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 15, 2025

TUHURA BIOSCIENCES, 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.)**

10500 University Center Dr., Suite 110
Tampa, Florida 33612

(Address of Principal Executive Offices, including zip code)

Registrant's Telephone Number, Including Area Code: (813) 875-6600

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, $0.001 par value per share	HURA	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 2.02 Results of Operations and Financial Condition.

On May 15, 2025, TuHURA Biosciences, Inc. (the "Company" or "TuHURA") issued a press release reporting its financial results for the three months ended March 31, 2025, and providing a corporate update. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein

The information contained in this Current Report, including Exhibit 99.1 attached hereto, is being furnished, shall not be deemed "filed" for any purpose, and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as expressly set forth by specific reference in such a filing.

Important Additional Information Regarding Proposed Merger with Kineta

In connection with the proposed acquisition by merger of Kineta, Inc. ("Kineta") by TuHURA (the "Merger"), TuHURA filed with the U.S. Securities and Exchange Commission (the "SEC") a registration statement on Form S-4, dated February 7, 2025 (the "Registration Statement"), which, as amended, contains a preliminary joint proxy statement of Kineta and TuHURA and a preliminary prospectus of TuHURA (the "Joint Proxy Statement/Prospectus"), and TuHURA and Kineta may file with the SEC other relevant documents regarding the Merger. ***Investors and securityholders of TuHURA and Kineta are urged to read the Joint Proxy Statement/Prospectus and such other materials carefully when they become available because they will contain important information about TuHURA, Kineta, and the proposed Merger. This Form 8-K is not a substitute for the definitive Joint Proxy Statement/Prospectus, when it becomes available, or any other documents that TuHURA may file with the SEC or send to securityholders in connection with the proposed Merger.***

A definitive copy of the Joint Proxy Statement/Prospectus will be mailed to Kineta and TuHURA stockholders when that document is final. Investors and stockholders will be able to obtain free copies of the documents filed or that will be filed with the SEC by TuHURA, when they become available, through the website maintained by the SEC at www.sec.gov. The documents filed by TuHURA with the SEC may also be obtained free of charge at TuHURA's website at www.tuhurabio.com or upon written request to: TuHURA, 10500 University Drive, Suite 110, Tampa, Florida 33612.

No Offer or Solicitation

This Form 8-K is not a proxy statement or solicitation of a proxy, consent or authorization with respect to any securities or in respect of the Merger and is not intended to and does not constitute an offer to sell or the solicitation of an offer to buy the securities of TuHURA or Kineta, nor shall there be any sale of any such securities in any state or jurisdiction in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of such state or jurisdiction. No offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act.

Participants in the Solicitation

TuHURA and Kineta and their respective directors and officers and other members of management may, under SEC rules, be deemed to be participants in the solicitation of proxies from stockholders in connection with the Merger and other matters that may be set forth in the Joint Proxy Statement/Prospectus. Information about TuHURA's directors and executive officers is set forth in TuHURA's filings with the SEC, including TuHURA's Form 10-K filed on March 31, 2025. Additional information regarding the direct and indirect interests, by security holdings or otherwise, of those

persons and other persons who may be deemed participants in the solicitation of proxies in the Merger may be obtained by reading the Joint Proxy Statement/Prospectus when it becomes available. You may obtain free copies of these documents as described above under "IMPORTANT ADDITIONAL INFORMATION REGARDING PROPOSED MERGER WITH KINETA".

Cautionary Statement Regarding Forward-Looking Statements

This Form 8-K contains certain "forward-looking statements" within the meaning of, and subject to the safe harbor created by, Section 27A of the Securities Act, Section 21E of the Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995. These Forward-looking statements are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and other future conditions. In some cases you can identify these statements by forward-looking words 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. Examples of such forward-looking statements include but are not limited to express or implied statements regarding TuHURA's expectations, hopes, beliefs, intentions or strategies regarding the future and include, without limitation, statements regarding TuHURA's IFx-Hu2.0 product candidate and anticipated Phase 3 trial, its tumor microenvironment modulators development program, its potential acquisition by merger of Kineta Inc. and the statements about Kineta's VISTA-101 development program and statements regarding the closing conditions for the transaction, TuHURA's needs and expectations regarding its existing capital resources and its need for additional capital (including financing to complete the Kineta merger), and any developments or results in connection therewith and the anticipated regulatory pathway and timing of the foregoing development programs, studies and trials. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. You are cautioned that such statements are not guarantees of future performance and that actual results or developments may differ materially from those set forth in these forward-looking statements. Factors that could cause actual results to differ materially from these forward-looking statements are described in detail in our registration statements, reports and other filings with the SEC, which are available on the combined company's website, and at www.sec.gov.

The forward-looking statements and other information contained in this Form 8-K are made as of the date hereof, and TuHURA does not undertake any obligation to update publicly or revise any forward-looking statements or information, whether as a result of new information, future events or otherwise, unless so required by applicable securities laws. Nothing herein shall constitute an offer to sell or the solicitation of an offer to buy any securities.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit

No. Document

99.1 Press Release, dated May 15, 2025

104 Cover Page Interactive Data File (embedded within the Inline XBRL document).

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.

