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May 19, 2025
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TuHURA Biosciences, Inc. (HURA: NASDAQ)

HURA: First Quarter 2025 Results

TuHURA's valuation relies on a DCF model and a 15% discount rate applied to our cash flow estimates. We apply a success probability of 60% to the IFx-2.0 program in MCC and 15% to the anti-VISTA program in AML generating a 50% blended rate. We separately value the ADC program. The adjustments recognize regulatory and commercialization risks. The model includes contributions from the US, EU, Australia & the developed world.

Current Price (5/16/2025)	$3.92
Valuation	**$9.25**

OUTLOOK

TuHURA is a clinical-stage, oncology-focused biotechnology company advancing innate immune agonists, checkpoint inhibitors & antibody-drug conjugates (ADCs). It offers the IFx platform technology featuring the IFx-2.0 tumoral injection delivery approach for Merkel cell carcinoma (MCC) & the IFx-3.0 intravenous delivery approach for lymphoma. IFx encodes a bacterial protein to be expressed in cancer cells, activating the innate immune system & subsequent cascade that may eliminate the tumor. Other assets include an anti-VISTA recently acquired from Kineta & the ADC Δ-opioid receptor which may be used to treat blood cancers.

IFx-2.0 uses pDNA to encode the production of Emm55 on cancer cells to elicit an immune response. A pivotal trial is planned for 1H:25, with a plan for FDA approval in 24 months using accelerated regulatory pathways & support from Project Frontrunner. Other assets in the portfolio may also advance quickly with supportive early data.

TuHURA recently reverse merged into a shell company and raised $36 million in 2024 to support its pipeline of products. Additional capital raises and partnerships with established biopharma companies are expected.

Initial clinical studies target rare and blood cancers, future opportunity lies in oncology using combinations with other immunotherapies.

SUMMARY DATA

52-Week High	**$7.93**
52-Week Low	**$1.80**
One-Year Return (%)	**-22.8**
Beta	**0.8**
Average Daily Volume (sh)	**196,560**
Shares Outstanding (mil)	**43.7**
Market Capitalization ($mil)	**171.3**
Short Interest Ratio (days)	**10.3**
Institutional Ownership (%)	**8.4**
Insider Ownership (%)	**42**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2025 Estimate	**N/A**
P/E using 2026 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of US$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2024	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2025	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2026					$0.0 E
2027					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2024	-$0.34 A	-$0.49 A	-$0.43 A	-$0.16 A	-$1.16 A
2025	-$0.16 A	-$0.14 E	-$0.17 E	-$0.16 E	-$0.63 E
2026					-$0.65 E
2027					-$0.64 E

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WHAT'S NEW

Operational and Financial Results

On May 15th, 2025, TuHURA Biosciences, Inc. (NASDAQ: HURA) reported first quarter 2025 financial and operational results and filed its Form 10-Q with the SEC. The company updated investors on the status of its IFx-2.0 Phase III trial in Merkel cell carcinoma (MCC) and the acquisition of Kineta. The Phase III trial is expected to begin and the Kineta acquisition is expected to close in 2Q:25. TuHURA recently launched a Phase Ib/II study for IFx-2.0 in MCC patients not eligible for the Phase III trial. Other important developments include presentations of clinical data at the American Association of Cancer Research (AACR) annual meeting in Chicago and the addition of a new executive. Below, we summarize 1Q:25's financial results.

TuHURA generated no revenues in 1Q:25 and expended $7.0 million on operational activities related to advancing IFx-2.0 and other programs producing a net loss of ($6.7) million or ($0.16) on a per share basis. For the quarter ending March 31st, 2025 and versus the same prior year period:

- Research & development expense totaled $4.6 million primarily attributable to greater expenses for preclinical research related to IFx-3.0 and myeloid derived suppressor cell (MDSC) initiatives and higher salary, personnel and facilities costs.
- General & administrative expense totaled $2.4 million, due to increases in non-stock compensation, costs related to being a public company and merger transaction costs related to the Kineta transaction;
- Other items included $253,000 in grant income related to Kintara's REM-001 asset and reimbursements from Health and Human Services;
- Interest income was $100,000 related to income paid on cash balances held;
- Net loss was ($6.7) million or ($0.16) per share.

