a broad therapeutic window, spanning the dose levels of 80, 120 and 160 milligrams, and has selected 120 milligrams as the initiating single agent expansion dose and 80mg as the initiating dose selected for combination with venetoclax. The trial is designed to confirm activity through patient enrichment of specific mutationally defined AML populations, including FLT3-mutant patients who have been failed by a prior FLT3 inhibitor, as supported by fast-track designation and significant response rate to date. In the FLT3-mutated group, tuspetinib demonstrated complete remissions in patients that have co-mutations in important genes including NPM1, NRAS, KRAS, PTPN11, DNMT3A, RUNX1, and MLL-PTD. Some of these mutations are typically associated with resistance to tyrosine kinase inhibitors, yet the patients are still able to respond to tuspetinib. Significant activity, including complete remissions and blast reductions, also have been observed in other diverse AML populations, including in FLT3 wildtype patients that harbor adverse mutations in genes like TP53 and NRAS. Current plans include an expansion trial of tuspetinib as a single agent and in combination with venetoclax in r/r AML patients, with planned segue into registrational trials for accelerated approval in subpopulations of r/r AML patients with high unmet medical needs.

- **Luxeptinib "G3" Formulation Significantly Boosts Oral Availability; Aptose to Proceed with Continuous Dosing** – In September, Aptose announced that the G3 formulation of luxeptinib, oral, dual lymphoid and myeloid kinase inhibitor, demonstrated an approximate 18-fold improvement in oral bioavailability relative to the original G1 formulation in testing as a single dose. To date, G3 has been tested as a single dose with dose levels ranging from 10mg to 200mg in 20 patients during 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 roughly equivalent to that of 900 mg of G1 Q12h, representing up to an 18-fold improvement in bioavailability with G3. The new G3 formulation could lead to greater absorption and higher steady-state exposure levels. Aptose has amended the protocol of its existing Phase 1 a/b clinical program to incorporate continuous dosing and dose escalation of G3 into the trial and submitted it to the FDA and expects to commence continuous dosing with G3 in patients shortly.

RESULTS OF OPERATIONS

A summary of the results of operations for the three and nine-month periods ended September 30, 2022 and 2021 is presented below:

(in thousands)	Three months ended September 30, 2022	2021	Nine months ended September 30, 2022	2021
Revenues	$ -	$ -	$ -	$ -
Research and development expenses	6,578	7,718	21,312	25,777
General and administrative expenses	3,448	3,641	10,887	15,322
Other income, net	249	26	376	69
Net loss	(9,777)	$ (11,333)	$ (31,823)	$ (41,030)
Other comprehensive income/(loss)	20	-	(17)	-
Total comprehensive loss	$ (9,757)	$ (11,333)	$ (31,840)	$ (41,030)
Basic and diluted loss per common share	$ (0.11)	$ (0.13)	$ (0.34)	$ (0.46)

Net loss for the three-month period ended September 30, 2022 decreased by $1.6 million to $9.8 million, as compared to $11.3 million for the comparable period in 2021. The net loss for the nine-month period ended September 30, 2022 decreased by $9.2 million to $31.8 million, as compared to $41.0 million for the comparable period in 2021. Components of net loss are presented below:

Research and Development

Research and development expenses consist primarily of costs incurred related to the research and development of our product candidates and include:

- External research and development expenses incurred under agreements with third parties, such as contract research organizations, consultants, members of our scientific advisory boards, external labs and contract manufacturing organizations; and

- Employee-related expenses, including salaries, benefits, travel, and stock-based compensation for personnel directly supporting our clinical trials, manufacturing and development activities.

We have ongoing Phase 1 clinical trials for our product candidates tuspetinib and luxeptinib. Tuspetinib was licensed to Aptose in the fourth quarter of 2021, and we assumed sponsorship, and the related costs, of the tuspetinib study effective January 1, 2022. In the fourth quarter of 2021, we discontinued the APTO-253 program and are exploring strategic alternatives for this compound.

We expect our research and development expenses to be higher than current period expenses for the foreseeable future as we advance tuspetinib into larger clinical trials.

The research and development expenses for the three-month and nine-month periods ended September 30, 2022, and 2021 were as follows:

(in thousands)	Three months ended September 30, 2022	2021	Nine months ended September 30, 2022	2021
Program costs – tuspetinib	$ 3,049	$ -	$ 6,570	$ -
Program costs – luxeptinib	1,390	4,412	6,624	14,111
Program costs – APTO-253	66	767	345	2,976
Personnel related expenses	1,627	1,929	5,821	5,702
Stock-based compensation	440	609	1,923	2,985
Depreciation of equipment	6	1	29	3
Total	$ 6,578	$ 7,718	$ 21,312	$ 25,777

Research and development expenses decreased by $1.1 million to $6.6 million for the three-month period ended September 30, 2022, as compared to $7.7 million for the comparative period in 2021. 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 $3.0 million for the three-month period ended September 30, 2022. The Company in-licensed the development rights of tuspetinib in the fourth quarter of 2021 and assumed sponsorship, and the related costs, of the study effective January 1, 2022.

- Program costs for luxeptinib decreased by approximately $3.0 million, primarily due to lower manufacturing costs as a result of the current formulation requiring less API than the prior formulation, partially offset by higher clinical trial costs, mostly related to higher contractor costs required to support the trials.

- Program costs for APTO-253 decreased by approximately $701 thousand, due to the Company's decision on December 20, 2021 to discontinue further clinical development of APTO-253.

