

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): June 3, 2024

KINTARA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction
of incorporation)

001-37823
(Commission
File Number)

99-0360497
(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 Disclosure.

On June 3, 2024 TuHURA Biosciences, Inc. (“TuHURA”) and Kintara Therapeutics, Inc. (“Kintara”) issued a press release announcing positive results from the primary analysis of the TuHURA’s completed Phase 1b clinical trial evaluating IFx-2.0 among patients with advanced or metastatic checkpoint inhibitor-resistant advanced Merkel Cell Carcinoma and Cutaneous Squamous Cell Carcinoma who exhibited primary resistance to immune checkpoint inhibitor therapy.

The press release and the information set forth therein shall not be deemed to be filed for purposes of Section 18 of the Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise be subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act.

Additional Information about the Proposed Merger and Where to Find It

This Current Report on Form 8-K does not constitute an offer to buy or sell or the solicitation of an offer to buy or sell any securities or a solicitation of any vote or approval. This Current Report on Form 8-K relates to the proposed merger (the “Merger”) of Kintara and TuHURA. In connection with the proposed Merger, Kintara has filed a Registration Statement on Form S-4, which includes a preliminary proxy statement and a preliminary prospectus of Kintara (the “proxy statement/prospectus”). This registration statement has not yet been declared effective and Kintara has filed or may file other documents regarding the proposed Merger with the SEC. No offering of securities shall be made, except by means of a prospectus meeting the requirements of Section 10 of the Securities Act. INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE PRELIMINARY PROXY STATEMENT/PROSPECTUS AND OTHER RELEVANT DOCUMENTS FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY, WHEN THEY BECOME AVAILABLE, BECAUSE THEY CONTAIN AND WILL CONTAIN IMPORTANT INFORMATION THAT STOCKHOLDERS SHOULD CONSIDER BEFORE MAKING ANY DECISION REGARDING THE PROPOSED MERGER. A definitive proxy statement/prospectus will be sent to Kintara’s stockholders once available. Investors and security holders will be able to obtain these documents (when available) free of charge from the SEC’s website at www.sec.gov. In addition, investors and stockholders should note that Kintara communicates with investors and the public using its website (www.kintara.com), the investor relations website (<https://www.kintara.com/investors>) where anyone will be able to obtain free copies of the proxy statement/prospectus and other documents filed by Kintara with the SEC, and stockholders are urged to read the proxy statement/prospectus and the other relevant materials when they become available before making any voting or investment decision with respect to the proposed Merger.

Participants in the Solicitation

Kintara, TuHURA and their respective directors and executive officers and other members of management and employees and certain of their respective significant stockholders may be deemed to be participants in the solicitation of proxies from Kintara and TuHURA stockholders in respect of the proposed Merger. Information about Kintara’s directors and executive officers is available in Kintara’s proxy statement, which was filed with the SEC on May 17, 2024 for the 2024 Annual Meeting of Stockholders, Kintara’s Annual Report on Form 10-K for the fiscal year ended June 30, 2023, which was filed with the SEC on September 18, 2023. Information regarding the persons who may, under the rules of the SEC, be deemed participants in the proxy solicitation and a description of their direct and indirect

interests, by security holding or otherwise, will be contained in the proxy statement/prospectus and other relevant materials to be filed with the SEC regarding the proposed Merger when they become available. Investors should read the proxy statement/prospectus carefully when it becomes available before making any voting or investment decisions. You may obtain free copies of these documents from the SEC and Kintara as indicated above.

No Offer or Solicitation

This Current Report on Form 8-K shall not constitute an offer to sell or the solicitation of an offer to buy any securities or a solicitation of any proxy, consent, authorization, vote or approval, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act.