As of March 31st, 2025, TuHURA held $6.2 million in cash on its balance sheet. 1Q:25 cash burn was ($4.8) million while cash used in financing was ($548,000) which consisted of warrant proceeds offset by transaction and liability payments related to Kintara.

AACR Presentations

TuHURA contributed to three presentations at the American Association for Cancer Research (AACR) Annual Meeting in Chicago, Illinois held from April 25th to 30th, 2025. The first was a poster that updated clinical data from the VISTA-101 trial for KVA12123 given by Dr. Thierry Guillaudeux of Kineta. The second poster was presented on behalf of the Markowitz Lab at Moffitt Cancer Center on TuHURA's IFx-Hu2.0 candidate on Merkel cell carcinoma patients that progressed while on checkpoint inhibitor (CPI) therapy. Details of the presentation were provided in an April 28th press release.

The anti-VISTA poster for KVA12123 is entitled Initial results from a first in human phase 1 study of KVA12123, an anti-VISTA antibody, alone and in combination with pembrolizumab in patients with advanced solid tumors. It presented updated results for the VISTA-101 trial which is a Phase I study evaluating KVA12123 alone and in combination with pembrolizumab in advanced solid tumors. No dose-limiting toxicities were shown in the data and KVA12123 presented a favorable pharmacokinetic (PK) and pharmacodynamic (PD) profile at all dose levels.

- At 1,000mg every two weeks, KVA12123 demonstrated greater than dose proportional PK profile exceeding 90% VISTA receptor occupancy, providing important PK data for determining recommended Phase 2 dose;
- No dose limiting toxicities were observed in the study, including at the 1,000 mg dose level, among the 24 patients treated in the monotherapy or in the 17 patients in the combination with pembrolizumab arms

The IFx-Hu2.0 poster reviewed patients on the therapy with advanced treatment refractory melanoma who progressed while on CPI therapy. Results from the study demonstrated that among heavily pre-treated patients with advanced melanoma who were resistant to anti-PD-1-based therapy, following IFx-Hu2.0, 75% (3 of 4) of patients achieved clinically meaningful, durable anti-tumor responses following re-administration of a CPI. The antibody specific response to IFx-Hu2.0's expressed bacterial protein supports further development of the candidate.

The second poster, entitled Mechanistic Insights into IFx-Hu2.0 Responses in the First Human Trial After Prior Anti-PD-1 Therapy Failure, demonstrated that IFx-Hu2.0 stimulated an innate immune response that increased T and B

cell production in peripheral blood compared to tumor tissue. This evidence supported IFx-Hu2.0's ability to generate an immune response to patients resistant to anti-PD1 checkpoint inhibitors. Additional information in the poster noted that IFx-Hu2.0 was generally safe and well tolerated with only mild Grade 1 and Grade 2 adverse reactions, mostly oriented around injection site reactions.

