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TuHURA Biosciences, Inc. (HURA: NASDAQ)

HURA: 2024 Financial 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 (4/11/2025)	$4.22
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	**$1.80**
One-Year Return (%)	**-2.8**
Beta	**0.8**
Average Daily Volume (sh)	**227,198**
Shares Outstanding (mil)	**43.7**
Market Capitalization ($mil)	**184.4**
Short Interest Ratio (days)	**6.6**
Institutional Ownership (%)	**13**
Insider Ownership (%)	**50**
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 E	$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	-$0.14 E	-$0.14 E	-$0.15 E	-$0.15 E	-$0.57 E
2026					-$0.65 E
2027					-$0.64 E

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WHAT'S NEW

Operational and Financial Results

On April 1st, 2025, TuHURA Biosciences, Inc. (NASDAQ: HURA) reported 2024 financial and operational results and filed its Form 10-K with the SEC. TuHURA provided updates on its Phase III trial in Merkel cell carcinoma (MCC), the acquisition of Kineta and introduced a new board member and executive. Initiation of the Phase III IFx-2.0 study in MCC is expected to begin in 2Q:25 and the acquisition of Kineta is targeted for 2Q:25. Below, we summarize 2024's financial results.

TuHURA generated no revenues in 2024 and expended $17.6 million on operational activities related to advancing IFx-2.0 and other programs producing a net loss of ($21.7) million or ($1.16) on a per share basis. For the year ending December 31st, 2024 and versus the same prior year period:

- Research & development expense totaled $13.3 million, up 42% from $9.4 million, primarily attributable to an increase in spending on the IFx-2.0 program, additional preclinical research for the IFx-3.0 and myeloid derived suppressor cell (MDSC) initiatives and higher salary, personnel and facilities costs.
- No in-process research and development expenses were recognized versus $16.2 million related to the ADC technology in 2023;
- General & administrative expenses totaled $4.3 million, up 4% from $4.1 million due to increases in non-stock compensation and costs related to being a public company partially offset by lower legal fees;
- Net interest expense was ($3.8) million versus net interest income of $71,000 due to interest paid on convertible notes which was absent in the prior year;
- Other items totaled ($256,000) vs. $377,000 as a small amount of grant income was more than offset by a reduction in the value of the derivative liability which compares to recognition of a small amount of grant income and an employee retention tax credit in 2023;
- Net loss was ($21.7) million vs ($29.3) million, or ($1.16) and ($2.47) per share, respectively.

As of December 31st, 2024, TuHURA held $12.7 million in cash on its balance sheet. 2024 cash burn was ($14.8) million while cash flows from financing were $29.8 million related to proceeds from the convertible note and common stock issuance as well as stock option and warrant exercise partially offset by financing costs.

Video Series with Dr. James Bianco

Exhibit I – Dr. James Bianco



Source: Video Series Screenshot

Video links are included below:

- CEO Talks ADCs - (1:17)
- ADC Program Highlights - (8:18)
- IFx-2.0 Has Expedited Status - (1:23)
- Upcoming Trial for IFx-2.0 in Merkel Cell Carcinoma - (8:01)
- Anti-VISTA Asset Acquisition - (8:04)
- Lead Target in Merkel Cell Carcinoma - (3:34)
- How IFx-2.0 Works - (1:21)
- Fireside Chat - (12:36)

