Zacks Small-Cap Research
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TuHURA Biosciences, Inc. (HURA: NASDAQ)

HURA: Picking Up Patents

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 (11/20/2026)	$1.25
Valuation	**$6.20**

OUTLOOK

TuHURA is a clinical-stage, oncology-focused biotechnology company advancing innate immune agonists, checkpoint inhibitors & antibody-drug conjugates (ADCs). Its IFx platform technology features IFx-2.0 tumoral injection delivery for Merkel cell carcinoma (MCC). 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 antibody & 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 Phase I/II & pivotal trial are 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 entered into a $50 million credit facility in April 2026 that should support operations until 2028. Additional capital raises and partnerships with established biopharma companies may augment these funds.

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

SUMMARY DATA

52-Week High	**$3.43**
52-Week Low	**$0.41**
One-Year Return (%)	**-21.1**
Beta	**-0.7**
Average Daily Volume (sh)	**329,756**
Shares Outstanding (mil)	**65.8**
Market Capitalization ($mil)	**82.2**
Short Interest Ratio (days)	**17.5**
Institutional Ownership (%)	**10.3**
Insider Ownership (%)	**33.4**
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 2026 Estimate	**N/A**
P/E using 2027 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)
2025	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2026	$0.0 A	$0.0 A	$0.0 A	$0.0 E	$0.0 E
2027					$0.0 E
2028					$5.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2025	-$0.16 A	-$0.21 A	-$0.14 A	-$0.12 A	-$0.63 A
2026	-$0.13 A	-$0.14 A	-$0.10 A	-$0.16 E	-$0.53 E
2027					-$0.62 E
2028					-$0.52 E

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WHAT'S NEW

Operational and Financial Results

On November 13th, 2026, TuHURA Biosciences, Inc. (NASDAQ: HURA) reported 3Q:26 financial and operational results and filed its Form 10-Q with the SEC. Since the previous quarterly update in August, TuHURA has received clearance from the FDA to begin the TBS-2025 study, been granted multiple U.S. patents, provided a first look at the Phase II IFx-2.0 study and attended medical and investor conferences.

TuHURA generated no revenues in 3Q:26 and expended $5.7 million on operational activities related to advancing IFx-2.0, TBS-2025 and other programs, producing a net loss of $6.4 million or $0.10 per share. For the quarter ending September 30th, 2026 and versus the same prior year period:

- Research & development expense totaled $3.7 million, falling 25% from $5.0 million due to lower expenditures on the IFx-2.0 program and preclinical costs. This was partially offset by a small increase in spending for the TBS-2025 program. Personnel and facilities costs also fell by 19% to $2.0 million of the total;
- General & administrative expense totaled $2.0 million, rising 11% from $1.8 million. Core G&A expenses, which excludes acquisition-related costs, were up 23% due to increases in non-cash stock compensation and public company costs. In the prior year period, TuHURA recognized $168,000 in acquisition-related costs that were not repeated in 2026;
- Net interest expense was $749,000 compared to $10,000 reflecting the amortization of debt issuance costs, annual cash facility fee and interest expense related to the Parkview credit facility;
- Net loss was $6.4 million or $0.10 per share versus $7.1 million or $0.14 per share.

As of September 30th, 2026, TuHURA held $1.9 million in cash and has borrowed $14.2 million of the $50 million facility with Parkview. Cash burn for the first nine months of 2026 was $18.2 million. The short- and long-term balances on the revolving credit facility stand at $9.5 million, including interest and annual fee.[1] Net cash from financing sources was $16.5 million which consisted of proceeds from common stock issuance and the revolving credit facility offset by Series A Preferred cash dividend and capital raising-related expenses. Following the end of the third quarter, TuHURA borrowed an additional $4.95 million from the Parkview Credit Facility.