Phase III IFx-2.0 Trial in MCC

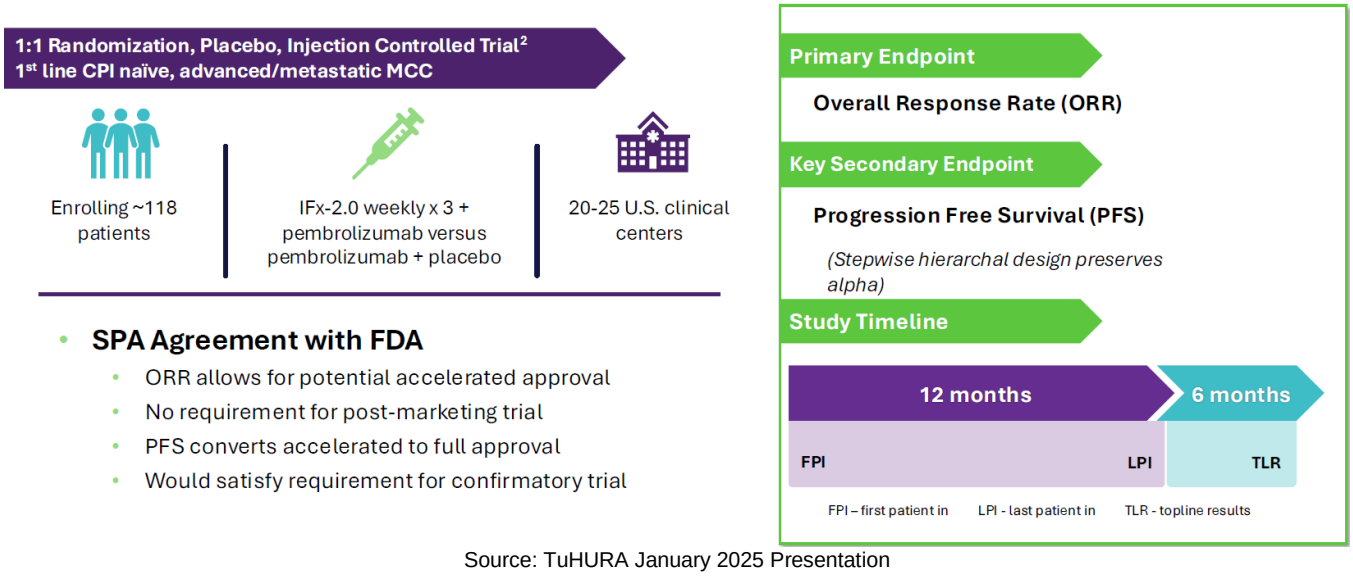
TuHURA plans to launch a pivotal Phase III study for its IFx-2.0 candidate in Merkel cell carcinoma (MCC) by the second quarter of 2025. It is working through chemistry, manufacturing and controls (CMC) requirements related to qualifying the potency assay and the mixing process[1] which have been resolved. IFx-2.0 will pursue a new drug application using the FDA's accelerated approval program under a special protocol assessment (SPA). The trial was designed with the input of the FDA's Oncology Center of Excellence (OCE). Accelerated approval allows the sponsor to use surrogate endpoints that predict clinical benefit and is appropriate when pursuing serious indications that lack other therapies. In most cases, an accelerated approval will require post-market confirmatory trials to verify the clinical benefit. However, in the case of this trial, the FDA has indicated that secondary endpoints that demonstrate clinical benefit may be used. If successfully achieved, the trial may satisfy the requirements for full approval.

The trial will be designed as a 1:1 randomized, placebo and injection-controlled trial in first-line, checkpoint inhibitor naïve, advanced metastatic MCC. It plans to enroll 118 subjects at 20 to 25 clinical centers in the United States. IFx-2.0 will be administered three times per week in combination with pembrolizumab vs. placebo with pembrolizumab. The primary endpoint will be overall response rate (ORR) which will allow for accelerated approval. The secondary endpoint, which indicates clinical benefit is progression free survival (PFS). If this endpoint is achieved, it will allow for full approval and satisfy the requirement for a confirmatory trial.

For the primary endpoints to support an accelerated approval, ORR needs to be 75% compared to the 50% which is the historical rate from other trials. For full approval, based on a continuation of this same trial, PFS has to achieve a 50% or better result.

The trial is expected to start in the second quarter of 2025 with enrollment lasting 12 months. ORR will be measured at six months, which indicates that top line results can be available 18 months after the trial begins. Accelerated approval will allow a rolling review and potential approval within six months of topline data.

