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): May 9, 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 May 9, 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 May 9, 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: May 9, 2022

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

EXHIBIT 99.1

Aptose Reports Results for the First Quarter 2022

Expands HM43239 dose cohort at 160 mg

Headway with luxeptinib "G3" formulation in patients

Conference call and webcast at 5:00 pm ET today

SAN DIEGO and TORONTO, May 09, 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 months ended March 31, 2022 and provided a corporate update.

The net loss for the quarter ended March 31, 2022 was $11.5 million ($0.12 per share) compared with $16.2 million ($0.18 per share) for the quarter ended March 31, 2021. Total cash and cash equivalents and investments as of March 31, 2022 were $69.5 million. Based on current operations, Aptose expects that cash on hand and available capital provide the Company with sufficient resources to fund all planned Company operations including research and development into the fourth quarter of 2023.

"Aptose has two meaningful clinical-stage kinome inhibitors in HM43239 and luxeptinib, and we continue to advance their development in distinct patient populations," said William G. Rice, Ph.D., Chairman, President and Chief Executive Officer. "To date, both have demonstrated clear activity and have been well-tolerated. As we define the next steps in the development program with our lead compound HM43239, we are encouraged by the clinical remissions we are seeing in AML patients, particularly in those with highly adverse mutations that typically are difficult to treat but respond to HM43239. We look forward to reporting all available data on our programs at an upcoming corporate event."

Key Corporate Highlights

- **Aptose Receives Fast Track Designation for HM43239** – The U.S. Food and Drug Administration (FDA) granted Fast Track designation to HM43239 (239), an oral, myeloid kinome inhibitor, for the treatment of patients with relapsed, refractory (R/R) acute myeloid leukemia (AML) who have FLT3 mutations. Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need.The purpose is to get important new drugs to patients earlier.

- **HM43239 Expansion at 160 mg in Diverse AML Patient Population** – HM43239, an oral, myeloid kinome inhibitor in an international Phase 1/2 trial in patients with relapsed or refractory acute myeloid leukemia (AML), thus far has delivered six composite complete remissions (CR) and a PR at the 80 mg and 120 mg doses. Aptose is now expanding at the 160 mg dose level, with the goal of understanding the breadth of activity of 239 in diverse mutations and identifying the best efficacious and safe doses to treat relapsed and refractory AML. HM43239 thus far has demonstrated a favorable safety profile with no DLTs and no drug discontinuations from drug related toxicity at doses up to 160 mg per day.

- **Headway with Luxeptinib "G3" Formulation in Patients** – Luxeptinib , a dual lymphoid and myeloid kinome inhibitor, currently is being evaluated in a Phase 1 a/b study in patients with relapsed or refractory AML and higher risk MDS, and in a separate Phase 1 a/b study in patients with relapsed or refractory B-cell malignancies. Aptose has made significant progress with the clinical evaluation of a new formulation of luxeptinib (Lux), that may enable greater exposures across patients. In the ongoing studies in AML and B-cell malignancies, a dose of the G3 formulation has been safely administered to three patients at the 50 mg dose level and is now being dosed at the 100 mg dose level. After patients receive the single G3 dose, samples are collected for PK evaluation and patients then go onto the original formulation of Lux for comparison.

- **Aptose Appoints Chief Commercial Officer** – Aptose recently appointed Dr. Philippe Ledru to the position of Chief Commercial Officer, responsible for providing executive leadership and vision for commercial development and marketing strategies for the future commercial launches of HM43239 and luxeptinib and to consolidate responsibilities over business development and licensing. Dr. Ledru most recently served as Associate Vice President and Head of Oncology New Products at Merck & Co., over 25 assets from discovery to mid-stage clinical development, across major solid tumors and hematological malignancies At Merck, he also provided leadership on all licensing and M&A activities, including the Peloton Therapeutics and Arqule acquisitions in 2019. Earlier, at Novartis, he had early commercial development and global marketing responsibilities for several new compounds, including FLT3 inhibitor midostaurin, and at Novartis Oncologie he helped lead launches of several oncology products, including imatinib (Gleevec).