New Patents

TuHURA reported the grant of U.S. Patent #12,734,168 which was issued on September 15th, 2026. The patent title is Delta Opioid Receptor Antagonists Reprogram Immunosuppressive Microenvironment to Boost Immunotherapy. It addresses the administration of DOR antagonists to subjects with cancer associated with DOR expressing MDSCs. It is also directed to uses of a variety of DOR antagonist combination therapies in treating, inhibiting, reducing, ameliorating and/or preventing cancer and/or metastasis. The patent covers administering a DOR antagonist to cancer subjects and mediating immunosuppressive myelopoiesis. Additionally, the patent discloses applications of DOR antagonists not only with bi-specific or bi-functional ADC technology, but also in the context of autologous or allogeneic adoptive cellular immunotherapies such as CAR-T, T reg or tumor-infiltrating lymphocyte (TIL) cellular therapies. The patent term runs through 2043 and may include additional protection from patent term extension.

TuHURA received patent #12,760,104 from the U.S. Patent office as disclosed in an October 13th, 2026 press release. The patent is entitled Anti-VISTA Antibodies and Uses Thereof. The new patent claims provide coverage for the VISTA inhibiting antibody TBS-2025, antigen-binding fragments, modifications to the frameworks and Fc regions of the antibody, and bi-specific/multi-specific antibodies across all classes of human antibodies. Additionally, the patent provides coverage for use as a single agent or in combination with radiotherapy, chemotherapy, targeted therapies, tyrosine kinase inhibitor therapies and immune checkpoint inhibitors, including PD-1 inhibitors. The new patent claims also provide coverage for methods of treatment that extend beyond cancer, expanding into new treatment areas like autoimmune disease and infection. The patent term extends to February 18th, 2042 and may be lengthened from patent term adjustment and/or regulatory patent term extension.

[1] The difference between the borrowing level and revolving credit facility balance is explained by the partial repayment of the debt through share issuances.

Upcoming Presentations at ASH

TuHURA will present three posters summarizing the research it has conducted on the role of the Delta Opioid Receptor (DOR) in controlling the immunosuppressive capabilities of Myeloid-Derived Suppressor Cells (MDSCs). The presentations will take place at the upcoming 68th American Society of Hematology (ASH) Annual Meeting and Exposition taking place from December 12th to 15th, 2026, in New Orleans, Louisiana. The DOR is a critical receptor due to its roles in the proliferation, recruitment and immune suppressing capabilities across MDSCs, T regs and M2 macrophages. While these immune suppressing cells are important for calming chronic inflammation, they can also support resistance to and failure of cancer immunotherapy. Below we list the three posters that will be presented:

- Inhibition of the delta opioid receptor (DOR) on myeloid-derived suppressor cells (MDSCs) significantly reduces Cxcl10, Saa3 and Acod1 gene expression, representing a single target to modulate MDSC proliferation, migration and immune suppression.
    - Presented by Dr. Krit Ritthipichai, Director of Immunology
    - Monday, December 14, 2026, 6:00pm to 8:00pm ET
- Delta opioid receptor (DOR) inhibition drives both proenkephalin (PENK) gene expression and met-enkephalin (mENK) protein in tumor-derived myeloid-derived suppressor cells (tMDSC) and bone marrow-derived macrophage subtype 2 (BMDM2): Implications for modulation of immune suppression in cancer and autoimmune disease.
    - Dr. Taekyoung Kwak, Lead Scientist, Immunology and Dr. Krit Ritthipichai, Director of Immunology
    - Monday, December 14, 2026, 6:00pm to 8:00pm ET
- Regulatory T cell (Treg) differentiation is blocked by a selective delta opioid receptor (DOR) antagonist: Implications for cancer immunotherapy and autoimmune disease.
    - Dr. Krit Ritthipichai, Director of Immunology
    - Monday, December 14, 2026, 6:00pm to 8:00pm ET

Interim Readout for IFx-2.0 Phase Ib/IIa Open-Label Study

TuHURA presented first data from its IFx-2.0 Phase Ib/IIa study in deep-seated Merkel cell carcinoma (MCC) patients while CEO Dr. James Bianco attended the European Society for Medical Oncology (ESMO) conference. TuHURA held a call in parallel with the event hosted by Rodman & Renshaw analyst Michael King for investors and stakeholders on October 26th to disseminate their findings.