Exhibit I – IFx-2.0 Phase III Trial Design



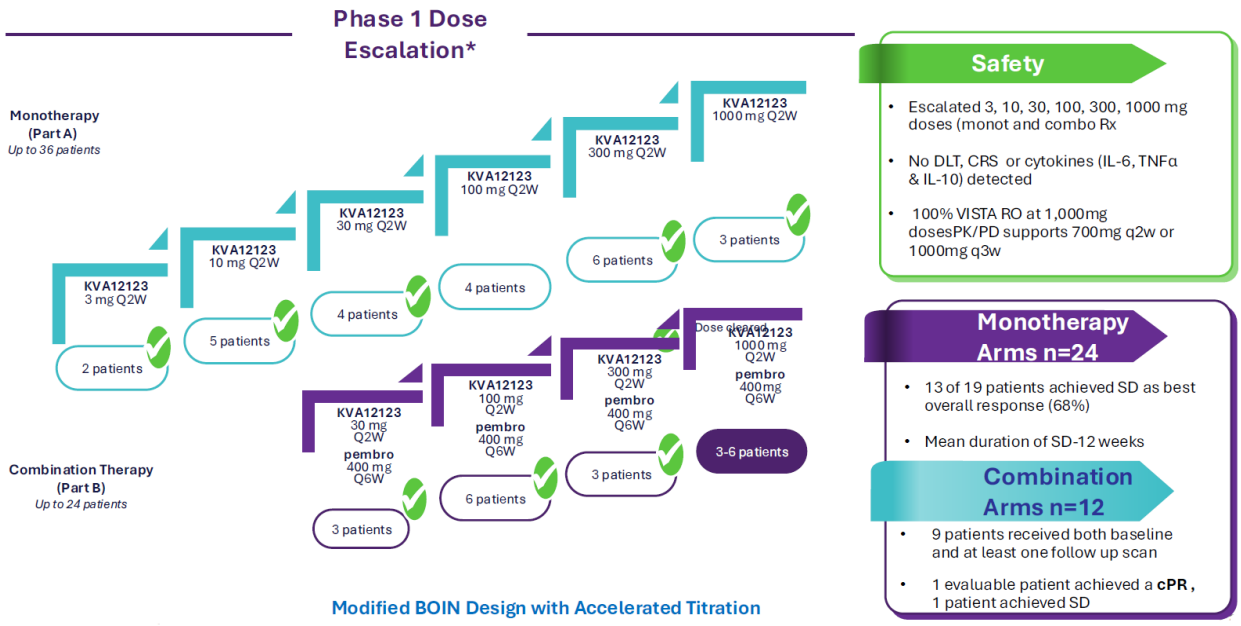
Source: TuHURA January 2025 Presentation

[1] Before administration, IFx-2.0 requires a specific mixing or compounding process at the clinical site. The mixing process involves combining pAc/emm55 (pDNA), complexed with two excipients: in vivo-jetPEI (a transfection reagent) and dextrose (a pDNA/polyethylenimine complex stabilizer) before administration. This step ensures that the plasmid DNA is prepared correctly for injection into the tumor. The process must be qualified and validated to meet regulatory standards, as outlined by the FDA. Validation includes in vitro testing and development to confirm potency and consistency.

KVA12 Phase I/II Clinical Trial in Solid Tumors

The KVA12 program is collaborating with Merck through the latter's contribution of pembrolizumab (Keytruda) to the alliance. It seeks to determine the safety and efficacy of KVA12 both alone and in combination with the PD-1 inhibitor in a Phase I/II clinical trial. A summary of the trial is posted on clinicaltrials.gov under NCT05708950. The primary endpoints are adverse events. Secondary endpoints include pharmacokinetics, immunogenicity, tumor response as per Immunotherapy Response Evaluation Criteria in Solid Tumors (iRECIST) standards and objective response rate (ORR). The study will be conducted in four parts: The first two will focus on dose escalation (single-agent and in combination), and the second two will concentrate on dose expansion (single-agent and in combination). Up to 10 dose escalation cohorts will be evaluated in Phase I and maximum tolerated dose will be identified. Exploratory endpoints will examine receptor occupancy, chemokine and cytokine levels in blood, immune cell populations in blood and VISTA expression in the tumor pre-and post-treatment. Up to 60 adult patients with advanced or metastatic solid tumors that have progressed or have been non-responsive to standard-of-care therapies are eligible to enroll. The next update for KVA12 will be by Chief Scientific Officer Thierry Guillaudeux, Ph.D. who will present a poster entitled Initial results from a first in human phase 1 study of KVA12123, an anti-VISTA antibody, alone and in combination with pembrolizumab in patients with advanced solid tumors at AACR in late April 2025.