TUHURA BIOSCIENCES, INC.

Date: May 15, 2025

By: */s/* Dan Dearborn
Name: Dan Dearborn
Title: Chief Financial Officer

TuHURA Biosciences, Inc. Reports First Quarter 2025 Financial Results and Provides a Corporate Update

Anticipates initiating the Company's Phase 3 accelerated approval trial of IFx-Hu2.0 as adjunctive therapy with Keytruda® (pembrolizumab) as a first-line therapy for advanced and metastatic Merkel cell carcinoma (MCC), conducted under Special Protocol Assessment (SPA) agreement with U.S. Food and Drug Administration (FDA), in Q2 2025

Initiated a Phase 1b/2a trial of IFx-Hu2.0 as adjunctive therapy with pembrolizumab in first-line Merkel cell carcinoma of unknown primary origin (MCCUP)

Targeting to close the acquisition of Kineta, Inc. in Q2 2025 and initiate a Phase 2 trial of Kineta's VISTA inhibiting monoclonal antibody (mAb) in NPM1-mutated acute myeloid leukemia (AML) in Q3 2025

TAMPA, Fla., May 15, 2025 - TuHURA Biosciences, Inc. (NASDAQ:HURA) ("TuHURA"), a Phase 3 immune-oncology company developing novel technologies to overcome resistance to cancer immunotherapy, today reported financial results for the Company's first quarter ended March 31, 2025, and provided a corporate update.

"TuHURA has had an impressive start to 2025, and we continue to execute our corporate strategy as we drive towards TuHURA's four major clinical data readouts anticipated over the next 24 months. We recently initiated our Phase 1b/2a study of IFx-Hu2.0 in combination with pembrolizumab in checkpoint-naïve MCCUP patients. Evaluating IFx-Hu2.0 in MCCUP patients is an important component of our overall strategy for the program, as the Phase 1b/2a trial will include patients without skin lesions who present with metastatic deep-seated tumors in the liver, lungs or retroperitoneum (abdomen), who are not eligible to participate in our Phase 3 accelerated approval trial due to the trial's primary lesion enrollment criteria. Approximately 30% of MCC patients have unknown primary lesions, and demonstrating safety and efficacy in the MCCUP patient population would allow us the opportunity to provide IFx-Hu2.0 to more patients with MCC," said James Bianco, M.D., President and Chief Executive Officer of TuHURA Biosciences. "We are also moving towards initiating our Phase 3 accelerated approval trial of IFx-Hu2.0 in first-line advanced and metastatic MCC and anticipate resolving the manufacturing-related partial clinical hold in the coming weeks. Our Phase 3 trial, for which we have an SPA agreement with the FDA, will be a single randomized placebo-controlled trial, and, if positive, may satisfy the requirement for a post-approval confirmatory trial, saving time, money and risk associated with a second trial."

"In addition to our IFx-Hu2.0 drug candidate, we continue to assemble an exciting late-stage pipeline through our pending acquisition of Kineta, Inc. and its VISTA inhibitor antibody, KVA12123. We are targeting to close the acquisition later this quarter subject to financing and other conditions and advance KVA12123 into a Phase 2 trial in relapsed or refractory *NPM1*-mutated AML where VISTA expression on leukemic blasts is believed to be responsible for how leukemic cells escape immune recognition contributing to poor responses to therapy and high

rates of relapse," stated Dr. Bianco. "We are also developing tumor microenvironment modulators in the form of bi-specific immune modulating Antibody Peptide Conjugates (APCs) and Antibody Drug Conjugates (ADCs) targeting myeloid-derived suppressor cells (MDSCs). We plan to present additional data at a scientific conference this year on the discovery of high-expression delta opioid receptor (DOR) and the effect on MDSCs and M2 macrophages in the tumor environment. We believe that our DOR program has the potential to reprogram the function of MDSCs and M2 macrophages within the tumor microenvironment, which could have broad implications," concluded Dr. Bianco.

Corporate Highlights

•**Initiation of Phase 1b/2a Study of IFx-Hu2.0 as Adjunctive Therapy to Keytruda in 1L MCCUP.** In May 2025, TuHURA announced that it initiated its Phase 1b/2a trial of IFx-Hu2.0 as an adjunctive therapy to pembrolizumab in MCCUP. This Phase 1b/2a trial is investigating safety and feasibility of IFx-Hu2.0 when administered via interventional radiology to patients with deep-seated tumors who would not be eligible for the Phase 3 trial.