TuHURA's CEO, James Bianco, presented initial data from the first three patients in its open-label study of IFx-2.0 as an adjunctive therapy to Keytruda in first-line treatment of metastatic MCC. The study is listed on the clinicaltrials.gov website under the NCT06940440 designator. Each patient addressed in the presentation achieved an objective anti-tumor response, with all three responses meeting the criteria for partial response (PR) under RECIST v.1.1 criteria. All responses were durable, as each of the responses were ongoing at the protocol-specified six-month assessment.

The trial was designed to initially enroll a total of nine patients with visceral tumors including hepatic, pulmonary or retroperitoneal or other deep-seated locations using computed tomography (CT) or ultrasound guided administration where standard-size injection needles are unable to effectively administer the intended dose of IFx-2.0.

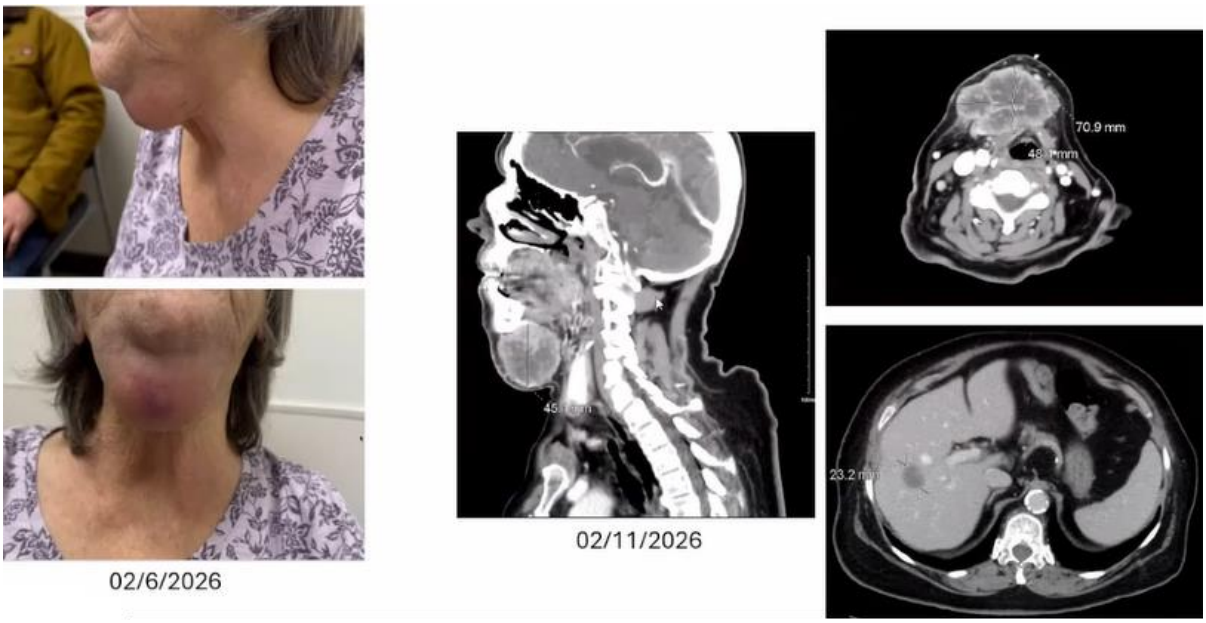
Enrolled patients present deep-seated MCC tumors and have measurable disease and no prior treatment with a checkpoint inhibitor. In the IFx-2.0 Phase Ib/IIa trial, these patients will be injected in a single lesion with IFx once per week for three consecutive weeks with the injection guided by CT and/or ultrasound. Keytruda (pembrolizumab) or avelumab were administered to the treated patients along with IFx within 48 hours of the first IFx injection.