Exhibit II – KVA12 Phase Ib Clinical Trial Design



Source: TuHURA January 2025 Presentation

Appointments

Over the last few months, TuHURA has made two new additions to the company's roster adding Craig Tendler, M.D. and Bertrand Le Bourdonnec, Ph.D. to serve as board member and head of drug discovery respectively.

Dr. Tendler has broad experience shepherding oncology candidates through the drug approval process at Johnson & Johnson. He can be a valuable resource as TuHURA moves IFx-2.0, the delta opioid receptor ADC and anti-VISTA through the drug development process. His appointment as director was announced on March 11th, 2025.

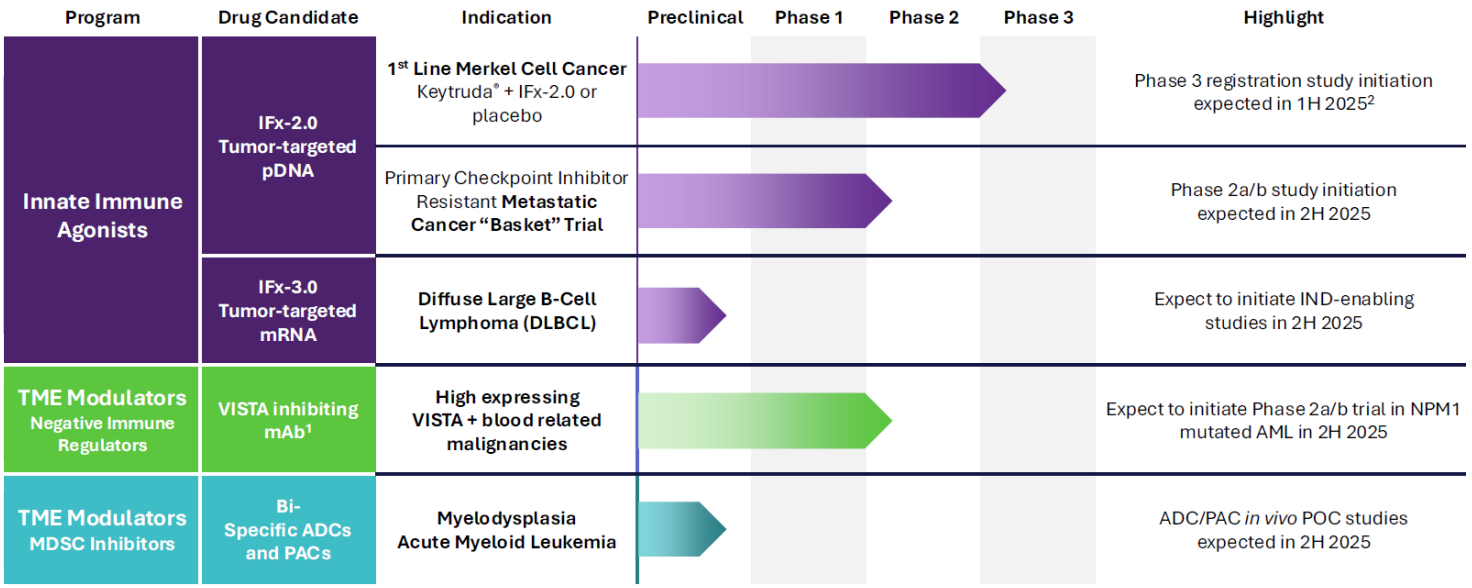
Dr. Le Bourdonnec was appointed as Head of Drug Discovery, Early Development and Program Management at TuHURA as detailed in an April 7th press release. He has a 20-year career in drug discovery and development honed at HDAX Therapeutics, Decipher Pharmaceuticals and Yumanity Therapeutics among other distinguished companies. His experience with the pharmacology and biochemistry of the Delta Opioid Receptor (DOR) will be valuable to TuHURA's development of its ADC and APC assets.

