

TuHURA Biosciences, Inc.

(HURA: NASDAQ)

HURA: Third Quarter 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 (11/14/2025) **\$2.05**
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 underway, 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 merged with Kineta and raised \$14 million since the close of the transaction to support its pipeline. Additional capital raises and partnerships with established biopharma companies are expected.

Initial clinical studies target rare and blood cancers. Future opportunities lie in oncology using combinations with other immunotherapies.

SUMMARY DATA

52-Week High **\$7.20**
52-Week Low **\$1.80**
One-Year Return (%) **-58.2**
Beta **0.8**
Average Daily Volume (sh) **212,951**

Shares Outstanding (mil) **51.3**
Market Capitalization (\$mil) **105.2**
Short Interest Ratio (days) **11.3**
Institutional Ownership (%) **12.2**
Insider Ownership (%) **35.8**

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	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2024	\$0.0 A	\$0.0 A	\$0.0 A	\$0.0 A	\$0.0 A
2025	\$0.0 A	\$0.0 A	\$0.0 A	\$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	-\$0.21 A	-\$0.14 A	-\$0.16 E	-\$0.66 E
2026					-\$0.65 E
2027					-\$0.74 E

WHAT'S NEW

Operational and Financial Results

On November 14th, 2025, TuHURA Biosciences, Inc. (NASDAQ: HURA) [reported](#) third quarter 2025 financial and operational results and filed its [Form 10-Q](#) with the SEC. The company is conducting its IFx-2.0 Phase III trial in Merkel cell carcinoma (MCC) which is expected to read out in early 2027. It continues to advance Kineta's VISTA asset, now designated TBS-2025, and start the Phase II trial in 1Q:26. Other announcements include planned participation at the American Society of Hematology (ASH) Annual Meeting taking place in Orlando, Florida. Below, we summarize TuHURA's quarterly financial results.

TuHURA generated no revenues in 3Q:25 and expended \$6.7 million on operational activities related to advancing IFx-2.0 and other programs, producing a net loss of (\$7.1) million or (\$0.14) per share. For the quarter ending September 30th, 2025 and versus the same prior year period:

- Research & development expense totaled \$5.0 million, increasing 69% from \$2.9 million due to greater expenses for the IFx-2.0 and TBS-2025 programs, 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 \$1.8 million, due to increases in non-cash stock compensation, merger transaction costs and expenses related to being a public company;
- Other items included \$138,000 in grant income related to Kintara's REM-001 asset and reimbursements from Health and Human Services and amounts related to share settlement to former Kineta employees;
- Net interest expense was \$10,000;
- Net loss was (\$7.1) million or (\$0.14) per share.

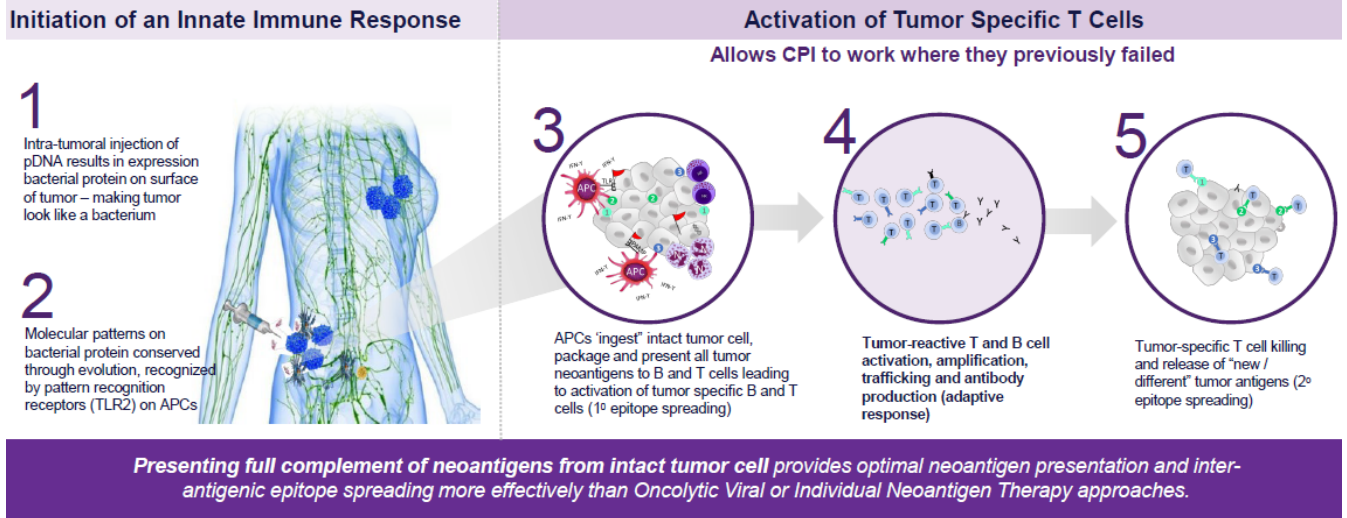
As of September 30th, 2025, TuHURA held \$2.7 million in cash on its balance sheet. Cash burn for the first nine months of 2025 was (\$22.1) million while net cash generated from financing sources was \$13.4 million which consisted of warrant proceeds and issuance of common stock partially offset by stock issuance costs and transaction and liability payments related to Kintara. In October, TuHURA entered into a \$3.0 million loan agreement of which \$1.5 million of the loan was advanced upon execution. In November, TuHURA entered into an at-the-market (ATM) facility with HC Wainwright as its sales agent. A [Form S-3](#) registration statement was filed to enable \$50 million in capacity for the ATM. TuHURA also has \$500,000 remaining on its final tranche offering which is expected to be executed prior to year end 2025.