Our Initiation

We initiated coverage of TuHURA in February with a valuation of $9.25 per share. The value is based on our estimates for successful development and commercialization of IFx-2.0 in patients with Merkel cell carcinoma (MCC) and KVA12 which will be advanced in acute myeloid leukemia (AML). IFx-2.0 is scheduled to begin its Phase III study in 2Q:25 under a Special Protocol Assessment (SPA) agreement with the FDA. The trial will benefit from the FDA's Project FrontRunner initiative which will allow IFx-2.0 to be evaluated in an earlier clinical setting with only one Phase III required for accelerated approval. The recently acquired anti-V-domain Immunoglobulin suppressor of T-cell activation (VISTA) asset is completing a Phase I dose-finding study in advanced solid tumors. It may work particularly well in blood cancers with mutated nucleophosmin 1 (NPM1). The antibody may be combined with a delta opioid receptor (DOR) inhibitor and/or a menin inhibitor in future studies if supported by clinical work. TuHURA will pursue an indication in AML, where there is evidence of a signal. A Phase IIa/b trial for the candidate in mutated NPM1 (mNPM1) AML is slated to begin later this year following the close of the merger with Kineta. TuHURA's antibody-drug conjugate (ADC) is expected to traverse a novel route in this space, binding to the DOR and carrying an immunotherapy, possibly TuHURA's very own anti-VISTA agent. We see the ADC asset as a desirable partnering asset with established biopharma companies.

IFx-2.0
IFx-2.0 is an intratumorally injected plasma DNA (pDNA) that infects cancer cells to produce bacterial proteins on their surface. These proteins stimulate an innate immune response which destroys cancer cells and subsequently activates an adaptive immune response to overcome resistance. TuHURA has demonstrated safety and proof of concept in several small early-stage trials. The company has completed four Phase I studies and has shown an overall response rate (ORR) for MCC in many subjects. The dose escalation portion of the study established that IFx-2.0 was well-tolerated at all dose levels. Further study evaluated MCC patients who had previously received checkpoint therapy. Results showed that IFx-2.0 may overcome primary resistance to checkpoint inhibitor therapy and may provide support for administering the agent before checkpoint inhibitor therapy to increase response rates.

Anti-VISTA
Recent research has shown a correlation between high NPM1 mutations and VISTA expression, particularly in AML. As mutated NPM1 (mNPM1) drives leukemogenesis through menin and the efficacy of menin inhibitors in producing treatment responses in mNPM1-associated AML, combination therapy using a VISTA-inhibiting antibody is a promising approach to improve response rates in AML. In 2H:25, TuHURA expects to evaluate this further with a proof-of-concept study. The anti-VISTA asset may be considered as a monotherapy or in combination with the ADC or IFx programs.

Merkel Cell Carcinoma (MCC)
Merkel cell carcinoma (MCC) is a type of skin cancer originating from Merkel cells which can proliferate rapidly if not treated. While a relatively high proportion of MCC patients respond to checkpoint inhibitors, there remains an unmet need in patients that do not respond or those that relapse. The annual incidence of MCC is about 3,300 persons in the United States and 4,500 in Europe and Australia.

Acute Myeloid Leukemia (AML)
Acute myeloid leukemia (AML) has a substantially higher incidence than MCC with over 20,000 cases per year and global incidence of about 1.5 per 100,000. AML is a cancer of the blood and bone marrow where immature blood cells proliferate and interfere with normal blood cell production. It primarily affects white blood cells called myeloid cells and progresses quickly without treatment. About a third of AML patients carry the NPM1 mutation, which drives overexpression on AML blasts, most of which, coincidentally, have high VISTA expression.

Other Programs
In addition to the lead programs for IFx-2.0 and VISTA, TuHURA has a portfolio of other programs in line for further development or divestiture. The IFx-3.0 program seeks to achieve intravenous delivery of the Emm55 mRNA targeting CD22, which is overexpressed on cancerous B-cells. The antibody-drug conjugate (ADC) program features a delta-receptor-selecting-small-molecule designed to target myeloid derived suppressor cells (MDSCs) and counteract their immunosuppressive effect. As part of its merger with Kintara, TuHURA inherited a photodynamic therapy for unresectable cutaneous metastatic breast cancer (CMBC) designated REM-001. The asset is in a small proof of concept trial that, if successful, will qualify Kintara shareholders for a contingent value right (CVR) to be paid in shares. Another party will advance REM-001 beyond this point.