Dr. Bianco summarized the response in three patients, including a 78-year-old male, a 79-year-old female and a 61-year-old female. The patients presented a variety of MCC tumor sites that include the gluteal region, below the jaw and in the right lower extremity. Investigators have observed similar favorable responses in these individuals.

A fourth patient, identified as an 88-year-old male, presented a preliminary response following administration of IFx to liver lesions. Dr. Bianco felt that this patient would also be a responder when measured at the upcoming 12-week mark; however, no RECIST response was recorded.

Of the patients referenced, the female patient with the tumor below her jaw showed a visually dramatic improvement following the treatment with IFx. Photographs and scans are provided on the following page, which demonstrate the marked change between the baseline, pre-treatment, CAT scan and the post-treatment scan. In the photographs on the left side of Exhibit I, the patient has a large mass below her jaw. The tumor was blocking her esophagus, making eating and swallowing difficult.

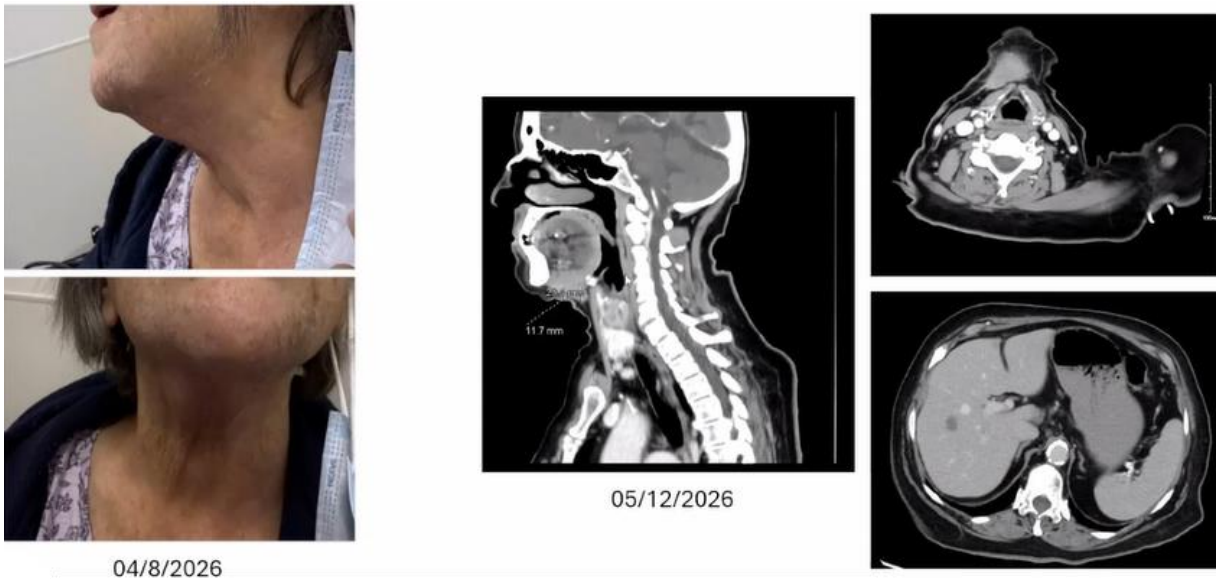
Exhibit I – Participant 1020-1, IFx-2.0 Pre-Treatment



Source: TuHURA Phase Ib/IIa Data Call at ESMO

At week 12, following initial treatment, additional photographs and scans were taken. They show substantial shrinkage of the tumor. The tumor appears to be gone and the patient was able to swallow normally. Dr. Bianco asserted that this represented an example of IFx providing a true clinical benefit.