Phase III IFx-2.0 Trial in MCC

TuHURA [launched](#) its pivotal Phase III study for its IFx-2.0 candidate in Merkel cell carcinoma (MCC) in June. In the latest quarterly report, TuHURA set forth two related milestones for the study. Enrollment is expected to be complete in 4Q:26 and topline results are anticipated in 1Q:27.

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. In most cases, an accelerated approval will require post-market confirmatory trials to verify the clinical benefit. However, in this case, 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.

Exhibit I – IFx-2.0 Mechanism of Action



Source: TuHURA September 2025 Corporate Presentation

The trial is 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 accelerated approval, ORR must reach 75% compared to the historical benchmark of 50%. For full approval, based on a continuation of this same trial, PFS has to achieve a 50% or better result. The trial began in June 2025 with enrollment expected to last 12 months. ORR will be measured at six months, which suggests 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 II – IFx-2.0 Phase III Trial Design

1st line CPI naïve, advanced/metastatic MCC

1:1 Randomization, Placebo, Injection Controlled Trial



Enrolling ~118 patients



IFx-2.0 weekly x 3 + pembrolizumab versus pembrolizumab + placebo



20-25 U.S. clinical centers

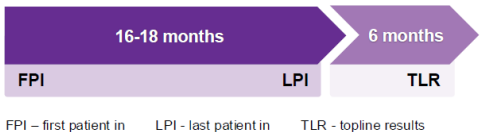
Primary Endpoint

Overall Response Rate (ORR)

Key Secondary Endpoint

Progression Free Survival (PFS)
Stepwise hierarchical design preserves alpha allocation

Study Timeline



SPA Agreement with FDA

- ORR allows for potential accelerated approval
- No requirement for post-marketing trial
- PFS converts accelerated to full approval
- Would satisfy requirement for confirmatory trial

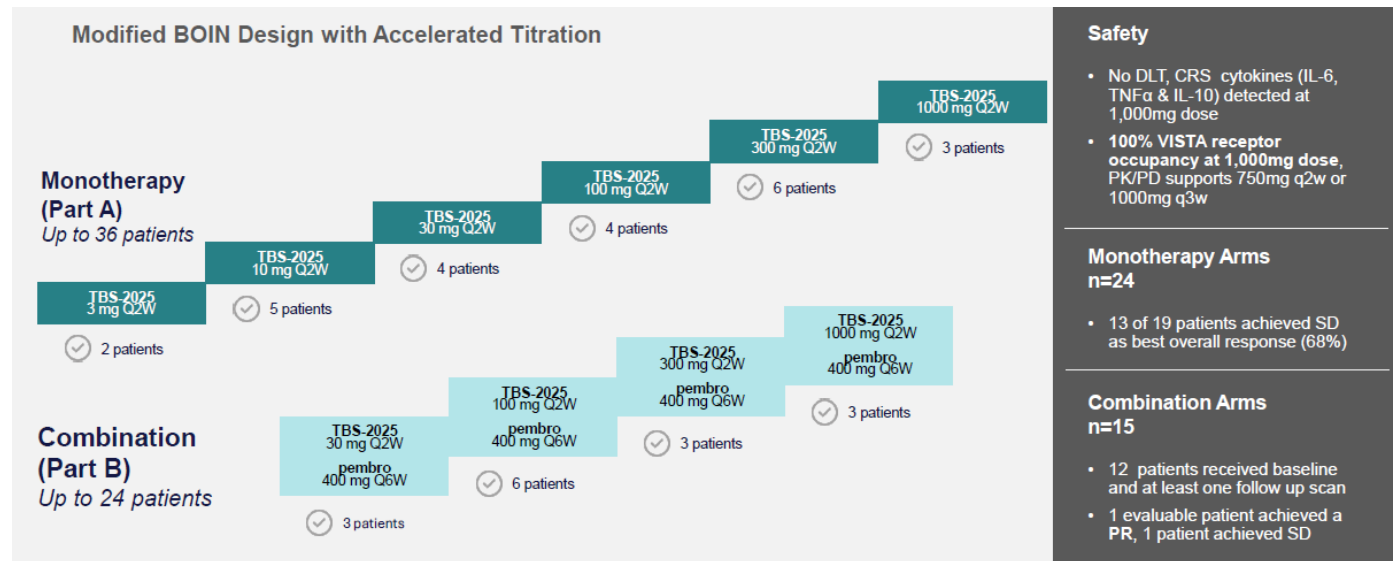
Source: TuHURA September 2025 Presentation