Financing
Based on the strong data generated, TuHURA raised $36 million in 2024. $15 million was spent to acquire Kineta in cash and stock. In addition to the cash on hand, TuHURA may raise additional funds via the private investment in public equity (PIPE) route. Company management has stated that it has sufficient capital to fund operations into late 2025. We expect another capital raise to provide further financial support to the pipeline programs.

Initiation Summary
TuHURA has outlined its plan to initiate the IFx-2.0 Phase III trial, begin the KVA12 Phase II trial in mutated NPM1 AML and conduct further preclinical research in its IFx-3.0 and targeted ADC programs. The company expects that it will be able to fully enroll the IFx-2.0 trial within twelve months of dosing the first patient. Six months later, topline results can be available for regulatory submission. Accelerated approval will allow for an expedited review of the application, a timeline that, if everything goes as planned, could support marketing IFx-2.0 about two years after starting the trial. KVA12's pathway could be similarly streamlined after a short proof-of-concept trial slated for 2H:25.

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 put the study on track to begin in late 2Q:25. 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.

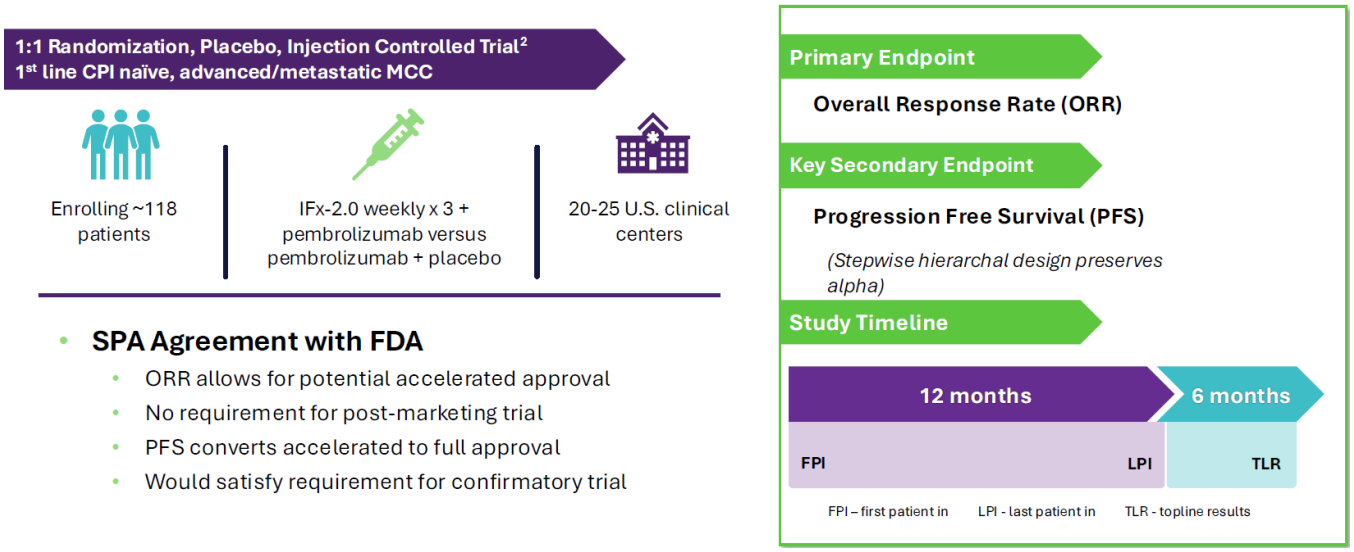
The trial will be designed as a 1:1 randomized, placebo and injection-controlled trial in first-line, checkpoint inhibitor naïve, advanced metastatic MCC. It plans to enroll 118 subjects at 20 to 25 clinical centers in the United States. IFx-2.0 will be administered three times per week in combination 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.

[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.