Exhibit II – Participant 1020-1, IFx-2.0 Post-Treatment



Source: TuHURA Phase Ib/IIa Data Call at ESMO

None of the four patients included in the interim update presented a serious adverse event (SAE) or suffered from immune related toxicities. Only Grade 1 and 2 non-immune related toxicities were observed. There were no Grade 3 or greater adverse events observed in the four patients evaluated as of the cutoff date.

If additional findings remain favorable, TuHURA plans to discuss the trial data with the FDA to determine whether it could support inclusion of patients with deep-seated tumors in its ongoing Phase III trial. Dr. Bianco believes that, if

80% of the patients that enroll in the trial show a meaningful response, this outcome would be sufficient to support a modification of the Phase III trial protocol to allow for an expansion of the population. The conversation would revolve around how many additional patients would be needed to show safety, feasibility and efficacy. If the supplement to the trial protocol was able to be modified at the time of the filing, the addressable population could increase by up to 30% according to management's guidance.

TuHURA expects to have at least 12 weeks of data for the anticipated 12 patients by mid-year 2027.

IFx-2.0 Phase III Placebo-Controlled Trial
As the call concluded, TuHURA provided an update on timing for the Phase III IFx-2.0 trial. This trial is listed on the clinicaltrials.gov website under the designator NCT06947928. Dr. Bianco noted that the company was initially focusing on 25 sites and has now activated most of them. There are additional sites that are in the process of coming online. This effort supports the effort to complete enrollment in the second half of 2027, likely at the end of the third quarter or early in the fourth quarter. Some of the enrollment is taking place in Australia.

Hierarchical Step-Down Statistical Approach
An important statistical note related to the Phase III trial design is its hierarchical step-down, stepwise design (also described as fixed-sequence hierarchical testing) that preserves alpha. We take a proverbial sidebar in this note to explain. This approach is favored by the investigators as there is no statistical reduction in significance from including multiple endpoints. Clinical trials usually test more than one hypothesis and each additional test raises the chance of a false positive. If an investigator runs k independent tests at $\alpha = 0.05$, the family-wise error rate (FWER) climbs to roughly $1 - (0.95)^k$. Regulators, such as the FDA and EMA, require that the FWER be controlled at 0.05 across the hypotheses that support a claim. Hierarchical testing is one way to do that.

Before unblinding, the sponsor pre-specifies an ordered list of hypotheses in the statistical analysis plan (SAP). Hypothesis one (H1 - primary), two (H2), and three (H3) and so on. Test H1 at the full $\alpha = 0.05$. If H1 is significant ($p \leq 0.05$), the full α passes down to the next endpoint and H2 is tested at the full 0.05. Continue down the chain. At the first failure ($p > 0.05$), testing stops. Everything below that point is treated as exploratory, and nominal p-values there carry no confirmatory weight.

The FWER is controlled because, under any configuration of true nulls, a false positive can only occur if the first true null in the sequence is rejected. Each hypothesis is tested only if all those before it were rejected, so the chance of a type I error is capped at 0.05 in total, not 0.05 per test. No alpha is spent on H2 and H3 unless H1 succeeds, so no alpha is taken away from H1.

For example:[2]