TBS-2025 Phase I/II Clinical Trial in Solid Tumors

The TBS-2025 (formerly known as KVA12) program is collaborating with Merck through the latter's contribution of pembrolizumab (Keytruda). It seeks to determine the safety and efficacy of TBS-2025 alone and in combination with the PD-1 inhibitor in a Phase I/II clinical trial. A trial summary is posted on [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT05708950) under [NCT05708950](https://clinicaltrials.gov/ct2/show/study/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 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.

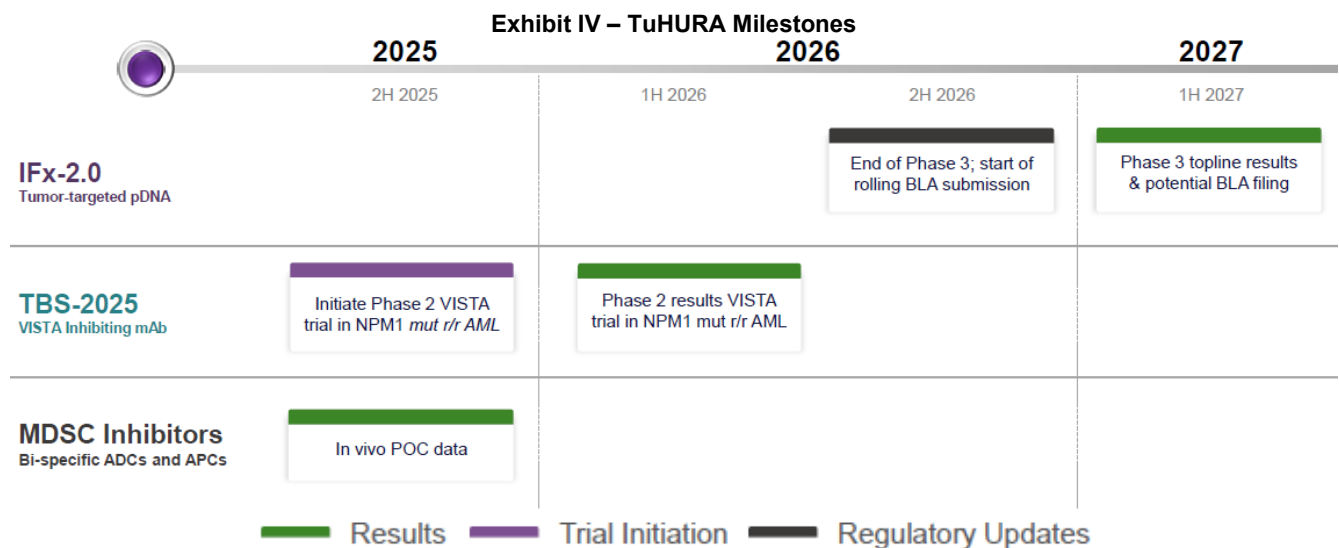
Exhibit III – TBS-2025 Phase Ib Clinical Trial Design



Source: TuHURA September 2025 Corporate Presentation

TuHURA has closed out the Phase I study report for TBS-2025 and is targeting the Phase II trial start towards the beginning of 2026. Before it can begin, it must deliver the clinical trial protocol to the FDA (planned for 4Q:25), and hold its end-of-study meeting with the FDA where it will validate the recommended dose. TuHURA will also select the menin inhibitor that will be used in combination with TBS-2025.