RESULTS OF OPERATIONS

A summary of the results of operations for the three-month periods ended March 31, 2022 and 2021 is presented below:

	Three months ended March 31,	
(in thousands except per Common Share data)	2022	2021
Revenues	$ -	$ -
Research and development expenses	7,393	8,228
General and administrative expenses	4,107	8,024

Net finance income		19		25
Net loss and comprehensive loss	$	(11,481)	$	(16,227)
Basic and diluted loss per Common Share	$	(0.12)	$	(0.18)

The net loss for the three-month period ended March 31, 2022, decreased by $4.7 million to $11.5 million as compared with $16.2 million for the comparable period in 2021. Components of the 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. Costs include the following:

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

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

We have ongoing Phase 1 clinical trials for our product candidates HM43239 and Luxeptinib. HM43239 was licensed into Aptose in Q4, 2021 and we have assumed sponsorship, and the related costs, of the HM43239 study effective January 1, 2022. In Q4, 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 for the foreseeable future as we continue to advance HM43239 and luxeptinib into larger clinical trials.

The research and development expenses for the three-month periods ended March 31, 2022, and 2021 were as follows:

	Three months ended March 31,	
(in thousands)	2022	2021
Program costs – HM43239	1,178	-
Program costs – Luxeptinib	2,830	3,971
Program costs – APTO-253	91	1,090
Personnel expenses	2,334	1,788
Stock-based compensation	946	1,378
Depreciation of equipment	14	1
	$ 7,393	$ 8,228

Research and development expenses decreased by $835 thousand to $7.4 million for the three-month period ended March 31, 2022 as compared with $8.2 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 HM43239 increased by approximately $1.2 million as 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 $1.1 million, primarily due to lower manufacturing costs as a result of the current formulation requiring less API than the prior formulation and also from lower clinical trial costs, mostly related to fewer contractors needed to support the trials.

- Program costs for APTO-253 decreased by approximately $1.0 million, due to the Company's decision on December 20, 2021 to discontinue further clinical development of APTO-253.

- Personnel-related expenses increased by $546 thousand, mostly related to new positions hired in 2021 to support our clinical trials and manufacturing activities.

- Stock-based compensation decreased by approximately $432 thousand in the three months ended March 31, 2022, compared with the three months ended March 31, 2021, primarily due to lower grant date fair value of options which were granted 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 resource, 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 periods ended March 31, 2022 and 2021 were as follows:

	Three months ended March 31,	
(in thousands)	2022	2021
General and administrative, excluding items below:	$ 2,521	$ 2,725
Stock-based compensation	1,568	5,265
Depreciation of equipment	18	34
	$ 4,107	$ 8,024

General and administrative expenses for the three-month period ended March 31, 2022 were $4.1 million as compared with $8.0 million for the comparative period in 2021, a decrease of approximately $3.9 million. The decrease was primarily as a result of the following:

- General and administrative expenses, other than stock-based compensation and depreciation of equipment, decreased by approximately $204 thousand in the three months ended March 31, 2022 primarily as a result lower professional fees.

- Stock-based compensation decreased by approximately $3.7 million in the three months ended March 31, 2022, compared with the three months ended March 31, 2021, primarily due to lower grant date fair value of options which were 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.

COVID-19 did not have a significant impact on our results of operations for the three-month period ended March 31, 2022. We have not experienced and do not foresee material delays to the enrollment of patients or timelines for the HM43239 Phase 1/2 trial or the luxeptinib Phase 1a/b trials due to the variety of clinical sites that we have actively recruited for these trials. As of the date of this report, we have not experienced material delays in the manufacturing of HM43239 or luxeptinib related to COVID-19. Should our manufacturers be required to shut down their facilities due to COVID-19 for an extended period of time, our trials may be negatively impacted.

Conference Call and Webcast

Aptose will host a conference call to discuss results for the quarter ended March 31, 2022 today, Monday, May 9, 2022 at 5:00 PM ET. Participants can access the conference call by dialing 1-866-374-5140 (North American toll-free number) and 1-404-400-0571 (international/toll number) and using conference ID 38238231#. The conference call can be accessed here and will also be available through a link on the Investor Relations section of Aptose's website at https://ir.aptose.com/. An archived version 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 March 31, 2021 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: HM43239, an oral, myeloid kinome 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 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 HM43239 and luxeptinib, the potential expansion of the list of the treatable population for HM43239, the HM43239 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 of a new formulation (G3) for luxeptinib, expected increases in R&D, general and administratives and intellectual property related legal expenses, impacts of COVID-19 on the Company, its results and its clinical trials, 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.

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