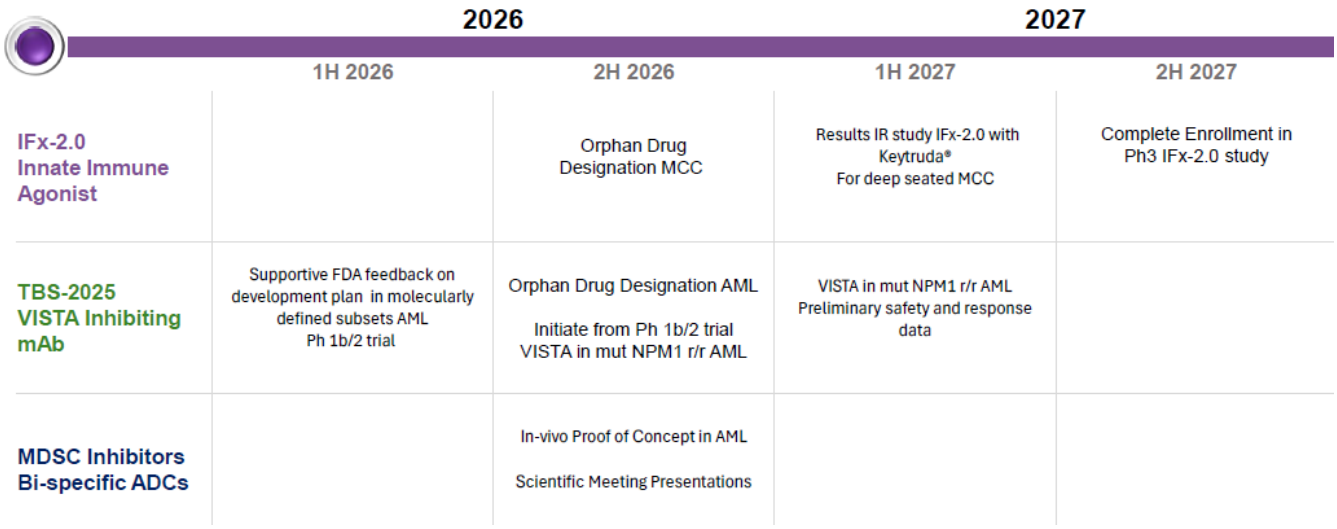
Step	Hypothesis	Test Level	Result	Outcome
1	ORR (primary)	0.05	p = 0.012	Pass; proceed
2	PFS (key secondary)	0.05	p = 0.031	Pass; proceed
3	DoR	0.05	p = 0.048	Pass; proceed
4	QoL score	0.05	p = 0.09	Fail; stop

Anything below step 4 would not be statistically significant. If PFS had generated a p = 0.06, the OS and ORR results, even at p = 0.001, could not be claimed as statistically significant in the confirmatory sense.

[2] Endpoints 3 and 4 do not reflect TuHURA's Phase III endpoints and are included as an illustrative example.

Upcoming and Historical Milestones

Exhibit III – TuHURA Upcoming Milestones



Source: TuHURA August 2026 Corporate Presentation

- FDA grants Orphan Drug Designation for IFx-2.0 in melanoma – February 2026
- Presentation at Oppenheimer Healthcare Life Sciences Conference – February 2026
- Compliance regained with NASDAQ minimum bid requirements – February 2026
- Presentations at Citizens Life Science & Leerink Global Healthcare conferences – March 2026
- Dr. Tendler appointed to lead TuHURA's anti-VISTA program – March 2026
- Appointment of Amanda Garofalo as SVP of Clinical Operations – April 2026
- $50 million credit facility executed with Parkview Holdings One – April 2026
- Canaccord Genuity Growth Conference[3] – August 2026
- Annual meeting which approved 1.88 million share issuance to Parkview – August 2026
- Attendance at HC Wainwright Conference, NYC – September 14th, 2026
- IND clearance for TBS-2025 Phase Ib study – September 2026.
- Orphan Drug Designation anticipated for IFx-2.0 in MCC – 2H:26
- Initiate ADC *in vivo* proof-of-concept studies – 2H:26
- TBS-2025 Phase Ib/II initiation – 2H:26
- Patent #12,734,168 issued – September 2026
- USPTO issued Patent #12,760,104: Anti-VISTA Antibodies and Uses Thereof – October 2026
- Scientific meeting presentations for lead ADC selection – 2H:26
- FDA discussions for adding deep-seated tumors to Phase III study – 2H:26
- Poster presentations at American Society of Hematology Meetings – December 12th to 15th, 2026
- IFx-2.0 Phase Ib/IIa IR study preliminary results – 1H:27
- Orphan drug designation anticipated for AML – 1H:27
- TBS-2025 preliminary safety & response data for VISTA study – 1H:27
- IFx-2.0 Phase III enrollment completion – 2H:27

[3] For an excellent summary of TuHURA's three main programs, watch this 26-minute discussion with CEO James Bianco.