Upcoming Milestones



Source: TuHURA September 2025 Corporate Presentation

Milestones

- IFx-2.0 trial [launch](#) – June 2025
- IFx-2.0 IR basket trial launch – May 2025
- [Close](#) of Kineta acquisition – June 2025
- IFx-3.0 CD22 tumor-targeted mRNA *in vivo* proof of concept studies – 2026
- [Participation](#) in the HC Wainwright Investment Conference – September 2025
- Appointment of Dr. Michael Turner as VP of Immunology – November 2025
- [Form S-3](#) filed and agreement entered for ATM facility – November 2025
- Delta Opioid Receptor presentation at ASH – December 7th, 2025
- Enrollment progress update for IFx-2.0 - Year end 2025
- Launch VISTA inhibitor (TBS-2025) Phase II trial in NPM1 mutated AML – 1Q:26
- Selection of lead DOR inhibitor – 1Q:26
- IFx-2.0 Phase Ib/IIa preliminary results – 2Q:26
- TBS-2025 (VISTA) interim readout – mid-2026
- First proof of concept with *in-vivo* results for lead antibody drug conjugate (ADC) – 3Q:26
- IFx-2.0 Phase III topline results – 1Q:27

Company Pipeline

Exhibit V – TuHURA Pipeline

PROGRAM	DRUG CANDIDATE	INDICATION	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	Upcoming Milestone Targets
Innate Immune Agonists	IFx-2.0 Tumor-targeted pDNA	1 st Line Merkel Cell Cancer Keytruda® + IFx-2.0 or placebo ¹					Q1 2027: Phase 3 Topline Results
		Primary Checkpoint Inhibitor Resistant Metastatic Cancer "Basket" Trial					Q2 2026: Phase 1a/2b "Basket" trial results
TME Modulators Negative Immune Regulators	TBS-2025 VISTA inhibiting mAb ¹	<i>mut</i> NPM1 Acute Myeloid Leukemia					Q4 2025: Phase 2 Trial Initiation
TME Modulators MDSC Inhibitors	Bi-specific ADCs and PACs	Myelodysplasia Acute Myeloid Leukemia					Q4 2025: ADC/APC <i>in vivo</i> POC studies

Source: TuHURA September 2025 Corporate Presentation

Summary

TuHURA reports 3Q:25 financial results with two active clinical trials on the IFx-2.0 platform and one to begin shortly for TBS-2025. Its ranks were augmented with the appointment of Dr. Michael Turner as VP of immunology in November. In December, the company will present its DOR technology at the ASH conference along with two other poster presentations. We expect to see a continuation of activity over the next several months as the IFx-2.0 studies enroll, preparations for the start of the Phase II TBS-2025 trial are completed and the trial is launched. We maintain our valuation of \$9.25 per share.

PROJECTED FINANCIALS

TuHURA Biosciences, Inc. - Income Statement

TuHURA Biosciences, Inc.	2024 A	Q1 A	Q2 A	Q3 A	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	\$4,927	\$4,969	\$4,770	\$19,247	\$24,000	\$30,000
General & Administrative	\$4,314	\$2,435	\$4,949	\$1,761	\$3,150	\$12,295	\$12,000	\$13,500
Other Operational Items								
Income from Operations	(\$17,649)	(\$7,017)	(\$9,876)	(\$6,730)	(\$7,920)	(\$31,543)	(\$36,000)	(\$43,500)
Restructuring & Impairments								
Other Items	(\$256)	\$253	\$323	(\$362)	\$0	\$213	\$0	\$0
Net Interest Expense	(\$3,777)	\$100	\$29	(\$10)	\$0	\$119	\$0	\$0
Pre-Tax Income	(\$21,682)	(\$6,664)	(\$9,524)	(\$7,102)	(\$7,920)	(\$31,211)	(\$36,000)	(\$43,500)
Provision for Income Tax <i>Tax Rate</i>	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Net Income	(\$21,682)	(\$6,664)	(\$9,524)	(\$7,102)	(\$7,920)	(\$31,211)	(\$36,000)	(\$43,500)
<i>Net Margin</i>								
Reported EPS	(\$1.16)	(\$0.16)	(\$0.21)	(\$0.14)	(\$0.16)	(\$0.66)	(\$0.65)	(\$0.74)
<i>YOY Growth</i>								
Basic Shares Outstanding	18,663	42,250	44,555	50,666	51,000	47,118	55,000	59,000

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

HISTORICAL STOCK PRICE

TuHURA Biosciences, Inc. – Share Price Chart¹



¹ 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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