Exhibit II – IFx-2.0 Phase III Trial Design

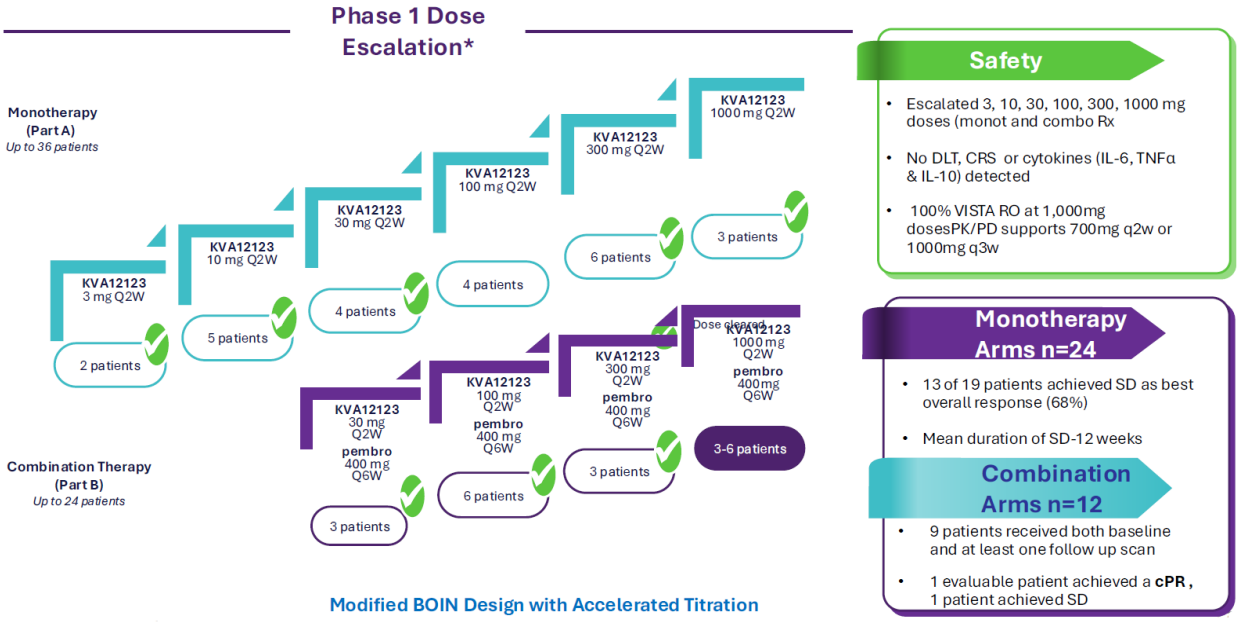


Source: TuHURA January 2025 Presentation

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 III – KVA12 Phase Ib Clinical Trial Design



Source: TuHURA January 2025 Presentation

SITC November 2024 Abstract and Poster
Data for KVA12 was presented at the Society for Immunotherapy of Cancer of Hematology (SITC) on November 8th, 2024 in Houston, Texas. It updated the ongoing Phase I/II VISTA 101 study and announced that the monotherapy arm was fully enrolled. As of the cutoff date in mid-October 2024, KVA12 cleared all six monotherapy dose levels and the second of four cohorts in combination with pembrolizumab. KVA12 was well tolerated with no dose limiting toxicities and a favorable safety profile at all dose levels in both arms of the study. 24 patients were enrolled in the six monotherapy dose cohorts. 19 of these patients had at least one follow-up scan and 13 of the patients experienced stable disease as per iRECIST standards. Dosing began at 3 mg and increased to 1000 mg and was administered every two weeks. Combination therapy included 30 mg to 100 mg of KVA12 administered every two weeks along with 400 mg of pembrolizumab given every six weeks. Complete and partial responses have been observed and the combination has been well tolerated. The two remaining combination cohorts are expected to be fully enrolled by the end of 2024.

TuHURA's Interest and Next Steps
TuHURA provided interim financing to continue Kineta's Phase I/II ascending dose trial in July 2024. At that time, the trial was only halfway through the dose escalation study. The pharmacokinetic and pharmacodynamic data suggested that receptor occupancy was linear, prompting TuHURA to surmise that at 1000 mg, 100% of the VISTA receptors would be occupied for four weeks. If confirmed, this profile would provide potency and long duration.