Company Pipeline

Exhibit IV – TuHURA Pipeline

PROGRAM	DRUG CANDIDATE	INDICATION	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	Upcoming Milestone
Innate Immune Agonists	IFx-2.0 Innate Immune Agonist	1st Line Merkel Cell Cancer Keytruda® +/- IFx-2.0 or placebo[1]					**2H 2027:** Phase 3 Expected Topline Results
		Primary Checkpoint Inhibitor Resistant Metastatic Cancer "Basket" Trial					**2H 2026:** Phase 1a/2b Preliminary results Q4
TME Modulators Negative Immune Regulators	TBS-2025 VISTA inhibiting mAb[1]	*mut*NPM1 Acute Myeloid Leukemia					**2H 2026:** Phase 1b/2 Expected Trial Initiation
TME Modulators MDSC Inhibitors	Bi-specific ADCs	Myelodysplasia Acute Myeloid Leukemia					**2H 2026** Expected to initiate ADC *in vivo* POC studies

Source: TuHURA August 2026 Corporate Presentation

Summary

TuHURA's third quarter 2026 earnings release reports several milestone achievements since the previous quarterly update. The company reported the grant of patents protecting the work done on DOR expressing MDSCs in combination with the use of ADCs for a variety of immunotherapies and for work done with the anti-VISTA antibody also for use in combination with other therapies. In late October, Dr. Bianco gave stakeholders a first look at results from its open-label study of IFx-2.0 showing dramatic improvement in a small set of patients. In the regulatory sphere, the FDA cleared TBS-2025 to begin clinical trials in molecularly defined subsets of blood cancers. Beyond the operational efforts, the TuHURA team is participating in investor and medical conferences. At ASH in December, three posters are to be presented which review the DOR and its impact on gene expression.

We reiterate the rationale behind the company's very low cash levels which serve to minimize the draw on the facility as it approaches important value-driving milestones. TuHURA's access to the $50 million credit facility and the ATM program temper the risk of this approach, although substantial disruptions to operations could occur if access is delayed. We maintain our valuation of $6.20 per share.

PROJECTED FINANCIALS

TuHURA Biosciences, Inc. - Income Statement

TuHURA Biosciences, Inc.	2025 A	Q1 A	Q2 A	Q3 A	Q4 E	2026 E	2027 E	2028 E
Total Revenues ($'000 USD)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$4,986**
Research & Development	$20,533	$5,233	$6,620	$3,705	$7,000	$22,558	$30,000	$30,000
General & Administrative	$11,263	$2,297	$2,143	$1,956	$2,870	$9,266	$13,000	$14,200
Other Operational Items								
Income from Operations	($31,796)	($7,530)	($8,763)	($5,661)	($9,870)	($31,824)	($43,000)	($39,214)
Other Items	$2,233	$0	$0	$0	$0	$0	$0	$0
Net Interest Expense	($489)	($7)	($460)	($749)	($800)	($2,016)	($4,230)	($6,200)
Pre-Tax Income	($30,052)	($7,537)	($9,223)	($6,410)	($10,670)	($33,840)	($47,230)	($45,414)
Provision for Income Tax	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate								
Net Income	**($30,052)**	**($7,537)**	**($9,223)**	**($6,410)**	**($10,670)**	**($33,840)**	**($47,230)**	**($45,414)**
Net Margin								
Reported EPS	**($0.63)**	**($0.13)**	**($0.14)**	**($0.10)**	**($0.16)**	**($0.53)**	**($0.62)**	**($0.52)**
YOY Growth								
Weighted Shares Outstanding	47,927	60,010	63,964	64,999	67,520	64,123	76,000	87,000

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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