Forward-Looking Statements

This Current Report on Form 8-K and the press release attached hereto as Exhibit 99.1 contain forward-looking statements based upon Kintara's and TuHURA's current expectations. This communication contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are identified by terminology such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "could," "should," "would," "project," "plan," "expect," "goal," "seek," "future," "likely" or the negative or plural of these words or similar expressions. These statements are only predictions. Kintara and TuHURA have based these forward-looking statements largely on their then-current expectations and projections about future events, as well as the beliefs and assumptions of management. Forward-looking statements are subject to a number of risks and uncertainties, many of which involve factors or circumstances that are beyond each of Kintara's and TuHURA's control, and actual results could differ materially from those stated or implied in forward-looking statements due to a number of factors, including but not limited to: (i) the risk that the conditions to the closing or consummation of the proposed Merger are not satisfied, including the failure to obtain stockholder approval for the proposed Merger; (ii) uncertainties as to the timing of the consummation of the proposed Merger and the ability of each of Kintara and TuHURA to consummate the transactions contemplated by the proposed Merger; (iii) risks related to Kintara's and TuHURA's ability to correctly estimate their respective operating expenses and expenses associated with the proposed Merger, as applicable, as well as uncertainties regarding the impact any delay in the closing would have on the anticipated cash resources of the resulting combined company upon closing and other events and unanticipated spending and costs that could reduce the combined company's cash resources; (iv) the occurrence of any event, change or other circumstance or condition that could give rise to the termination of the proposed Merger by either Kintara or TuHURA; (v) the effect of the announcement or pendency of the proposed Merger on Kintara's or TuHURA's business relationships, operating results and business generally; (vi) costs related to the proposed Merger; (vii) the outcome of any legal proceedings that may be instituted against Kintara, TuHURA, or any of their respective directors or officers related to the Merger Agreement or the transactions contemplated thereby; (viii) the ability of Kintara or TuHURA to protect their respective intellectual property rights; (ix) competitive responses to the proposed Merger; (x) unexpected costs, charges or expenses resulting from the proposed Merger; (xi) whether the combined business of TuHURA and Kintara will be successful; (xii) legislative, regulatory, political and economic developments; and (xiii) additional risks described in the "Risk Factors" section of Kintara's Annual Report on Form 10-K for the fiscal year ended June 30, 2023, and the registration statement on Form S-4 related to the proposed Merger filed with the SEC. Additional assumptions, risks and uncertainties are described in detail in Kintara's registration statements, reports and other filings with the SEC, which are available on Kintara's website, and at www.sec.gov. Accordingly, you should not rely upon forward-looking statements as predictions of future events. Neither Kintara nor TuHURA can assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. The forward-looking statements made in this communication relate only to events as of the date on which the statements are made. Except as required by applicable law or regulation, Kintara and TuHURA undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. Investors should not assume that any lack of update to a previously issued "forward-looking statement" constitutes a reaffirmation of that statement.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press release of TuHURA Biosciences, Inc. and Kintara Therapeutics, Inc. issued June 3, 2024

SIGNATURES

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: June 3, 2024

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

TuHURA Biosciences and Kintara Therapeutics Announce Positive Results from Phase 1b Trial of IFx-2.0, a Novel Personalized Cancer Vaccine, in Checkpoint Inhibitor Resistant Advanced Merkel Cell Carcinoma (MCC) and Cutaneous Squamous Cell Carcinoma (cSCC)

TuHURA's lead candidate, IFx-2.0, was safe and well tolerated at once weekly dosing for 3 weeks

Eighty percent (80%) of ICI naïve patients with advanced MCC who failed to respond to pembrolizumab or avelumab therapy achieved a durable Complete Response (CR), pathologic CR or Partial Response (PR) following IFx-2.0 therapy and rechallenge with an anti-PD(L)-1 checkpoint inhibitor

Data presented at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting

TAMPA, FL & SAN DIEGO, CA, June 3, 2024 –TuHURA Biosciences, Inc. (“TuHURA”), a Phase 3 registration-stage immunology company developing novel technologies to overcome resistance to cancer immunotherapy and Kintara Therapeutics, Inc. (Nasdaq: KTRA) (“Kintara”), a biopharmaceutical company focused on the development of new solid tumor cancer therapies, today announced positive results from the primary analysis of TuHURA’s completed Phase 1b trial evaluating IFx-2.0 among patients with advanced or metastatic MCC or cSCC who exhibited primary resistance to immune checkpoint inhibitor (ICIs) therapy.

The abstract titled, “*Phase 1b trial of IFx-Hu2.0, a novel in situ cancer vaccine, in checkpoint inhibitor-resistant Merkel Cell Carcinoma (MCC) and Cutaneous Squamous Cell Carcinoma (cSCC)*,” was presented by Andrew Brohl, MD, H. Lee Moffitt Cancer Center and Research Institute, in a poster presentation as part of the Melanoma/Skin Cancers session held at the 2024 ASCO Annual Meeting in Chicago, IL.