NPM1-mutated AML is considered a distinct genetic entity in the World Health Organization (WHO) classification of hematopoietic malignancies.[2] NPM1 mutations are acquired driver mutations essential to the pathogenesis of mutated NPM1 AML. In this subtype of AML, menin interacts with wild-type KMT2A which drives the expression of genes that contribute to leukemogenesis. Despite the advances in the treatment of NPM1-mutated AML, about 50% of patients still die of progressive disease.[3]

30% to 35% of all adult Acute Myeloid Leukemia present NPM1 gene mutations. Immune evasion of NPM1-mutated AML is stimulated by VISTA which is upregulated in these patients. This suppresses proliferation of T cells and reduces production of T cell cytokines making it a potential VISTA target. Data presented at December's American Society of Hematology (ASH) meeting evinced a correlation between NPM1 mutations and elevated VISTA expression, particularly in AML, where high VISTA levels on leukemia cells, associated with the mutations, can potentially contribute to immune evasion and disease progression reducing the treatment response. Mutated NPM1 drives leukemogenesis through menin. Administering menin inhibitors may improve treatment responses in mutated NPM1-associated AML. Menin inhibitors produce responses by blocking the oncogenesis and proliferation of leukemia cells. Combining menin with a VISTA-inhibiting antibody could produce improved response rates in AML.

Management believes that it could run a 20-patient trial in AML to demonstrate that the NPM1 mutated cancer is expressing VISTA and administer a menin inhibitor along with a VISTA inhibiting antibody to see if response rates increase materially. If KVA12 can produce this result, it could support an accelerated approval discussion with the FDA. TuHURA estimates that this 20-patient trial could cost as little as $2 million.

Anti-VISTA Phase II Proof of Concept Trial in AML

Following the acquisition of Kineta, TuHURA anticipates launching a Phase II proof of concept trial with the anti-VISTA monoclonal antibody. This is expected to begin in 4Q:25. The interest in using KVA12 in AML emerged from research showing that VISTA is overexpressed on myeloid-derived suppressor cells (MDSCs). The NPM1 mutation, found in 30–35% of AML cases, is another important biomarker in AML.

Work done by Vanderbilt University and presented at the December 2024 ASH meeting demonstrated that AML with mutated NPM1 expresses high levels of VISTA which creates an immunosuppressive environment. A recently approved class of drug called menin inhibitors, represented by Syndax Pharmaceuticals' revumenib, can treat this group. Menin inhibitors bind to the menin protein and prevent it from binding to the KMT2A protein. This disrupts the interaction between the two, forcing leukemia cells to differentiate into normal cells. These AML cells may also express the VISTA checkpoint receptor that prevents T cells from recognizing and attacking them.

