# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
# Washington, D.C. 20549

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# FORM 8-K

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## CURRENT REPORT

**Pursuant to Section 13 or 15(d)**
**of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): August 2, 2022**

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## APTOSE BIOSCIENCES INC.

(Exact name of registrant as specified in its charter)

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| **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)

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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 August 2, 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 August 2, 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: August 2, 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 Second Quarter 2022

*— HM43239 Preliminary Response Rate of 43% Among R/R AML Patients with FLT3 Mutations Who Failed Prior Therapy with FLT3 inhibitors —*

*— HM43239 Complete Remissions and Safety Across Three Dose Levels and Multiple Genotypic Subpopulations —*

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

SAN DIEGO and TORONTO, Aug. 02, 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 June 30, 2022 and provided a corporate update.

The net loss for the quarter ended June 30, 2022 was $10.6 million ($0.11 per share) compared with $13.5 million ($0.15 per share) for the quarter ended June 30, 2021. The net loss for the six months ended June 30, 2022 was $22.0 million ($0.24 per share) compared with $29.7 million ($0.33 per share) for the six months ended June 30, 2021. Total cash and cash equivalents and investments as of June 30, 2022 were $62.4 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.

"Our mandate at Aptose is to develop targeted kinase inhibitors to safely and effectively treat patients with deadly hematologic malignancies and to avoid the rapid emergence of drug resistance," said William G. Rice, Ph.D., Chairman, President and Chief Executive Officer. "Acute myeloid leukemia (AML) is not a single-mutation disease, but rather a highly heterogeneous cancer that can emerge from a different spectrum of genetic and epigenetic alterations in each patient. For this reason, Aptose's lead clinical agent, HM43239, was designed as a highly targeted myeloid kinase inhibitor to suppress specific pathways operative in AML and to treat the disease in multiple subpopulations of AML, rather that treating a single target and a prescriptive subpopulation that generally leads to rapid mutational escape. The breadth of activity of HM43239 could support sizable markets in FLT3-mutated patients (including those previously treated with FLT3 inhibitors), TP53-mutated patients, NPM1-mutated/MLL-rearrangement patients and the RUNX1/DNMT3A/RAS-mutated populations. Plus, the robust safety profile of HM43239 to date supports potential use as the agent of choice for combination therapy and for use in maintenance therapy."

"Although it is very challenging to achieve complete remissions with a single agent in the relapsed/refractory (R/R) AML patient population, 239 has achieved such activity even in AML patients with highly adverse mutations," said Rafael Bejar, M.D., Ph.D., Senior Vice President and Chief Medical Officer. "Patients with FLT3 mutation who already have been failed by FLT3 inhibitors have a grim prognosis, yet our current data with HM43239, albeit early, reveal a significant response rate of about 43 percent, and this genetically- and phenotypically defined population represents a potential path for accelerated approval."

**Key Corporate Highlights**

- **Aptose Appoints Chief Financial Officer** – In June, Aptose appointed Fletcher Payne to the position of Senior Vice President, Chief Financial Officer. In this role, Mr. Payne will lead Aptose's financial operations and serve as a member of the Company's executive management team. With a healthcare tenure of more than two decades, Mr. Payne brings to Aptose extensive experience in corporate finance, strategy and operations within the biotechnology industry. He most recently served as CFO of Syapse, where he completed several financings and oversaw accounting, finance, corporate development, and legal functions. Prior, he was CFO at Catalyst Bioscience, a publicly traded biotech company. Mr. Payne also served in a CFO capacity and senior financial positions at CytomX Therapeutics, Plexxikon Inc., Rinat Neuroscience Corporation, Dynavax Technologies Corporation, and Cell Genesys, among others.

- **HM43239 Remissions Across Three Safe Doses in Diverse AML Patient Populations** – HM43239 (239), an oral, myeloid kinase inhibitor in an international Phase 1/2 trial in patients with R/R AML, thus far has delivered composite complete remissions (CRc) at three separate dose levels (80 mg, 120 mg and 160mg) and no drug-related discontinuations, DLTs, SAEs, QTc prolongations, or safety concern trends have been observed at these doses. Among patients treated with ≥ 80 mg HM43239, an overall response rate (ORR) of 43% has been observed for R/R AML patients with FLT3 mutations who failed prior therapy with FLT3 inhibitors. Since our KOL event on June 2nd, 2022 that highlighted the safety and efficacy of HM43239, the pace of enrollment has increased markedly and continues to enroll at the 120 mg and 160 mg dose levels, with the goals of understanding the breadth of activity of 239 in patients with diverse mutations, observing signs of additional clinical activity in certain of these patients early in their course of treatment, and identifying the most efficacious and safe doses to treat R/R AML. In addition, Aptose is now further exploring the 40 mg dose level to identify the lowest dose level that can deliver responses and exposures in the therapeutic range. Current plans take HM43239 into an Expansion Trial beginning 2H2022 as a single agent, and then combination therapy, in R/R AML patients as a planned segue into registrational trials for accelerated approval in subpopulations of R/R AML patients with high unmet medical needs.

- **Rapid Clinical Evaluation of Luxeptinib "G3" Formulation in Patients** – Luxeptinib (Lux), a dual lymphoid and myeloid kinase inhibitor, currently is being evaluated in a Phase 1 a/b study in patients with R/R AML and higher risk MDS, and in a separate Phase 1 a/b study in patients with R/R refractory B-cell malignancies. The company is continuing to observe signs of clinical activity with the original Lux formulation, and two R/R B-cell cancer patients still on study at the 900 mg BID level have observed 35% or more in tumor reductions thus far. Aptose is ahead of schedule in the clinical evaluation of a new formulation (G3) of luxeptinib, that may enable greater exposures from a reduced pill burden and lower dosages. In the ongoing studies in AML and B-cell malignancies, a single dose of G3 formulation at four different dose levels has been administered to patients. PK profiles of the G3 formulation have been collected and computational modeling is ongoing to simulate PK parameters if G3 were dosed continuously at different dose levels and on different

dosing schedules. Such studies will define how the G3 might be dosed in patients going forward.