“It is encouraging that IFx-2.0 demonstrated the ability to overcome resistance to ICI in 63% of patients with advanced MCC, even in patients who progressed on both anti-PD1 therapy followed by anti-PD1/CTLA-4 combination therapy, many of whom also received chemotherapy and several investigational agents post ICI failure and prior to IFx-2.0 treatment,” commented Dr. James Bianco, Chief Executive Officer of TuHURA.

The group that was of most interest were the seven (7) patients with ICI naïve, advanced MCC, who, prior to IFx-2.0 treatment, received no subsequent systemic or investigational therapies that may confound the ability to determine IFx-2.0’s contribution to overcoming primary

resistance to ICI therapy. Five (5) of these 7 patients progressed within 3.8 months while receiving single agent anti-PD(L)-1 therapy. IFx-2.0 was administered as the immediate post ICI therapy. Following IFx-2.0 treatment, patients were rechallenged with an anti-PD(L)-1 agent. Four (4) of the 5 patients (80%) achieved a durable objective response (CR, pCR, 2 PRs) lasting, on average, 25 months, with 2 responses ongoing at 19 and 23 months.

The remaining 2 of 7 patients, after progressing on anti-PD-1 therapy, also received and progressed on combination anti-PD1/anti-CTLA4 therapy prior to IFx-2.0 treatment. Following IFx-2.0, 1 patient (50%) achieved a PR, ongoing at 6 months following rechallenge with single agent anti-PD-1 rechallenge.

The promising efficacy signal demonstrated in the Phase 1b study showing the potential for IFx-2.0 to overcome primary resistance to anti-PD(L)-1 therapy formed the rationale for TuHURA's planned Phase 3 registration-directed clinical trial. The Phase 3 trial will examine IFx-2.0 as an adjunctive therapy with Keytruda® (pembrolizumab, an anti-PD-1 agent) to improve tumor overall response rates when compared to Keytruda® plus placebo in first line treatment of ICI naïve patients with advanced or metastatic MCC. This Phase 3 trial is expected to begin enrollment in 2H-2024 under the FDA's Accelerated Approval Pathway.

TuHURA's IFx-2.0 personalized cancer vaccine product involves the injection into a patient's tumor of a small amount of pDNA that is designed to encode for an immunogenic bacterial protein that gets expressed on the surface of the patient's tumor so that the surface of the tumor looks like a bacterium. By making the surface of a tumor look like a bacterium, IFx-2.0 is designed to use each patient's tumor itself as the source of foreign neoantigens to prime and initiate a patient's innate immune response against the tumor irrespective of whether the tumor escaped immune recognition prior to IFx-2.0 administration. In doing so, IFx-2.0 is designed to harness the power of the patient's innate immune response, which has evolved over time to be conserved to detect foreign pathogens like bacterial proteins.

The primary objective of the Phase 1b study was to establish safety and feasibility of repeated administrations of IFx-2.0. The study met its primary safety objective: ≥80% completion of planned study therapy was predefined as a successful feasibility outcome. Given the proposed potential for immune priming effects of IFx-2.0, researchers performed an unplanned exploratory analysis of post-protocol treatment efficacy to evaluate response to ICI rechallenge.

As reported at ASCO, following completion of protocol directed therapy, 11 patients with MCC and 6 patients with cSCC who, prior to study entry, failed anti-PD(L)1 or anti-PD-1/CTLA-4 therapy, were re-treated with anti-PD(L)1 monotherapy or combination therapy as the immediate IFx-2.0 post-protocol therapy: pembrolizumab (7), nivolumab + ipilimumab (2), or avelumab (2) in MCC and cemiplimab (6) in cSCC. The study concluded that IFx-Hu2.0 is safe and well tolerated at weekly dosing repeated up to 3 weeks. In an exploratory post-hoc analysis, 7 of 11 MCC patients (63%) treated with standard of care ICI agents immediately following protocol therapy experienced durable disease control despite prior failure of this same drug class prior to protocol enrollment, suggesting an "immune priming" effect of study therapy. Based on this

promising efficacy signal, a randomized study of pembrolizumab +/- IFx-Hu2.0 is planned in the advanced MCC 1st line setting.