- Personnel-related expenses decreased by $302 thousand, related to fewer employees in the current three-month period and partially offset by salary increases and certain employees hired during the first half of 2021.

- Stock-based compensation decreased by approximately $169 thousand in the three months ended September 30, 2022, compared to the three months ended September 30, 2021, primarily due to stock options granted with lower grant date fair values, in the current period.

Research and development expenses decreased by $4.5 million to $21.3 million for the nine-month period ended September 30, 2022, as compared to $25.8 million for the comparative period in 2021. 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 approximately $6.6 million for the nine-month period ended September 30, 2022. The Company in-licensed the development rights of HM43239 in the fourth quarter of 2021 and assumed sponsorship, and the related costs, of the study effective January 1, 2022.

- Program costs for luxeptinib decreased by approximately $7.5 million, primarily due to lower manufacturing costs as a result of the current formulation requiring less API than the prior formulation, and partially offset by lower clinical trial costs, mostly related to higher contractor costs required to support the trials.

- Program costs for APTO-253 decreased by approximately $2.6 million, due to the Company's decision on December 20, 2021 to discontinue further clinical development of APTO-253.

- Personnel-related expenses increased by $119 thousand, mostly related to certain employees hired in 2021 to support our clinical trials and manufacturing activities, salary plan, and offset by lower personnel in the nine months ended September 2022.

- Stock-based compensation decreased by approximately $1.1 million in the nine months ended September 30, 2022, as compared to the nine months ended September 30, 2021, primarily due to stock options granted with lower grant date fair values, in the current period.

General and Administrative

General and administrative expenses consist primarily of salaries, benefits and travel, including stock-based compensation for our executive, finance, business development, human resources, and support functions. Other general and administrative expenses are professional fees for auditing and legal services, investor relations and other consultants, insurance and facility-related expenses.

We expect that our general and administrative expenses will increase for the foreseeable future as we incur additional costs to support the expansion of our pipeline of activities. We also expect our intellectual property related legal expenses to increase as our intellectual property portfolio expands.

The general and administrative expenses for the three-month and nine-month periods ended September 30, 2022, and 2021 were as follows:

	Three months ended September 30,		Nine months ended September 30,	
(in thousands)	2022	2021	2022	2021
General and administrative, excluding items below	$ 2,811	$ 2,387	$ 8,401	$ 7,568
Stock-based compensation	613	1,219	2,423	7,650
Depreciation of equipment	24	35	63	104
Total	$ 3,448	$ 3,641	$ 10,887	$ 15,322

General and administrative expenses for the three-month period ended September 30, 2022 were $3.5 million, as compared to $3.6 million for the comparative period in 2021, a decrease of approximately $193 thousand. The decrease was primarily due the following:

- General and administrative expenses, other than stock-based compensation and depreciation of equipment, increased by approximately $424 thousand in the three months ended September 30, 2022, primarily as a result of higher salaries expenses, higher travel expenses, and higher professional fees.

- Stock-based compensation decreased by approximately $606 thousand in the three months ended September 30, 2022, as compared to the three months ended September 30, 2021, mostly as a result of a lower number of options granted in the current period and that those options granted in the current period had a lower grant date fair value.

General and administrative expenses for the nine-month period ended September 30, 2022 were $10.9 million as compared to $15.3 million for the comparative period, a decrease of approximately $4.4 million. The decrease was primarily due to the following:

- General and administrative expenses, other than share-based compensation and depreciation of equipment, increased by approximately $833 thousand in the nine months ended September 30, 2022, primarily as a result of higher salaries expenses, higher travel expenses and higher professional fees.

- Stock-based compensation decreased by approximately $5.2 million in the nine months ended September 30, 2022, compared to the nine

months ended September 30, 2021, primarily due to lower grant date fair value of options granted in the current period, and additional compensation recognized in the comparative period for modifications made to then vested and unvested stock options for one officer, as part of a separation and release agreement.

Conference Call and Webcast

Date:	Tuesday, November 1, 2022
Time:	5:00 PM ET
Audio Webcast Only:	**link**
Q&A Participant Registration Link*:	**here**

(https://register.vevent.com/register/BIc687e1f1cee54e22b3d29e917044b145)

*Please note the change in platform. 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 personal PIN, which are required to access the conference call. They also will have the option to take advantage of a new Call Me button and the system will automatically dial out to connect to the Q&A session.

The audio webcast can also 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 and nine months ended September 30, 2022 will be available on SEDAR at www.sedar.com 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 (formerly 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 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 clinical development plans and dose escalations, the clinical potential, anti-cancer activity, therapeutic potential and applications and safety profile of tuspetinib and luxeptinib, the tuspetinib Phase 1/2 AML clinical trial, the luxeptinib Phase 1 a/b B-cell malignancy and Phase 1 a/b AML clinical trials and the upcoming milestones of such trials, the development and clinical potential of a new formulation (G3) for luxeptinib, expected increases in R&D, general and administrative and intellectual property related legal expenses, upcoming updates regarding the clinical trials, the exploration of strategic alternatives for the APTO-253 program and operations 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; 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:

Aptose Biosciences Inc. **LifeSci Advisors, LLC**

Susan Pietropaolo

Corporate Communications & Investor Relations
201-923-2049
spietropaolo@aptose.com

Dan Ferry, Managing Director

617-535-7746
Daniel@LifeSciAdvisors.com