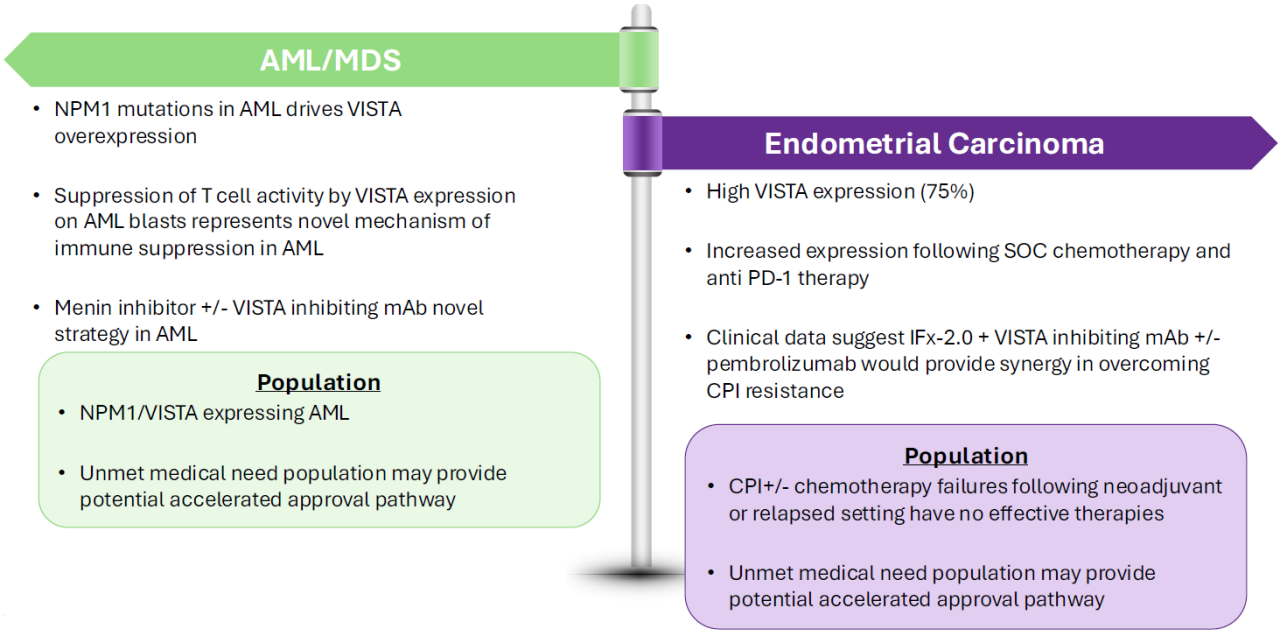
TuHURA plans to evaluate the combination of its anti-VISTA candidate KVA12 along with a menin inhibitor to identify if there is a material benefit. If the combination can block the NPM1 cascade and VISTA receptor, it can eliminate two important therapeutic choke points represented by proliferation and escape mechanism respectively. TuHURA

[2] Ranieri, R. Current status and future perspectives in targeted therapy of NPM1-mutated AML. Leukemia. August 2022.
[3] Ranieri, R. Current status and future perspectives in targeted therapy of NPM1-mutated AML. Leukemia. August 2022.

estimates that for a few million dollars they can design a study that will show if the combination of KVA12 with re-vumenib provides greater complete remission compared with revumenib alone.

If the trial is successful, TuHURA will consult with the FDA to pursue a similar route to approval as IFx-2.0 with a Phase III trial. The candidate would seek the accelerated approval pathway and employ a trial design that obtains approval using a primary endpoint of a biomarker and a secondary endpoint demonstrating clinical benefit. Further details on the design and pathway forward are expected to be disclosed in upcoming quarters.

Exhibit IV – VISTA Phase II Trials Under Consideration



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.

