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): February 12, 2024

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** (Address of principal executive office)	**92121** (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 February 12, 2024, Kintara Therapeutics, Inc. (the "Company") issued a press release announcing the initiation of a REM-001 15-patient clinical trial in cutaneous metastatic breast cancer ("CMBC") patients. 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 February 12, 2024, the Company announced the initiation of a REM-001 15-patient clinical trial in CMBC patients. The open label 15-patient study in CMBC patients is evaluating REM-001, a second-generation photodynamic therapy photosensitizer agent, and is designed to test the 0.8 mg dose as well as optimize the study design in advance of a Phase 3 trial initiation. The primary endpoint in the study is Best Overall Objective Response Rate (complete response or partial response) of the target treatment fields at any time from treatment up to, and including, week 24.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated February 12, 2024
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: February 12, 2024

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

Exhibit 99.1

Kintara Therapeutics Announces Initiation of REM-001 Clinical Trial for the Treatment of Cutaneous Metastatic Breast Cancer

- 15-patient Open Label Study to Confirm Planned Dose and Optimized Study Design Leading to a Phase 3 Clinical Trial in CMBC Patients -

SAN DIEGO, February 12, 2024/PRNewswire/ -- Kintara Therapeutics, Inc. (Nasdaq: KTRA) ("Kintara" or the "Company"), a biopharmaceutical company focused on the development of new solid tumor cancer therapies, today announced the initiation of a REM-001 15-patient clinical trial (NCT05374915) in cutaneous metastatic breast cancer (CMBC) patients.

This open label 15-patient study in CMBC patients is evaluating REM-001, a second-generation photodynamic therapy (PDT) photosensitizer agent, and is designed to test the 0.8 mg dose as well as optimize the study design in advance of a Phase 3 trial initiation. The primary endpoint in the study is Best Overall Objective Response Rate (bORR) (complete response or partial response) of the target treatment fields at any time from treatment up to, and including, week 24.

In June 2023, Kintara was awarded a $2.0 million Small Business Innovation Research (SBIR) grant from the National Institutes of Health (NIH) to support the clinical development of REM-001 in CMBC. This grant will cover the majority of the costs to run this clinical study.

"We are encouraged by the extensive data from prior REM-001 therapy trials supporting its strong efficacy in CMBC patients, providing us with an opportunity to address a significant unmet medical need," said Robert E. Hoffman, President and CEO of Kintara. "With an 80% complete response rate for evaluable lesions in CMBC patients observed in previous late-stage clinical trials and the support of the NIH, along with the FDA's Fast Track Designation, we are confident in the potential of REM-001 to help CMBC patients."

"CMBC is a devastating disease with limited treatment options for patients," said Alina Markova, M.D., Section Head, General Dermatology and Oncodermatology at Memorial Sloan Kettering Cancer Center and Principal Investigator of the REM-001 15-patient study. "I am looking forward to testing the therapeutic potential of REM-001 in this trial and bringing novel therapies to CMBC patients to improve their quality of life."

Cutaneous metastases can develop with any metastatic cancer but are believed to occur most frequently in metastatic breast cancer. A 2003 meta-analysis of over 20,000 metastatic cancer patients found that 24% of the breast cancer patients included in the analysis had developed cutaneous metastases, which was the highest rate of any cancer type. Based on a 2017 analysis, the current prevalence of metastatic breast cancer in the United States is estimated to be over 168,000. Accordingly, the prevalence of CMBC may be in excess of 40,000 cases annually in the United States.

ABOUT KINTARA

Located in San Diego, California, Kintara is dedicated to the development of novel cancer therapies for patients with unmet medical needs. Kintara develops therapeutics for clear unmet medical needs with reduced risk development programs. The Company's lead program is REM-001 Therapy for cutaneous metastatic breast cancer.

Kintara has 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.

For more information, please visit www.kintara.com or follow us on X 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 Company's REM-001 15-patient clinical trial in CMBC patients. 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 Company's review of strategic alternatives; 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 status of the Company's clinical trials; 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

Investors:
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