For more information about TuHURA's Phase 1b IFx-2.0 study, visit clinicaltrials.gov and reference identifier: NCT04160065.

As previously announced, TuHURA entered into a definitive agreement for an all-stock transaction with Kintara to form a company combining expertise and resources to advance a risk diversified late-stage oncology pipeline. In conjunction with the execution of the definitive agreement, TuHURA entered into subscription agreements for a \$31 million financing. The combined company will focus on advancing TuHURA's personalized cancer vaccine(s) and first-in-class bi-functional Antibody Drug Conjugates ("ADCs"), two technologies that seek to overcome the major obstacles that limit the effectiveness of current immunotherapies in treating cancer. The combined company is expected to operate under the name "TuHURA Biosciences, Inc." and to trade on The Nasdaq Capital Market under the ticker "HURA". The transaction is subject to customary closing conditions, including stockholder approval of both companies, and is expected to close in the third quarter of 2024.

About TuHURA Biosciences, Inc.

TuHURA Biosciences, Inc. is a Phase 3 registration-stage immuno-oncology company developing novel technologies to overcome resistance to cancer immunotherapy. TuHURA's lead personalized cancer vaccine candidate, IFx-2.0, is designed to overcome primary resistance to checkpoint inhibitors. TuHURA is preparing to initiate a single randomized placebo-controlled Phase 3 registration trial of IFx-2.0 administered as an adjunctive therapy to Keytruda® (pembrolizumab) in first line treatment for advanced or metastatic Merkel Cell Carcinoma.

In addition to its cancer vaccine product candidates, TuHURA is leveraging its Delta receptor technology to develop first-in-class bi-functional ADCs, targeting Myeloid Derived Suppressor Cells to inhibit their immune suppressing effects on the tumor microenvironment to prevent T cell exhaustion and acquired resistance to checkpoint inhibitors and cellular therapies.

For more information, please visit tuhurabio.com and connect with TuHURA on Facebook, X, and LinkedIn.

About Kintara

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

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.

No Offer or Solicitation

This communication shall not constitute an offer to sell or the solicitation of an offer to buy any securities or a solicitation of any proxy, consent, authorization, vote or approval, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the U.S. Securities Act of 1933, as amended (the "Securities Act").

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as to the timing of the consummation of the proposed Merger and the ability of each of Kintara and TuHURA to consummate the transactions contemplated by the proposed Merger; (iii) risks related to Kintara's and TuHURA's ability to correctly estimate their respective operating expenses and expenses associated with the proposed Merger, as applicable, as well as uncertainties regarding the impact any delay in the closing would have on the anticipated cash resources of the resulting combined company upon closing and other events and unanticipated spending and costs that could reduce the combined company's cash resources; (iv) the occurrence of any event, change or other circumstance or condition that could give rise to the termination of the proposed Merger by either Kintara or TuHURA; (v) the effect of the announcement or pendency of the proposed Merger on Kintara's or TuHURA's business relationships, operating results and business generally; (vi) costs related to the proposed Merger; (vii) the outcome of any legal proceedings that may be instituted against Kintara, TuHURA, or any of their respective directors or officers related to the Merger Agreement or the transactions contemplated thereby; (viii) the ability of Kintara or TuHURA to protect their respective intellectual property rights; (ix) competitive responses to the proposed Merger; (x) unexpected costs, charges or expenses resulting from the proposed Merger; (xi) whether the combined business of TuHURA and Kintara will be successful; (xii) legislative, regulatory, political and economic developments; and (xiii) additional risks described in the "Risk Factors" section of Kintara's Annual Report on Form 10-K for the fiscal year ended June 30, 2023, and the Registration Statement on Form S-4 related to the proposed Merger filed with the SEC. Additional assumptions, risks and uncertainties are described in detail in Kintara's registration statements, reports and other filings with the SEC, which are available on Kintara's website, and at www.sec.gov. Accordingly, you should not rely upon forward-looking statements as predictions of future events. Neither Kintara nor TuHURA can assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. The forward-looking statements made in this communication relate only to events as of the date on which the statements are made. Except as required by applicable law or regulation, Kintara and TuHURA undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. Investors should not assume that any lack of update to a previously issued "forward-looking statement" constitutes a reaffirmation of that statement.

Investor Contacts:

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