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): October 31, 2023

KINTARA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Nevada	**001-37823**	**99-0360497**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

9920 Pacific Heights Blvd, Suite 150 **San Diego, CA**	**92121**
(Address of principal executive office)	(Zip Code)

Registrant's telephone number, including area code: (858) 350-4364

N/A
(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 Stock	**KTRA**	**The 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 7.01 Regulation FD.

On October 31, 2023, Kintara Therapeutics, Inc. (the "Company") issued a press release announcing the preliminary topline results of the Global Coalition for Adaptive Research Glioblastoma Adaptive Global Innovative Learning Environment study for VAL-083 (the "GBM AGILE Study"). A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Current Report on Form 8-K under Item 7.01, including the information contained in Exhibit 99.1, is being furnished to the Securities and Exchange Commission, and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by a specific reference in such filing.

Item 8.01 Other Events.

On October 31, 2023, the Company announced that preliminary topline results of the GBM AGILE Study showed that VAL-083 did not perform better than the current standards of care in glioblastoma. The topline results included preliminary safety data for VAL-083 that was similar to that of the current standards of care used to treat glioblastoma. With the GBM AGILE Study outcome, the Company is suspending the development of VAL-083 and turning its focus to its second program, REM-001. In addition to focusing on its REM-001 program, the Company will evaluate a wide range of strategic options aimed at potentially maximizing shareholder value. The Company expects to enroll the first subject in a 15-patient study of REM-001 in cutaneous metastatic breast cancer around the end of calendar year 2023.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated October 31, 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.

KINTARA THERAPEUTICS, INC.

Date: October 31, 2023

By: /s/ *Robert E. Hoffman*
Name: Robert E. Hoffman
Title: Chief Executive Officer

Exhibit 99.1

Kintara Therapeutics Announces Preliminary Topline Results From GBM AGILE Study

- VAL-083 Did Not Perform Better Than Current Standards of Care -

- Company Suspending Development of VAL-083, Shifting Focus to REM-001 Program and Other Strategic Opportunities -

SAN DIEGO, Oct. 31, 2023 -- Kintara Therapeutics, Inc. (Nasdaq: KTRA) (“Kintara” or the “Company”), a biopharmaceutical company focused on the development of new solid tumor cancer therapies, today announced that preliminary topline results from the Glioblastoma Adaptive Global Innovative Learning Environment (GBM AGILE) study showed that VAL-083 did not perform better than the current standards of care in glioblastoma. These topline results included preliminary safety data for VAL-083 that was similar to that of the current standards of care used to treat glioblastoma. With this study outcome, Kintara is suspending the development of VAL-083 and turning its focus to its second program, REM-001. In addition to focusing on its REM-001 program, Kintara will evaluate a wide range of strategic options aimed at potentially maximizing shareholder value.

"Glioblastoma represents a high unmet medical need, and patients with this disease have very few treatment options," said Robert E. Hoffman, President and Chief Executive Officer of Kintara. “We are very disappointed that the VAL-083 GBM AGILE Study preliminary results do not support continued development efforts to give patients additional treatment options. We sincerely appreciate the exceptional support from patients and their families as well as patient advocates, physicians and our employees who have been committed to the rigorous study of VAL-083. As we shift priorities, we look forward to enrolling our first patient in our 15-patient study of REM-001 in cutaneous metastatic breast cancer (CMBC). Additionally, we will conduct a thorough review of potential strategic opportunities for us to maximize shareholder value in the Company.”

“GBM AGILE is a rigorous mechanism for us to efficiently evaluate investigational drugs in a well-controlled, randomized setting,” said Meredith Buxton, CEO and President of Global Coalition of Adaptive Research, Sponsor of GBM AGILE. “While we are disappointed that the preliminary results for VAL-083 did not show benefit over standard of care, GBM AGILE is operating as designed and we await final data for VAL-083 in 2024 to better understand if there are possible pathways for further development.”

All development activities and related costs for VAL-083 will be suspended while the Company awaits the full dataset from the GBM AGILE Study which is expected at the end

of the first quarter/beginning of second quarter of calendar year 2024. At such time Kintara will analyze the full results as it seeks to maximize the value of the VAL-083 asset.

Kintara expects to enroll the first subject in a 15-patient CMBC study around the end of calendar year 2023. The Company was recently awarded a $2 million grant from the National Institutes of Health (NIH) which is expected to cover the majority of the cost to run the CMBC study. In November 2022, the United States Food and Drug Administration (FDA) granted Fast Track Designation (FTD) to Kintara's REM-001 Therapy for the treatment of patients with CMBC.

REM-001 is a proprietary, late-stage photodynamic therapy platform that holds promise as a localized cutaneous, or visceral, tumor treatment as well as in other potential indications. REM-001 Therapy, which consists of the laser light source, the light delivery device, and the REM-001 drug product, has been previously studied in four Phase 2/3 clinical trials in patients with CMBC who had previously received chemotherapy and/or failed radiation therapy. In CMBC, REM-001 has a clinical efficacy to date of 80% complete responses of CMBC evaluable lesions and an existing robust safety database of approximately 1,100 patients across multiple indications.

ABOUT KINTARA

Located in San Diego, California, Kintara is dedicated to the development of novel cancer therapies for patients with unmet medical needs and reduced development risk. Kintara’s focus is the development of REM-001 as a treatment for CMBC.

For more information, please visit www.kintara.com or follow us on X (formerly Twitter) at @Kintara_Thera, Facebook and LinkedIn.

SAFE HARBOR STATEMENT

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995, including statements regarding the status of the Company's clinical trials, the topline results of the GBM AGILE Study and the Company’ review of strategic alternatives. Any forward-looking statements contained herein are based on current expectations but are subject to a number of risks and uncertainties. The factors that could cause actual future results to differ materially from current expectations include, but are not limited to, risks and uncertainties relating to the Company's ability to develop, market and sell products based on its technology; the expected benefits and efficacy of the Company's products and technology; the availability of substantial additional funding for the Company to continue its operations and to conduct research and development, clinical studies and future product commercialization; the Company's business, research, product development, regulatory approval, marketing and distribution plans and strategies; and global unrest. These and other factors are identified and described in more detail in the Company's filings with the SEC, including the Company's Annual Report

on Form 10-K for the year ended June 30, 2023, the Company's Quarterly Reports on Form 10-Q, and the Company's Current Reports on Form 8-K.

CONTACTS

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