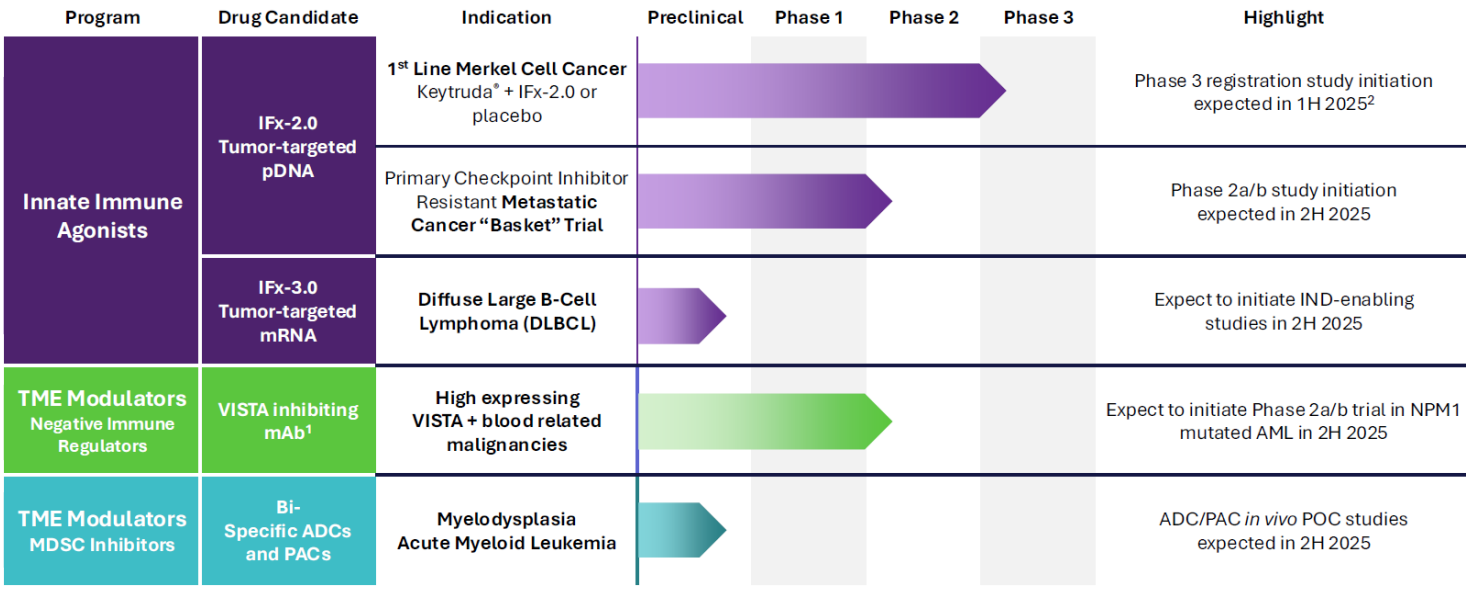
Dr. Le Bourdonnec was appointed as Head of Drug Discovery, Early Development and Program Management at TuHURA as detailed in an April 7th press release. He has a 20-year career in drug discovery and development honed at HDAX Therapeutics, Decipher Pharmaceuticals and Yumanity Therapeutics among other 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
- 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 V – TuHURA Pipeline



Source: TuHURA January 2025 Presentation

Summary

TuHURA reported 2024 financial results surrounded by a number of other important events for the company. Two new experts were added to the company's board and executive ranks and presentations at investor and scientific 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 target price of $12 per share.

PROJECTED FINANCIALS

TuHURA Biosciences, Inc. - Income Statement

TuHURA Biosciences, Inc.	2023 A	2024 A	Q1 E	Q2 E	Q3 E	Q4 E	2025 E	2026 E	2027 E
Total Revenues ($USD)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Research & Development	$9,402	$13,335	$4,025	$4,125	$4,580	$4,770	$17,500	$24,000	$30,000
General & Administrative	$4,145	$4,314	$1,700	$1,750	$1,750	$1,800	$7,000	$7,000	$7,500
Other Operational Items	$16,218								
Income from Operations	($29,765)	($17,649)	($5,725)	($5,875)	($6,330)	($6,570)	($24,500)	($31,000)	($37,500)
Restructuring & Impairments									
Other Items	$377	($256)	$0	$0	$0	$0	$0	$0	$0
Net Interest Expense	$71	($3,777)	$0	$0	$0	$0	$0	$0	$0
Pre-Tax Income	($29,317)	($21,682)	($5,725)	($5,875)	($6,330)	($6,570)	($24,500)	($31,000)	($37,500)
Provision for Income Tax	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate									
Net Income	**($29,317)**	**($21,682)**	**($5,725)**	**($5,875)**	**($6,330)**	**($6,570)**	**($24,500)**	**($31,000)**	**($37,500)**
Net Margin									
Reported EPS	**($2.47)**	**($1.16)**	**($0.14)**	**($0.14)**	**($0.15)**	**($0.15)**	**($0.57)**	**($0.65)**	**($0.64)**
YOY Growth									
Basic Shares Outstanding	11,889	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[4]



[4] 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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