**RESULTS OF OPERATIONS**

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

| | Three months ended June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| (in thousands) | 2022 | 2021 | 2022 | 2021 |
| Revenues | $ - | $ - | $ - | $ - |
| Research and development expenses | 7,341 | 9,831 | 14,734 | 18,059 |
| General and administrative expenses | 3,332 | 3,657 | 7,439 | 11,681 |
| Net finance income | 108 | 18 | 127 | 43 |
| Net loss | (10,565) | (13,470) | (22,046) | (29,697) |
| Other comprehensive loss | (37) | - | (37) | - |
| Total comprehensive loss | $ (10,602) | $ (13,470) | $ (22,083) | $ (29,697) |
| Basic and diluted loss per common share | $ (0.11) | $ (0.15) | $ (0.24) | $ ($0.33) |

The net loss for the three-month period ended June 30, 2022 decreased by $2.9 million to $10.6 million as compared with $13.5 million for the comparable period in 2021. The net loss for the six-month period ended June 30, 2022 decreased by $7.7 million to $22.0 million as compared with $29.7 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 to Aptose in the fourth quarter of 2021 and we have assumed sponsorship, and the related costs, of the HM43239 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 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 and six-month periods ended June 30, 2022, and 2021 were as follows:

| | Three months ended June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| (in thousands) | 2022 | 2021 | 2022 | 2021 |
| Program costs – HM43239 | $ 2,343 | - | $ 3,521 | - |
| Program costs – luxeptinib | 2,404 | $ 5,728 | 5,234 | $ 9,699 |
| Program costs – APTO-253 | 188 | 1,119 | 279 | 2,209 |
| Personnel related expenses | 1,860 | 1,985 | 4,194 | 3,773 |
| Stock-based compensation | 537 | 998 | 1,483 | 2,376 |
| Depreciation of equipment | 9 | 1 | 23 | 2 |
| Total | $ 7,341 | $ 9,831 | $ 14,734 | $ 18,059 |

Research and development expenses decreased by $2.5 million to $7.3 million for the three-month period ended June 30, 2022 as compared with $9.8 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 HM43239 were $2.3 million for the three-month period ended June 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 $3.3 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 lower contractor costs required to support the trials.

- Program costs for APTO-253 decreased by approximately $931 thousand, due to the Company's decision on December 20, 2021 to discontinue further clinical development of APTO-253.

- Personnel-related expenses decreased by $125 thousand, related to fewer employees in the current three-month period and partially offset by salary increases and certain employees hired during the second half of 2021.

- Stock-based compensation decreased by approximately $461 thousand in the three months ended June 30, 2022, compared with the three months ended June 30, 2021, primarily due to stock options granted with lower grant date fair values, in the current period.

Research and development expenses decreased by $3.3 million to $14.7 million for the six-month period ended June 30, 2021 as compared with $18.1 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 were approximately $3.5 million for the six-month period ended June 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 $4.5 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 $1.9 million, due to the Company's decision on December 20, 2021 to discontinue further clinical development of APTO-253.

- Personnel-related expenses increased by $421 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 current three-month period.

- Stock-based compensation decreased by approximately $893 thousand in the six months ended June 30, 2022, compared with the three months ended June 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 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 and six-month periods ended June 30, 2022, and 2021 were as follows:

| | Three months ended June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| (in thousands) | 2022 | 2021 | 2022 | 2021 |
| General and administrative, excluding items below | $ 3,069 | $ 2,456 | $ 5,590 | $ 5,181 |
| Stock-based compensation | 242 | 1,166 | 1,810 | 6,431 |
| Depreciation of equipment | 21 | 35 | 39 | 69 |
| | $ 3,332 | $ 3,657 | $ 7,439 | $ 11,681 |

General and administrative expenses for the three-month period ended June 30, 2022 were $3.3 million as compared with $3.7 million for the comparative period in 2021, a decrease of approximately $325 thousand. The decrease was primarily as a result of the following:

- General and administrative expenses, other than stock-based compensation and depreciation of equipment, increased by approximately $613 thousand in the three months ended June 30, 2022 primarily as a result of higher salaries expenses and higher professional fees.

- Stock-based compensation decreased by approximately $924 thousand in the three months ended June 30, 2022, compared with the three months ended June 30, 2021, primarily due to lower grant date fair value of options which were granted in the current period.

General and administrative expenses for the six-month period ended June 30, 2022 were $7.4 million as compared with $11.7 million for the comparative period, a decrease of approximately $4.2 million. The decrease was primarily a result of the following:

- General and administrative expenses, other than share-based compensation and depreciation of equipment, increased by approximately $409 thousand in the six months ended June 30, 2021, primarily as a result of higher salaries expense and higher professional fees.

- Stock-based compensation decreased by approximately $4.6 million in the six months ended June 30, 2022, compared with the six months ended June 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**

Aptose will host a conference call today to discuss results for the quarter ended June 30, 2022:

| | |
|---|---|
| **Date:** | Tuesday, August 2, 2022 |
| **Time:** | 5:00 PM ET |
| **Audio Webcast Only:** | link |
| **Participant Registration Link*:** | here |

(https://register.vevent.com/register/BI8803d12ec6d04e93af962f01cbc8ae7d)

*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 also can 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 ended June 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: 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 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 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:

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