Milestones

- TuHURA Biosciences formed – 1995
- TuHURA becomes public via reverse merger – October 2024
- Entry into definitive merger agreement with Kineta – December 2024
- Launch IFx-2.0 Phase III trial – 2Q:25
- American Association for Cancer Research (AACR) abstracts accepted – April 2025
    - Initial results from a first in human phase 1 study of KVA12123, an anti-VISTA antibody, alone and in combination with pembrolizumab in patients with advanced solid tumors
    - Mechanistic insights into IFx-Hu2.0 responses in the first human trial after prior anti-PD-1 therapy failure
- Presentations at HC Wainwright BioConnect Conference – May 2025
- IFx-2.0 IR basket trial – 2Q:25
- Anticipated close of Kineta acquisition – 2Q:25
- Bi-specific MDSC targeted ADC & PDC proof of concept study – 3Q:25
- IFx-3.0 CD22 tumor-targeted mRNA *in vivo* proof of concept studies – 3Q:25
- VISTA inhibitor Phase II trial in NPM1 mutated AML – 4Q:25

Company Pipeline

Exhibit III – TuHURA Pipeline



Source: TuHURA March 2025 Presentation

Summary

TuHURA reported 1Q:25 financial results confirming the start of the Phase III IFx-2.0 trial in MCC and the close of the Kineta acquisition in 2Q:25. It also initiated its Phase Ib/II study of IFx-2.0 for MCC patients not eligible for the Phase III study which will initially enroll nine patients. New experts were added to the company's board and executive ranks and presentations at scientific and investor conferences are on the calendar. We expect to see a dramatic acceleration in activity over the next several months as the IFx-2.0 is launched, Kineta is acquired and its lead asset in anti-VISTA begins a Phase II study. We maintain our valuation of $9.25 per share.

PROJECTED FINANCIALS

TuHURA Biosciences, Inc. - Income Statement

TuHURA Biosciences, Inc.	2024 A	Q1 A	Q2 E	Q3 E	Q4 E	2025 E	2026 E	2027 E
Total Revenues ($USD)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Research & Development	$13,335	$4,582	$4,125	$4,580	$4,770	$18,057	$24,000	$30,000
General & Administrative	$4,314	$2,435	$2,000	$2,500	$2,650	$9,585	$7,000	$7,500
Other Operational Items								
Income from Operations	($17,649)	($7,017)	($6,125)	($7,080)	($7,420)	($27,642)	($31,000)	($37,500)
Restructuring & Impairments								
Other Items	($256)	$253	$0	$0	$0	$253	$0	$0
Net Interest Expense	($3,777)	$100	$0	$0	$0	$100	$0	$0
Pre-Tax Income	($21,682)	($6,664)	($6,125)	($7,080)	($7,420)	($27,289)	($31,000)	($37,500)
Provision for Income Tax	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate								
Net Income	**($21,682)**	**($6,664)**	**($6,125)**	**($7,080)**	**($7,420)**	**($27,289)**	**($31,000)**	**($37,500)**
Net Margin								
Reported EPS	**($1.16)**	**($0.16)**	**($0.14)**	**($0.17)**	**($0.16)**	**($0.63)**	**($0.65)**	**($0.64)**
YOY Growth								
Basic Shares Outstanding	18,663	42,250	42,300	42,738	45,015	43,076	48,000	59,000

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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HISTORICAL STOCK PRICE

TuHURA Biosciences, Inc. – Share Price Chart[2]



[2] Source: Barchart. Note that the price chart measures share price since the October 18th, 2024 date of the reverse merger with Kintara.

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