•**Presentation of Two Posters at the American Academy of Cancer Research (AACR) Annual Meeting.** In April 2025, TuHURA presented a poster at the AACR Annual Meeting outlining a greater than 90% VISTA receptor occupancy following treatment with the Kineta's VISTA inhibitor mAb as monotherapy and in combination with pembrolizumab in advanced solid tumors. Additionally, the Markowitz Lab at Moffitt Cancer Center presented a poster of IFx-Hu2.0, demonstrating increased T Cell and B Cell production in peripheral blood relative to tumor tissue following adjunctive administration of IFx-Hu2.0 in combination with pembrolizumab.

•**Appointment of Dr. Bertrand Le Bourdonnec as Head of Drug Discovery.** In April 2025, TuHURA announced the appointment of Dr. Le Bourdonnec as the Company's Executive Vice President, Head of Drug Discovery, Early Development and Program Management. Dr. Le Bourdonnec has extensive experience in the biology and molecular pharmacology of the DOR, TuHURA's core target on MDSCs for the Company's emerging suite of ADC and APC development candidates.

•**Appointment of Dr. Craig L. Tendler to Board of Directors.** In March 2025, TuHURA announced the appointment of industry veteran Dr. Craig Tendler to its Board of Directors. Dr. Tendler brings to TuHURA decades of experience in cancer therapeutic development, and most recently served as Johnson & Johnson's Vice President, Oncology Clinical Development. During his tenure at J&J, Dr. Tendler oversaw 30 major drug approvals, and led development planning from proof of concept through registration and life-cycle management, for J&J's treatments in hematological malignancies and more prevalent solid tumor diseases.

Upcoming Anticipated Milestones by Program

IFx-Hu2.0

- Q2 2025: TuHURA anticipates the FDA's complete response letter lifting the partial clinical hold relating to completion of certain CMC requirements.
- Q2 2025: Initiation of Phase 3 accelerated approval trial in first line Merkel cell carcinoma

VISTA Inhibiting Monoclonal Antibody

- Q2 2025: TuHURA expects to close its acquisition of Kineta, Inc. and Kineta's VISTA inhibiting mAb.
- Q3 2025: Initiation of Phase 2 trial of VISTA inhibiting mAb in combination with a menin inhibitor for the treatment of *NPM1*-mutated AML.

ADC and APC Development Candidates

- TuHURA continues to advance its bi-specific, bi-functional immune modulating ADCs and APCs that target the DOR on MDSCs, inhibiting their immune suppressing effects in the tumor microenvironment while localizing a checkpoint inhibitor like the VISTA inhibiting antibody.
- In 2025, TuHURA anticipates presenting non-clinical data at relevant medical meetings.

Financial Results for the Three Months Ended March 31, 2025

Research and development expenses were $4.6 million and $3.6 million for the three months ended March 31, 2025, and 2024, respectively.

General and administrative expenses were $2.4 million and $1.0 million for the three months ended March 31, 2025, and 2024, respectively.

As of March 31, 2025, TuHURA's total shares outstanding was approximately 43.7 million.

As previously announced, on December 11, 2024, TuHURA entered into a definitive agreement with Kineta, Inc. (OTC Pink: KANT) in which, as amended, TuHURA agreed to acquire Kineta, including the rights to Kineta's novel KVA12123 antibody, for a combination of cash and shares of TuHURA common stock via a merger transaction upon the terms and conditions described in TuHURA's Form 8-Ks filed on December 12, 2024 and May 7, 2025. The merger is currently targeted to close in Q2 2025 pending the satisfaction of certain financing and other closing conditions.

About TuHURA Biosciences, Inc.

TuHURA Biosciences, Inc. (Nasdaq: HURA) is a Phase 3 immuno-oncology company developing novel technologies to overcome primary and acquired resistance to cancer immunotherapy, two of the most common reasons cancer immunotherapies fail to work or stop working in the majority of patients with cancer.

TuHURA's lead innate immune agonist, 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) compared to Keytruda® plus placebo in first-line treatment for advanced or metastatic Merkel Cell Carcinoma.

In addition to its innate immune agonist product candidates, TuHURA is leveraging its Delta Opioid Receptor technology to develop first-in-class, bi-specific antibody drug conjugates and antibody peptide conjugates 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 www.tuhurabio.com and connect with TuHURA on Facebook, X, and LinkedIn.

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NO OFFER OR SOLICITATION

This press release is not a proxy statement or solicitation of a proxy, consent or authorization with respect to any securities or in respect of the Merger and is not intended to and does not constitute an offer to sell or the solicitation of an offer to buy the securities of TuHURA or Kineta, nor shall there be any sale of any such securities in any state or jurisdiction in which such

offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of such state or jurisdiction. No offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act.

PARTICIPANTS IN THE SOLICITATION

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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our registration statements, reports and other filings with the SEC, which are available on the combined company's website, and at www.sec.gov.

The forward-looking statements and other information contained in this press release are made as of the date hereof, and TuHURA does not undertake any obligation to update publicly or revise any forward-looking statements or information, whether as a result of new information, future events or otherwise, unless so required by applicable securities laws. Nothing herein shall constitute an offer to sell or the solicitation of an offer to buy any securities.

Investor Contact:

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